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Guideline

# Preferred reporting of case series in surgery; the PROCESS guidelines

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## HIGHLIGHTS

- Reporting guidelines can improve transparency and reporting quality.
- No guideline exists for reporting case series.
- Our objective was to develop reporting guidelines for surgical case series.

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## ABSTRACT

*Introduction:* Case series have been a long held tradition within the surgical literature and are still frequently published. Reporting guidelines can improve transparency and reporting quality. No guideline exists for reporting case series, and our recent systematic review highlights the fact that key data are being missed from such reports. Our objective was to develop reporting guidelines for surgical case series.

*Methods:* A Delphi consensus exercise was conducted to determine items to include in the reporting guideline. Items included those identified from a previous systematic review on case series and those included in the SCARE Guidelines for case reports. The Delphi questionnaire was administered via Google Forms and conducted using standard Delphi methodology. Surgeons and others with expertise in the reporting of case series were invited to participate. In round one, participants voted to define case series and also what elements should be included in them. In round two, participants voted on what items to include in the PROCESS guideline using a nine-point Likert scale to assess agreement as proposed by the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) working group.

*Results:* In round one, there was a 49% (29/59) response rate. Following adjustment of the guideline with incorporation of recommended changes, round two commenced and there was an 81% (48/59) response rate. All but one of the items were approved by the participants and Likert scores 7-9 were awarded by >70% of respondents. The final guideline consists of an eight item checklist.

*Conclusion:* We present the PROCESS Guideline, consisting of an eight item checklist that will improve the reporting quality of surgical case series. We encourage authors, reviewers, editors, journals, publishers and the wider surgical and scholarly community to adopt these.



## 1. Introduction

Case series often appear in the surgical and wider healthcare literature but also in social sciences and the humanities [3]. Dekkers et al. defined a case series as an uncontrolled study that either samples participants with both a specific intervention (exposure) and a specific outcome, or samples participants with a specific outcome of interest regardless of their exposure status [1]. A series sampled only on exposure is a cohort study. A report of a case series is commonly a retrospective review of a string of patients with a unifying feature - be that exposure (including treatment) or outcome, or both. There has also been significant confusion

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between case series and single group cohort studies [2].

As with case reports, their value has been debated [3,4]. In the age of evidence-based medicine (EBM), with the randomised controlled trial as the standard to show the efficacy of a particular treatment, what is their role? Level four evidence was still the most common study type in a bibliometric analysis of research published in 2013 in the specialties of plastic surgery, orthopaedic surgery, otolaryngology and neurosurgery, with significant outputs in maxillo-facial surgery (33%) and vascular surgery (15%) [5]. The use of a case series in the recognition of a new disease was exemplified in 1999 by the epidemic of West Nile encephalitis in New York [6]. Historically, case series were important in identifying the impact of maternal drinking and pregnancy outcome and the role of vitamin C in preventing scurvy [7,8]. A single case series can lead to very significant change, from the widespread use of negative pressure dressings following a case series of 10 patients [9] to a 49 patient case series that led to a new classification system for haemangiomas and vascular malformations in 1982, still in use today [10].

Albrecht et al. studied reports of case series and found that a high proportion led to follow-up trials and that they were useful in establishing an early evidence base for new treatments of rare diseases in which trials would not be feasible [11]. For some specialties, establishing control groups may be difficult, such as in accident and emergency medicine or paediatric medicine or surgery. In the social sciences, many social psychology studies have been case series, for example Yale psychologist Stanley Milgram's seminal work on obedience to authority figures [12].

In a 2005 report, Dalziel et al. found that case series were used in 30% of Health Technology Assessments (HTA) used in the provision and suitability of care [13]. Poor reporting in the case series included in their study, however, severely constrained their analysis and investigation of the hypothesis that findings in case series may be affected by methodological characteristics [10]. Readers need complete, transparent information in all reports of research. Poor reporting of case series undermines critical appraisal, assessment of external validity and whether, for instance, surgeons should change their practice.

No standardised reporting criteria have been developed within a robust methodological framework for case series. The aim of the present study was to close this gap and produce a reporting guideline for case series that is methodologically robust, easy to use, and accepted internationally across a broad range of specialties and disciplines. Following guidance on guideline development, the early steps in this process require an analysis of previous literature to identify previous guidance (if any) and to analyse relevant evidence on the quality of reporting of published research articles within the domain of interest [14]. Our group recently completed a systematic review on the reporting quality of case series in surgery over the period 1990–2014 [15]. From 92 articles that met the inclusion criteria, methodological and reporting issues identified were: failure to use standardised definitions (57%), missing or selective data (66%), lack of transparency or incomplete reporting (70%), whether alternative study designs were considered (11%) and other issues (52%) such as failure to clearly define the patient population under investigation, selection bias, insufficient follow-up time, need for validated outcomes.

