Guidelines

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Preferred Reporting Of Case Series in Surgery (PROCESS) 2023 guidelines

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Introduction: The Preferred Reporting Of CasE Series in Surgery (PROCESS) guidelines were developed in 2016 in order to improve the reporting quality of surgical case series. Since its inception, it has been updated twice, in 2018 and 2020, and has been cited over 1000 times. PROCESS guidelines have enjoyed great acceptance within the surgical research community. Our aim is to update the PROCESS guidelines in order to maintain its applicability in the field of surgical research.

Methods: A PROCESS 2023 steering group was created. By working in collaboration, members of this group came up with proposals to update the PROCESS 2020 guidelines. These proposals were presented to an expert panel of researchers, who in turn scrutinised these proposals and decided whether they should become part of PROCESS 2023 guidelines or not, through a Delphi consensus exercise.

Results: A total of 38 people participated in the development of PROCESS 2023 guidelines. The majority of items received a score between 7 and 9 from greater than 70% of the participants, indicating consensus with the proposed changes to those items. However, two items (3c and 6a) received a score between 7 and 9 from less than 70% of the participants, indicating a lack of consensus with the proposed changes to those items. Those items will remain unchanged.

Discussion: The updated PROCESS 2023 guidelines are presented with an aim to continue improving the reporting quality of case series in surgery.

Keywords: PROCESS, reporting guidelines, surgical case series

Introduction

A case series is an observational study, which involves following a particular group of patients with a similar disease or exposure/intervention, over a specific period of time, in order to study their characteristics and outcomes, in the absence of a control group[1]. Although case series come lower down in the hierarchy of evidence, they are among the most commonly published studies in the surgical literature[2]. Additionally, despite the utility of case series being contested, they can add to the scientific literature in several ways such as describing rare diseases, unusual presentations of a common disease, novel interventions, and unexpected results of an intervention[3].

A systematic review published in 2016 showed that the methodological and reporting quality of case series in surgery were below par and required improvement[4]. In order to better the reporting quality among surgical case series and hence increase their trustworthiness and usefulness, the Preferred Reporting Of CasE Series in Surgery (PROCESS) guidelines were developed in 2016[5]. Subsequently, the PROCESS guidelines were updated in 2018 and 2020[6,7].

HIGHLIGHTS

- We present an updated version of Preferred Reporting Of CasE Series in Surgery (PROCESS) guidelines; they were first published in 2016 in order to improve the reporting quality of surgical case series.
- Updated PROCESS 2023 guidelines were produced using a Delphi consensus exercise. A total of 38 people participated in the development of PROCESS 2023 guidelines and there was a high level of agreement among the Delphi group members with the proposed amendments to the PROCESS 2020 guidelines.
- We present PROCESS 2023 guidelines with an aim to continue improving the reporting quality of surgical case series.

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Table 1

PROCESS 2020 guidelines and the proposed version of PROCESS 2023 guidelines.

