Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): One year on

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Outline

- Rationale
- Development
- The checklist and E&E paper
- Support and critique
- Implementation by journals
- Your experiences and views
Background

• Articles reporting studies should be written such that the reader can evaluate the information and reach his or her own conclusions about results.
• Assessment of reliability of much published research is hampered by inadequate reporting.
• Authors and journals have an obligation to ensure that research is reported adequately.
„We recommend that editors improve the reporting of clinical trials by giving authors a list of the important items to be reported.“
Reporting guidelines

- 1996 CONSORT: RCTs
- 1999 QUOROM: Meta-analyses of RCTs
- 2001 CONSORT II: RCTs
- 2003 STARD: Diagnostic studies
- 2005 REMARK: Tumour marker studies
- 2007 STROBE: Case-control studies, Cross-sectional studies, Cohort studies

*new: PRISMA*
• “Our readers would be amazed to learn how often we have to remind authors to simply mention where and when their study was conducted.”

Alfredo Morabia, Editor, Preventive Medicine
Cohort studies published in *Antiviral Therapy* 2005-2007 (n=33)

- Loss to follow up defined: 9%
- Description of how loss to follow up was addressed in the analysis: 59%
- No. of patients lost to follow up reported: 33%
- Comparison of patients lost with patients not lost to follow up: 3%

*Antiviral Therapy*, in press
Cohort studies published in *STI* or *STD* 2004-2007 (n=60)

- Inclusion criteria described 93%
- Outcomes and diagnostic criteria defined 65%
- Censoring strategies described 47%
- Baseline characteristics described 53%
- Length of follow-up given 50%
- No. of patients lost to follow up given 40%
## History of STROBE

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td>Mar 2001</td>
<td>Idea was first discussed</td>
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<tr>
<td>Nov 2001</td>
<td>Discussion meeting</td>
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<tr>
<td>Apr 2003</td>
<td>Planning meeting</td>
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<tr>
<td>Aug 2003</td>
<td>Idea presented at World Epidemiology Conference in Montreal</td>
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<td><strong>Sep 2004</strong></td>
<td><strong>Workshop in Bristol, Grant from European Science Foundation</strong></td>
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<td>May 2005</td>
<td>Posted 1&lt;sup&gt;st&lt;/sup&gt; draft checklist on website</td>
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<td>Oct 2007</td>
<td>Publication</td>
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Over 40 contributors

Contributors to the STROBE Initiative. The following persons have contributed to the content and elaboration of the STROBE Statement: Douglas G. Altman, Maria Blettner, Paolo Boffetta, Hermann Brenner, Geneviève Chène, 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 Röösli, 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.
Journal editors

George Davey Smith (*IJE*)
Phil Greenland (*Archives of Internal Medicine*)
Astrid James (*The Lancet*)
Giselle Jones (*BMJ*)
Hooman Momen (*Bulletin WHO*)
Alfredo Morabia (*Preventive Medicine*)
Cynthia Mulrow (*Annals of Internal Medicine*)
Drummond Rennie (*JAMA*)
Kenneth Rothman (Former, *Epidemiology*)
Donna Stroup (*JASA*)
Evolution of item on “Study size”

First version
• “Describe how sample size was determined, including practical and statistical considerations.”

Intermediate version
• “Describe rationale for study size, including practical and statistical considerations.”

Final
• “Explain how the study size was arrived at.”
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<tr>
<th>Annals of Internal Medicine</th>
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<tr>
<td>British Medical Journal</td>
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<td>PLoS Medicine</td>
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www.strobe-statement.org
加强流行病学中观察性研究报告质量 (STROBE)声明：观察性研究报告规范

很多生物医学研究都是观察性的。但很多研究的报告却通常不完整，从而限制了对其优缺点及普及性的评价。“加强流行病学中观察性研究报告质量 (STROBE)”工作组针对一篇完整明确的观察性研究报告应包括的内容提供了一套建议。建议涵盖了流行病学研究的三种主要设计类型：队列设计、病例对照设计和横断面设计。2004年9月，我们召开了为期2天的研讨会，与会的方法学专家、研究人员和期刊编辑共同起草了一份观察性研究报告应纳入的条目清单草案。此后，又通过协调小组数次会议及与有关人员电子邮件讨论等对该草案进行了修改，纳入了经验性证据和方法学方面的意见。通过研讨会及之后反复的咨询和修订，我们制定出了一个包含22个条目的清单 (STROBE声明)，分为论文的题目、摘要、引言、方法、结果和讨论等部分。其中

