

STROBE Guideline for Observational Studies

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The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline was developed in 2004 through a collective consensus and initiative of epidemiologists, statisticians, researchers, journal editors, and methodologists. It was developed with a checklist to describe the process of conducting an observational study and guarantee a transparent explanation of the steps involved in planning the study.¹ An observational study is a type of research method in which samples or, at times, outcomes are observed and measured without any intervention or manipulation of participants; thus, it is considered a non-experimental study. This type of study aims to find the association between the exposure and the outcome. Observational studies can be used for anything from confirming the strength of previously reported relationships to providing the first indication of a possible cause of a disease.² They are broadly categorized into three study designs: cross-sectional, case-control, and cohort. The STROBE guideline was developed to ensure the best reporting of these types of studies.^{1,2} To ensure a uniform presentation of the studies conducted, ascertain sufficient reporting, and assess the potential weaknesses and strengths of the studies, the STROBE guideline has been a vital asset. This guideline is also considered crucial in helping reviewers, journal editors, and, above all, readers, critically evaluate the study.

The STROBE Checklist

The STROBE checklist contributes to the STROBE guideline and consists of 22

items. All three observational designs share eighteen common items, while items 6, 12, 14, and 15 differ according to the type of study design.^{2,3} The items and their brief descriptions are as follows:

Title and Abstract (Item 1)

The title should include an identification of the study design. This helps the reader as well as the process of indexing the study in the electronic database. The abstract consists of key information about the study and the study design, which may prompt the reader to either read the article or discard it. The abstract serves as a summary and explains only the information present in the article. Many journals use structured abstracts that follow uniform headings. It is suggested to present the results in numerical form, which may include measures of variability or estimates of the associations.

Introduction (Items 2 and 3)

It should describe the reason for the study and include the research questions or possible hypotheses that the current study addresses. It should also highlight the research gap that justifies the need for the current study. Additionally, it should provide an overview of the already established knowledge on the topic. The background also outlines the areas of focus and overlays the stage for the study. The objectives reflect the major aims of the study. They should specify the population to be studied and the parameters to be estimated. Objectives may be derived as hypotheses or formulated as questions that the study aims to address.

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Methods (Items 4-12)

The method section describes the targeted plan and process by which the study was conducted. It allows readers to critically appraise the methods applied. The STROBE guideline recommends that authors avoid using the terms 'prospective' or 'retrospective' or their alternatives, and instead, provide exact details of the data collection process. Information about the setting and location of the study, including the study site and its justification, should be provided, as this may help in the interpretation of the results. It is advised to use exact dates rather than time periods. There should be a detailed description of the study participants, although the selection procedure may vary depending on the study design. Eligibility criteria should be specified in terms of inclusion and exclusion criteria. Information about follow-up procedures or loss to follow-up should also be included. All variables considered for statistical analysis and descriptive purposes should be noted, as these factors are crucial in analyzing the validity and applicability of the study. The sample size should be determined, and the method used to calculate it should be reported, including the confidence interval. Potential confounders, effect modifiers, and any missing data should be explained. Any potential bias should be described, along with the steps taken to mitigate such biases.

Results (Items 13-17)

It addresses the findings of the study. It should explore the characteristics, including the demographic details of the study participants, along with comparisons between groups. It should identify participants with missing data. In a cohort study, the follow-up time should be summarized and presented. In a case-control study, the numbers in each exposure category should be reported, while in a cross-sectional study, the numbers of outcomes should be reported. The results section also includes explanations of the statistical techniques applied to analyze the data or make any correlations, including any adjustments for confounders. In the case of important correlations or analyses, the p-value and confidence interval should be reported.

Discussion (Items 18 -21)

This section focuses on the validity and significance of the study. A properly structured discussion prevents over-interpretation of the results and minimizes speculations. The discussion should begin with a summary of the relevant results of the study, which helps readers connect the interpretation provided by the author with the subsequent findings. The limitations of the study should be explained, with a particular focus on various biases and their magnitude. When discussing limitations, authors may relate the study's validity, generalizability, and accuracy

to other research. This approach ensures that each study contributes to the body of knowledge, rather than serving as an isolated basis for conclusions and actions. For clarity, the discussion section can be subdivided into various parts to facilitate an excellent interpretation of the findings. The discussion should conclude with an evaluation of the external validity and recommendations for further studies. Authors should discuss whether the findings are applicable to other populations, settings, or time periods beyond the scope of the current study.

Funding and Sponsorship (Item 22)

At the end of the article, the source of funding should be mentioned, if any, along with the role of the funders. The authors, co-authors, and funders should disclose any conflict of interest of any kind.

To conclude, the STROBE guideline was developed to improve clarity in reporting and achieve complete reporting of observational studies. It aims to establish a uniform reporting modality for observational studies through the 22 items of the STROBE checklist. The guideline is believed to help readers, journal editors, and authors enhance the understanding of the study, present its strengths and validity, and critically analyze the results. Authors must now adhere to the STROBE guideline and have a comprehensive understanding of its components, as it has become a requirement for many journals.

References

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