Topic	Item	PROCESS 2020	Proposed PROCESS 2023
Title	1	The phrase 'case series' and the area of focus should appear in the title (e.g. patient population, diagnosis, intervention or outcome).	The phrase 'case series' is included • The focus of the research study is mentioned (e.g. patient population, setting, diagnosis, intervention, outcome etc.)
Keywords	2	Include three to six keywords that identify what is covered in the case series (e.g. patient population, diagnosis, intervention or outcome). • Include 'case series' as one of the keywords.	Include three to six keywords that identify what is covered in the case series (e.g. patient population, setting, diagnosis, intervention, outcome etc.) • Include 'case series' as one of the keywords • Include the surgical subspeciality the case series pertains to as a keyword
Abstract	3a	Introduction and Importance • Describe what is unique or educational. • What is the overarching theme of the case series?	Introduction – briefly describe: • Background • Scientific rationale for this study • Overarching theme of the case series • Aims and objectives
	3b	Methods • Describe what was done, how and when was it done and by whom.	Methods – briefly describe: • Sample size • Timeframe of research • Characteristics of study design (e.g. prospective/retrospective, single-/multicentre, informal/formal, consecutive/nonconsecutive, exposure-/outcome-based sampling, clinical/population-based etc.)
	3c	Outcomes • Describe the outcomes of the intervention and management strategy.	Results – briefly describe: • Outcomes of the intervention/management strategy
	3d	Conclusion • Describe the take-home message(s), including what has been learnt? • How will this impact future clinical practice?	Conclusion – briefly describe: • Key findings and take-home messages • Impact on future clinical practice • Direction of future research
	3e		Present a structured abstract • Informal case series – introduction, case presentations (brief description of each case) and discussion/conclusion • Formal case series – introduction, methods, results and discussion/conclusion
Highlights	4		Convey the key findings of the research study in 3–5 bullet points
Introduction	5	Describe the background of the case series and specify the overarching theme (e.g. common disease, intervention, or outcome). • The introduction should explain what is unique or educational about the case series. • Relevant scientific literature should be referenced. • Introduction should be 1–2 paragraphs in length.	Introduction – comprehensively describe: • Relevant background and scientific rationale for case series with reference to key scientific literature • Overarching theme (e.g. common patient population, setting, diagnosis, intervention, outcome etc.) • Aims and objectives
Methods	6a	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, for example, ResearchRegistry.com, ClinicalTrials.gov, or ISRCTN. • If a protocol already exists, state the corresponding registration number and access directions (e.g. website or journal, and include a hyperlink that is publicly accessible). It must be written in the English language.	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"*
	6b		Protocol • If a protocol exists, state the corresponding registration number and access directions (e.g. website or journal, and include a hyperlink that is publicly accessible). • It must be written in the English language.
	6c		Ethical approval • State whether ethical approval was needed or not, with reason(s) • If appropriate, state name of body giving ethical approval and approval number
	6d	Study Design • State that the study is a case series. • State whether the case series is: (1) prospective/retrospective, (2) single/multicentre, and if (3) cases are consecutive/nonconsecutive.	Study design • State that the study is a case series • Describe key characteristics of study design (e.g. prospective/retrospective, single-/multicentre, informal/formal, consecutive/nonconsecutive, exposure-/outcome-based sampling, clinical/population-based etc.)
	6e	Settings and Time-Frames • Describe the setting(s) in which the patient was managed (e.g. research institution, teaching/district general hospital, community, or private practice). • Document any relevant dates (e.g. recruitment, intervention, follow-up, and data collection time-frames).	Setting and timeframe – comprehensively describe: • Geographical location • Nature of setting(s) where the patient was managed (e.g. primary/secondary/tertiary care setting, district general hospital/teaching hospital, public/private, low-resource setting etc.) • Relevant dates (e.g. recruitment, intervention, follow-up, data collection etc.)
	6f	Participants • Describe the relevant characteristics (e.g. demographics, comorbidities, tumour staging, smoking status) and if relevant, exposure(s) of the participants. • Describe the method of participant recruitment, if relevant. • State any subsequent inclusion or exclusion criteria, and how the participants were selected. • Methods used to ensure the de-identification of patient information.	Participants – comprehensively describe: • Relevant participant characteristics (e.g. demographics, comorbidities, ASA score, severity of surgery, urgency of surgery, smoking status, tumour staging etc.) and if relevant, exposure(s) of the participants (e.g. COVID-19) • Subsequent inclusion and exclusion criteria with clear definitions • Approach to selecting patients (e.g. consecutive/nonconsecutive, exposure-/outcome-based, formal/informal etc.) • Methods used to ensure de-identification of patient information
	6g		Recruitment – comprehensively describe: • Sources of recruitment (e.g. physician referral, electronic health record etc.) • Any monetary incentivisation of patients for recruitment and retention should be declared; clarify the nature of any incentives provided
	6h	Preintervention Patient Optimisation • Lifestyle (e.g. weight loss). • Medication review (e.g. anticoagulation, oral hypoglycemics/insulin). • Presurgical stabilisation/preparation (e.g. treating hypothermia/hypovolemia/hypotension, ICU care for sepsis, nil by mouth, or enema). • Other (e.g. psychological support).	Preintervention patient optimisation: • Lifestyle (e.g. weight loss, nutritional support, exercise, smoking cessation etc.) • Medication review (e.g. anticoagulation, oral hypoglycemics, insulin, oral contraceptive pill etc.) • Presurgical stabilisation/preparation (e.g. treating hypothermia/-volemia/-tension, ICU care, nil by mouth, bowel preparation etc.) • Other (e.g. psychological support, preoperative education/counselling etc.)
	6i	Interventions • Describe the type(s) of intervention(s) used (e.g. pharmacological, surgical, physiotherapy, psychological, preventative).	Interventions – comprehensively describe: • Type of intervention (e.g. pharmacological, surgical, physiotherapy, psychological etc.) • Aim of intervention (preventative/therapeutic)

Table 1

(Continued)

