
Downloaded from: http://researchonline.lshtm.ac.uk/1831376/

DOI: 10.1016/j.ijsu.2014.07.013

Usage Guidelines

Please refer to usage guidelines at http://researchonline.lshtm.ac.uk/policies.html or alternatively contact researchonline@lshtm.ac.uk.

Available under license: http://creativecommons.org/licenses/by/2.5/
Guideline

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for reporting observational studies

Erik von Elm, Douglas G. Altman, Matthias Egger, Stuart J. Pocock, Peter C. Gøtzsche, Jan P. Vandenbroucke, for the STROBE Initiative

Institute of Social and Preventive Medicine (ISPM), University of Bern, Bern, Switzerland
Centre for Statistics in Medicine, Oxford, United Kingdom
Centre for Infectious Diseases Epidemiology and Research (CIDER), University of Cape Town, South Africa
London School of Hygiene and Tropical Medicine, University of London, London, United Kingdom
Nordic Cochrane Centre, Copenhagen, Denmark
Department of Clinical Epidemiology, Leiden University Hospital, Leiden, The Netherlands
Centre Hospitalier Universitaire Vaudois (CHUV) and University of Lausanne, IUMSP – Institut universitaire de médecine sociale et préventive, Lausanne, Switzerland

Article info

Article history:
Available online 18 July 2014

A B S T R A C T

Much biomedical research is observational. The reporting of such research is often inadequate, which hampers the assessment of its strengths and weaknesses and of a study's generalisability. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Initiative developed recommendations on what should be included in an accurate and complete report of an observational study. We defined the scope of the recommendations to cover three main study designs: cohort, case–control, and cross-sectional studies. We convened a 2-day workshop in September 2004, with methodologists, researchers, and journal editors to draft a checklist of items. This list was subsequently revised during several meetings of the coordinating group and in e-mail discussions with the larger group of STROBE contributors, taking into account empirical evidence and methodological considerations. The workshop and the subsequent iterative process of consultation and revision resulted in a checklist of 22 items (the STROBE Statement) that relate to the title, abstract, introduction, methods, results, and discussion sections of articles. 18 items are common to all three study designs and four are specific for cohort, case–control, or cross-sectional studies. A detailed Explanation and Elaboration document is published separately and is freely available on the Web sites of PLoS Medicine, Annals of Internal Medicine, and Epidemiology. We hope that the STROBE Statement will contribute to improving the quality of reporting of observational studies.

© 2014 The Authors. Published by Elsevier Ltd on behalf of Surgical Associates Ltd. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/3.0/).

1. Introduction

Many questions in medical research are investigated in observational studies [1]. Much of the research into the cause of diseases relies on cohort, case–control, or cross-sectional studies. Observational studies also have a role in research into the benefits and harms of medical interventions [2]. Randomised trials cannot answer all important questions about a given intervention. For example, observational studies are more suitable to detect rare or late adverse effects of treatments, and are more likely to provide an indication of what is achieved in daily medical practice [3].

Research should be reported transparently so that readers can follow what was planned, what was done, what was found, and
what conclusions were drawn. The credibility of research depends on a critical assessment by others of the strengths and weaknesses in study design, conduct, and analysis. Transparent reporting is also needed to judge whether and how results can be included in systematic reviews [4,5]. However, in published observational research important information is often missing or unclear. An analysis of epidemiological studies published in general medical and specialist journals found that the rationale behind the choice of potential confounding variables was often not reported [6]. Only few reports of case-control studies in psychiatry explained the methods used to identify cases and controls [7]. In a survey of longitudinal studies in stroke research, 17 of 49 articles (35%) did not specify the eligibility criteria [8]. Others have argued that without sufficient clarity of reporting, the benefits of research might be achieved more slowly [9], and that there is a need for guidance in reporting observational studies [10,11].

Recommendations on the reporting of research can improve reporting quality. The Consolidated Standards of Reporting Trials (CONSORT) Statement was developed in 1996 and revised 5 years later [12]. Many medical journals supported this initiative [13], which has helped to improve the quality of reports of randomised trials [14,15]. Similar initiatives have followed for other research areas—e.g., for the reporting of meta-analyses of randomised trials [16] or diagnostic studies [17]. We established a network of methodologists, researchers, and journal editors to develop recommendations for the reporting of observational research: the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement.

2. Aims and use of the STROBE Statement

The STROBE Statement is a checklist of items that should be addressed in articles reporting on the 3 main study designs of analytical epidemiology: cohort, case-control, and cross-sectional studies. The intention is solely to provide guidance on how to report observational research well: these recommendations are not prescriptions for designing or conducting studies. Also, while clarity of reporting is a prerequisite to evaluation, the checklist is not an instrument to evaluate the quality of observational research.

