

Review Update

Strengthening the reporting of observational studies in epidemiology (STROBE) statement: New guidelines for reporting observational studies

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A vast majority of observational studies have been reported in journals compared to the experimental studies.¹ Many of those are cross sectional, case-control and cohort studies. These study designs are used not only to determine the risk factors for diseases but also to determine the prognostic factors as well. Observational studies also have a role in describing and determining harms of medical interventions. In some situations where the randomized trials are not appropriate or feasible for assessing interventions, observational studies are the alternatives. Therefore observational studies are useful not only for improving public health by changing policies but also for clinical practice.

However, the information provided in published observational studies have many deficiencies. The essential information is not reported at all or, though reported, sometimes appear to be unclear. For example, a review of longitudinal studies on stroke found that 17 out of 49 articles did not report eligibility criteria for recruiting participants.² Readers need to know what was planned (and what was not), what was done, what was found, and what the results mean. The assessment of the strengths and weaknesses of the studies reported in the medical literature is hampered by incomplete, inadequate and inaccurate reporting of research. Transparent reporting of research has many advantages. It allows the critical appraisal of the research articles and it will ultimately facilitate to assess the quality of the studies. It also facilitates adequate inclusion of data which are essential to be extracted for conducting systematic reviews.

The STROBE statement is a checklist of items that should be addressed in articles reporting the three main study designs of analytical epidemiology: cohort, case-control, and cross sectional studies.³ The authors of the STROBE claim that the intention is solely to provide guidance on how to report observational research well.³ These recommendations are used for neither prescriptions for designing/ conducting studies nor an instrument to evaluate the quality of observational research. The STROBE statement is being endorsed by a growing number of

biomedical journals to improve the quality of reporting (www.strobe-statement.org). The authors strongly recommend using the STROBE checklist in conjunction with the explanatory article, which is available freely on the websites of the publishing journals.⁴

The STROBE initiative was established in 2004 including editorial staff from several international journals as well as epidemiologists, methodologists, statisticians, and practitioners. The STROBE statement is a checklist of 22 items that is considered essential for good reporting of observational studies (table). These items are related to the article's title and abstract (item 1), the introduction (items 2 and 3), methods (items 4-12), results (items 13-17), discussion sections (items 18-21), and other information (item 22 on funding). Eighteen items are common to all three designs, while four (items 6, 12, 14, and 15) are design specific, with different versions for all or part of the item. For some items (indicated by asterisks), information should be given separately for cases and controls in case-control studies, or exposed and unexposed groups in cohort and cross sectional studies. Although the table is a single checklist, the STROBE website provides separate checklists for each of the three study designs.

The STROBE statement should not be interpreted as an attempt to prescribe the reporting of observational research in a rigid format. The checklist items should be addressed in sufficient detail and with clarity somewhere in an article, but the order and format for presenting information depends on author preferences, journal style, and the traditions of the research field. The authors do not aim at standardising reporting.³

The authors stress the fact that STROBE and other recommendations on the reporting of research should be seen as evolving documents that require continual assessment, refinement, and, if necessary, change. They invite readers to submit their comments through the STROBE website.

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Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —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 <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
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
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses

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 (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures
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 (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

Discussion

Key results	18	Summarise key results with reference to study objectives
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
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results

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
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*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.

References

1. Glasziou P, Vandenbroucke JP, Chalmers I. Assessing the quality of research. *BMJ* 2004;328:39-41.
2. Tooth L, Ware R, Bain C, Purdie DM, Dobson A. Quality of reporting of observational longitudinal research. *Am J Epidemiol* 2005;161:280-8.
3. Erik von Elm, Douglas G Altman, Matthias Egger, Stuart J Pocock, Peter C Gøtzsche, Jan P Vandenbroucke. Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies *BMJ* 2007;335:806-808
4. Vandenbroucke JP, von Elm E, Altman DG, Gøtzsche PC, Mulrow CD, Pocock SJ, et al. Strengthening the reporting of observational studies in epidemiology (STROBE): explanation and elaboration. *Epidemiology* 2007;18:805-35.