Topic	Item	PROCESS 2020	Proposed PROCESS 2023
		• Describe any concurrent treatments (e.g. antibiotics, analgesia, antiemetics, venous thromboembolism prophylaxis).	• Concurrent treatments (e.g. antibiotics, analgesia, antiemetics, venous thromboembolism prophylaxis etc.)
	6j	Intervention Details • Describe the rationale behind the treatment offered, how it was performed and time to intervention. • For pharmacological therapies, include information on the formulation, dosage, strength, route, and duration. • For surgery, include details such as anaesthesia, patient position, preparation used, use of other relevant equipment, sutures, devices, and surgical stage. • The degree of novelty for a surgical technique/device should be mentioned (e.g. 'first in human' or 'first in this context'). • Medical devices should have manufacturer and model specifically mentioned.	Intervention specifics – comprehensively describe: • Rationale for the treatment offered • Techniques involved in the administration of the intervention • Time to intervention • For pharmacological therapies, include details such as formulation, dosage, strength, route and duration • For surgical intervention, include details on anaesthesia, patient positioning, preparation used, equipment needed, devices, sutures, surgical stage etc. • Degree of novelty of surgical technique/device (e.g. 'first in human' or 'first in this context') • Manufacturer and model of any medical devices used
	6k	Operator Details • Where applicable, include operator experience and position on the learning curve, any relevant training, and specialisation (e.g. 'junior trainee with 3 years of surgical specialty training in Plastic Surgery and seven similar cases completed previously under direct supervision').	Operator details – comprehensively describe: • Relevant training, specialisation and operator's experience (e.g. average number of the relevant procedures performed annually, independent, needs direct/indirect supervision etc.) • Learning curve for technique • Requirement for additional training
	6l	Quality Control • What measures were taken to reduce inter- or intra-operator/operation variation, to ensure quality, and to maintain consistency between cases (e.g. independent observers, lymph node counts, standard surgical technique). • State any specific disparities between cases.	Quality control – comprehensively describe: • Measures taken to reduce inter- or intra-operator/operation variation, ensure quality and maintain consistency between cases (e.g. independent observers, lymph node counts, standard surgical technique etc.) • Any specific disparities between cases
	6m	Follow-Up • When (e.g. how long after discharge, frequency, maximum follow-up length at the time of submission). • Where (e.g. home via video consultation, primary care, secondary care). • How (e.g. telephone consultation, clinical examination, blood tests, imaging). • Any specific long-term surveillance requirements (e.g. imaging surveillance of endovascular aneurysm repair or clinical exam/ultrasound of regional lymph nodes for skin cancer). • Any specific postoperative instructions (e.g. postoperative medications, targeted physiotherapy, psychological therapy). • State if any participants were lost to follow-up and why.	Postoperative care and follow-up – comprehensively describe: • Postoperative care (e.g. patient education, postoperative medications, early mobilisation, targeted physiotherapy, early enteral nutrition, early removal of catheters/drains, psychological therapy etc.) • Follow-up time-frames (e.g. first follow-up postdischarge, follow-up duration at the time of submission etc.) and frequency • Follow-up setting (e.g. home via phone/video consultation, primary care, secondary care etc.) • Follow-up method (e.g. history, clinical examination, blood tests, imaging etc.) • Follow-up personnel (e.g. operating surgeon) • Any specific long-term surveillance requirements (e.g. imaging surveillance of endovascular aneurysm repair, clinical/ultrasound examination of regional lymph nodes for skin cancer etc.) • State if any participants were lost to follow-up and why
Results	7a	Participants • Please state the number of patients involved, the patient characteristics (e.g. demographics, comorbidities, smoking status, and if applicable, tumour staging (e.g. TNM)).	Participants – comprehensively describe: • Number of patients involved • Patient characteristics (e.g. demographics, comorbidities, ASA score, severity of surgery, urgency of surgery, smoking status, tumour staging etc.) and if relevant, exposure(s) of the participants • Include table showing baseline patient characteristics
	7b	Deviation from the Initial Management Plan • State if there were any changes in the planned intervention(s) (e.g. what was changed and why). • Please include a suitable schematic diagram if appropriate.	Deviation from the initial management plan – comprehensively describe: • Any changes to the planned intervention with rationale • If appropriate, include a suitable schematic diagram •
	7c	Outcomes and Follow-Up • Expected versus attained clinical outcome as assessed by the clinician. Reference literature used to inform expected outcomes. • When appropriate, include patient-reported measures (e.g. questionnaires including quality-of-life scales). • Describe and explain the percentage of patients lost to follow-up.	Outcomes and follow-up – comprehensively describe: • Expected versus attained clinician assessed outcome, providing reference to scientific literature used to inform expected outcomes (e.g. core outcome set) • If appropriate, include patient-reported outcomes (e.g. quality-of-life) • Percentage of patients lost to follow-up with rationale
	7d	Intervention Adherence and Compliance • Where relevant, detail how well the patient adhered to and tolerated the advice provided (e.g. avoiding heavy lifting for abdominal surgery, or tolerance of chemotherapy and pharmacological agents). • Explain how adherence and tolerance were measured.	Intervention adherence and compliance – comprehensively describe: • Assessment of patient's adherence and tolerability of intervention and postoperative instructions (e.g. avoiding heavy lifting/strenuous activity, tolerance of chemotherapy/pharmacological agents etc.) • Impact on long-term applicability of intervention in clinical practice
	7e	Complications and Adverse Events • Precautionary measures taken to prevent complications (e.g. antibiotic or venous thromboembolism prophylaxis). • All complications and adverse or unanticipated events should be described in detail and ideally categorised in accordance with the Clavien–Dindo Classification (e.g. blood loss, length of operative time, wound complications, re-exploration or revision surgery, impact on length of stay). • If relevant, was the complication reported to the relevant national agency or pharmaceutical company. • Specify the duration of time between completion of the intervention and discharge, and whether this was within the expected timeframe (if not, why not). • Where applicable, the 30-day postoperative and long-term morbidity/mortality may need to be specified. • State if there were no complications or adverse outcomes	Complications and adverse events – comprehensively describe: • Precautionary measures taken to prevent complications (e.g. antibiotic/venous thromboembolism prophylaxis) • Complications and adverse events (e.g. blood loss, wound infection, deep vein thrombosis, pulmonary embolism etc.), categorised in accordance with the Clavien–Dindo classification • Timing of adverse events • Mitigation for adverse events (e.g. blood transfusion, wound care, re-exploration/revision surgery etc.) • If appropriate, whether complications or adverse events were discussed locally (e.g. morbidity and mortality meetings) • If appropriate, whether complications or adverse events were reported to the relevant national agency or pharmaceutical company • Specify time to discharge following completion of intervention and whether this was within the expected timeframe or not (if not, why not) • Where applicable, specify the 30-day postoperative and long-term morbidity/mortality • State if there were no complications or adverse events
Discussion	8a	Summarise the key results.	Key results–comprehensively describe: • Key results with relevant raw data • Include table showing key results
	8b	Relevant Literature and Placing the Results in Context • Include a discussion of the relevant literature and, if appropriate, similar published studies. • Describe the implications for clinical practice guidelines (e.g. NICE) and any relevant hypotheses generated	Scientific context and implications–comprehensively describe: • Relevant literature and if appropriate, similar published studies • Implications for clinical practice and guidelines (e.g. NICE) • Comparison to current gold standard of care • Relevant hypothesis generation