Here we present the STROBE Statement and explain how it was developed. In a detailed companion paper, the Explanation and Elaboration article [18–20], we justify the inclusion of the different checklist items and give methodological background and published examples of what we consider transparent reporting. We strongly recommend using the STROBE checklist in conjunction with the explanatory article, which is available freely on the Web sites of PLoS Medicine (http://www.plosmedicine.org), Annals of Internal Medicine (http://www.annals.org), and Epidemiology (http://www.epidem.com).

3. Development of the STROBE Statement

We established the STROBE Initiative in 2004, obtained funding for a workshop and set up a Web site (http://www.strobe-statement.org). We searched textbooks, bibliographic databases, reference lists, and personal files for relevant material, including previous recommendations, empirical studies of reporting and articles describing relevant methodological research. Because observational research makes use of many different study designs, we felt that the scope of STROBE had to be clearly defined early on. We decided to focus on the 3 study designs that are used most widely in analytical observational research: cohort, case-control, and cross-sectional studies.

We organised a 2-day workshop in Bristol, UK, in September 2004. 23 individuals attended this meeting, including editorial staff from Annals of Internal Medicine, BMJ, Bulletin of the World Health Organization, International Journal of Epidemiology, JAMA, Preventive Medicine, and The Lancet, as well as epidemiologists, methodologists, statisticians, and practitioners from Europe and North America. Written contributions were sought from 10 other individuals who declared an interest in contributing to STROBE, but could not attend. Three working groups identified items deemed to be important to include in checklists for each type of study. A provisional list of items prepared in advance (available from our Web site) was used to facilitate discussions. The 3 draft checklists were then discussed by all participants and, where possible, items were revised to make them applicable to all three study designs. In a final plenary session, the group decided on the strategy for finalizing and disseminating the STROBE Statement.

After the workshop we drafted a combined checklist including all three designs and made it available on our Web site. We invited participants and additional scientists and editors to comment on this draft checklist. We subsequently published 3 revisions on the Web site, and 2 summaries of comments received and changes made. During this process the coordinating group (i.e., the authors of the present paper) met on eight occasions for 1 or 2 days and held several telephone conferences to revise the checklist and to prepare the present paper and the Explanation and Elaboration paper [18–20]. The coordinating group invited 3 additional co-authors with methodological and editorial expertise to help write the Explanation and Elaboration paper, and sought feedback from more than 30 people, who are listed at the end of this paper. We allowed several weeks for comments on subsequent drafts of the paper and reminded collaborators about deadlines by e-mail.

4. STROBE components

The STROBE Statement is a checklist of 22 items that we consider essential for good reporting of observational studies (Table 1). These items relate to the article's title and abstract (item 1), the introduction (items 2 and 3), methods (items 4–12), results (items 13–17) and discussion sections (items 18–21), and other information (item 22 on funding). 18 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 presented here as a single checklist, separate checklists are available for each of the 3 study designs on the STROBE Web site.

5. Implications and limitations

The STROBE Statement was developed to assist authors when writing up analytical observational studies, to support editors and reviewers when considering such articles for publication, and to help readers when critically appraising published articles. We developed the checklist through an open process, taking into account the experience gained with previous initiatives, in particular CONSORT. We reviewed the relevant empirical evidence as well as methodological work, and subjected consecutive drafts to an extensive iterative process of consultation. The checklist presented here is thus based on input from a large number of individuals with diverse backgrounds and perspectives. The comprehensive explanatory article [18–20], which is intended for use alongside the checklist, also benefited greatly from this consultation process.

Observational studies serve a wide range of purposes, on a continuum from the discovery of new findings to the confirmation or refutation of previous findings [18–20]. Some studies are essentially exploratory and raise interesting hypotheses. Others
pursue clearly defined hypotheses in available data. In yet another type of studies, the collection of new data is planned carefully on the basis of an existing hypothesis. We believe the present checklist can be useful for all these studies, since the readers always need to know what was planned (and what was not), what was done, what was found, and what the results mean. We acknowledge that STROBE is currently limited to three main observational study designs. We would welcome extensions that adapt the checklist to other designs—e.g., case-crossover studies or ecological studies—and also to specific topic areas. Four extensions are now available for the CONSORT statement [21–24]. A first extension to STROBE is underway for gene–disease association studies: the STROBE Extension to Genetic Association studies (STREGA) initiative [25]. We ask those who aim to develop extensions of the STROBE Statement to contact the coordinating group first to avoid duplication of effort.
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. For instance, we
discuss the reporting of results under a number of separate items,
while recognizing that authors might address several items within
a single section of text or in a table. Also, item 22, on the source of
funding and the role of funders, could be addressed in an appendix
or in the methods section of the article. We do not aim at stand-
ardising reporting. Authors of randomised clinical trials were asked
by an editor of a specialist medical journal to "CONSORT" their
manuscripts on submission [26]. We believe that manuscripts
should not be "STROBED", in the sense of regulating style or ter-
mology. We encourage authors to use narrative elements,
including the description of illustrative cases, to complement the
essential information about their study, and to make their articles
an interesting read [27].

