What a reporting guideline is, and isn't

Matthias Egger

WCE
WORLD CONGRESS OF EPIDEMIOLOGY 2024

STROBE

Strengthening the reporting of observational studies in epidemiology (strobe-statement.org)

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UNIVERSITÄT
BERN

Review

Empirical Evidence of Bias

JAMA, February 1, 1995—Vol 273, No. 5

Dimensions of Methodological Quality Associated With Estimates of Treatment Effects in Controlled Trials

Kenneth F. Schulz, PhD, MBA; Iain Chalmers, MBBS, MSc; Richard J. Hayes, MSc; Douglas G. Altman

"Readers of trial reports should be wary of these pitfalls, and investigators must improve their design, execution, and reporting of trials."

- **Meta-analyses of RCTs**
- **Meta-analyses of observational studies**
- **Diagnostic test accuracy studies**

Special Communication

Improving the Quality of Reporting of Randomized Controlled Trials

The CONSORT Statement

Colin Begg, PhD; Mildred Cho, PhD; Susan Eastwood, ELS(D); Richard Horton, MB; David Moher, MSc; Ingram Olkin, PhD; Roy Pitkin, MD; Drummond Rennie, MD; Kenneth F. Schulz, PhD; David Simel, MD; Donna F. Stroup, PhD

JAMA, August 28, 1996—Vol 276, No. 8

Table 1 Simulation-Based Research Extensions for the CONSORT Statement

Item	Item number	CONSORT description (Randomized Controlled Trials)	Extension for SBR
Title and abstract	1	a. Identification as a randomized trial in the title b. Structured summary of trial design, methods, results, and conclusions	In abstract or key terms, the MESH or searchable keyword term must have the word "simulation" or "simulated."
Introduction			
Background	2	a. Scientific background and explanation of rationale b. Specific objectives or hypotheses	Clarify whether simulation is subject of research or investigational method for research.
Methods			
Trial design	3	a. Description of trial design (such as parallel, factorial) including allocation ratio b. Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4	a. Eligibility criteria for participants b. Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow for replication, including how and when they were actually administered.	Describe the theoretical and/or conceptual rationale for the design of each intervention. Clearly describe all simulation-specific exposures, potential confounders, and effect modifiers.
Outcomes	6	a. Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed b. Any changes to trial outcomes after the trial commenced, with reasons	In describing the details of methods of assessment, include (when applicable) the setting, instrument, simulator type, timing in relation to the intervention, along with any methods used to enhance the quality of measurements. Provide evidence to support the validity and reliability of assessment tools in this context (if available).

Cheng *et al. Advances in Simulation* (2016) 1:25
DOI 10.1186/s41077-016-0025-y

Advances in Simulation

RESEARCH Open Access

Reporting guidelines for health care simulation research: extensions to the CONSORT and STROBE statements

Adam Cheng[1*], David Kessler[2], Ralph Mackinnon[3,4], Todd P. Chang[5], Vinay M. Nadkarni[6], Elizabeth A. Hunt[7], Jordan Duval-Arnould[7], Yiqun Lin[8], David A. Cook[9], Martin Pusic[10], Joshua Hui[11], David Moher[12], Matthias Egger[13], Marc Auerbach[14] and for the International Network for Simulation-based Pediatric Innovation, Research, and Education (INSPIRE) Reporting Guidelines Investigators

Clinical Review & Education

JAMA | Special Communication

Strengthening the Reporting of Observational Studies in Epidemiology Using Mendelian Randomization
The STROBE-MR Statement

Veronika W. Skrivankova, PhD; Rebecca C. Richmond, PhD; Benjamin A. R. Woolf, MSc; James Yarmolinsky, PhD; Neil M. Davies, PhD; Sonja A. Swanson, ScD; Tyler J. VanderWeele, PhD; Julian P. T. Higgins, PhD; Nicholas J. Timpson, PhD; Niki Dimou, PhD; Claudia Langenberg, PhD; Robert M. Golub, MD; Elizabeth W. Loder, MD; Valentina Gallo, PhD; Anne Tybjaerg-Hansen, MD, DMSc; George Davey Smith, MD, DSc; Matthias Egger, MD; J. Brent Richards, MD

Cookbook science?

The Making of STROBE

Jan P. Vandenbroucke

(*Epidemiology* 2007;18: 797–799)

- Within the world of randomized controlled trials (RCTs), the CONSORT guidelines for reporting trials have been successful: they have improved the quality of reporting.
- However, I was wary when I heard about a group wanting to make a similar type of recommendations for observational research.
- Guidelines might be fit for highly-codified evaluation, but what about etiologic research? … Why stifle scientific creativity by guidelines?”

Areas of tension in the making of STROBE

- Finding common ground among researchers with different research backgrounds
- The intended audience (professional epidemiologists or statisticians vs. all researchers who use epidemiologic study designs)
- The fine line between encouraging clarity of reporting vs. prescribing how to do research.
- The misuse of the STROBE checklist as an instrument to evaluate the quality of observational research: research can be reported clearly or not, irrespective of its intrinsic quality

Key messages

- Our study provides further evidence that authors of systematic reviews inappropriately use reporting guidelines to assess methodological study quality. Given the identified common misuse of STROBE, we discuss possible reasons and potential pitfalls of such misuse.

