

AME Case Series Checklist –Adapted from CARE Checklist and PROCESS Checklist

Section	Item	Checklist description	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title	1	The diagnosis or intervention of primary focus followed by the words “case series”.	Page 1/Line 1-2	Title page/title
Key Words	2	2 to 5 key words that identify diagnoses or interventions in this case series, including "case report" or "case series".	Page 2/Line 47-48	Key Words
Abstract (no references)	3a	Introduction—What is unique about this case series and what does it add to the scientific literature?	Page 2/Line 28-30	Abstract/Paragraph 1
	3b	Methods—describe what was done, how and when was it done and by whom.	Page 2/Line 31-39	Abstract/Paragraph 2
	3c	Results—what was found.	Page 2/Line 40-43	Abstract/Paragraph 3
	3d	Conclusion—What is the main take-away lesson(s)? What have we learned and what does it mean?	Page 2/Line 44-45	Abstract/Paragraph 4
Introduction	4	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?	Page 3-4/Line 57-91	Introduction/Paragraph 1-3
Methods	5a	Registration and ethics— 5a.1 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). 5a.2 State whether ethical approval was passed. 5a.3 Provide the patient consent form too.	Page 4/line 94-96	Methods/Paragraph 1
	5b	Study design—state the study is a case series and whether prospective or retrospective in design, whether single or multi-center and whether cases are consecutive or non-consecutive.	Page 4/line 94-97	Methods/Paragraph 1
	5c	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.	Page 4/line 94-97	Methods/Paragraph 1
	5d	Participants— 5d.1 Describe the relevant characteristics of the participants (history, comorbidities, tumor staging, smoking, etc.). 5d.2 State any eligibility (inclusion/exclusion) criteria and the sources and methods of selection of participants.	Page 4/line 96-97	Methods/Paragraph 1

	5e	Intervention—types of intervention (such as pharmacologic, surgical, preventive, self-care) deployed and reasoning behind treatment offered. Pharmacological therapies should include formulation, dosage, strength, route and duration.	Page 4/line 99-102	Methods/Paragraph 1
	5f	Follow up—describe length and methods of follow-up.	Page 4-5/line 106-126	Methods/Paragraph 2-3
Results	6a	Participants—reports numbers involved and their characteristics (comorbidities, tumor staging, smoking, etc.).	Page 5-6/line 129-154	Results/Paragraph 1-3
	6b	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.	Page 6/156-157	Results/Paragraph 4
	6c	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.	Page 6/156-161	Results/Paragraph 4
	6d	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.	NA	NA
	6e	Complications and adverse or unanticipated events.	NA	NA
Discussion	7a	Summarize key results.	Page 6/line 164-166	Discussion/Paragraph 1
	7b	Discussion of the relevant literature, implications for clinical practice guidelines. How do outcomes compare with established therapies and the prevailing gold standard? Generate a hypothesis if possible.	Page 6-8/ line 168-221	Discussion/Paragraph 2-6
	7c	Strengths and limitations of the study.	Page 6-8/ line 168-221	Discussion/Paragraph 2-6
	7d	The rationale for any conclusions.	Page 6-8/ line 168-221	Discussion/Paragraph 2-6
Conclusion	8a	State the key conclusions from the study.	Page 8/ line 224-227	Conclusion//Paragraph 1
	8b	State what needs to be done next, further research with what study design.	Page 8/ line 227-228	Conclusion//Paragraph 1

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.

STROBE Statement—checklist of items that should be included in reports of observational studies

Section/item	Item No	Recommendation	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 1/Line 1-2	Title
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2/Line 28-45	Abstract
Introduction				
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 3-4/ line 58-87	Introduction/Paragraph 1-2
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 4/line 89-91	Introduction/Paragraph 3
Methods				
Study design	4	Present key elements of study design early in the paper	Page 4/line 94	Methods/Paragraph 1
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 4/line 96-97	Methods/Paragraph 1
Participants	6	(a) Cohort study —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Case-control study —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls Cross-sectional study —Give the eligibility criteria, and the sources and methods of selection of participants	Page 4/line 94-97	Methods/Paragraph 1
		(b) Cohort study —For matched studies, give matching criteria and number of exposed and unexposed Case-control study —For matched studies, give matching criteria and the number of controls per case	N/A	N/
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 4-5/line 102-126	Methods/Paragraph 2-3
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 4-5/line 102-126	Methods/Paragraph 2-3
Bias	9	Describe any efforts to address potential sources of bias	N/A	N/A
Study size	10	Explain how the study size was arrived at	N/A	N/A
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 4-5/line 102-126	Methods/Paragraph 2-3

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 5/128-129	Methods/Paragraph 4
		(b) Describe any methods used to examine subgroups and interactions	N/A	N/A
		(c) Explain how missing data were addressed	N/A	N/A
		(d) Cohort study —If applicable, explain how loss to follow-up was addressed Case-control study —If applicable, explain how matching of cases and controls was addressed Cross-sectional study —If applicable, describe analytical methods taking account of sampling strategy	N/A	N/A
		(e) Describe any sensitivity analyses	N/A	N/A
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 5/line 129-130	Results/Paragraph 1
		(b) Give reasons for non-participation at each stage	N/A	N/A
		(c) Consider use of a flow diagram	N/A	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 5-6/line 129-154	Results/Paragraph 1-3
		(b) Indicate number of participants with missing data for each variable of interest	N/A	N/A
		(c) Cohort study —Summarise follow-up time (eg, average and total amount)	Page 6/line 157-159	Results/Paragraph 4
Outcome data	15*	Cohort study —Report numbers of outcome events or summary measures over time	Page 6/line 159-161	Results/Paragraph 4
		Case-control study —Report numbers in each exposure category, or summary measures of exposure	N/A	N/A
		Cross-sectional study —Report numbers of outcome events or summary measures	N/A	N/A
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A	N/A
		(b) Report category boundaries when continuous variables were categorized	N/A	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A	N/A
Discussion				
Key results	18	Summarise key results with reference to study objectives	Page 6/line 164-166	Discussion/Paragraph 1
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	N/A	N/A

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 6-8/line 207-272	Discussion/Paragraph 2-5
Generalisability	21	Discuss the generalisability (external validity) of the study results	N/A	N/A
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 8/line 284	Acknowledgment/Funding

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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