Key reporting guidelines and other EQUATOR resources

Iveta Simera

The EQUATOR Network workshop
31 October 2013, WHO, Geneva

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CSM

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Enhancing the QUAlity and Transparency Of health Research

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The resource centre for good reporting of health research studies

Library for health research reporting

The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.

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Key reporting guidelines

CONSORT	Full Record | Checklist | Flow Diagram
STROBE	Full Record | Checklist
PRISMA	Full Record | Checklist | Flow Diagram
STARD	Full Record | Checklist | Flow Diagram
COREQ	Full Record
ENTREQ	Full Record
SQUIRE	Full Record | Checklist
CHEERS	Full Record | Checklist
CARE	Full Record | Checklist
SAMPL	Full Record

Toolkits

The EQUATOR Network works to improve the reliability and value of medical research literature by promoting transparent and accurate reporting of research studies.

Our Toolkits support different user groups, including:

Authors
Information and resources for authors

Editors

EQUATOR highlights

3/10/2013 - OPEN: To overcome failure to publish negative findings

The EU-funded OPEN project (Overcome failure to Publish nEgative fiNdings) brought together key opinion leaders from across Europe to address the issue of publications bias. Read More

17/09/2013 - EQUATOR Network at the Peer Review Congress 2013 in Chicago

EQUATOR actively participated at the Seventh International Congress on Peer Review and Biomedical Publication, 8-10 September 2013, Chicago, USA. We organised the EQUATOR workshop for editors on reporting of research studies (Saturday 7 September am) and the EQUATOR 5th Annual ... Read More

10/08/2013 - Declaration of transparency

News

EQUATOR Network Newsletter October 2013
22/10/2013

The Checklist Manifesto Meets Clinical Trials
9/10/2013

Publicly available sources provide insufficient information on patient-relevant outcomes of clinical trials
9/10/2013

New EASE Science Editors' Handbook published
1/10/2013

Clinical Trials 2013 – 2014
20/09/2013

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1. Launch of a checklist for reporting longitudinal observational drug studies in rheumatology: a EULAR extension of STROBE guidelines based on experience from biologics registries
2. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies
3. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

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Some reporting guidelines are also available in languages other than English. Find out more in our Translations section.

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CONsolidated Standards Of Reporting Trials

CONSORT

TRANSPARENT REPORTING of TRIALS

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+AllTrials

Please join CONSORT in supporting the All Trials campaign to get all clinical trial results reported.

Reporting Examples

Submit Example

If you find an example of good reporting, login here to submit it to our Library.

Welcome to the CONSORT Statement Website

CONSORT, which stands for Consolidated Standards of Reporting Trials, encompasses various initiatives developed by the CONSORT Group to alleviate the problems arising from inadequate reporting of randomized controlled trials (RCTs).

The main product of CONSORT is the CONSORT Statement, which is an evidence-based, minimum set of recommendations for reporting RCTs. It offers a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation.

The CONSORT Statement comprises a 25-item checklist and a flow diagram, along with some brief descriptive text. The checklist items focus on reporting how the trial was designed, analyzed, an interpreted; the flow diagram displays the progress of all participants through the trial.

Considered an evolving document, the CONSORT Statement is subject to periodic changes as new evidence emerges. This website contains the current definitive version of the CONSORT Statement and up-to-date information on extensions.

News

In Memoriam

Dr. Vincent Kokich, Editor-in-Chief of the American Journal of Orthodontics and Dentofacial Orthopedics (AJODO) and strong promoter of CONSORT and PRISMA passes away

Read more

Reporting randomised trials

- CONSORT Statement first published in 1996, revised 2001, 2010

  History:

  - Two sets of recommendations for reporting RCTs published in 1994 (SORT Group, Asilomar Group)
  - CONSORT meeting in Chicago, 1995

- CONSORT Statement is an evidence-based, minimum set of recommendations for reporting RCTs

  It offers a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation.