Table 1

(*Continued*)

Topic	Item	PROCESS 2020	Proposed PROCESS 2023
	8c	Strengths • Describe the relevant strengths of the study. • Detail any multidisciplinary or cross-speciality relevance. • Weaknesses and Limitations • Describe the relevant weaknesses or limitations of the study. • For novel techniques or devices, outline any contraindications and alternatives, potential risks and possible complications if applied to a larger population	Strengths–comprehensively describe: • Strengths of the study • Any multidisciplinary or cross-speciality relevance
	8d		Weaknesses and limitations – comprehensively describe: • Weaknesses and limitations of the study, with potential impact on results and their interpretation • Deviations from protocol, with reasons • For novel techniques or devices, outline any contraindications/alternatives and potential risks/complications if applied to a larger population
	8e	Directions for Future Research • State how the methodology and findings discussed can impact future research and clinical practice. Describe the questions that have arisen as a result of this study. • State the alternative study design(s) best suited to address these questions	Directions for future research – comprehensively describe: • Impact on future research and clinical practice • Questions that have arisen as a result of the study • Alternative study design(s) best suited to address these questions
	8f		Cost – comprehensively describe: • Cost of intervention • Justify cost if intervention more expensive than current gold standard of care • Any cheaper alternatives
Conclusions	9a	Key Conclusions • Outline the key conclusions from this study	Key conclusions • Outline the key conclusions from this study
	9b	Rationale • Ensure that any of the conclusions made are supported by a strong rationale	Rationale • Explain the rationale behind those conclusions
	9c	Future Work • Briefly discuss any questions arisen from this study and any differences in approach to patient diagnosis or management which the authors might adopt in future similar studies	Future work – briefly describe: • Any questions arisen from the study • Any differences in approach to patient diagnosis or management which authors might adopt in future similar studies
Patient and/or Carer Perspective	10	Where appropriate, the patients should be given the opportunity to share their perspective on the intervention(s) they received (e.g. sharing quotes from a consented, anonymised interview, or questionnaire)	Where appropriate, the patients should be given the opportunity to share their perspective on the intervention(s) they received (e.g. sharing quotes from a consented, anonymised interview or questionnaire)
Informed Consent	11	The authors must provide evidence of consent, where applicable, and if requested by the journal. • State the method of consent at the end of the article (e.g. verbal or written). • If not provided by the patients, explain why (e.g. death of patient and consent provided by next of kin). If the patients or family members were untraceable then document the tracing efforts undertaken	The authors must provide evidence of consent, where applicable, and if requested by the journal • State the method of consent at the end of the article (e.g. verbal or written) • If not provided by the patients, explain why (e.g. death of patient and consent provided by next of kin). If the patients or family members were untraceable then document the tracing efforts undertaken
Additional Information	12a	State any conflicts of interest	State any conflicts of interest
	12b	State any sources of funding	State any sources of funding (e.g. grant details) • Role of funder
	12c	Other Relevant Disclosures • Please state any author contributions, acknowledgements, and where required, institutional review board and ethical committee approval. • Disclose whether the case has been presented at a conference or regional meeting	Other relevant disclosures • State any author contributions and acknowledgements • If appropriate, give details of institutional review board and ethical committee approval • Disclose whether the case has been presented at a conference or regional meeting
Clinical Images and Videos	13	Where relevant and available, include clinical images to help demonstrate the cases pre-, peri-, and postintervention (e.g. radiological, histopathological, patient photographs, intraoperative images). • Where relevant and available, include a link (e.g. Google Drive, YouTube) to the narrated operative video to highlight specific techniques or operative findings. • Ensure all media files are appropriately captioned and indicate points of interest to allow for easy interpretation	Where relevant and available, include clinical images to help demonstrate the cases pre-, peri- and postintervention (e.g. radiological, histopathological, patient photographs, intraoperative images etc.) • Where relevant and available, include a link (e.g. Google Drive, YouTube etc.) to the narrated operative video to highlight specific techniques or operative findings • Ensure all media files are appropriately captioned and indicate points of interest to allow for easy interpretation
Referencing the Checklist	14	Include reference to the PROCESS 2020 publication by stating: 'This case series has been reported in line with the PROCESS Guideline' at the end of the methods section (and include citation in the references section)	Include reference to the PROCESS 2023 publication by stating: 'This case series has been reported in line with the PROCESS Guideline' at the end of the methods section and include citation in the references section

A study published in 2017 evaluated the impact of PROCESS guidelines by comparing the reporting quality of surgical case series that were published in three journals across two time periods: pre-PROCESS period (September 2016 to December 2016) and post-PROCESS period (January 2017 to April 2017); a 5% improvement in the reporting quality of surgical case series was noted following the introduction of PROCESS guidelines[8]. Since it was designed in 2016, PROCESS guidelines have been cited over 1000 times, further conveying its impact in the field of surgical research[5–7].

