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Appendix 6 Strengthening the Reporting of Observational studies in Epidemiology (STROBE) checklist

The STROBE statement: checklist of items that should be included in reports of observational studies

Item name	Item no.	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract **(p. v)**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found **(p. v–vi)**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **(p. 1, paragraph 2 + p. 2, paragraph 2)**
Objectives	3	State specific objectives, including any prespecified hypotheses **(p. 3, paragraph 2 + p. 5)**
Methods		
Study design	4	Present key elements of study design early in the paper **(pp. 7–9)**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection **(pp. 7–9)**
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 **(p. 7)**
		(*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 **(pp. 7–9, p. 19)**
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable **(clinical: pp. 9–11; imaging: pp. 10–11 + p. 13)**
Data sources/measurement	8[a]	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 **(pp. 9–16)**
Bias	9	Describe any efforts to address potential sources of bias **(p. 7)**

Item name	Item no.	Recommendation
Study size	10	Explain how the study size was arrived at **(p. 16)**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why **(pp. 9–16)**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **(p. 16)**
		(*b*) Describe any methods used to examine subgroups and interactions **(p. 16)**
		(*c*) Explain how missing data were addressed **(p. 19 +** ***Figure 3*** **flow diagram)**
		(*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)**
		(*e*) Describe any sensitivity analyses **(p. 16)**
Results		
Participants	13[a]	(a) Report numbers of individuals at each stage of study, e.g. numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed **(p. 19 +** ***Figure 3*** **flow diagram)**
		(b) Give reasons for non-participation at each stage **(pp. 19–23 + pp. 30–2)**
		(c) Consider use of a flow diagram **(** ***Figure 3*** **flow diagram)**
Descriptive data	14[a]	(a) Give characteristics of study participants (e.g. demographic, clinical, social) and information on exposures and potential confounders **(** ***Table 3*** **)**
		(b) Indicate number of participants with missing data for each variable of interest **(** ***Table 3*** **,** ***Table 4*** **,** ***Figure 11*** **, pp. 30–2)**
		(c) *Cohort study* – Summarise follow-up time (e.g. average and total amount) **(all 6/12)**
Outcome data	15[a]	*Cohort study* – Report numbers of outcome events or summary measures over time **(pp. 30–2,** ***Table 5*** **)**
		Case–control study – Report numbers in each exposure category, or summary measures of exposure **(** ***Figure 3*** **, pp. 36–41)**
		Cross-sectional study – Report numbers of outcome events or summary measures **(pp. 30–32,** ***Table 5*** **, pp. 36–41)**
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g. 95% confidence interval). Make clear which confounders were adjusted for and why they were included **(** ***Table 5*** **, p. 36)**
		(*b*) Report category boundaries when continuous variables were categorised **(N/A)**

Item name	Item no.	Recommendation
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done, e.g. analyses of subgroups and interactions, and sensitivity analyses **(p. 43)**
Discussion		
Key results	18	Summarise key results with reference to study objectives **(p. 45 + p. 49)**
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 **(pp. 45–6)**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence **(pp. 46–9)**
Generalisability	21	Discuss the generalisability (external validity) of the study results **(p. 49)**
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 **(pp. 51–2)**

a 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 websites of *PLOS Medicine* at www.plosmedicine.org/, *Annals of Internal Medicine* at www.annals.org/ and *Epidemiology* at www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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