We recently developed the SCARE Guidelines for Case Reports using a DELPHI consensus exercise, which have now been adopted by several journals [16]. Following this experience, the objective of this research was to conduct a Delphi consensus exercise amongst experienced surgical case series reviewers and editors to develop the **P**referred **R**eporting **O**f **C**as**E** **S**eries in **S**urgery (PROCESS) Guideline.

## 2. Developing the PROCESS guideline

We issued a survey using Google Forms (https://www.google.co.uk/forms/about) asking participants in round one to help define surgical case series and what items should be included in them. In a subsequent round, participants were asked to rate their level of agreement with the guideline items from round one as well as items from the SCARE guidelines and any additional items that were suggested using a nine-point Likert scale as proposed by the GRADE group [17]. In this scale 1 to 3 signifies an outcome of limited importance, 4 to 6 important but not critical and 7 to 9 critical. If 70% or more of respondents scored an item 7 to 9 and fewer than 15% scored it 1 to 3, that item was incorporated in the reporting guideline. Similarly, consensus that an outcome should not be included was 70% or more scoring it 1 to 3 and 15% or less scoring it 7 to 9. The entire process was conducted electronically and there was no pre-determined number of Delphi rounds.

## 3. Participant selection

Surgeons and others with significant experience in reviewing or editing case reports were selected. They were drawn from the reviewer pool of IJS Case Reports (the top 150 were invited) as well as those who have written on the topic of case series and case reports in the past. In total 59 participants agreed to the invitation to participate in this study, representing 21 countries and all ten surgical specialties as well as allied specialties including; dermatology, pathology, oncology, clinical pharmacology, acute care surgery, with many participants also occupying positions on journal editorial boards [18].

## 4. Results

In round 1, there was a 49% (29/59) response rate. The participant responses are integrated into Table 1.

Following adjustment of the guideline with incorporation of recommended changes, round 2 commenced (see Tables 2 and 3). There was an 81% (48/59) response rate. All guideline items were approved by the participants with Likert scores 7–9 awarded by >70% of respondents, apart from "4a - registration and ethics - state the research registry number in accordance with the declaration of Helsinki", which had scores of 7–9 from 65% of participants. However, as this item is part of the declaration of Helsinki, it cannot be removed or augmented.

## 5. PROCESS guideline

Table 3 constitutes the PROCESS guideline, and this is provided again in an Appendix, together with a column in which the author can state the page number on which the criterion was achieved. We recommend that all authors submitting case series should submit a completed PROCESS checklist with their manuscript and also state explicitly in their report that they have complied with the PROCESS guideline, which they should cite in their paper. The guideline represents the minimum of what should be reported and we encourage authors to provide additional details that are relevant. So, when should a case series be performed and when should these guidelines be used? For surgical case series specifically, the following can also be advocated: rare diseases or rare circumstances (such as emergencies), logistical difficulties or where ethical issues may arise with prospective randomised studies e.g. paediatric populations, new diseases – their description, natural history and management, studying the mechanism of disease and studying the impact of established procedures. In addition, late or delayed effects following surgical interventions, such as biliary

**Table 1**
DELPHI round 1 responses.

| Question | Responses ($n = 29$) |
|---|---|
| We are defining a case series as follows: A case series is a descriptive study of an uncontrolled group of patients who are sampled on the basis of a specific exposure/intervention or a specific outcome of interest regardless of their exposure status | 62.1% agree (18/29)<br>37.9% disagree (11/29)<br>Comments – should be mentioned they are observational studies and they may relate to a specific disease. |
| How do you differentiate a case series from a cohort study? Should a Cohort study always have two or more groups? Other reasons? | Both are observational studies but cohort studies are comparative and patients in them are always sampled on the basis of exposure, whereas case series may be sampled on the basis of; disease/exposure/intervention or a specific outcome of interest |
| What are the important elements that should be reported in a case series? | |
| • What is the unifying theme - common presentation, diagnosis, intervention, outcome, etc | 93% (27/29) |
| • Whether it is prospective or retrospective Whether alternative study designs were considered e.g. cohort, RCT, etc | 76% (22/29) |
| • Whether alternative study designs were considered e.g. cohort, RCT, etc | 31% (9/29) |
| • Whether the cases are consecutive or not | 86% (25/29) |
| • Whether it is multi centre or single centre | 90% (26/29) |
| • What the time interval over which cases were collected giving years and potentially months as well if collected over a short period of time | 90% (26/29) |
| • Patient population should detailed | 90% (26/29) |
| • Patient selection should be described in detail | 83% (24/29) |
| • Changes to the intervention during the course of the series should be detailed | 6% (25/29) |
| • A comment on learning curves should be made for new techniques | 72% (21/29) |
| • Loss to follow-up should be detailed e.g. % of sample lost to follow-up and reasons if known | 83% (24/29) |
| • Other elements not already included in the SCARE checklist (please state) | 28% (8/29) |
| Other than the items above and those in the SCARE checklist, please let us know if anything else should be reported in a case series? | Why cases were non-consecutive.<br>State if patients were excluded. |