2010 Revision of CONSORT

- Revised checklist
- Short paper
  (published in 9 journals)
- Revised (and expanded)
  explanatory paper (E&E)

CONSORT checklist

Section / topic	#	Checklist item
TITLE & ABSTRACT	1a	Identification as a randomised trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)
INTRODUCTION		
Background and objectives	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses
METHODS		
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines
Randomisation		
Sequence generation	8a	Method used to generate the random allocation sequence
	8b	Type of randomisation; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

- 25 items
- Rationale for the items:
  - Necessary to evaluate the study
  - Evidence-based, whenever possible
  - Minimum set of essential items

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CONSORT checklist (2)

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Major changes in CONSORT 2010

Added 3 new items

Registration, Protocol, Funding

Added several sub-items, e.g.

Any important changes to methods after trial commencement, with a discussion of reasons

Why the trial ended or was stopped

Made some items more specific

e.g. allocation concealment mechanism, blinding

Simplified and clarified the wording throughout

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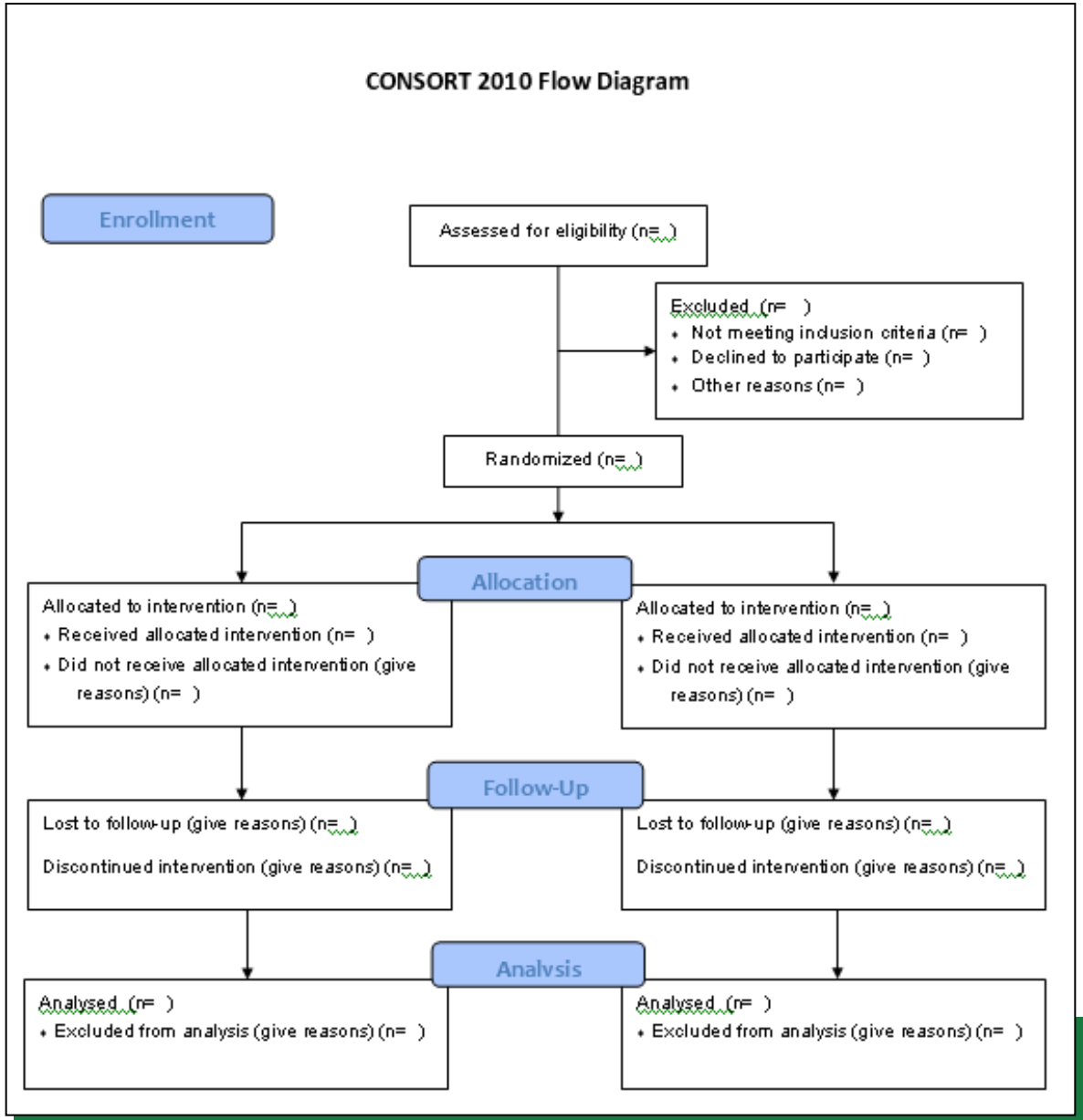
CONSORT flow diagram



