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Guideline

Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and elaboration☆

Jan P. Vandenbroucke [a], Erik von Elm [b, c], Douglas G. Altman [d], Peter C. Gøtzsche [e], Cynthia D. Mulrow [f], Stuart J. Pocock [g], Charles Poole [h], James J. Schlesselman [i], Matthias Egger [j, k, *], for the STROBE Initiative

[a] Department of Clinical Epidemiology, Leiden University Medical Center, Leiden, The Netherlands
[b] Centre Hospitalier Universitaire Vaudois (CHUV) and University of Lausanne, IUMSP – Institut universitaire de médecine sociale et préventive, Biopôle 2, Route de la Corniche 10, CH-1010 Lausanne, Switzerland
[c] Department of Medical Biometry and Medical Informatics, University Medical Centre, Freiburg, Germany
[d] Centre for Statistics in Medicine, Oxford, United Kingdom
[e] Nordic Cochrane Centre, Rigshospitalet, Copenhagen, Denmark
[f] University of Texas Health Science Center, San Antonio, United States
[g] Medical Statistics Unit, London School of Hygiene and Tropical Medicine, London, United Kingdom
[h] Department of Epidemiology, University of North Carolina School of Public Health, Chapel Hill, United States
[i] Department of Biostatistics, University of Pittsburgh Graduate School of Public Health, United States
[j] Centre for Infectious Disease Epidemiology and Research (CIDER), University of Cape Town, South Africa
[k] Institute of Social and Preventive Medicine (ISPM), University of Bern, Bern, Switzerland

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ABSTRACT

Much medical research is observational. The reporting of observational studies is often of insufficient quality. Poor reporting hampers the assessment of the strengths and weaknesses of a study and the generalisability of its results. Taking into account empirical evidence and theoretical considerations, a group of methodologists, researchers, and editors developed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations to improve the quality of reporting of observational studies. The STROBE Statement consists of a checklist of 22 items, which relate to the title, abstract, introduction, methods, results and discussion sections of articles. Eighteen items are common to cohort studies, case–control studies and cross-sectional studies and four are specific to each of the three study designs. The STROBE Statement provides guidance to authors about how to improve the reporting of observational studies and facilitates critical appraisal and interpretation of studies by reviewers, journal editors and readers. This explanatory and elaboration document is intended to enhance the use, understanding, and dissemination of the STROBE Statement. The meaning and rationale for each checklist item are presented. For each item, one or several published examples and, where possible, references to relevant empirical studies and methodological literature are provided. Examples of useful flow diagrams are also included. The STROBE Statement, this document, and the associated Web site (http://www.strobe-statement.org/) should be helpful resources to improve reporting of observational research.

1. Introduction

Rational health care practices require knowledge about the aetiology and pathogenesis, diagnosis, prognosis and treatment of diseases. Randomised trials provide valuable evidence about treatments and other interventions. However, much of clinical or public health knowledge comes from observational research [1]. About nine of ten research papers published in clinical speciality journals describe observational research [2,3].

Abbreviations: CI, confidence interval; RERI, Relative Excess Risk from Interaction; RR, relative risk; STROBE, Strengthening the Reporting of Observational Studies in Epidemiology.

* Corresponding author. Institute of Social and Preventive Medicine (ISPM), University of Bern, Bern, Switzerland.
E-mail addresses: strobe@ispm.unibe.ch, egger@ispm.unibe.ch (M. Egger).

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1.1. The STROBE Statement

Reporting of observational research is often not detailed and clear enough to assess the strengths and weaknesses of the investigation [4,5]. To improve the reporting of observational research, we developed a checklist of items that should be addressed: the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement (Table 1). Items relate to title, abstract, introduction, methods, results and discussion sections of articles. The STROBE Statement has recently been published in several journals [6]. Our aim is to ensure clear presentation of what was planned, done, and found in an observational study. We stress that the recommendations are not prescriptions for setting up or conducting studies, nor do they dictate methodology or mandate a uniform presentation.

Table 1
The STROBE Statement—checklist of items that should be addressed in reports of observational studies.

	Item number	Recommendation
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/rational	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) *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 (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
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
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
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) *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 (e) Describe any sensitivity analyses
Results		
Participants	13[a]	(a) Report the numbers of individuals at each stage of the study—e.g., 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	14[a]	(a) Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential data confounders (b) Indicate the number of participants with missing data for each variable of interest (c) *Cohort study*—Summarise follow-up time (e.g., average and total amount)
Outcome data	15[a]	*Cohort study*—Report numbers of outcome events or summary measures over time *Case–control study*—Report numbers in each exposure category, or summary measures of exposure *Cross-sectional study*—Report numbers of outcome events or summary measures
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 (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—e.g., 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.

[a] Give such 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/). Separate versions of the checklist for cohort, case–control, and cross-sectional studies are available on the STROBE Web site at http://www.strobe-statement.org/.