About this Class

- Overview of key concepts
- Reporting guidelines for authors
- Checklists for reviewers
- Additional resources

Reporting and Evaluating Studies Guide

galter.northwestern.edu > Explore Galter > Guides > Evidence-Based Practice > Reporting Research and Evaluating Studies
Writing & Research Resources at NU

- The Writing Place
- CLIMB Written Communication Resources
- Writing and Terminology GalterList
- Northwestern University Office for Research
- Feinberg Research Office
- Biostatistics Collaboration Center (BCC)
Poor Reporting

- Missing Information
- Ambiguity
- Misrepresentation

10 of 100 of papers clearly stated the purpose of the study in the Introduction.

Gender was not reported in 11% of papers.

20% of papers introduced new statistical methods in the results section.

A systematic survey of the quality of research reporting in general orthopaedic journals.
Parsons et al, J Bone Joint Surg Br 2011
Impact of Poor Reporting

- Delayed publication
- Biased results and misleading information published
- Adverse effects on researchers, clinicians, and patients
What to Report

- Methodology
- Results
- Potential conflicts
The PICO framework is a great tool for identifying key methodological information.

**Patient/Population/Problem**
- Important characteristics – Inclusion/exclusion criteria – Sample size – Recruitment and assignment – Address confounders

**Intervention or Exposure**
- Explicit mention of the intervention or exposure. This can be a treatment, procedure, diagnostic test, prognostic factors

**Comparator**
- Main alternative to compare with the intervention. This is often optional and can be a placebo.

**Outcome**
- Description of what you hope to accomplish, measure, improve or affect. Mention primary and secondary outcomes.
What to Report

Results

Inferences
Demonstrate statistical significance

Confidence interval, P-value
Type I error, Type II error

Estimates
Strength of the associations or relationships

Relative risk (RR), Odds ratio (OR)

Adjustments
Account for differences between groups

Stratification, Multivariate models, Logistic regression, Linear regression
## Bias in Research

### Pre
- Selection
- Allocation
- Detection

### During
- Performance
- Interviewer
- Attrition

### Post
- Outcome reporting
- Citation
- Publication
What to Report
Potential Conflicts

Conflicts of Interests

Acknowledge potential conflicts
• Disclosure statements
• Funding sources
Reporting Guidelines

- Recommend the minimum set of information
- Specific to a study design
- Checklists, flow diagrams, or structured text
- Usually include “explanation and elaboration”
Reporting Guidelines

- Based on evidence
- Developed by consensus
- Provide guidance not requirements
- Remember - cite your reporting guideline!
Reporting Guidelines

Benefits

- Improve accuracy and transparency of research
- Promote replication by researchers
- Improve efficiency of literature searching
- Enable readers to critically appraise the study
- Help clinicians apply research to clinical decision-making
Reporting Guidelines

GENERIC & SPECIFIC
Reporting Guidelines
“Generic”

- Generally applicable
- Include key methodology features

Critical Appraisal Resources Guide

galter.northwestern.edu > Explore Galter > Guides > Evidence-Based Practice > Critical Appraisal Resources

https://galter.northwestern.edu/guides-and-tutorials/critical-appraisal-resources?category=28
CONSORT
Consolidated Standards of Reporting Trials