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Current CONSORT extensions

DESIGNS	**Cluster**	**Non-inferiority/ equivalence**	**Pragmatic**
INTERVENTIONS	**Herbal**	**Non-pharmacological**	**Acupuncture (STRICTA)**
DATA	**Harms**	**Abstracts**	**Patient-reported outcomes**

Full details (pdfs and checklists) on CONSORT website:

http://www.consort-statement.org/

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STROBE Statement

STrengthening the Reporting of OBservational Studies in Epidemiology

STROBE Statement

Strengthening the reporting of observational studies in epidemiology

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What is STROBE?

STROBE stands for an international, collaborative initiative of epidemiologists, methodologists, statisticians, researchers and journal editors involved in the conduct and dissemination of observational studies, with the common aim of **STrengthening the Reporting of OBservational studies in Epidemiology**.

The STROBE Statement is being endorsed by a growing number of biomedical journals. Click here for full list.

For STROBE-related entries in PubMed click here.

What's new in the STROBE Initiative?

29.08.2013

PLOS Collection: Reporting Guidelines Collection

PLOS journals launches an open access collection of reporting guidelines, commentaries, and related research on guidelines from across PLOS journals. This Collection coincides with the Seventh International Congress on Peer... [more]

[more]

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STROBE Statement

- **Guidance on how to report observational studies well (which is rare!)**
  - Focus on 3 main study designs: cohort, case-control, cross-sectional studies
- **Published in Oct 2007: short paper and E&E**
- **Adopted by many journals**

Find it on:

www.equator-network.org

www.strobe-statement.org

OPEN ACCESS Freely available online PLOS MEDICINE

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

Erik von Elm[1*], Douglas G. Altman[2], Matthias Egger[1,3], Stuart J. Pocock[4], Peter C. Gøtzsche[5],

OPEN ACCESS Freely available online PLOS MEDICINE

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

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

Funding: The initial STROBE 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 & Development Methodology Programme. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

ABSTRACT

Much medical research is observational. The reporting of observational studies is often of insufficient quality. Poor reporting hampers the assessment of the strengths and weaknesses of a study and the generalisability of its results. Taking into account empirical evidence and theoretical considerations, a group of methodologists, researchers, and editors developed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations to improve the quality of reporting of observational studies. The STROBE Statement consists of a checklist of 22 items, which relate to the title, abstract, introduction, methods, results and discussion sections of articles. Eighteen items are common to cohort studies, case-

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STROBE

- **Checklist with 22 items**
  - Heading (where in paper), item No
  - Recommendation, divided into:
    cohort, case-control, cross-sectional study - where different

	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

Three STROBE extensions (1)

- **STREGA (2009)**
  - reporting of genetic association studies

Table 1. STREGA Reporting Recommendations, Extended from STROBE Statement

Item	Item Number	STROBE Guideline	Extension for Genetic Association Studies (STREGA)
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 pre-specified hypotheses.	***State if the study is the first report of a genetic association, a replication effort, or both.***
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.	***Give information on the criteria and methods for selection of subsets of participants from a larger study, when relevant.***
		(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	(a) Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	***(b) Clearly define genetic exposures (genetic variants) using a widely-used nomenclature system. Identify variables likely to be associated with population stratification (confounding by ethnic origin).***

Three STROBE extensions (2)

- **STROBE – ME (Oct 2011)**
  - Reporting molecular epidemiology (biomarker studies)

Table 1. The Strengthening the Reporting Observational studies in Epidemiology – Molecular Epidemiology (STROBE-ME) Reporting Recommendations: Extended from STROBE statement.

