



Guideline

STROCCS 2019 Guideline: Strengthening the reporting of cohort studies in surgery



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ABSTRACT

Introduction: The STROCSS guideline was developed in 2017 to improve the reporting quality of observational studies in surgery. Building on its impact and usefulness, we sought to update the guidelines two years after its publication. **Methods:** A steering group was formed to review the existing guideline and propose amendments to the 17-item checklist. A Delphi consensus exercise was utilised to determine agreement across a list of proposed modifications to the STROCSS 2017 guideline. An expert panel of 46 surgeons were invited to assess the proposed updates via Google Forms.

Results: The response rate was 91% (n = 42/46). High agreement was reached across all the items and the guideline was finalised in the first round. The checklist maintained 17-items, with modifications primarily considered to improve content and readability.

Conclusions: The STROCSS 2019 guideline is hereby presented as a considered update to improve reporting of cohort, cross-sectional and case-control studies in surgery.

1. Introduction

The STROCSS Guideline [1] was developed to improve the reporting quality of observational studies in surgery. While cohort studies account for a large proportion of the published literature in surgery, reporting quality has been poor [2]. The guidelines published in 2017 improved reporting standards and was internationally utilised across a large number of journals [1].

Subsequently the STROCSS Guideline has been cited 470 times at the time of writing [3]. It therefore appears that the guideline has been well accepted amongst the surgical community. Since its introduction and repeated usage, ideas for development and refinement of the guideline were considered.

The STROCSS 2019 steering group compiled a list of proposals for amendments to the STROCSS 2017 Guideline, with a primary aim of improving its content, readability and layout. The new guideline aims to be more accessible to researchers from all backgrounds, building on its proven ability to improve the reporting of cohort studies in surgery.

2. Methods

A similar methodology to the one used in the development of the STROCSS 2017 Guideline was implemented. Internal discussions regarding possible further development of the STROCSS Guideline were held by the STROCSS steering group via telephone and online Skype (Microsoft®, Washington, US) conversations. Proposals were compiled and built onto the pre-existing 2017 Guideline. An expert panel of surgeons was invited, through a Delphi consensus exercise, to assess the new proposals, and decide on their inclusion within the 2019 Guideline. Some of this panel had previously engaged in the design of the 2017 Guideline.

2.1. The Delphi process

The Delphi questionnaire was administered using Google Forms (Google®, California, US) <https://www.google.co.uk/forms/about/>, similar to the first version of the guideline. The questionnaire was conducted using standard Delphi Methodology [4]. The same questionnaire was completed by all participants. Participants were invited to score each of the 17 items in accordance with their agreement with them.

Agreement was assessed according to a nine-point Likert scale, where 1 indicated 'not important', and 9 indicated 'critically important.' This methodology follows the recommendations outlined by the Grading

Recommendations, Assessment, Development, and Evaluations (GRADE) working group [3]. An item's importance - in this case, to the reporting of observational studies - was summarised by the score allocated to it by each expert. In accordance with the Likert scale: 1–3 indicated an item was of little importance; 4–6 indicated the item was important but not critical; 7–9 indicated the item was critically important.

An item could proceed to the reporting guideline if it was scored at 7–9 by at least 70% of the respondents, while also having no more than 30% of the responders scoring it at 1–3. Any items unable to meet these requirements were removed from the guideline. The entire scoring process was completed electronically, via the Google Forms. There was no pre-determined number of rounds, with the scoring process continuing until all items reached the required rate of scoring with unanimous agreement.

3. Participant selection

A total of 46 people were invited to participate, some of whom were involved in the STROCSS 2017 guideline. They represented countries across North and South America, Europe, Africa, Asia and Australasia. Participants represented ten surgical specialties, as well as allied specialties including; dermatology, pathology, oncology, clinical pharmacology and acute care surgery. Many participants were experienced researchers, authors, journal reviewers, editorial board members and editors.

4. Results

4.1. Updates

The Guideline was developed between the STROCSS steering group, in collaboration with the expert panel, and the changes are detailed in Table 1. Changes were intended to improve clarity, enhance the reporting of cohort studies, and make the guidelines more readable to the user.