<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Item No</th>
<th>Checklist Item</th>
<th>Reported on page No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title and abstract</td>
<td>1a</td>
<td>Identification as a randomised trial in the title</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1b</td>
<td>Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstract)</td>
<td></td>
</tr>
<tr>
<td>Introduction</td>
<td>2a</td>
<td>Scientific background and explanation of rationale</td>
<td></td>
</tr>
<tr>
<td>Background and objectives</td>
<td>2b</td>
<td>Specific objectives or hypotheses</td>
<td></td>
</tr>
<tr>
<td>Methods</td>
<td>3a</td>
<td>Description of trial design (such as parallel, factorial) including allocation ratio</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3b</td>
<td>Important changes to methods after trial commencement (such as eligibility criteria), with reasons</td>
<td></td>
</tr>
<tr>
<td>Participants</td>
<td>4e</td>
<td>Eligibility criteria for participants</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4b</td>
<td>Settings and locations where the data were collected</td>
<td></td>
</tr>
<tr>
<td>Interventions</td>
<td>5</td>
<td>The interventions for each group with sufficient details to allow replication, including how and when they were actually administered</td>
<td></td>
</tr>
<tr>
<td>Outcomes</td>
<td>6a</td>
<td>Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6b</td>
<td>Any changes to trial outcomes after the trial commenced, with reasons</td>
<td></td>
</tr>
<tr>
<td>Sample size</td>
<td>7a</td>
<td>How sample size was determined</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7b</td>
<td>When applicable, explanation of any interim analyses and stopping guidelines</td>
<td></td>
</tr>
<tr>
<td>Randomisation:</td>
<td>8a</td>
<td>Method used to generate the random allocation sequence</td>
<td></td>
</tr>
<tr>
<td>Sequence generation</td>
<td>8b</td>
<td>Type of randomisation, details of any restriction (such as blocking and block size)</td>
<td></td>
</tr>
<tr>
<td>Allocation concealment mechanism</td>
<td>9</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>Implementation</td>
<td>10</td>
<td>Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions</td>
<td></td>
</tr>
</tbody>
</table>
### STROBE Statement—Checklist of items that should be included in reports of cohort studies

<table>
<thead>
<tr>
<th>Item No</th>
<th>Recommendation</th>
</tr>
</thead>
</table>
| 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.                                                              |
| 2       | Explain the scientific background and rationale for the investigation being reported |
| 3       | State specific objectives, including any prespecified hypotheses                 |
| 4       | Present key elements of study design early in the paper                          |
| 5       | Describe the setting, locations, and relevant dates, including periods of recruitment,  
        | exposure, follow-up, and data collection                                           |
| 6       | (a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up  
        | (b) For matched studies, give matching criteria and number of exposed and unexposed |
| 7       | Clearly define all outcomes, exposures, predictors, potential confounders, and effect  
        | modifiers. Give diagnostic criteria, if applicable                                 |
| 8       | 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 |
| 9       | Describe any efforts to address potential sources of bias                         |
| 10      | Explain how the study size was arrived at                                          |
| 11      | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why |
| 12      | (a) Describe all statistical methods, including those used to control for confounding  
        | (b) Describe any methods used to examine subgroups and interactions              |
# PRISMA

Preferred Reporting Items for Systematic Reviews and Meta-Analyses

<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>#</th>
<th>Checklist Item</th>
<th>Reported on page #</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TITLE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Identify the report as a systematic review, meta-analysis, or both.</td>
<td></td>
</tr>
<tr>
<td><strong>ABSTRACT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured summary</td>
<td>2</td>
<td>Provide a structured summary including, as applicable: background, objectives, data sources, study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.</td>
<td></td>
</tr>
<tr>
<td><strong>INTRODUCTION</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rationale</td>
<td>3</td>
<td>Describe the rationale for the review in the context of what is already known.</td>
<td></td>
</tr>
<tr>
<td>Objectives</td>
<td>4</td>
<td>Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICO/S).</td>
<td></td>
</tr>
<tr>
<td><strong>METHODS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol and registration</td>
<td>5</td>
<td>Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.</td>
<td></td>
</tr>
<tr>
<td>Eligibility criteria</td>
<td>6</td>
<td>Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.</td>
<td></td>
</tr>
<tr>
<td>Information sources</td>
<td>7</td>
<td>Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.</td>
<td></td>
</tr>
<tr>
<td>Search</td>
<td>8</td>
<td>Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.</td>
<td></td>
</tr>
<tr>
<td>Study selection</td>
<td>9</td>
<td>State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).</td>
<td></td>
</tr>
<tr>
<td>Data collection process</td>
<td>10</td>
<td>Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.</td>
<td></td>
</tr>
<tr>
<td>Data items</td>
<td>11</td>
<td>List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.</td>
<td></td>
</tr>
<tr>
<td>Risk of bias in individual studies</td>
<td>12</td>
<td>Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.</td>
<td></td>
</tr>
<tr>
<td>Summary measures</td>
<td>13</td>
<td>State the principal summary measures (e.g., risk ratio, difference in means).</td>
<td></td>
</tr>
<tr>
<td>Synthesis of results</td>
<td>14</td>
<td>Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I²; for each meta-analysis).</td>
<td></td>
</tr>
</tbody>
</table>
Reporting Guidelines