Over 2 years have passed since the previous update to the PROCESS guidelines in 2020[7]. Our aim is to revise the PROCESS guidelines in accordance with new developments in the field of surgical research and hence maintain the utility of PROCESS guidelines in the surgical research community.

Methods

A PROCESS 2023 steering group was formed; proposals to update PROCESS 2020 guidelines were devised by members of the PROCESS 2023 steering group through collaboration over e-mail and Google Docs.

In a similar fashion to how the initial PROCESS guidelines were created, the Delphi method was used in order to develop PROCESS 2023 guidelines[5]. Members of the Delphi groups that were involved in the development of previous PROCESS guidelines were emailed invitations to participate in the creation of PROCESS 2023 guidelines. Predominantly, participants who were requested to join the Delphi group, belonged to the editorial board or the pool of reviewers of the International Journal of Surgery Publishing Group (IJSPG), an ardent supporter of the PROCESS guidelines, having employed compliance with the

guidelines as a compulsory requirement for the submission of case series[7]. Invitees included 53 people, across 21 countries covering 6 continents, in a range of surgical specialities as well as other specialities such as dermatology, gastroenterology, psychiatry, and dental public health.

Those who agreed to participate in the development of PROCESS 2023 guidelines were sent a survey using Google Forms, outlining the proposed changes to the PROCESS 2020 guidelines. Participants were asked to indicate their agreement/disagreement with the proposed changes to the guidelines, using a nine-point Likert scale, where a score of 1 indicated strong disagreement and a score of 9 indicated strong agreement.

Consensus was deemed as greater than 70% agreement with the proposed changes to an item (i.e. a score between 7 and 9).

Results

A total of 41 out of the 53 invitees expressed an interest in participating in the development of PROCESS 2023 guidelines. Out of those who showed an interest to participate, 38 people completed the Google Forms survey and hence took part in the development of PROCESS 2023 guidelines. Table 1 shows PROCESS 2020 guidelines and the proposed version of PROCESS 2023 guidelines. Table 2 shows a summary of the scores given by the Delphi group members to indicate whether they agree or disagree with the proposed changes made to each item of the PROCESS 2020 guidelines. The majority of the items received a score between 7 and 9 from greater than 70% of the participants, indicating consensus with the proposed changes to those items. However, two items (3c and 6a) received a score between 7 and 9 from less than 70% of the participants, indicating lack of consensus with the proposed changes to those items. Those items will remain unchanged.

Delphi group characteristics

Out of the 38 participants, 16 participants were from Asia, 16 participants were from Europe, 5 participants were from North America, and 1 participant was from Australia. There were no participants from South America or Africa.

Of the 38 participants, eight were from United Kingdom (UK), seven from India, four from United States of America (USA), four from Italy, two from Pakistan, and two from Singapore. There was one participant from each of the following countries: Malaysia, China, Saudi Arabia, Türkiye, Egypt, Australia, Canada, Spain, Portugal, Finland, and Norway.

Contribution from participants across different parts of the world allowed socioeconomic diversity among the Delphi group members; participants belonged to a range of developing and developed countries.

Of the 38 participants, 32 were experts in a range of specialities within the surgical field. Out of the other six participants, two participants were experts in dermatology, one in gastroenterology, one in pulmonary and critical care, one in psychiatry, and one in public health dentistry.

Supplementary Figure 1 (Supplemental Digital Content 1, http://links.lww.com/JS9/B337) shows the characteristics of the Delphi group members.

Table 2

Summary of scores given by Delphi group members to indicate whether they agree or disagree with the proposed changes made to each item of the PROCESS 2020 guidelines.

Item	1–3	4–6	7–9
1	2.6%	10.5%	86.8%
2	5.3%	15.8%	79.0%
3a	2.6%	21.0%	76.4%
3b	7.9%	10.5%	81.6%
3c	2.6%	31.6%	65.8%
3d	2.6%	18.4%	79.0%
3e	2.6%	10.5%	86.8%
4	2.6%	15.8%	81.6%
5	5.2%	15.8%	79.0%
6a	13.1%	21.0%	65.9%
6b	7.9%	18.4%	73.7%
6c	7.8%	5.3%	86.9%
6d	2.6%	5.3%	92.1%
6e	5.3%	15.8%	79.0%
6f	0.0%	10.5%	89.5%
6g	5.3%	13.2%	81.6%
6h	0.0%	15.8%	84.2%
6i	0.0%	5.3%	94.8%
6j	0.0%	10.5%	89.5%
6k	0.0%	21.1%	78.9%
6l	2.6%	23.7%	73.7%
6m	0.0%	10.5%	89.5%
6n	0.0%	26.3%	73.7%
7a	0.0%	5.3%	94.7%
7b	0.0%	18.4%	81.6%
7c	0.0%	5.2%	94.7%
7d	0.0%	13.2%	86.8%
7e	0.0%	15.8%	84.2%
8a	5.2%	18.5%	76.4%
8b	2.6%	7.9%	89.5%
8c	5.3%	18.4%	76.3%
8d	0.0%	21.1%	79.0%
8e	0.0%	15.8%	84.3%
8f	2.6%	18.4%	79.0%
9a	5.2%	21.1%	73.7%
9b	7.9%	7.9%	84.3%
9c	0.0%	18.4%	81.7%
10	2.6%	21.0%	76.3%
11	5.2%	18.4%	76.3%
12a	2.6%	13.2%	84.3%
12b	0.0%	5.2%	94.8%
12c	0.0%	15.7%	84.2%
13	0.0%	29.0%	71.0%
14	0.0%	13.2%	86.9%

