Guidelines for disclosing the results from observational trials

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Abstract

Observational trials are a relevant part of clinical research. Publishing their results can be challenging for scientists and writers. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement was the first guideline developed to identify the minimal information that should be included in articles reporting observational and epidemiological research. More than 50 ancillary guidelines tailored to specific needs are now available to assist authors in preparing successful articles on observational studies.

Introduction

In observational studies (OSs), the researcher collects information on the attributes or measurement of interest but does not influence events. OSs include surveys and most epidemiological studies, and they can be prospective or retrospective. Many OSs are carried out to investigate possible associations between various factors and the development of a disease or condition. In general, OSs are used to investigate factors or exposures that cannot be controlled by the investigators, such as jobs or smoking habits.[1]

Randomised controlled trials (RCTs) are widely considered as the "gold standard" in research; nevertheless, they have several limitations. In some cases, RCTs can be unnecessary, inappropriate, impossible, or inadequate.[2] Moreover, researchers can now answer many questions using the enormous amount of clinical data that have become available through registries and other powerful digital platforms.[3] This has become increasingly important as research and development costs grow and budgets decrease. OSs also play an important role in identifying the benefits and harms of medical interventions in ways that RCTs cannot. For example, OSs are more suitable for detecting rare or late adverse effects of treatments, and they can help show what is achieved in daily medical practice.[4]

Publications based on OSs, however, often lack critical information or are unclear due to insufficient reporting of potential confounding variables,[5] methods used for identifying cases and controls,[6] and eligibility criteria.[7] Reporting guidelines have therefore been developed for OSs.

The STROBE Statement

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement was developed to provide researchers with an appropriate tool to improve reporting of OSs.[8] STROBE was the first guideline especially designed for OSs and can be applied to any study type, although many additional guidelines are now available for more specific observational study designs.

History of STROBE

The first reporting guideline for researchers was the Consolidated Standards of Reporting Trials (CONSORT) Statement, developed in 1996 and revised 5 years later.[9,10] It helped improve the quality of reports from RCTs. Similar initiatives have followed for different studies, such as diagnostic studies and OSs. STROBE was created by a network of methodologists, researchers, and journal editors who met in 2004 to develop recommendations for the reporting of OSs. STROBE contains recommendations on the minimal information to be included in an accurate and complete article for the three main OSS designs: cohort, case-control, and cross-sectional.[4] The STROBE statement was published in eight journals and was accompanied by simultaneous publication of an explanation and elaboration article in three journals.[8]

The STROBE checklist

The STROBE Statement includes a checklist of 22 items that should be addressed in articles

Table 1. The STROBE checklist

Section	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/	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe measurement 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
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
Participants	13*	(a) Report numbers of individuals at each stage of study – e.g. 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 (e.g. 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 (e.g. 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 categorised
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done –e.g. 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

reporting OSs (Table 1). The checklist was intended to provide guidance on reporting OSs but does not provide guidance on designing or conducting them. The checklist is also not designed as an instrument for evaluating the quality of OSs.

The 22 items in the STROBE checklist relate to what should be included and how in the different sections of the article, from title and abstract to discussion section. An item for study funding is also included. Of the 22 items in the checklist, 18 are common to all three main observational study designs. The remaining four are specific to the study design, and different versions for all or part of the item are provided. For some items, information should be provided separately for cases and controls in case-control studies or for exposed and unexposed groups in cohort and cross-sectional studies. Although presented here as a single checklist, separate checklists are available.

Website

The STROBE checklist and other related documents are available at the site for the STROBE Statement (www.strobe-statement.org). Included on the website are lists of journals where the statement and the explanatory paper were published, journals that refer to the STROBE Statement in their instructions for authors, and members of the STROBE group. The website contains the original English version of the STROBE statement and translations in eight other languages.[11]

Addenda to the STROBE Statement and other related guidance

Although the STROBE statement was designed to cover the three main types of OSs, several extensions or related guidelines have been developed for other designs or specific topic areas, such as case studies/series, genetics studies, and epidemiological studies (Table 2). Key guidelines include CARE for case reports,[12] STREGA for genomic studies,[13] and RECORD for routinely collected health data.[14]

