Key reporting guidelines and other EQUATOR resources

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The EQUATOR Network workshop
31 October 2013, WHO, Geneva
Displaying 218 reporting guidelines found.

Most recently added records are displayed first.

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

Translations

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

About the Library

For information about Library scope and content, identification of reporting guidelines and inclusion/exclusion criteria please visit About the Library.
CONsolidated Standards Of Reporting Trials

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, and 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.

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

  
  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 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials

David Moher, Sally Hopewell, Kenneth F. Schulz, Victor Montori, Peter C. Gøtzsche, P.J. Devereaux, Diana Elbourne, Matthias Egger, Douglas G. Altman

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

Kenneth F. Schulz, Douglas G. Altman, David Moher, for the CONSORT Group

BMC Medicine

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

Kenneth F. Schulz, Douglas G. Altman, David Moher, for the CONSORT Group
CONSORT checklist

- 25 items
- Rationale for the items:
  - Necessary to evaluate the study
  - Evidence-based, whenever possible
  - Minimum set of essential items
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
CONSORT flow diagram
### Current CONSORT extensions

<table>
<thead>
<tr>
<th>DESIGNS</th>
<th>Cluster</th>
<th>Non-inferiority/equivalence</th>
<th>Pragmatic</th>
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<tr>
<td>INTERVENTIONS</td>
<td>Herbal</td>
<td>Non-pharmacological</td>
<td>Acupuncture (STRICTA)</td>
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<td>Harms</td>
<td>Abstracts</td>
<td>Patient-reported outcomes</td>
</tr>
</tbody>
</table>

Full details (pdfs and checklists) on CONSORT website:

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

PLOS Collection: Reporting Guidelines Collection

PLOS journals launch 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]
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
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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*

<table>
<thead>
<tr>
<th>Item No</th>
<th>Recommendation</th>
</tr>
</thead>
</table>
| **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** | 2
| Explain the scientific background and rationale for the investigation being reported |
| **Objectives** | 3
| State specific objectives, including any prespecified hypotheses |
| **Methods** | 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 | 2 | Explain the scientific background and rationale for the investigation being reported. | State if the study is the first report of a genetic association, a replication effort, or both. |
| Objectives | 3 | State specific objectives, including any pre-specified hypotheses. |  |
| Methods | 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. | Give information on the criteria and methods for selection of subsets of participants from a larger study, when relevant. |
| 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.

<table>
<thead>
<tr>
<th>Item</th>
<th>Item number</th>
<th>STROBE Guidelines</th>
<th>Extension for Molecular Epidemiology Studies (STROBE-ME)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title and abstract</td>
<td>1</td>
<td>(a) Indicate the study's design with a commonly used term in the title or the abstract</td>
<td>ME-1 State the use of specific biomarker(s) in the title and/or in the abstract if they contribute substantially to the findings</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) Provide in the abstract an informative and balanced summary of what was done and what was found</td>
<td></td>
</tr>
<tr>
<td>Introduction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Background rationale</td>
<td>2</td>
<td>Explain the scientific background and rationale for the investigation being reported</td>
<td>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)</td>
</tr>
<tr>
<td>Objectives</td>
<td>3</td>
<td>State specific objectives, including any pre-specified hypotheses</td>
<td>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)</td>
</tr>
<tr>
<td>Methods</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study design</td>
<td>4</td>
<td>Present key elements of study design early in the paper</td>
<td>ME-4 Describe the special study designs for molecular epidemiology (in particular nested case/control and case/cohorts) and how they were implemented</td>
</tr>
<tr>
<td>Biological sample collection</td>
<td></td>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>
### Three STROBE extensions (3)

- **STROBE abstract**
  - Reporting observational studies in conference abstracts (online draft)

<table>
<thead>
<tr>
<th>Item</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Indicate the study’s design with a commonly used term in the title (e.g., cohort, case-control, cross-sectional)</td>
</tr>
<tr>
<td>Authors</td>
<td>Contact details for the corresponding author</td>
</tr>
<tr>
<td>Study design</td>
<td>Description of the study design (e.g., cohort, case-control, cross-sectional)</td>
</tr>
<tr>
<td>Objective</td>
<td>Specific objectives or hypothesis</td>
</tr>
<tr>
<td>Methods</td>
<td>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).</td>
</tr>
<tr>
<td>Setting</td>
<td>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.</td>
</tr>
<tr>
<td>Participants</td>
<td>Variables—Clearly define primary outcome for this report.</td>
</tr>
<tr>
<td></td>
<td>Statistical methods—Describe statistical methods, including those used to control for confounding.</td>
</tr>
<tr>
<td>Results</td>
<td>Participants—Report number of participants at the beginning and end of the study.</td>
</tr>
<tr>
<td></td>
<td>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).</td>
</tr>
<tr>
<td></td>
<td>Conclusions—General interpretation of study results.</td>
</tr>
</tbody>
</table>
E & E papers

- Both guidelines have Explanation and Elaboration papers
- Both can be accessed through their websites or on EQUATOR website – full record