**Table 2**
DELPHI round 2 responses to definitions.

| Question | Responses ($n = 46$) and comments |
|---|---|
| From the first round results, a case series is being defined as: "an observational study of an uncontrolled group of patients collected or sampled on the basis of a specific disease/exposure/intervention or a specific outcome of interest." | 96% (44/46) |
| A Case Series must be differentiated from a Cohort Study so we have defined those to following the first round results. "A Cohort Study is a comparative study typically involving two or more groups of patients that are sampled only on the basis of a specific exposure or intervention." This definition is similar to that put forward by the Centre of Evidence Based Medicine at Oxford University: http://www.cebm.net/glossary/. | 76% (35/46)<br>A single group cohort may still be utilised e.g. for prognostic studies. |

malignancy after biliodigestive anastomosis, could be collated into a case series. Where a new technique or device has been conceived and requires development and assessment, the IDEAL (Idea, Development, Exploration, Assessment and Long-term follow-up) framework is recommended [19].

## 6. Endorsement

The PROCESS guideline has been endorsed by the IJS, IJS Case Reports, IJS Open, Annals of Medicine and Surgery, IJS Oncology, and IJS Short Reports.

## 7. Conclusion

After completion of two DELPHI rounds consensus was reached among a multidisciplinary and expert group in the area of surgery and case series. If used appropriately, the PROCESS guidelines will aid in raising the reporting quality of surgical case series. We encourage authors, reviewers, editors, journals, publishers and the wider surgical and scholarly community to adopt these. We look forward to feedback from the community as well as studies of its implementation to help inform a future revision of these guidelines.

## 8. PROCESS group participants

The following people contributed to the PROCESS Guideline: Raafat Afifi, Cairo University, Raha Alahmadi, King Faisal Specialist Hospital and Research Centre, Joerg Albrecht, John H. Stroger Jr. Hospital of Cook County, Abdulrahman Alsawadi, Colchester Hospital University NHS Foundation Trust, Jeffrey K. Aronson, Radcliffe Infirmary, Oxford, M. Hammad Ather, Aga Khan University, Mohammad Bashashati, Texas Tech University Health Sciences Centre, Somprakas Basu, Banarus Hindu University, Patrick Bradley, Nottingham University Hospitals, Mushtaq Chalkoo, Govt. medical college, Srinagar Kashmir, Ben Challacombe, Guy's and St Thomas' NHS Foundation Trust, Trent Cross, James Cook University, Laura Derbyshire, North West Deanery, Naheed Farooq, Central Manchester University Hospital Foundation Trust, Jerome Hoffman, University of California Los Angeles, Huseyin Kadioglu, Bezmialem Vakif University, Veeru Kasivisvanathan, University College London, Boris Kirshtein, Soroka University Medical Centre, Roberto Klappenbach, Simplemente Evita Hospital, Daniel Laskin, Virginia Commonwealth University, Diana Miguel, University Hospital Jena, James Milburn, Queens Medical Centre, Oliver Muensterer, University Medicine Mainz, James Ngu, Changi General Hospital, Iain Nixon, East Kent University Hospitals, Ashraf Noureldin, Cumberland Royal Infirmary, Benjamin Perakath, Dr. Gray's Hospital,

