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Guideline

The PROCESS 2018 statement: Updating Consensus **P**referred **R**eporting **O**f **C**as**E** **S**eries in **S**urgery (PROCESS) guidelines

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ABSTRACT

Introduction: The PROCESS guidelines were published in 2016 to provide a structure for reporting surgical case series. The PROCESS guidelines have since been widely endorsed by a number of journals. The requirement to report compliance with each item outlined in the PROCESS statement has improved the reporting transparency of case series across a number of surgical specialties. Here, we undertook a new Delphi consensus exercise to update the PROCESS guidelines.

Methods: All members of the previous Delphi group were invited to participate. In addition, researchers, editors, and reviewers who have previously published or reviewed case series with the International Journal of Surgery were invited to collaborate. An online questionnaire was sent to participants asking them to rate their agreement with amendments to each of the 29 items.

Results: 140 experts were invited to participate, 56 people agreed to participate, and 45 (80%) recipients completed the survey. There was a high level of agreement amongst the expert group, and unanimous consensus was reached in the first round. All except three proposed items were accepted, and the original guidelines were modified accordingly.

Conclusion: A modified and improved PROCESS checklist is presented, after a Delphi consensus exercise was completed.

1. Introduction

Case series have an integral role in the reporting of rare diseases and in identifying adverse or beneficial outcomes of interventions. Although case series comprise a large percentage of published research articles, particularly amongst surgical specialities [1], the quality of published work is often poor and reporting is inconsistent [2]. This has detrimental consequences on their ability to safely and ethically inform clinical practice. The PROCESS statement [3] (Preferred Reporting of Case Series in Surgery, www.processguideline.com) was published in 2016 to improve reporting of case series in surgery. It was composed of 29 items divided into 8 main sections pertaining to the abstract and main text. These were developed through expert Delphi consensus. Since its publication, the PROCESS guidelines have been endorsed by numerous journals and have been reported in a number of research articles. One study demonstrated a 5% increase in concordance with the items depicted by the PROCESS guidelines since their publication [4], which illustrates the beneficial impact that the PROCESS guidelines have had on reporting transparency in surgical research. Despite these encouraging results, compliance can still be improved. In the two years since their publication, we have received feedback on the items in the PROCESS guidelines from researchers and editors. Here, we update the guidelines through a new Delphi consensus exercise in effort to further improve reporting quality of case series studies.

2. Methods

The same Delphi methodology was used, as described in the original guideline [3].

2.1. Delphi development

We recently conducted a before-after study on impact of the PROCESS guidelines on reporting of case series since publication of the

Table 1
Scoring results for PROCESS Delphi. Items indicated are changes made to individual sections of PROCESS. Items were rated from a score of 1 (strongly disagree) to 9 (strongly agree).

	Scoring		
	1–3	4–6	7–9
Item 1	4.4	15.5	80
Item 2b	22.2	13.3	64.5
Item 3	2.2	8.9	88.9
Item 4a	4.4	15.5	80.1
Item 4b	4.4	11	84.4
Item 4c	11.1	26.7	62.2
Item 4d	15.5	17.8	66.6
Item 4e	17.7	6.6	75.6
Item 4f	20	6.6	73.3
Item 4g	4.4	13.3	82.2
Item 4h	4.4	13.3	82.2
Item 4i	2.2	13.3	84.5
Item 4j	2.2	11.1	86.7
Item 5a	0	15.5	84.5
Item 5b	4.4	11.1	84.5
Item 5c	2.2	8.9	88.9
Item 5d	4.4	17.7	77.8
Item 5e	2.2	8.8	88.9
Item 6b	0	13.3	86.7
New Item 6c/d	0	13.3	86.7
Item 6d	8.9	15.5	75.5
New item 6e	4.4	20	75.5

Table 2
Outlines the new PROCESS guideline.