研究报告应该透彻明晰，以便读者能够了解研究计划是什么、研究过程怎样，发现了什么、得出了怎样的结论。研究的可信性取决于如何对研究设计、执行和分析的优缺点的批判性评价。一篇明确的研究报告还能帮助他人决定是否以及如何将其研究结果纳入系统评价中。可是，在已发表的观察性研究报告中，重要的信息往往缺失或含糊不清。一项对发表在综合医学期刊或专业期刊上的流行病学研究报告的分析显示，这些报告通常不解释为何会选择某些可能导致混杂效应的变量。在精神病学文献中，只有少数病例 - 对照设计的研究报告解释了确立病例和对照的方法。一项对罕见文献中的纵向研究报告的分析显示，49篇中约有17篇 (35%)没有详细说明受试者的纳入标准。有人认为如果研究报告不具有足够的明确性，研究的效益将不易实现，所以有必要制定一个撰写观察性研究报告的规范。
Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and Elaboration

Jan P. Vandenbroucke¹, Erik von Elm², Douglas G. Altman⁴, Peter C. Götzsche⁵, Cynthia D. Mulrow⁶, Stuart J. Pocock⁷, Charles Poole⁸, James J. Schlesselman⁹, Matthias Egger²,¹⁰* for the STROBE Initiative

1 Department of Clinical Epidemiology, Leiden University Medical Center, Leiden, The Netherlands, 2 Institute of Social & Preventive Medicine (ISPM), University of Bern, Bern, Switzerland, 3 Department of Medical Biometry and Medical Informatics, University Medical Centre, Freiburg, Germany, 4 Cancer Research UK/NHS Centre for Statistics in Medicine, Oxford, United Kingdom, 5 Nordic Cochrane Centre, Rigshospitalet, Copenhagen, Denmark, 6 University of Texas Health Science Center, San Antonio, United States of America, 7 Medical Statistics Unit, London School of Hygiene and Tropical Medicine, London, United Kingdom, 8 Department of Epidemiology, University of North Carolina School of Public Health, Chapel Hill, United States of America, 9 Department of Biostatistics, University of Pittsburgh Graduate School of Public Health, and University of Pittsburgh Cancer Institute, Pittsburgh, United States of America, 10 Department of Social Medicine, University of Bristol, Bristol, United Kingdom
8. Data sources/measurement: 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.

**Example 2**

“Samples pertaining to matched cases and controls were always analyzed together in the same batch and laboratory personnel were unable to distinguish among cases and controls” [61].

**Explanation**

The way in which exposures, confounders and outcomes were measured affects the reliability and validity of a study. Measurement error and misclassification of exposures or outcomes can make it more difficult to detect cause-effect relationships, or may produce spurious relationships. Error
10. Study size: Explain how the study size was arrived at.

Example 1

“The number of cases in the area during the study period determined the sample size” [73].
16. Main results:
16 (a). Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence intervals). Make clear which confounders were adjusted for and why they were included.

Example 1

“We initially considered the following variables as potential confounders by Mantel-Haenszel stratified analysis: (...) The variables we included in the final logistic regression models were those (...) that produced a 10% change in the odds ratio after the Mantel-Haenszel adjustment” [155].
13 (c). Consider use of a flow diagram.

Example

Pre-school children attending 124 recruitment sessions*  
\( n = 883 \)

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Assessed for eligibility  
\( n = 843 \)

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NOT ASSESSED FOR ELIGIBILITY:

- Missed invitation to participate  
  \( n = 29 \)
- Declined to be invited  
  \( n = 11 \)

---

EXCLUDED (Total = 586):

1. INELIGIBLE  
   \( n = 553 \)
   - No cough  
     \( n = 453 \)
   - Known Asthma  
     \( n = 44 \)
   - Cough > 28 days  
     \( n = 30 \)
   - Previously invited/participated  
     \( n = 18 \)
   - Congenital Heart Disease  
     \( n = 5 \)
   - Tracheo-oesophageal fistula  
     \( n = 1 \)
Box 6. Missing data: problems and possible solutions

A common approach to dealing with missing data is to restrict analyses to individuals with complete data on all variables required for a particular analysis. Although such ‘complete-case’ analyses are unbiased in many circumstances, they can be biased and are always inefficient [108]. Bias arises if individuals with missing data are not typical of the whole sample. Inefficiency arises because of the reduced sample size for analysis.

Using the last observation carried forward for repeated measures can distort trends over time if persons who experience a foreshadowing of the outcome selectively drop out [109]. Inserting a missing category indicator for a confounder may increase residual confounding [107]. Imputation, in which each missing value is replaced with an assumed or estimated value, may lead to attenuation or exaggeration of the association of interest, and without the use of sophisticated methods
Support and critique

Is There a Dark Phase of This STROBE?

Strobe and the standardisation of scientific practice

Brian MacMahon* and Noel S. Weiss††

Suggestions for STROBE Recom

Lewis H. Kuller and Bernard D. Golden

Some Guidelines on Guidelines

They Should Come With Expiration Dates

Kenneth J. Rothman*†‡ and Charles Poole§

Probing STROBE

The Edit

Everybody’s talkin’ ‘bout a new way of reportin’

STROBE: strongly recommended by IJPH – but not enforced!

