CHAPTER 17

STROBE (STrengthening the Reporting of Observational studies in Epidemiology)

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Timetable

Meeting/event date	Objective
March 2001	Idea first discussed
November 2001	Small exploratory meeting at University of Bristol, United Kingdom
April 2003	Planning meeting at University of Bristol, United Kingdom
August 2003	Need for reporting guidelines discussed at World Epidemiology Conference in Montreal, Canada
September 2004	Large workshop at University of Bristol, funded by European Science Foundation
May 2005	First draft checklist posted on STROBE website
October 2007	Publication of checklist and Explanation and Elaboration document in several journals
August 2010	Revision meeting at University of Bern, Switzerland

STROBE Statement

The STrengthening the Reporting of OBservational Studies in Epidemiology (STROBE) statement is a set of recommendations to improve the reporting of observational studies. STROBE addresses the three main types of observational studies: cohort, case–control, and cross-sectional studies. The statement consists of a checklist of 22 items that relate to the title, abstract, introduction, methods, results, and discussion sections of articles.

Guidelines for Reporting Health Research: A User's Manual, First Edition. Edited by David Moher, Douglas G. Altman, Kenneth F. Schulz, Iveta Simera and Elizabeth Wager.

A diagram showing the number of individuals at each stage of the study, from assessment of eligibility to inclusion in the analysis, may also be considered.

The STROBE checklist, the accompanying comprehensive Explanation and Elaboration (E&E) document, and the website, offer guidance to authors on how to prepare reports on observational research, enhance the completeness and transparency of reporting, and facilitate the critical appraisal and interpretation of studies by reviewers, journal editors, and readers.

History/development

The STROBE statement is the result of an international collaborative effort by epidemiologists, methodologists, statisticians, and journal editors. The idea of a reporting guideline for observational studies was first discussed by a small group of epidemiologists working in the United Kingdom in 2001 and further developed in several meetings. The STROBE initiative was formally established in 2004 in Bristol, United Kingdom, during a two-day workshop funded by the European Science Foundation. In the same year, the STROBE website (www.strobe-statement.org) was launched. Prior to the workshop, the group conducted an extensive literature search of textbooks, bibliographic databases, previous recommendations, etc., to collect all relevant information related to observational research. The group decided early on to restrict the scope of the STROBE statement to three study designs.

The workshop was attended by 23 epidemiologists, methodologists, statisticians, journal editors, and practitioners from Europe and North America and was used to write the first draft of the checklist. The draft was subsequently revised during several meetings of the coordination group and in email discussions with the wider group. Subsequently three revisions were published on the website, two summaries of received comments were prepared, and any changes were documented. During this process, the coordinating group met on eight occasions and held several telephone conferences to revise the checklist and to prepare the article reporting the STROBE statement as well as the E&E document. The STROBE statement and the E&E paper were finally simultaneously published in several journals, with open access to both articles.

When to use this guideline (what types of studies it covers)

The STROBE recommendations are designed to inform the reporting of observational epidemiological studies. STROBE covers descriptive studies of, for example, the prevalence or incidence of a disease, as well as

analytical studies that investigate associations between exposures and health outcomes. STROBE is limited to the three main observational study designs: cohort, case–control, and cross-sectional studies.

The cohort design refers to studies where the investigators follow people over time. They obtain information about people and their exposures at baseline, let time pass, and then assess the occurrence of outcomes. Investigators often compare people who are exposed to a factor of interest (e.g., particle matter in the air) with people who are not exposed or exposed to a lesser degree, and assess exposure and outcome variables at multiple points during follow-up. Incidence rates, rate ratios, and relative risks may then be calculated.

In case–control studies, investigators compare exposures between people with a particular disease outcome (cases) with people without that outcome (controls). All cases or a large fraction of cases diagnosed during a period are typically included in the study. The sample of controls represents the cohort or population of people from which the cases arose. Depending on the sampling strategy for cases and controls and the nature of the population studied, the odds ratio obtained in a case–control study is interpreted as the risk ratio, rate ratio, or (prevalence) odds ratio [1].

In cross-sectional studies, investigators assess all individuals in a sample at the same point in time, often to examine the prevalence of exposures, risk factors, or disease.

Other designs such as genetic linkage studies, infectious disease modeling or case reports and case series are *not* covered by STROBE. However, as many of the key elements in STROBE also apply to these designs, authors who report such studies may nevertheless find the recommendations useful. The STROBE statement was not developed to assess the methodological quality of epidemiological studies and should not be used for this purpose.

Current versions

The STROBE statement includes a checklist of 22 items that 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 items are specific to each of the three study designs. For some items, information should be given separately for cases and controls in case–control studies or exposed and unexposed groups in cohort and cross-sectional studies. Separate checklists for each of the three study designs are available on the STROBE website.

The E&E paper offers detailed explanations of each checklist item, gives methodological background, and provides published examples of what the STROBE group considered transparent reporting.