PROCESS Checklist			
Section	Item	Checklist Description	Page Number
Title	1	Both the words “case series” and the area of focus should appear in the title (e.g. disease, exposure/intervention or outcome)	
Abstract	2a	Introduction - what is the unifying theme of the case series.	
	2b	Methods - describe what was done, how and when was it done and by whom.	
	2c	Results - what was found.	
	2d	Conclusion - what have we learned and what does it mean	
Introduction	3	Background and relevance - Explain the scientific background and rationale for the case series (e.g. specify the unifying theme - common disease, exposure, intervention and outcome). The introduction should explain why this study needed.	
Methods	4a	Registration - 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" (this can be obtained from; ResearchRegistry.com or ClinicalTrials.gov or ISRCTN). If a protocol exists already, state where it can be accessed (must be publicly accessible).	
	4b	Study design - state the study is a case series. In addition, it is necessary to state whether the case series is: 1) prospective or retrospective in design; 2) single or multi-centre; and 3) cases are consecutive or non-consecutive.	
	4c	Setting - describe the setting(s)and nature of the institution in which the patient was managed; academic, community or private practice setting? Location(s), and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	
	4d	Participants - describe the relevant characteristics of the participants (comorbidities, tumour staging, smoking status, etc). State any eligibility (inclusion/exclusion) criteria and the sources and methods of selection of participants. Describe length and methods of follow-up.	
	4e	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.	
	4f	Types of intervention(s) deployed (pharmacological, surgical, physiotherapy, psychological, preventive) and reasoning behind treatment offered.	
	4g	Intervention details – details on how the intervention was carried out. For surgery, for example, include information on anaesthesia, patient position, use of tourniquet and other relevant equipment, preparation used, sutures, devices, surgical stage (1 or 2 stage, etc). For pharmacological therapies, include formulation, dosage, strength, route and duration.	
	4h	Who performed the procedures – the operator position and their experience experience (position on the learning curve for the technique if established, specialisation and prior relevant training). For example, ‘A junior resident, three years into specialized training’. Degree of novelty for a surgical technique/device should be mentioned and a comment on learning curves should be made for new techniques/devices.	
	4i	Quality control - what measures were taken to reduce inter or intra-operator variation, ensure quality, and maintain consistency between each case in the delivery of the intervention e.g. independent observers, lymph node counts, standard surgical technique.	
	4j	Post-intervention considerations – following the main intervention: 1) when were the patients followed-up; 2) where; 3) what did follow-up entail (additional tests, scans, clinical examination) and what were the results of these; and 4) were there any post-operative instructions.	
Results	5a	Participants - reports numbers involved and their characteristics (including, most importantly, their comorbidities and smoking status, as well as other demographic details). For all cancer patients it is necessary to include details on tumour staging (e.g. TNM)	
	5b	Changes to reports – report any changes in the interventions during the course of the case series (what the change was, reasons for the change, what learning occurred, together with rationale and a diagram if appropriate).	
	5c	Outcomes and follow-up - Clinician assessed and patient-reported outcomes (when appropriate, including, for example questionnaires or comments at outpatient visits) should be stated. Include details on the time periods at which assessed. Relevant photographs/radiological images should be provided e.g. 12 month follow-up. Describe loss to follow-up (express as a percentage) and any explanations for it.	
	5d	Intervention adherence/compliance - where relevant how well patients adhered to and tolerated their treatment. For example, post-operative advice (heavy lifting for abdominal surgery) or tolerance of chemotherapy and pharmacological agents.	
	5e	Adverse events – all complications and adverse or unanticipated events should be described in detail and ideally categorised in accordance with the Clavien-Dindo Classification. How they were prevented, diagnosed and managed. Blood loss, operative time, wound complications, re-exploration/revision surgery, 30-day post-op and long-term morbidity/mortality may need to be specified. If there were no complications or adverse outcomes this should also be included.	
Discussion	6a	Summarise key results	
	6b	Placing results in context – describe all relevant literature, describe the prevailing gold standard should one exist, and describe how findings reported compare with established therapies. State the implications for clinical practice guidelines and any relevant hypotheses that have been generated as a result of this worth	
	6c	Strengths and limitations of the study	
	6d	Future – State the further research that can be done to build on the findings and methodology discussed. State the study design next best suited to address these areas.	
	6e	Rational – ensure any conclusions made have strong rationale	
Conclusions	7a	State the key conclusions from the study	
	7b	State what needs to be done next, further research with what study design.	
Additional Information	8a	State any conflicts of interest	
	8b	State any sources of funding	
	8c	State Ethics- State whether ethical approval was needed and if so, what the relevant judgement reference was?	

guidelines in 2016 [4]. Using the insight gained from this review, we amended each of the 29 items in the PROCESS guidelines to improve clarity and relevance; items were reworded, composite items were broken down numerically, and points that were not applicable to all surgical specialties were removed. A Google Form was created presenting the modified items, and the expert panel was asked to comment on each change and suggest additional amendments.

2.2. Consensus group

The Delphi group comprised experts from a range of countries and surgical specialties. Individuals were considered to be "experts" and make valuable contributions if they had experience in reporting and/or reviewing of surgical case series. The same Delphi group from the inception of the PROCESS guidelines was invited to participate. In order to increase the depth and breadth of the group, individuals from the editorial board and reviewer base of the International Journal of Surgery (IJS) were also invited to participate. This was essential as IJS is a key supporter of the guidelines and have been implemented the PROCESS guidelines as a mandatory requirement for submission.