Thomas Kohlmann
Support

• „An important and timely initiative“
• „An excellent approach“
• „A useful reference for those who wish to publish and critique“
• „A major step forward“
• „A most important step forward“
• „...will likely make a strong contribution to improving the quality of reporting“
• „A useful service for the epidemiological community“
Support

• „...will contribute to widening the spectrum of what evidence the scientific consensus regards as acceptable“

• „STROBE should provide clinical research with a new impetus toward valuing observational studies“
Critique and concerns

• „This smacks of condescension“
• „...will be found in any text targeted at Masters students“
Journals that published the 100 most recent articles indexed as ‘cohort studies’

- Acta Derm Venereol (1)
- Acta Myol (1)
- Am J Health Syst Pharm (1)
- Am J Transplant (1)
- Arch Bronconeumol (2)
- Arch Phys Med Rehabil (1)
- Arch Surg (5)
- Arterioscler Thromb Vasc Biol (4)
- Asian J Surg (2)
- BJOG (1)
- BMC Genet (1)
- Can J Gastroenterol (1)
- Can Respir J (1)
- Cancer Causes Control (3)
- Circulation (1)
- Clin Implant Dent Relat Res (1)
- Clin Nephrol (1)
- Clin Ther (1)
- Community Dent Health (3)
- Curr Diab Rep (1)
- Epidemiology (3)
- Eur J Cardiothorac Surg (2)
- Eur J Clin Pharmacol (1)
- Eur J Nucl Med Mol Imaging (1)
- Haematologica (1)
- Heart Surg Forum (3)
- Hypertension (9)
- Int J Technol Assess Health Care (1)
- J Am Coll Cardiol (6)
- J Fam Pract (2)
- J Hum Genet (1)
- J Hypertens (3)
- J Infect (1)
- J Korean Med Sci (2)
- J Neurosurg (1)
- J Neurovirol (1)
- J Nutr (1)
- J Oral Sci (1)
- J Prosthet Dent (1)
- J Surg Oncol (2)
- J Surg Res (1)
- Lancet (1)
- Lung Cancer (3)
- Med J Aust (1)
- Methods Mol Biol (1)
- Mol Med (1)
- Nephrol Dial Transplant (2)
- Neurosurgery (1)
- Nord J Psychiatry (2)
- Otolaryngol Head Neck Surg (1)
- Pediatr Infect Dis J (1)
- Phys Med Biol (1)
- Psychiatr Serv (1)
- Respir Res (1)
- Rev Invest Clin (1)
- Rev Med Chir Soc Med Nat Iasi (1)
- Spine (2)
- Stat Med (1)
- World J Urol (1)
Critique and concerns

- "...will lead to losses in the 'discovery potential'"
- "...a breach in the capacity for scientific creativity"
- "...ventures into matters of study conduct"
- "...will evolve into a tool for judging study"
- "...we try to avoid judging an apple by how well it is polished"
Implementation by journals
INSTRUÇÕES AOS AUTORES

• Artigos Originais
  – Recomenda-se ao autor que antes de submeter seu artigo utilize o "checklist" correspondente:
    • STROBE para estudos observacionais em epidemiologia
Extensión y presentación del manuscrito

- Se aconseja a los autores a fin de evitar omitir elementos importantes revisar las guias de reporte anexadas a continuación.
Implementation by journals

• „Please follow the STROBE guidelines“
• “Please report your data using the STROBE guidelines which are designed to improve the value of such reports”
• “Authors are encouraged to consult …”
• „Authors should use / consider / follow …“
• “Authors are requested / required to follow …”
• „Authors are strongly advised to refer to …“
• „We urge authors to follow …“
• „Authors need to adhere to …“
• „Must be reported according to …“
• “We encourage creativity and originality and recognize that not all papers can or should meet these guidelines.“
• “We suggest that authors complete the STROBE checklist for submission with their articles.
• In your cover letter, be sure to indicate that you have followed the STROBE guidelines.
• It is up to the authors to decide which of the checklist items are applicable to their study“
• “Please note that we need the STROBE checklist for an observational study (as a supplemental file)”
Suggestions for improvements

• Many helpful suggestions received
• More are welcome!
• Please submit yours at www.strobe-statement.org/Forum.html
• All will be considered in next revision
Thank you

- Jan Vandenbroucke, Doug Altman, Erik von Elm, STROBE group
- Editors
- Funders (about 20,000 UK£)
  - European Science foundation
  - Medical Research Council R&D
  - Medical Research Council HSRC
  - Swiss National Science Foundation
Over to you