Discussion

Despite being lower down in the hierarchy of evidence, case series can add to the scientific literature in numerous ways (e.g. describing rare diseases, unusual presentations of a common disease, novel interventions, unexpected results of an intervention etc.)[2,3]. Given how easy, quick and inexpensive it is to perform case series, they abundantly feature in the surgical literature[2]. However, the methodological and reporting quality of surgical case series have been shown to be substandard and requiring improvement; this can compromise the utility and trustworthiness of surgical case series[4]. PROCESS guidelines were introduced to remedy the poor reporting quality among surgical case

Table 3

PROCESS 2023 guidelines.

PROCESS 2023 Guidelines		
Topic	**Item**	**Item description**
Title	1	The phrase 'case series' is included • The focus of the research study is mentioned (e.g. patient population, setting, diagnosis, intervention, outcome etc.)
Keywords	2	Include three to six keywords that identify what is covered in the case series (e.g. patient population, setting, diagnosis, intervention, outcome etc.) • Include 'case series' as one of the keywords • Include the surgical subspeciality the case series pertains to as a keyword
Abstract	3a	Introduction – briefly describe: • Background • Scientific rationale for this study • Overarching theme of the case series • Aims and objectives
	3b	Methods – briefly describe: • Sample size • Timeframe of research • Characteristics of study design (e.g. prospective/retrospective, single-/multicentre, informal/formal, consecutive/nonconsecutive, exposure-/outcome-based sampling, clinical/population-based etc.)
	3c	Outcomes • Describe the outcomes of the intervention and management strategy
	3d	Conclusion – briefly describe: • Key findings and take-home messages • Impact on future clinical practice • Direction of future research
	3e	Present a structured abstract • Informal case series – introduction, case presentations (brief description of each case) and discussion/conclusion • Formal case series – introduction, methods, results and discussion/conclusion
Highlights	4	Convey the key findings of the research study in 3 to 5 bullet points
Introduction	5	Introduction – comprehensively describe: • Relevant background and scientific rationale for case series with reference to key scientific literature • Overarching theme (e.g. common patient population, setting, diagnosis, intervention, outcome etc.) • Aims and objectives
Methods	6a	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, for example, ResearchRegistry.com, ClinicalTrials.gov, or ISRCTN. • If a protocol already exists, state the corresponding registration number and access directions (e.g. website or journal, and include a hyperlink that is publicly accessible). It must be written in the English language
	6b	Ethical approval • State whether ethical approval was needed or not, with reason(s) • If appropriate, state name of body giving ethical approval and approval number
	6c	Study design •State that the study is a case series • Describe key characteristics of study design (e.g. prospective/retrospective, single-/multicentre, informal/formal, consecutive/nonconsecutive, exposure-/outcome-based sampling, clinical/population-based etc.)
	6d	Setting and timeframe – comprehensively describe: •Geographical location • Nature of setting(s) where the patient was managed (e.g. primary/secondary/tertiary care setting, district general hospital/teaching hospital, public/private, low-resource setting etc.) • Relevant dates (e.g. recruitment, intervention, follow-up, data collection etc.)
	6e	Participants – comprehensively describe: •Relevant participant characteristics (e.g. demographics, comorbidities, ASA score, severity of surgery, urgency of surgery, smoking status, tumour staging etc.) and if relevant, exposure(s) of the participants (e.g. COVID-19) • Subsequent inclusion and exclusion criteria with clear definitions • Approach to selecting patients (e.g. consecutive/nonconsecutive, exposure-/outcome-based, formal/informal etc.) • Methods used to ensure de-identification of patient information
	6f	Recruitment – comprehensively describe: • Sources of recruitment (e.g. physician referral, electronic health record etc.) • Any monetary incentivisation of patients for recruitment and retention should be declared; clarify the nature of any incentives provided
	6g	Preintervention patient optimisation: • Lifestyle (e.g. weight loss, nutritional support, exercise, smoking cessation etc.)