4.2. Results of Delphi exercise

Table 2 summarizes the results of the Delphi exercise. A high response rate (91%, n = 42/46) was achieved. The first round resulted in high agreement between all experts, meaning the study was complete after a single round of expert panel review. At the end of the scoring exercise, participants were invited to suggest new ideas on the revised Guidelines. No consensus could be made on missing items, or beneficial additional items to the Guideline.

Table 1
Updated STROCCS Guideline, with rationale for any changes.

The STROCCS Guideline		
Item no.	Original Item description	Rationale for change
TITLE		
1	Title. The words "cohort" and the area of focus should appear in the title (e.g. disease, exposure/intervention or outcome). Whether the study is retrospective or prospective should also be stated.	Presentation changes to improve clarity
ABSTRACT		
2a	Abstract - Introduction What is the background and scientific rationale for the research question.	Presentation changes to improve clarity
2b	Abstract - Methods - Describe the study design (cohort design, retrospective or prospective, single or multi-centre, etc), what was done to each group, how, when was it done and by whom.	Presentation changes to improve clarity. Inclusion of outcome measures so the reader is immediately aware what was assessed.
2c	Abstract - Results What was found. Give the results for the main outcomes.	Presentation changes to improve clarity. Addition of statistical relevance (if relevant).
2d	Abstract - Conclusion - What have we learned and what does it mean. Where should future research go.	Presentation changes to improve clarity
INTRODUCTION		
3	Explain the scientific background and rationale for the cohort study. What are objectives, research questions and the hypotheses.	Presentation changes to improve clarity
METHODS		
4a	Registration and ethics State the research registry number in accordance with the declaration of Helsinki - "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). Even retrospective studies should be registered prior to submission.	Presentation changes to improve clarity. Separation of quote for clarity
4b	Ethical Approval - State whether ethical approval was needed and if so, what the relevant judgement reference from the IRB or local ethics committee was? If ethical approval was not needed, state why.	Presentation changes to improve clarity

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Table 1 (continued)

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Table 1 (continued)

The STROCSS Guideline			
Item no.	Original Item description	Revised Item description	Rationale for change
Intervention and Considerations			
7a	Pre-intervention considerations - e.g. Patient optimisation: measures taken prior to surgery or other intervention e.g. treating hypothermia/hypovolaemia/hypotension in burns patients, ICU care for sepsis, dealing with anticoagulation/other medications and so on.	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)	Presentation changes to improve clarity
7b	Types of intervention(s) deployed - To include reasoning behind treatment offered (pharmacological, surgical, physiotherapy, psychological, preventive) and concurrent treatments (antibiotics, analgesia, anti-emetics, nil by mouth, VTE prophylaxis, etc). Medical devices should have manufacturer and model specifically mentioned.	Intervention: the following areas are described comprehensively - Type of intervention and reasoning (e.g. pharmacological, surgical, physiotherapy, psychological) - Aim of intervention (preventative/therapeutic) - Concurrent treatments (antibiotics, analgesia, anti-emetics, NBM, VTE prophylaxis) - Manufacturer and model details where applicable	Presentation changes to improve clarity
7c	Peri-intervention considerations - Administration of intervention (what, where, when and how was it done, including details for surgery; anaesthesia, patient position, use of tourniquet and other relevant equipment, preparation used, sutures, devices, surgical stage (1 or 2 stage, etc) and operative time. Pharmacological therapies should include formulation, dosage, strength, route and duration). Authors are encouraged to use figures, diagrams, photos, video and other multimedia to explain their intervention.	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	Presentation changes to improve clarity
7d	Who performed the procedure(s) - Operator experience for each group (position on the learning curve for the technique if established, specialisation and prior relevant training).	Operator Details: the following areas are described comprehensively - Training needed - Learning curve for technique - Specialisation and relevant training	Presentation changes to improve clarity
7e	Quality control - What measures were taken to reduce inter or intra-operator variation. What measures were taken to ensure quality and consistency in the delivery of the intervention e.g. independent observers, lymph node counts, etc	Quality Control: the following areas are described comprehensively - Measures taken to reduce variation - Measures taken to ensure quality and consistency in intervention delivery	Presentation changes to improve clarity
7f	Post-intervention considerations - e.g. post-operative instructions and place of care. Important follow-up measures - diagnostic and other test results. Future surveillance requirements - e.g. imaging surveillance of endovascular aneurysm repair (EVAR) or clinical exam/ultrasound of regional lymph nodes for skin cancer.	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)	Presentation changes to improve clarity
8	Outcomes - What primary and secondary (if any) outcomes will be assessed and how are they defined. Definitions should be clear and precise. Appropriate references to validation of outcome measures used should be provided if they exist.	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	Presentation changes to improve clarity