“Specific”

- Include greater degree of specificity
- Designed around a specific condition/field/intervention
- Used with relevant generic guideline

i.e., Reporting in implementation research of nurturing care interventions designed to promote early childhood development (ECD).
Sources of Reporting Guidelines

- Equator Network
- For author pages
- Published studies
- Galter Guide
The EQUATOR mission is to achieve accurate, complete, and transparent reporting of all health research studies to support research reproducibility and usefulness.

https://www.equator-network.org/

Consists of:

- Researchers
- Editors
- Peer reviewers
- Developers of reporting guidelines
- Research funding bodies
- Other collaborators
EQUATOR Reporting Guideline Decision Tree
Which guidelines are relevant to my work?

- Was the research on humans? [Yes/No]
- Was your research on animals in the lab? [Yes/No]
- Did your research generate quantitative data? [Yes/No]
- Did you combine and analyse (review) the results of previous studies? [Yes/No]
- Is it a review of observational (cohort, case-control, or cross-sectional) studies? [Yes/No]
- Was your research on animals in the lab? [Yes/No]
- Did you pool the results of previous studies (a review)? [Yes/No]
- Was your study a randomized trial comparing two or more health interventions? [Yes/No]
- Did your study explore the relationship between exposure to risk or protective factors and outcomes? [Yes/No]
- Did the research develop, validate or update a general prediction model for diagnosis or prognosis? [Yes/No]
- Did the study evaluate the prognostic value of one or more biomarkers? [Yes/No]

A. ARRIVE
- Do you describe a clinical case or a series of cases? [Yes/No]

B. SRQR
- Did you compare the accuracy of a new or alternative diagnostic test against an established one (reference standard)? [Yes/No]

C. STARD
- Did you compare the accuracy of a new or alternative diagnostic test against an established one (reference standard)? [Yes/No]

D. PRISMA
- Is it a review of observational (cohort, case-control, or cross-sectional) studies? [Yes/No]

E. MOOSE
- MOOSE

F. ENTREQ
- Did you pool the results of previous studies (a review)? [Yes/No]

G. CARE
- Did you pool the results of previous studies (a review)? [Yes/No]

H. STROBE
- Did the research develop, validate or update a general prediction model for diagnosis or prognosis? [Yes/No]

I. REMARK
- Did the study evaluate the prognostic value of one or more biomarkers? [Yes/No]

None of the most popular checklists are appropriate for your study design, but you may still find useful guidelines by searching the full EQUATOR library, which covers 250+ study designs.

CC-BY 4.0 The EQUATOR Network 26 February 2016
Good reporting is not an optional extra: it is an essential component of doing good research

Vellore, 11 January 2010
Critical appraisal is the process of carefully and systematically examining research evidence to judge its trustworthiness, its value and relevance in a particular context.

Evaluating Published Studies
Critical Appraisal

Assess methodological soundness
- Does this study address a clearly focused question? Remember PICO
- Did the study use valid methods to address this question?
- Are the appropriate sample, assignment, and assessment points addressed?

Evaluate results and interpretations
- Are the results valid?
- Are the interpretations accurate?
Evaluating Published Studies
Critical Appraisal

Identify and assess bias

- Did the study use valid methods to address their question?
- Do the authors address potential sources of conflict?

Bias in Research

Pre
- Selection
- Allocation
- Detection

During
- Performance
- Interviewer
- Attrition

Post
- Outcome reporting
- Citation
- Publication
Evaluating Published Studies

Critical Appraisal

Determine relevancy

- Is the study design appropriate for the research question?
  - Check out the Oxford CEBM – Levels of Evidence
- Are the valid results of this study important?
- Are the results applicable to your patient, population, or problem?
Critical Appraisal Checklists

- Developed around a study design
- More concise with fewer checklist items
- Based on evidence
- Developed by consensus
Additional Resources

- Calculators
- Books and articles
- Guide
References

- Richards, D. (2009). GRADING--levels of evidence. Evid Based Dent, 10(1), 24-25. doi:10.1038/sj.ebd.6400636
Thank you

Questions?