Table 3

(*Continued*)

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Topic	Item	Item description
		• Medication review (e.g. anticoagulation, oral hypoglycemics, insulin, oral contraceptive pill etc.) • Presurgical stabilisation/preparation (e.g. treating hypothermia/-volemia/-tension, ICU care, nil by mouth, bowel preparation etc.) • Other (e.g. psychological support, preoperative education/counselling etc.)
	6h	Interventions – comprehensively describe: • Type of intervention (e.g. pharmacological, surgical, physiotherapy, psychological etc.) • Aim of intervention (preventative/therapeutic) • Concurrent treatments (e.g. antibiotics, analgesia, antiemetics, venous thromboembolism prophylaxis etc.)
	6i	Intervention specifics – comprehensively describe: • Rationale for the treatment offered • Techniques involved in the administration of the intervention • Time to intervention • For pharmacological therapies, include details such as formulation, dosage, strength, route and duration • For surgical intervention, include details on anaesthesia, patient positioning, preparation used, equipment needed, devices, sutures, surgical stage etc. • Degree of novelty of surgical technique/device (e.g. 'first in human' or 'first in this context') • Manufacturer and model of any medical devices used
	6j	Operator details – comprehensively describe: • Relevant training, specialisation and operator's experience (e.g. average number of the relevant procedures performed annually, independent, needs direct/indirect supervision etc.) • Learning curve for technique • Requirement for additional training
	6k	Quality control – comprehensively describe: • Measures taken to reduce inter- or intra-operator/operation variation, ensure quality and maintain consistency between cases (e.g. independent observers, lymph node counts, standard surgical technique etc.) • Any specific disparities between cases
	6l	Postoperative care and follow-up – comprehensively describe: • Postoperative care (e.g. patient education, postoperative medications, early mobilisation, targeted physiotherapy, early enteral nutrition, early removal of catheters/drains, psychological therapy etc.) • Follow-up time-frames (e.g. first follow-up post-discharge, follow-up duration at the time of submission etc.) and frequency • Follow-up setting (e.g. home via phone/video consultation, primary care, secondary care etc.) • Follow-up method (e.g. history, clinical examination, blood tests, imaging etc.) • Follow-up personnel (e.g. operating surgeon) • Any specific long-term surveillance requirements (e.g. imaging surveillance of endovascular aneurysm repair, clinical/ultrasound examination of regional lymph nodes for skin cancer etc.) • State if any participants were lost to follow-up and why
Results	7a	Participants – comprehensively describe: • Number of patients involved • Patient characteristics (e.g. demographics, comorbidities, ASA score, severity of surgery, urgency of surgery, smoking status, tumour staging etc.) and if relevant, exposure(s) of the participants • Include table showing baseline patient characteristics
	7b	Deviation from the initial management plan – comprehensively describe: • Any changes to the planned intervention with rationale • If appropriate, include a suitable schematic diagram
	7c	Outcomes and follow-up – comprehensively describe: • Expected versus attained clinician assessed outcome, providing reference to scientific literature used to inform expected outcomes (e.g. core outcome set) • If appropriate, include patient-reported outcomes (e.g. quality-of-life) • Percentage of patients lost to follow-up with rationale
	7d	Intervention adherence and compliance – comprehensively describe: • Assessment of patient's adherence and tolerability of intervention and postoperative instructions (e.g. avoiding heavy lifting/strenuous activity, tolerance of chemotherapy/pharmacological agents etc.) • Impact on long-term applicability of intervention in clinical practice
	7e	Complications and adverse events – comprehensively describe: • Precautionary measures taken to prevent complications (e.g. antibiotic/venous thromboembolism prophylaxis) • Complications and adverse events (e.g. blood loss, wound infection, deep vein thrombosis, pulmonary embolism etc.), categorised in accordance with the Clavien–Dindo classification • Timing of adverse events • Mitigation for adverse events (e.g. blood transfusion, wound care, re-exploration/revision surgery etc.) • If appropriate, whether complications or adverse events were discussed locally (e.g. morbidity and mortality meetings) • If appropriate, whether complications or adverse events were reported to the relevant national agency or pharmaceutical

Table 3

(*Continued*)

PROCESS 2023 Guidelines

Topic	Item	Item description
		company • Specify time to discharge following completion of intervention and whether this was within the expected timeframe or not (if not, why not) • Where applicable, specify the 30-day postoperative and long-term morbidity/mortality • State if there were no complications or adverse events
Discussion	8a	Key results – comprehensively describe: • Key results with relevant raw data • Include table showing key results
	8b	Scientific context and implications – comprehensively describe: • Relevant literature and if appropriate, similar published studies • Implications for clinical practice and guidelines (e.g. NICE) • Comparison to current gold standard of care • Relevant hypothesis generation
	8c	Strengths – comprehensively describe: • Strengths of the study • Any multidisciplinary or cross-speciality relevance
	8d	Weaknesses and limitations – comprehensively describe: • Weaknesses and limitations of the study, with potential impact on results and their interpretation • Deviations from protocol, with reasons • For novel techniques or devices, outline any contraindications/alternatives and potential risks/complications if applied to a larger population
	8e	Directions for future research – comprehensively describe: • Impact on future research and clinical practice • Questions that have arisen as a result of the study • Alternative study design(s) best suited to address these questions
	8f	Cost – comprehensively describe: • Cost of intervention • Justify cost if intervention more expensive than current gold standard of care • Any cheaper alternatives
Conclusions	9a	Key conclusions • Outline the key conclusions from this study
	9b	Rationale • Explain the rationale behind those conclusions
	9c	Future work – briefly describe: • Any questions arisen from the study • Any differences in approach to patient diagnosis or management which authors might adopt in future similar studies
Patient and/or Carer Perspective	10	Where appropriate, the patients should be given the opportunity to share their perspective on the intervention(s) they received (e.g. sharing quotes from a consented, anonymised interview or questionnaire)
Informed Consent	11	The authors must provide evidence of consent, where applicable, and if requested by the journal • State the method of consent at the end of the article (e.g. verbal or written) • If not provided by the patients, explain why (e.g. death of patient and consent provided by next of kin). If the patients or family members were untraceable then document the tracing efforts undertaken
Additional Information	12a	State any conflicts of interest
	12b	State any sources of funding (e.g. grant details) • Role of funder
	12c	Other relevant disclosures • State any author contributions and acknowledgements • If appropriate, give details of institutional review board and ethical committee approval • Disclose whether the case has been presented at a conference or regional meeting
Clinical Images and Videos	13	Where relevant and available, include clinical images to help demonstrate the cases pre-, peri- and postintervention (e.g. radiological, histopathological, patient photographs, intraoperative images etc.) • Where relevant and available, include a link (e.g. Google Drive, YouTube etc.) to the narrated operative video to highlight specific techniques or operative findings • Ensure all media files are appropriately captioned and indicate points of interest to allow for easy interpretation
Referencing the Checklist	14	Include reference to the PROCESS 2023 publication by stating: 'This case series has been reported in line with the PROCESS Guideline' at the end of the methods section and include citation in the references section