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Table 1 (continued)

The STROCSS Guideline			
Item no.	Original Item description	Revised Item description	Rationale for change
9	Statistical methods - Clearly outlined statistical tests used to compare the outcomes between an intervention group and a comparison group, state whether pre-existing differences and known confounders were controlled. The statistical package used should be mentioned.	Statistics: the following areas are described comprehensively - Statistical tests, packages/software used, and interpretation of significance - Confounders and their control, if known - Analysis approach (e.g. intention to treat/per protocol) - Sub-group analysis, if any	Presentation changes to improve clarity. Analysis approach added to aid reviewing the article.
RESULTS			
10a	Participants recruited with a flow diagram - Report numbers involved in each group and use a flow diagram to show recruitment, non-participation, cross-over, withdrawal from the study with reasons.	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)	Presentation changes to improve clarity
10b	Comparison between groups including a table - Provide a table comparing the demographic, clinical/prognostic features (co-morbidities, tumour staging, smoking status, etc) and relevant socioeconomic characteristics of each group and whether numerical differences are significant (using p-values and/or confidence intervals as appropriate). Were the groups matched and if so, how.	Participant Comparison: the following areas are described comprehensively - Table comparing demographics included - Differences, with statistical relevance - Any group matching, with methods	Presentation changes to improve clarity
10c	Changes - Any changes in the interventions during the course of the study (how has it evolved, been altered or tinkered with, what learning occurred, etc) together with rationale and a diagram if appropriate. Degree of novelty for a surgical technique/device should be mentioned and a comment on learning curves should be made for new techniques/devices.	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	Presentation changes to improve clarity
11a	Outcomes and follow-up - Clinician assessed and patient-reported outcomes (when appropriate) should be stated for each group (size of effect with raw numbers and percentages) with inclusion of the time periods at which assessed. Relevant photographs/radiological images should be provided e.g. 12-month follow-up. Make it clear which confounders were adjusted for and which were not.	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	Presentation changes to improve clarity
11b	Intervention adherence/compliance and tolerability - How was this assessed. Describe loss to follow-up (express as a percentage and a fraction) or cross-over between group and any explanations for them.	Tolerance: the following areas are described comprehensively - Assessment of tolerance - Loss to follow up, with reasons (percentage and fraction) - Cross-over with explanation	Presentation changes to improve clarity

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Table 1 (continued)

The STROCSS Guideline			
Item no.	Original Item description	Revised Item description	Rationale for change
11c	Complications and adverse or unanticipated events - Described in detail and ideally categorised in accordance with the Clavien-Dindo Classification. How they were prevented, mitigated, diagnosed and managed. Blood loss, wound complications, re-exploration/revision surgery, 30-day post-op and long-term morbidity/mortality may need to be specified.	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	Presentation changes to improve clarity. Reference added for user's benefit.
12	Summarise key results	Key Results: the following areas are described comprehensively - Key results, including relevant raw data - Statistical analyses with significance	Presentation changes to improve clarity. Addition of statistical significance.
DISCUSSION			
13	Discussion of the relevance of the findings and rationale for conclusions - Relevant literature, implications for clinical practice guidelines, how have the indications for a new technique/device been refined and how do outcomes compare with established therapies and the prevailing gold standard should one exist and any relevant hypothesis generation. The rationale for any conclusions.	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	Presentation changes to improve clarity
14	Strengths and limitations of the study	Strengths and Limitations: the following areas are described comprehensively - Strengths of the study - Limitations and potential impact on results	Presentation changes to improve clarity. Addition of bias and management.
15	State what needs to be done next, further research with what study design(s).	Assessment of bias and management 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	Presentation changes to improve clarity
CONCLUSION			
16	State the key conclusions from the study and key directions for future research	Conclusions: - Key conclusions are summarised - Key directions for future research are summarised	Presentation changes to improve clarity
DECLARATIONS			
17a	State any conflicts of interest	Conflicts of interest - Conflicts of interest, if any, are described	Presentation changes to improve clarity
17b	State any sources of funding	Funding - Sources of funding (e.g. grant details), if any, are clearly stated	Presentation changes to improve clarity

