

PROCESS Checklist

Section/Topic	Item No	Item	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title	1	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	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?		
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" (this can be obtained from; ResearchRegistry.com or ClinicalTrials.gov or ISRCTN). State whether ethical approval was needed and if so, what the relevant judgement reference was?		
	4b	Study design - 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.		
	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 and 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.		

	4g	Peri-intervention considerations - administration of intervention (what, where, when and how was it done, including for surgery; anaesthesia, patient position, use of tourniquet and other relevant equipment, preparation used, sutures, devices, surgical stage (1 or 2 stage, etc). Pharmacological therapies should include formulation, dosage, strength, route and duration).		
	4h	Who performed the procedures - operator experience (position on the learning curve for the technique if established, specialisation and prior relevant training).		
	4i	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		
	4j	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.		
Results	5a	Participants - reports numbers involved and their characteristics (comorbidities, tumour staging, smoking status, etc).		
	5b	Any changes in the interventions during the course of the case series (how has it evolved, been 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.		
	5c	Outcomes and follow-up - 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.		
	5d	Where relevant - intervention adherence/compliance and tolerability (how was this assessed). Describe loss to follow-up (express as a percentage) and any explanations for it.		
	5e	Complications and adverse or unanticipated events. 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.		
Discussion	6a	Summarise key results		
	6b	Discussion of the 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.		
	6c	Strengths and limitations of the study		
	6d	The rationale for any conclusions?		

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		