Evolution of item on Study Size in STROBE

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.”

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].

Example 2

"A survey of postnatal depression in the region had documented a prevalence of 19.8%. Assuming depression in mothers with normal weight children to be 20% and an odds ratio of 3 for depression in mothers with a malnourished child we needed 72 case-control sets (one case to one control) with an 80% power and 5% significance" [74].

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

Jan P. Vandenbroucke[1], Erik von Elm[2,3], Douglas G. Altman[4], Peter C. Gøtzsche[5], Cynthia D. Mulrow[6], Stuart J. Pocock[7], Charles Poole[8], James J. Schlesselman[9], Matthias Egger[2,10*] for the STROBE Initiative

Commentaries in *Epidemiology*, 2007

- MacMahon and Weiss:
  - "…we try to avoid judging an apple by how well it is polished"…
  - "the prescription … could lead to adverse effects that are as or more serious than the problem that prompted the prescription"
- Rothman and Poole:
  - "sigh of relief" that the guidelines are "benign", but still add to the general guideline burden; critical of some examples, propose expiration date 2010.
- Editors:
  - "…too many remnants of clinical-trial thinking"…
  - "One of the Editors' deepest concerns is that STROBE will evolve from a set of reporting guidelines into a tool for judging the studies themselves"

Reporting of observational studies

New recommendations should help researchers, journal editors, and readers

Strobe and the standardisation of scientific practice

Louise Potvin, PhD

COMMENTARY

Suggestions for STROBE Recommendations

Lewis H. Kuller and Bernard D. Goldstein

EDITORIAL

Probing STROBE

The Editors

STROBE: strongly recommended by IJPH

Thomas Kohlmann

COMMENTARY

Is There a Dark Phase of This STROBE?

Brian MacMahon and Noel S. Weiss†‡*

COMMENTARY

Some Guidelines on Guidelines

They Should Come With Expiration Dates

Kenneth J. Rothman†‡ and Charles Poole§*

STROBE

A Beacon for Observational Studies

This Month in *Preventive Medicine*

Everybody's talkin' 'bout a new way of reportin' observational studies

Observational Study

Medicine

OPEN

The determinants of collateral circulation status in patients with chronic cerebral arterial circle occlusion

A STROBE Study

Chenghui Pi, PhD[a,b], Jun Wang, PhD[b], Dengfa Zhao, BS[b], Shengyuan Yu, PhD[a,b,*]

Clinical Trial/Experimental Study

Medicine

OPEN

The low glutamate diet reduces blood pressure in veterans with Gulf War Illness

A CONSORT randomized clinical trial

Prairie R. Fiebel, BS[a], Shalini S. Ramachandra, BS[b,c], Kathleen F. Holton, PhD, MPH[a,b,d,*]

Summary

They are

- Helping authors report what they did
  - Helpful for authors, editors, reviewers
  - The Explanation and Elaboration (E&E) document is educational for early career researchers

They are not:

- Telling authors what to do, how to design and execute their study
- Instruments to assess the quality of studies or assigning quality labels to studies

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 described below may produce standard errors that are too small.

Rubin developed a typology of missing data problems, based on a model for the probability of an observation being missing [108,110]. Data are described as missing completely at random (MCAR) if the probability that a particular observation is missing does not depend on the value of any observable variable(s). Data are missing at random (MAR) if, given the observed data, the probability that observations are missing is independent of the actual values of the missing data. For example, suppose younger children are more prone to missing spirometry measurements, but that the probability of missing is unrelated to the true unobserved lung function, after accounting for age. Then the missing lung function measurement would be MAR in models including age. Data are missing not at random (MNAR) if the probability of missing still depends on the missing value even after taking the available data into account. When data are MNAR valid inferences require explicit assumptions about the mechanisms that led to missing data.

Methods to deal with data missing at random (MAR) fall into three broad classes [108,111]: likelihood-based approaches [112], weighted estimation [113] and multiple imputation [111,114]. Of these three approaches, multiple imputation is the most commonly used and flexible, particularly when multiple variables have missing values [115]. Results using any of these approaches should be compared with those from complete case analyses, and important differences discussed. The plausibility of assumptions made in missing data analyses is generally unverifiable. In particular it is impossible to prove that data are MAR, rather than MNAR. Such analyses are therefore best viewed in the spirit of sensitivity analysis (see items 12e and 17).

Summary

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- Helping authors report what they did
  - Helpful for authors, editors, reviewers
  - The Explanation and Elaboration (E&E) document is educational for early career researchers

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They have become an industry…

- The are highly cited and published in prominent journals

Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
Systematic reviews	PRISMA	Extensions
Study protocols	SPIRIT	PRISMA-P
Diagnostic/prognostic studies	STARD	TRIPOD
Case reports	CARE	Extensions
Clinical practice guidelines	AGREE	RIGHT
Qualitative research	SRQR	COREQ
Animal pre-clinical studies	ARRIVE	
Quality improvement studies	SQUIRE	Extensions
Economic evaluations	CHEERS	Extensions

17 extensions for STROBE alone…

A history of the evolution of guidelines for reporting medical research: the long road to the EQUATOR Network

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