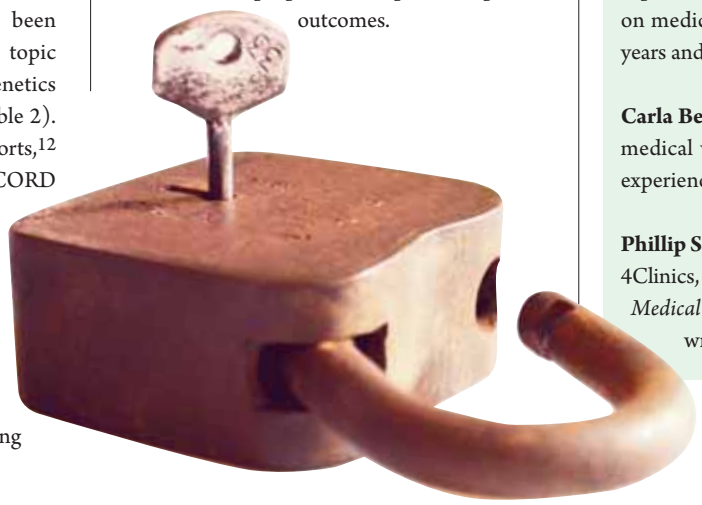
The EQUATOR Network: a tool for searching all available guidelines

The EQUATOR Network (www.equator-network.org) is an international initiative started in 2006 that consolidates reporting guidelines. Its goal is to improve the reliability and value of published research by promoting transparent and accurate reporting through the use of reporting guidelines. Although Table 2 contains an up-to-date list, new guidelines continue to be developed, so the best way to find the right guidelines is to use the search function, available at www.equator-network.org/ reporting-guidelines/and depicted in Figure 1.

Figure 1. The EQUATOR Network guideline search page
The search page is available at http://www.equator-network.org/reporting-guidelines/.

OS reporting guidelines under development

As summarised on the EQUATOR Network website (www.equator-network.org/library/reporting-guidelines-under-development/), several guidelines are under development in other areas of OSs. Importantly, they include an extension of STROBE for conference abstracts and recommendations for preparing protocols for OSs (SPIROS). Also under development are a guideline for reporting of observational epidemiology studies integrating data on humans, animals and/or vectors, and their shared environments (COHERE); a guideline specific for environmental epidemiology analyses (GREEN); guidance for reporting the long-term impact of genocide and war on mental health (GESUQ); and guidance on the psychometric properties of patient-reported outcomes.



Conclusion

More than 50 guidelines are available for reporting OSs, and more are under development. These guidelines are of great help to medical writers preparing publications on OSs and should help improve their accuracy and completeness.

Disclaimers

The opinions expressed in this article are the authors' own and not necessarily shared by their employers or EMWA.

Conflicts of interest

The authors declare no conflicts of interest related to this article.

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Table 2. Additional guidelines for observational studies

OSS study/data type	Acronym	Full name	Reference
Case studies/series			
Case reports	CARE	Consensus-based clinical case report guideline development	12
Case series in surgery	PROCESS	Preferred reporting of case series in surgery	15
Organisational case studies	–	Developing a methodological framework for organisational case studies: a rapid review and consensus development process	16
Case series in plastic surgery	–	Designing and reporting case series in plastic surgery	17
Case series of colon and rectum tumours	–	Guidelines for reporting case series of tumours of the colon and rectum	18
Uncontrolled case series	–	Appropriate use and reporting of uncontrolled case series in the medical literature	19
Case series in acupuncture	–	Conducting and reporting case series and audits – author guidelines for acupuncture in medicine	20
Poisoning case studies	–	Guidelines for reporting case studies on extracorporeal treatments in poisonings	21
Surveys			
E-surveys	CHERRIES	Checklist for Reporting Results of Internet E-Surveys for reporting Web-based surveys	22
Surveys of clinicians	–	A guide for the design and conduct of self-administered surveys of clinicians	23
Reporting using mobile phones	mERA	Guidelines for reporting of health interventions using mobile phones: mobile health (mHealth) evidence reporting and assessment (mERA) checklist	24
	–	Good practice in the conduct and reporting of survey research	25
Genomics & genetics			
Genetic association	STREGA	STrengthening the REporting of Genetic Association Studies	13
Molecular epidemiology	STROBE-ME	STrengthening the Reporting of OBservational studies in Epidemiology – Molecular Epidemiology	26
Immunogenomics	–	A community standard for immunogenomic data reporting and analysis	27
Genetic risk prediction	GRIPS	Strengthening the reporting of Genetic RIsk Prediction Studies	28
Epidemiology & routinely collected data			
Kidney disease prevalence	–	Methodology used in studies reporting chronic kidney disease prevalence	29
Neuoroepidemiology	STROND	Standards of Reporting of Neurological Disorders	30
Nutritional epidemiology	STROBE-nut	Strengthening the Reporting of Observational Studies in Epidemiology – Nutritional Epidemiology	31
Routinely collected health data	RECORD	The REporting of studies Conducted using Observational Routinely-collected Health Data	14
Health estimates	GATHER	Guidelines for Accurate and Transparent Health Estimates Reporting	32
Infectious diseases			
Neonatal infection	STROBE-NI	Strengthening the Reporting of Observational Studies in Epidemiology for Newborn Infection	33
Antimicrobial resistance	STROBE-AMS	Recommendations to optimise reporting of epidemiological studies on antimicrobial resistance and informing improvement in antimicrobial stewardship for epidemiologic studies focused on the link between antimicrobial-resistant bacteria and antibiotic usage	34
Molecular epidemiology of infectious diseases	STROME-ID	Strengthening the reporting of molecular epidemiology for infectious diseases	35
Nosocomial infection	ORION	Guidelines for transparent reporting of Outbreak Reports and Intervention Studies Of Nosocomial infection	36
Seroepidemiologic studies for influenza	CONSISE ROSES-I	Statement on the reporting of Seroepidemiologic Studies for Influenza	37
Rheumatology			
Drug studies in rheumatology	–	Launch of a checklist for reporting longitudinal observational drug studies in rheumatology: a EULAR extension of STROBE guidelines based on experience from biologics registries	38
Biologics registries in rheumatology	–	EULAR points to consider when establishing, analysing and reporting safety data of biologics registers in rheumatology for disclosing the results from biologics registers in in rheumatology	39