Table 2
Summarised results of the STROCCS 2019 Delphi exercise.

The STROCCS Guideline 2019		
Item no.	Revised Item	% Agreement
TITLE		
1	– The word cohort/cross-sectional/case-control is included – The area of focus is described (e.g. disease, exposure/intervention, outcome) – Key elements of the study design are stated (e.g. retrospective/prospective)	98% (41/42)
ABSTRACT		
2a	Introduction: the following points are briefly described – Background – Scientific Rationale for this study	95% (40/42)
2b	Methods: the following areas are briefly described – Study design (cohort/cross-sectional/case-control, retro-/prospective, single/multi-centred) – Patient populations and/or groups, including control group, if applicable – Interventions (type, operators, recipients, timeframes) – Outcome measures	98% (41/42)
2c	Results: the following areas are briefly described – Summary data (with statistical relevance) with qualitative descriptions, where appropriate	100% (42/42)
2d	Conclusion: the following areas are briefly described – Key conclusions – Implications for practice – Direction of and need for future research	93% (39/42)
INTRODUCTION		
3	The following areas are described comprehensively: – Relevant background and scientific rationale – Aims and objectives – Research question and hypotheses, where appropriate	100% (42/42)
METHODOLOGY		
4a	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)	90% (38/42)
4b	Ethical Approval: the following areas are described comprehensively – Necessity for ethical approval – Ethical approval, with relevant judgement reference from ethics committees – Where ethics was unnecessary, reasons are provided	98% (41/42)
4c	Protocol: the following areas are described comprehensively – Protocol (a priori or otherwise) details, with access directions – If published, journal mentioned with the reference provided	88% (37/42)
4d	Patient Involvement in Research: – Description of patient involvement in study design, if any (e.g. involvement in study steering committee, involvement in outcome selection)	81% (34/42)
5a	Study Design: the following areas are described comprehensively – 'Cohort' study is mentioned – Design (e.g. retro-/prospective, single/multi-centred)	98% (41/42)
5b	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)	95% (40/42)
5c	Cohort Groups: the following areas are described comprehensively – Number of groups – Division of intervention between groups	100% (42/42)
5d	Subgroup Analysis: the following areas are described comprehensively – Planned subgroup analyses – Methods used to examine subgroups and their interactions	98% (41/42)
6a	Participants: the following areas are described comprehensively – Eligibility criteria – Recruitment sources – Length and methods of follow-up	98% (41/42)
6b	Recruitment: the following areas are described comprehensively – Methods of recruitment to each patient group – Period of recruitment	98% (41/42)
6c	Sample Size: the following areas are described comprehensively – Margin of error calculation – Analysis to determine study population – Power calculations, where appropriate	95% (40/42)
7	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	98% (41/42)
8	Statistics: the following areas are described comprehensively – Statistical tests, packages/software used, and interpretation of significance – Confounders and their control, if known – Analysis approach (e.g. intention to treat/per protocol) – Sub-group analysis, if any	98% (41/42)

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Table 2 (continued)