The STROBE recommendations have so far been published in eight journals, including the *BMJ*, *Annals of Internal Medicine*, *PLoS Medicine*, and *The Lancet* [2–9]. The E&E article was published in *PLoS Medicine*, *Annals of Internal Medicine*, and *Epidemiology* [10–12].

Previous versions

No major changes to the original version have been published.

Extensions to be aware of

The STrengthening the REporting of Genetic Association (STREGA) recommendations were published in 2009 and are the first extension of STROBE [13]. STREGA provides additions to 12 of the 22 original items of the STROBE checklist to facilitate the reporting of genetic association studies. An extension in the field of molecular epidemiology has been published [27] and one on neuro-epidemiology is in preparation.

Translations

The STROBE recommendations have been translated into Chinese, Spanish, German, Italian, Japanese, Portuguese, Greek, and Persian. Translations to French, Korean, and Bahasa Indonesian are under way. The E&E document is available in Spanish, Japanese, and a Korean version will become available soon.

Related activities

An idea that was discussed during the 2010 workshop was to bring STROBE and PRISMA together and extend the PRISMA guidelines [14] for systematic reviews and meta-analyses of clinical trials to observational studies. In the first step, conceptual issues specific to observational studies were identified and the first impression was gained of the PRISMA items that would need to be changed and the new items that may need to be added.

How best to use the guideline

We strongly recommend authors to use the checklist alongside the STROBE E&E document when writing reports of observational studies, to make sure

that they understand what is meant (and what is not) by a given item. Many authors will also find the examples of good reporting useful. The STROBE website may also be useful to identify additional information and background. The STROBE checklist can also support editors and reviewers when assessing submitted articles for completeness of reporting of important methodological details.

The recommendations are only intended to provide guidance on how to report observational research in a transparent and complete manner. They are not prescriptions for designing or conducting studies or an instrument to assess the quality of published articles.

Development process

The STROBE statement and other reporting guidelines should be considered as evolving documents that require periodic changes and updates in light of experience and new evidence [15]. Indeed, two distinguished commentators argued that STROBE should come with an "expiration date," and should be updated in 2010 [16]. This was the aim of the workshop held in Bern, Switzerland, in August 2010.

During this workshop the group discussed the impact of STROBE and its endorsement by journals, and the uses (and misuses) of STROBE. The group revisited the checklist to identify items in need of revision and discussed the addition of new items, based on recent developments in study methodology and new empirical evidence on the reporting of cohort, case–control, and cross-sectional studies. The group identified only minor revisions and additions, and it was felt that these did not justify a new version of the checklist. A draft of a revised checklist with the suggestions for modifications proposed during the meeting will serve as the basis for further discussions at the next meeting.

Evidence of effectiveness of guideline

The possible contribution of the STROBE statement in improving the quality of reporting of observational studies has been a matter for discussion and criticism in more than 30 commentaries and editorials [17]. The fact that the STROBE website receives about 3000 hits per month gives further indication of its impact.

Several recent bibliographic studies have used the STROBE statement to assess the quality of reporting of observational studies in defined medical fields [18–24]. We are, however, not aware of any systematic study

comparing the quality of reporting before and after the publication of the STROBE guidelines.

Endorsement and adherence

The STROBE recommendations have been cited over 600 times and have been endorsed by over 100 journals and the International Committee of Medical Journal Editors (see website for complete list of endorsing journals) [17]. The type of endorsement and instructions to authors on the use of STROBE, however, vary widely between journals.

Cautions and limitations (including scope)

The STROBE developers stress that their recommendations are about reporting and should not be seen as prescriptions for designing or conducting studies. Moreover, the checklist should not be used as an instrument to evaluate the quality of observational research. In a recent bibliographic study [25] we looked at a sample of 100 randomly selected articles and examined where, when, and why STROBE was cited. We found that in most observational study reports, STROBE was used as a reporting guideline, whereas half of systematic reviews used STROBE inappropriately as a tool to assess the methodological quality of studies. The absence of reliable tools to assess the quality of observational studies [26] may explain why authors sometimes use reporting guidelines for this purpose.

The STROBE recommendations are limited to three common observational study designs but do not cover many other designs and variations that exist in epidemiological research. The group welcomes extensions that adapt the checklist to other study designs.

Creators' preferred bits

The creators of STROBE do not have preferred items as such, but generally feel that the items closely linked to the prevention of bias in a given observational study are those where transparent and complete reporting is most likely to make a difference. These items will vary between the different study designs and within designs from study to study.

Future plans

The STROBE group will meet again in one or two years to review the need for a revision of the statement. The group is in the process of developing a

short checklist for journal and conference abstracts of observational studies based on the STROBE statement. Last but not least and also resulting from our first revision meeting in 2010, we plan to explore an extension of the PRISMA recommendations for systematic reviews and meta-analyses of observational studies.

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

	Item No	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/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) *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*	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

(*continued*)

	Item No	Recommendation
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) 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) *Cohort study* – Summarise follow-up time (eg, average and total amount)
Outcome data	15*	*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 (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

	Item No	Recommendation
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

*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.