**Table 3**
DELPHI round 2 responses to guideline items.

| Section | Item | Checklist Description | Responses ($n = 48$) Scores 7-9 |
|---|---|---|---|
| Title | 1 | The words "case series" and the area of focus should appear in the title (e.g. disease, exposure/intervention or outcome). | 80% (37/46) |
| Abstract | 2a | **Introduction**<br>What is the unifying theme of the case series. | 89% (41/46) |
| | 2b | **Methods**<br>Describe what was done, how and when was it done and by whom. | |
| | 2c | **Results**<br>What was found. | |
| | 2d | **Conclusion**<br>What have we learned and what does it mean | |
| Introduction | 3 | Explain the scientific background and rationale for the case series. What is the unifying theme - common disease, exposure, intervention and outcome, etc. Why is this study needed? | 96% (44/46) |
| Methods | 4a | **Registration and ethics**<br>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. 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. | 65% (30/46) |
| | 4b | **Study design**<br>State the study is a case series and whether prospective or retrospective in design, whether single or multi-centre and whether cases are consecutive or non-consecutive. | 91% (42/46) |
| | 4c | **Setting**<br>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 | 87% (40/46) |
| | 4d | **Participants**<br>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. | 93% (43/46) |
| | 4e | **Pre-intervention considerations**<br>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. | 80% (37/46) |
| | 4f | **Types of intervention(s) deployed**<br>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. | 87% (40/46) |
| | 4g | **Peri-intervention considerations**<br>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. | 89% (41/46) |
| | 4h | **Who performed the procedure(s)**<br>Operator experience (position on the learning curve for the technique if established, specialisation and prior relevant training). | 83% (38/46) |
| | 4i | **Quality control**<br>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 | 76% (35/46) |
| | 4j | **Post-intervention considerations**<br>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. | 89% (41/46) |
| Results | 5a | **Participants**<br>Report numbers involved and their characteristics (co-morbidities, tumour staging, smoking status, etc). | 96% (44/46) |
| | 5b | **Changes**<br>Any changes in the interventions during the course of the case series (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. | 89% (41/46) |
| | 5c | **Outcomes and follow-up**<br>Clinician assessed and patient-reported outcomes (when appropriate) should be stated with inclusion of the time periods at which assessed. Relevant photographs/radiological images should be provided e.g. 12-month follow-up. | 93% (43/46) |
| | 5d | **Intervention adherence/compliance and tolerability**<br>How was this assessed. Describe loss to follow-up (express as a percentage and a fraction) and any explanations for it. | 91% (42/46) |
| | 5e | **Complications and adverse or unanticipated events**<br>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. | 89% (41/46) |
| Discussion | 6a | **Summarise key results** | 93% (43/46) |

**Table 3** (*continued*)

| Section | Item | Checklist Description | Responses ($n = 48$) Scores 7-9 |
|---|---|---|---|
| | 6b | **Discussion of relevance** 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. | 91% (42/46) |
| | 6c | **Strengths and limitations of the study** | 93% (43/46) |
| | 6d | **The rationale for any conclusions?** | 96% (44/46) |
| Conclusions | 7a | **State the key conclusions from the study** | 93% (43/46) |
| | 7b | **State what needs to be done next, further research with what study design.** | 78% (36/46) |
| Additional information | 8a | **State any conflicts of interest** | 98% (45/46) |
| | 8b | **State any sources of funding** | 96% (44/46) |

Nicholas Raison, King's College London, Kandiah Raveendran, Fatimah Hospital, Timothy Sullivan, Minneapolis Heart Institute, Achilleas Thoma, McMaster University, Mangesh A. Thorat, Wolfson Institute of Preventative Medicine, Queen Mary University of London, Andy Petroianu, Federal University of Minas Gerais, Ashwini Rao, Manipal College of Dental Sciences, Mangalore, Manipal University, Michele Valmasoni, Università di Padova, Samuele Massarut, Centro di Riferimento Oncologico Aviano Italy, Anil D'cruz, Tata Memorial Hospital, Baskaran Vasudevan, MIOT Hospitals, Salvatore Giordano, Turku University Hospital, Donagh Healy, University Hospital Waterford, David Machado-Aranda, University of Michigan, Frederick H. Millham, Newton-Wellesley Hospital, Bryan Carroll, Eastern Virginia Medical School, Indraneilm Mukherjee, Florida Hospital Tampa, Peter McCulloch, University of Oxford, Yasuhiko Sugawara, Japanese Red Cross Hospital and David Rosin, University of West Indies.

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## Author contribution

Authors:

**Riaz A. Agha**: Concept and design of study, data collection, data interpretation and analysis, drafting, revision, approval of final manuscript.

**Alexander J Fowler**: Study design, data collection, revision, approval of final manuscript.

**Shivanchan Rajmohan**: Data Collection, revision, approval of final manuscript.

**Ishani Barai**: Data collection, revision, approval of final manuscript.

**Dennis P. Orgill**: Design of study, revision, approval of final manuscript.

## Conflicts of interest

None declared. The authors have no financial, consultative, institutional, and other relationships that might lead to bias or conflict of interest.

## Guarantor

Riaz. A. Agha.

## Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.ijsu.2016.10.025.

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