Guideline

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

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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.

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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 sys-
tematic 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—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 rec-
ommendations for the reporting of observational research: the
Strengthening the Reporting of Observational Studies in Epidemi-
ology (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
eamples 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 ar-
ticles describing relevant methodological research. Because obser-
vational 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, Pre-
ventive 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 (indi-
cated 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 ac-
count 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
Table 1
The STROBE Statement—checklist of items that should be addressed in reports of observational studies.

<table>
<thead>
<tr>
<th>Item number</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title and Abstract</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td>2</td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td>3</td>
</tr>
<tr>
<td><strong>Participants</strong></td>
<td>4</td>
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<tr>
<td><strong>Variables</strong></td>
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<tr>
<td><strong>Data sources/measurement</strong></td>
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<tr>
<td><strong>Bias</strong></td>
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</tr>
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<td><strong>Statistical methods</strong></td>
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<td><strong>Results</strong></td>
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<td><strong>Interpretation</strong></td>
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</tr>
</tbody>
</table>

*4 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 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/.
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 standardising 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 terminology. 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 generalisability could become more transparent, which might help temper the over-enthusiastic reporting of new findings in the scientific 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 contributors was influenced by existing networks and was not representative in terms of geography (it was dominated by contributors from Europe and North America) and probably was not representative 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 republication 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’ve Chel, Cyrus Cooper, George Davey-Smith, Erik von Elm, Matthias Egger, France Gagnon, Peter C Gøtzsche, Philip Greenland, Sander 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 Röösl, Dietrich Rothenbacher, Kenneth Rothman, Caroline Sabin, Willi Sauerbrei, Lale Say, James Schlesselman, Jonathan Sterne, Holly Syddall, Jan P Vandebroucke, Ian White, Susan Wieland, Hywel Williams, Guang Yong Zou.

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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.

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References