series and a study conducted shortly after the introduction of PROCESS guidelines showed a 5% improvement in the reporting quality of surgical case series[5,8].

A study in 2017 showed that out of 193 surgical journals that were analysed, the majority (62%) did not require their authors to conform to any reporting guidelines, which in turn are integral to making research trustworthy and useful[9].

PROCESS guidelines have already made a substantial impact in the field of surgical research, having been cited over 1000 times since its inception[5–7]. In order to maintain its value and applicability in the surgical research field, PROCESS guidelines were updated; some of the key updates are discussed below.

Item 3b in the abstract section and 6d in the methods section have been amended to encourage authors to specify characteristics of the study design (e.g. prospective/retrospective, single-/multicentre, informal/formal, consecutive/nonconsecutive, exposure-/outcome-based sampling, clinical/population-based etc.). Substandard reporting of study designs makes it difficult for readers to effectively scrutinise and/or compare research studies and hence diminishes their usefulness. Revisions have been made to items 3b and 6d with a view to improving the reporting of study designs among surgical case series[10].

Item 3e has been added to the abstract section, encouraging authors to present their abstract in a structured fashion. This will allow the readers to gain a quick overview of the research study, its salient findings and how the author(s) arrived at those findings[11]. Structured abstracts have been noted to convey information with a higher quality in comparison to unstructured abstracts[12].

Items 6h and 6m in the methods section have been amended, in order to prompt authors to report any strategies that were adopted in line with the Enhanced Recovery After Surgery (ERAS) protocol (e.g. preoperative counselling, early mobilisation, early enteral nutrition, early removal of catheters/drains etc.)[13]. ERAS is a relatively new concept within the surgical field and aims to improve the postoperative recovery and outcomes in patients[14]. Positive outcomes such as reduction in length of hospital stay, hospital costs, and rates of postoperative complications have been noted with the implementation of ERAS protocol[13]. Hence, authors are urged to report any measures that were undertaken as per the ERAS protocol so that readers can judge whether patients received care as per the current evidence-based surgical practice whilst scrutinising patient outcomes.

Item 8f in the discussion section reminds authors to report their analysis of cost-effectiveness. Researchers, policy makers, and clinicians evaluate the cost-effectiveness of an intervention in comparison to the gold standard of care when determining research priorities and making decisions regarding funding health services[15].

Table 3 presents the updated PROCESS 2023 guidelines; we urge journals, editors, reviewers and authors to adopt these guidelines and hence contribute to the improvement of the reporting quality of surgical case series.

Authors should cite PROCESS 2023 guidelines in their methods section and provide a completed PROCESS 2023 checklist along with their manuscript for scrutiny by the reviewers and editors in order to ensure optimal research reporting. To guarantee accessibility, we will update the PROCESS website (https://www.processguideline.com/) with the PROCESS 2023 guidelines checklist, providing it in a variety of formats.

Conclusion

We have presented the updated version of PROCESS guidelines. In order to improve the reporting quality of surgical case series, we encourage journals, editors, reviewers, and authors to utilise these guidelines.

PROCESS Group

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Not applicable.

Consent

Not applicable.

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Author contribution

R.A.: concept and design, data interpretation and analysis, draughting, revision, and approval of final manuscript; G.M.: design, data collection, data interpretation and analysis, draughting, revision, and approval of final manuscript; C.S., T.F., M.N., and A.K.: design, data interpretation and analysis, draughting, revision, and approval of final manuscript. Delphi group members: design of PROCESS 2023 guidelines.

Conflicts of interest disclosure

The authors have no financial, consultative, institutional, or other relationships that might lead to bias or conflict of interest.

Research registration unique identifying number (UIN)

Not applicable.

Guarantor

Riaz Agha.

Data availability statement

The data in this guideline is derived from individual responses to the DELPHI survey and so is confidential and not in the public domain.

Provenance and peer review

Not applicable.

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