We emphasise that the STROBE Statement was not developed as
a tool for assessing the quality of published observational research.
Such instruments have been developed by other groups and were
the subject of a recent systematic review [28]. In the Explanation
and Elaboration paper, we used several examples of good reporting
from studies whose results were not confirmed in further research
– the important feature was the good reporting, not whether the
research was of good quality. However, if STROBE is adopted by
authors and journals, issues such as confounding, bias, and gen-
eralisability could become more transparent, which might help
temper the over-enthusiastic reporting of new findings in the sci-
entific community and popular media [29], and improve the
methodology of studies in the long term. Better reporting may also
help to have more informed decisions about when new studies are
needed, and what they should address.

We did not undertake a comprehensive systematic review for
each of the checklist items and sub-items, or do our own research to
fill gaps in the evidence base. Further, although no one was
excluded from the process, the composition of the group of con-
tributors was influenced by existing networks and was not repre-
sentative in terms of geography (it was dominated by contributors
from Europe and North America) and probably was not representa-
tive in terms of research interests and disciplines. We stress 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. We welcome
suggestions for the further dissemination of STROBE—e.g., by re-
publication of the present article in specialist journals and in
journals published in other languages. Groups or individuals who
intend to translate the checklist to other languages should consult
the coordinating group beforehand. We will revise the checklist in
the future, taking into account comments, criticism, new evidence,
and experience from its use. We invite readers to submit their
comments via the STROBE Web site (http://www.strobe-statement.
org/).

6. Contributors to the STROBE Initiative

The following individuals have contributed to the content and
elaboration of the STROBE Statement: Douglas G Altman, Maria
Blettner, Paolo Boffetta, Hermann Brenner, Genevie’e Chenu, Cyrus
Cooper, George Davey-Smith, Erik von Elm, Matthias Egger, France
Gagnon, Peter C Gotzsche, Philip Greenland, Sandor Greenland,
Claire Infante-Rivard, John Ioannidis, Astrid James, Giselle Jones,
Bruno Ledergerber, Julian Little, Margaret May, David Moher,
Hooman Momen, Alfredo Morabia, Hal Morgenstern, Cynthia D
Mulrow, Fred Paccaud, Stuart J Pocock, Charles Poole, Martin Rööslı,
Dietrich Rothenbacher, Kenneth Rothman, Caroline Sabin, Willi
Sauerbrei, Lale Say, James J Schlesselman, Jonathan Sterne, Holly
Syddall, Jan P Vandenbroucke, Ian White, Susan Wieland, Hywel
Williams, Guang Yong Zou.

Funding

The workshop was funded by the European Science Foundation
(ESF). Additional funding was received from the Medical Research
Council Health Services Research Collaboration and the National
Health Services Research and Development Methodology Pro-
gramme. The funders had no role in study design, data collection
and analysis, decision to publish, or preparation of the manuscript.

Author contributions

The authors coordinated the STROBE Initiative and contributed
to the writing of the paper. EVe wrote the first draft of the paper and
takes care of most of the practical coordination of STROBE. ME
initiated STROBE and, together with EVe, organised the first
workshop.

Competing interests

The authors have declared that no competing interests exist.

Acknowledgements

We are grateful to Gerd Antes, Kay Dickersin, Shah Ebrahim, and
Richard Lilford for supporting the STROBE Initiative. We are grateful
to the following institutions that have hosted working meetings of
the coordinating group: Institute of Social and Preventive Medicine
(ISPM), University of Bern, Bern, Switzerland; Department of Social
Medicine, University of Bristol, Bristol, UK; London School of Hy-
giene and Tropical Medicine, London, UK; Nordic Cochrane Centre,
Copenhagen, Denmark; and Centre for Statistics in Medicine, Ox-
ford, UK. We are grateful to six reviewers who provided helpful
comments on a previous draft of this paper.

References

[1] P. Glasziou, J.P. Vandenbroucke, I. Chalmers, Assessing the quality of research,
[2] N. Black, Why we need observational studies to evaluate the effectiveness of
harm of medical interventions in randomized and nonrandomized studies, CMAJ
[8] L. Tooth, R. Ware, C. Bain, D.M. Purdie, A. Dobson, Quality of reporting of
[10] Anonymous, Guidelines for documentation of epidemiologic studies. Epide-
mology Work Group of the Interagency Regulatory Liaison Group, Am. J.
dendations for improving the quality of reports of parallel-group randomised