Item	Item number	STROBE Guidelines	Extension for Molecular Epidemiology Studies (STROBE-ME)
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	**ME-1** State the use of specific biomarker(s) in the title and/or in the abstract if they contribute substantially to the findings
		(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	**ME-2** Explain in the scientific background of the study how/why the specific biomarker(s) have been chosen, potentially among many others (e.g., others are studied but reported elsewhere, or not studied at all)
Objectives	3	State specific objectives, including any pre-specified hypotheses	**ME-3** *A priori* hypothesis: if one or more biomarkers are used as proxy measures, state the *a priori* hypothesis on the expected values of the biomarker(s)
Methods			
Study design	4	Present key elements of study design early in the paper	**ME-4** Describe the special study designs for molecular epidemiology (in particular nested case/control and case/cohort) and how they were implemented
Biological sample collection			**ME-4.1** Report on the setting of the biological sample collection; amount of sample; nature of collecting procedures; participant conditions; time between sample collection and relevant clinical or physiological endpoints.

Three STROBE extensions (3)

- **STROBE abstract**

  - Reporting observational studies in conference abstracts (online draft)

Item	Recommendation
Title	Indicate the study's design with a commonly used term in the title (e.g cohort, case-control, cross sectional)
Authors	Contact details for the corresponding author
Study design	Description of the study design (e.g cohort, case-control, cross sectional)
Objective	Specific objectives or hypothesis
Methods	
Setting	Description of setting, follow-up dates or dates at which the outcome events occurred or at which the outcomes were present, as well as any points or ranges on other time scales for the outcomes (e.g., prevalence at age 18, 1998-2007).
Participants	*Cohort study*—Give the most important eligibility criteria, and the most important sources and methods of selection of participants. Describe briefly the methods of follow-up *Case-control study*—Give the major eligibility criteria, and the major sources and methods of case ascertainment and control selection *Cross-sectional study*—Give the eligibility criteria, and the major sources and methods of selection of participants
	Cohort study—For matched studies, give matching and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	Clearly define primary outcome for this report.
Statistical methods	Describe statistical methods, including those used to control for confounding
Results	
Participants	Report Number of participants at the beginning and end of the study
Main results	Report estimates of associations. If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period Report appropriate measures of variability and uncertainty (e.g., odds ratios with confidence intervals
Conclusions	General interpretation of study results

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E & E papers

- **Both guidelines have Explanation and Elaboration papers**

- **Both can be accessed through their websites or on EQUATOR website – full record**

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Use your browser's Back button to return to your search results

CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

Full bibliographic reference	Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. Ann Int Med. 2010;152(11):726-32. PMID: 20335313 BMC Medicine. 2010;8:18. PMID: 20334633 BMJ. 2010;340:c332. PMID: 20332509 J Clin Epidemiol. 2010;63(8): 834-40. PMID: 20346629 Lancet. 2010;375(9721):1136 supplementary webappendix Obstet Gynecol. 2010;115(5):1063-70. PMID: 20410783 Open Med. 2010;4(1):60-68. PLoS Med. 2010;7(3): e1000251. PMID: 20352064 Trials. 2010;11:32. PMID: 20334632
Language	English
Relevant URLs (full-text if available)	Full-text PDF documents of the CONSORT 2010 Statement, CONSORT 2010 checklist, CONSORT 2010 flow diagram and the CONSORT 2010 Explanation and Elaboration document are available from: http://www.consort-statement.org /resources/downloads/
Explanation and elaboration papers	Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG, for the CONSORT Group. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trial. BMJ. 2010;340:c869. PMID: 20332511 J Clin Epidemiol. 2010;63(8): e1-e37. PMID: 20346624
Previous versions of this guideline / Guideline history	CONSORT 2001

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