The STROCSS Guideline 2019		
Item no.	Revised Item	% Agreement
INTERVENTION AND CONSIDERATIONS		
9a	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)	88% (37/42)
9b	Intervention: the following areas are described comprehensively – Type of intervention and reasoning (e.g. pharmacological, surgical, physiotherapy, psychological) – Aim of intervention (preventative/therapeutic) – Concurrent treatments (antibiotics, analgesia, anti-emetics, NBM, VTE prophylaxis) – Manufacturer and model details where applicable	98% (41/42)
9c	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	98% (41/42)
9d	Operator Details: the following areas are described comprehensively – Training needed – Learning curve for technique – Specialisation and relevant training	86% (36/42)
9e	Quality Control: the following areas are described comprehensively – Measures taken to reduce variation – Measures taken to ensure quality and consistency in intervention delivery	98% (41/42)
9f	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)	95% (40/42)
RESULTS		
10a	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)	95% (40/42)
10b	Participant Comparison: the following areas are described comprehensively – Table comparing demographics included – Differences, with statistical relevance – Any group matching, with methods	95% (40/42)
10c	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	86% (36/42)
11a	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	95% (40/42)
11b	Tolerance: the following areas are described comprehensively – Assessment of tolerance – Loss to follow up, with reasons (percentage and fraction) – Cross-over with explanation	95% (40/42)
11c	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)	90% (38/42)
*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: the following areas are described comprehensively – Key results, including relevant raw data – Statistical analyses with significance	98% (41/42)
DISCUSSION		
13	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	98% (41/42)
14	Strengths and Limitations: the following areas are described comprehensively – Strengths of the study – Limitations and potential impact on results – Assessment of bias and management	98% (41/42)
15	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	90% (37/42)
CONCLUSIONS		
16	– Key conclusions are summarised – Key directions for future research are summarised	93% (39/42)
DECLARATIONS		
17a	– Conflicts of interest, if any, are described	100% (42/42)
17b	– Sources of funding (e.g. grant details), if any, are clearly stated	98% (41/42)

4.3. STROCCS 2019 Guideline

Whilst [Tables 1 and 2](#) include the new guideline, a final version of the STROCCS 2019 Guideline is presented in the [Appendix](#), in a printer friendly table format. We hope this format allows researchers, authors and editors to easily 'mark' work against the guideline and for authors, report where each item is included within their written manuscript by providing a reference page number.

With these improvements, authors are advised to explicitly state they have used the STROCCS 2019 Guideline, include a completed version in their manuscript to allow review, and cite the 2019 Guideline. Authors should be aware that the guideline is appropriate for cohort studies, cross-sectional studies and case-control studies, due to the similarity of their methodology.

4.4. Endorsement

The STROCCS 2019 Guideline is endorsed by the IJS Publishing Group journals, which include:

- International Journal of Surgery (IJS)
- IJS Case Reports
- IJS Open
- IJS Protocols
- IJS Oncology
- IJS Short Reports
- Annals of Medicine and Surgery

A dedicated website has been formed to facilitate distribution of the guideline: www.stroccsguideline.com. The authors hope that more journals will endorse the guideline in due course and incorporate it as part of routine manuscript submission for cohort, cross-sectional and case-control studies.

5. Conclusion

The STROCCS 2019 Guideline is hereby presented for usage by authors, reviewers and editors with the aim of improving reporting quality of cohort studies as well as cross-sectional and case-control studies. It follows a rigorous Delphi exercise, including internationally-active experienced researchers and clinicians within surgery. We look forward to the guideline being used, assessed, and studied for its implementation and effectiveness as a tool to improve the quality of cohort study reporting.

Provenance and peer review

Not Commissioned, internally reviewed.

Data statement

Data will be made available on request.

Ethical approval

None necessary.

Sources of funding

None.

Author contribution

RAA was involved in concept, data acquisition, analysis and interpretation, wrote the first draft. AAR, EC, ND, CI and GM were involved in guideline development, data acquisition, analysis and interpretation,

and manuscript revision. All authors approved the final submission.

Research registration Unique Identifying number

Name of the registry:

Unique Identifying number or registration ID:

Hyperlink to the registration (must be publicly accessible):

Guarantor

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STROCCS group participants

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Declaration of competing interest

None.

Appendix A. Supplementary Material

STROCCS 2019 Guideline <https://doi.org/10.1016/j.ijsu.2019.11.002>.

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