2.3. Consensus round

Potential contributors were invited to participate via email. Once participation was confirmed, the Delphi exercise took place electronically. In the first consensus round, the expert group was asked to indicate whether they agree or disagreed to suggested changes made to each of the 29 items in the PROCESS guidelines, on a scale of 1 (strongly disagree) to 9 (strongly agree). A two-week period was given for the initial round of responses and a reminder email was sent after one week to those who had not yet responded. As per the previous Delphi exercise, consensus was defined as $\geq$70% of participants rating an item change 7 to 9, and $\leq$15% rating an item change 1 to 3. If this was not reached, the item would remain unchanged. The whole exercise was conducted in electronic format with no pre-determined number of Delphi rounds.

3. Results

Invitations were sent to 140 people. 56 people agreed to participate and 45 (80%) completed the Delphi survey. 16 of the participants contributed to the original Delphi exercise in 2016. A summary of the scores is shown below (Tables 1 and 2).

4. Discussion

Case series are a popular study design across a range of surgical specialties given their ease of conduct, and cost efficiency. Despite their abundance in published literature, case series often suffer from poor quality and inadequate reporting [5]. The PROCESS statement [3] was published in 2016 to guide authors, journal editors, and reviewers as to the minimum necessary items to report in surgical case series. Since their implementation there has been a 5% increase in reporting completeness when followed [4]. However, it often takes substantial time for journals to adopt reporting guidelines. Only 38% of the 193 surgical journals listed in the Journal Citation Report 2014 mention such guidelines in their submission requirements provided to authors[9]. In addition, in the two years since the original PROCESS statement publication, feedback and insight has been gained by researchers using and reviewing the guidelines. In order to update the guidelines with suggested revisions, and to increase uptake and compliance of the PROCESS guidelines, a Delphi exercise with an expert panel was undertaken.

The Delphi exercise was completed by 56 participants, and there was high consensus amongst those invited to participate. A modified PROCESS statement is presented accommodating all of the agreed changes. This revised statement aims to improve the reporting quality of case series. We encourage journal reviewers, editors, and authors to read and comply with the items listed. Authors should cite the guidelines in their methods section and upload a completed checklist of compliance for reviewers and editors to inspect. Such checklists will be provided in a variety of formats for easy usage on the PROCESS website: http://www.processguideline.com. We encourage future research to assess the effectiveness of this revised guideline.

This approach to guideline development has a number of limitations. Firstly, there may be overrepresentation of the editors of a single journal – The IJS, but this journal has editors who work across multiple journals and bring a broad breadth of surgical experience. In addition, modifications are cross-checked against a range of individuals with specific surgical experience, however, it may be the case that additional points, more relevant to certain specialties may not have been captured. We therefore invite individuals who adopt these guidelines in their work to suggest future modifications and revisions that they feel are necessary.

5. Conclusion

Updated PROCESS guidelines are presented. We recommend that these guidelines are implemented by authors, reviewers, editors and journals with the aim of improving reporting quality of surgical case series in the literature.

Ethical approval

No ethical approval was required.

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Author contribution

RAA - Concept and design, data collection, data interpretation and analysis, revision and approval of final manuscript; MRB drafting of the manuscript, data collection, revision and approval of final manuscript; RF, KK, & AF, data collection, revision and approval of final manuscript; DPO - Design of study, revision, approval of final manuscript. The PROCESS 2018 Update Statement: Updating Consensus **P**referred **R**eporting **O**f **C**as**E** **S**eries in **S**urgery (PROCESS) Guidelines.

Conflicts of interest

None.

Research registration number

N/A – this was not a human study.

Guarantor

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References

[1] R.A. Agha, et al., Levels of evidence in plastic surgery—bibliometric trends and comparison with five other surgical specialties, Eur. J. Plast. Surg. 39 (2016) 365–370.
[2] R.A. Agha, et al., Systematic review of the methodological and reporting quality of case series in surgery, Br. J. Surg. 103 (2016) 1253–1258.
[3] R.A. Agha, et al., Preferred reporting of case series in surgery; the PROCESS guidelines, Int. J. Surg. 36 (2016) 319–323.
[4] R. Agha, et al., Impact of the PROCESS guideline on the reporting of surgical case series: a before and after study, Int. J. Surg. 45 (2017) 92–97.
[5] R. Agha, et al., Support for reporting guidelines in surgical journals needs improvement: a systematic review, Int. J. Surg. 36 (2016) S138–S139.