OSS study/data type	Acronym	Full name	Reference
Imaging and markers			
Magnetic resonance imaging for prostate cancer	PRECISE	Reporting Magnetic Resonance Imaging in Men on Active Surveillance for Prostate Cancer.	40
Magnetic resonance-targeted biopsy studies of the prostate	START	Standards of reporting for MRI-targeted biopsy studies of the prostate	41
Tumour marker prognostic studies	REMARK	REporting recommendations for tumour MARKer prognostic studies	42
Markers of cardiovascular risk	–	Criteria for evaluation of novel markers of cardiovascular risk	43
Psychiatry and heart rate variability	GRAPH	Guidelines for Reporting Articles on Psychiatry and Heart rate variability	44
Neuroimaging	–	Neuroimaging standards for research into small vessel disease and its contribution to ageing and neurodegeneration	45
Surgery & illnesses			
Medical abortion efficacy	MARE	Medical abortion reporting of efficacy	46
Intraoperative complications	CLASSIC	Definition and classification of intraoperative complications	47
Glaucoma surgery	–	A new manner of reporting pressure results after glaucoma surgery	48
Metabolic and bariatric surgery	–	Standardised outcomes reporting in metabolic and bariatric surgery	49
Emergency medicine			
Emergency department syncope risk	-	Standardised reporting guidelines for emergency department syncope risk-stratification research	50
Disaster medicine	CONFIDE	Disaster medicine reporting	51
Pain & fatigue			
Pain intensity assessment	ACTTION	Quality of pain intensity assessment reporting	52
Back pain		A consensus approach toward the standardisation of back pain definitions for use in prevalence studies	53
Chronic fatigue syndrome	–	Minimum data elements for research reports on chronic fatigue syndrome	54
Psychology & counselling			
Counselling	–	Guidelines for conducting and reporting mixed research in the field of counselling and beyond	55
Neuropsychology	–	Point and interval estimates of effect sizes for the case-controls design in neuropsychology	56
Other			
Violence risk assessment	RAGEE	Reporting guidance for violence risk assessment predictive validity studies	57
Thromboembolism	–	Risk of recurrent venous thromboembolism after stopping treatment in cohort studies: recommendation for acceptable rates and standardised reporting	58
Aneurysm	–	Reporting Standards for Endovascular Repair of Saccular Intracranial Cerebral Aneurysms	59
Chinese medicine	–	Recommendations for reporting adverse drug reactions and adverse events of traditional Chinese medicine	60
Menopause	STROMA	Overview of methods used in cross-cultural comparisons of menopausal symptoms and their determinants: Strengthening the Reporting of Menopause and Ageing studies	61
End-of-life care	MORECare	Evaluating complex interventions in end of life care	62
Viscerotropic disease	–	Viscerotropic disease: case definition and guidelines for collection, analysis, and presentation of immunisation safety data	63
Veterinary OSs	STROBE-Vet	Methods and processes of developing the strengthening the reporting of observational studies in epidemiology	64
Health care simulation research	INSPIRE	Reporting Guidelines for Health Care Simulation Research	65
Respondent-driven sampling studies	STROBE-RDS	Strengthening the Reporting of Observational Studies in Epidemiology for Respondent-Driven Sampling Studies	66
Narratives in clinical research	–	Suggestions for improving the reporting of clinical research: the role of narrative	67
Raw clinical data	–	Preparing raw clinical data for publication: guidance for journal editors, authors, and peer reviewers	68
Participation in case-control studies	–	Reporting participation in case-control studies	69
Comparative safety and effectiveness research	–	Instrumental variable methods in comparative safety and effectiveness research	70

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