About this Class

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

Reporting Research and Evaluating Studies Guide
galter.northwestern.edu > Research Services > GalterGuides > 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

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

GENDER
Gender was not reported in 11% of papers.

METHODS
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.

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**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
Identify and address bias

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

CONSORT 2010 checklist of information to include when reporting a randomised trial

<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 (as would be given to a funding agency)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2c</td>
<td>Scientific background and explanation of rationale</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2d</td>
<td>Specific objectives or hypotheses</td>
<td></td>
</tr>
<tr>
<td>Methods</td>
<td>3a</td>
<td>Description of trial design (such as randomisation, 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></td>
<td>3c</td>
<td>Eligibility criteria for participants</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3d</td>
<td>Settings and locations where data were collected</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3e</td>
<td>The interventions for each group (with sufficient detail to allow replication, including how and when they were actually administered)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4a</td>
<td>Completely defined primary and secondary outcome measures, including how and where they were measured</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4b</td>
<td>Any changes to trial outcomes after the trial commenced, with reasons</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4c</td>
<td>Sample size</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4d</td>
<td>How sample size was determined</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4e</td>
<td>When applicable, explanation of any interim analyses and stopping guidelines</td>
<td></td>
</tr>
<tr>
<td>Randomisation: Sequence generation</td>
<td>5a</td>
<td>Method used to generate the random allocation sequence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5b</td>
<td>Type of randomisation, details of any restriction (such as blocking and block size)</td>
<td></td>
</tr>
<tr>
<td>Allocation concealment mechanisms</td>
<td>6a</td>
<td>Method used to implement the randomisation 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>7a</td>
<td>Whether randomisation was adequate and described how and where it was implemented</td>
<td></td>
</tr>
</tbody>
</table>
STROBE
STrengthening the Reporting of OBservational studies in Epidemiology

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>
<tbody>
<tr>
<td>1</td>
<td>(a) Include the study objectives in the title or the abstract.</td>
</tr>
<tr>
<td>2</td>
<td>(a) Describe the setting, location, and referents, including periods of recruitment, response, follow-up, and data collection.</td>
</tr>
<tr>
<td>3</td>
<td>(a) Give the eligibility criteria, the sources and methods of selection.</td>
</tr>
<tr>
<td>4</td>
<td>(a) Describe the setting, location, and referents, including periods of recruitment, response, follow-up, and data collection.</td>
</tr>
<tr>
<td>5</td>
<td>(a) Give the eligibility criteria, the sources and methods of selection.</td>
</tr>
<tr>
<td>6</td>
<td>(a) Give the eligibility criteria, the sources and methods of selection.</td>
</tr>
<tr>
<td>7</td>
<td>(a) Give the eligibility criteria, the sources and methods of selection.</td>
</tr>
<tr>
<td>8</td>
<td>(a) Give the eligibility criteria, the sources and methods of selection.</td>
</tr>
<tr>
<td>9</td>
<td>(a) Give the eligibility criteria, the sources and methods of selection.</td>
</tr>
<tr>
<td>10</td>
<td>(a) Give the eligibility criteria, the sources and methods of selection.</td>
</tr>
<tr>
<td>11</td>
<td>(a) Give the eligibility criteria, the sources and methods of selection.</td>
</tr>
</tbody>
</table>

PRISMA
Preferred Reporting Items for Systematic Reviews and Meta-Analyses

<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Checklist Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>TITLE</td>
<td>Identify the report as a systematic review, meta-analysis, or both.</td>
</tr>
<tr>
<td>ABSTRACT</td>
<td>Identify the review protocol. If absent, it can be searched (e.g., Web searches), and if available, provide registration information.</td>
</tr>
<tr>
<td>Structured summary</td>
<td>Identify the structured summary.</td>
</tr>
<tr>
<td>Objectives</td>
<td>Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).</td>
</tr>
<tr>
<td>INTRODUCTION</td>
<td>Briefly describe the rationale for the review.</td>
</tr>
<tr>
<td>METHODS</td>
<td>Identify the search strategies used in the study.</td>
</tr>
<tr>
<td>Eligibility criteria</td>
<td>Identify the eligibility criteria used in the study.</td>
</tr>
<tr>
<td>Intervention</td>
<td>Identify all interventions used.</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Identify all outcomes used.</td>
</tr>
<tr>
<td>Data collection process</td>
<td>Identify the data collection process.</td>
</tr>
<tr>
<td>Data sources</td>
<td>Identify the data sources used.</td>
</tr>
<tr>
<td>Risk of bias in individual studies</td>
<td>Identify the risk of bias in individual studies.</td>
</tr>
<tr>
<td>Synthesis of results</td>
<td>Describe the methods of combining results of studies.</td>
</tr>
</tbody>
</table>

Northwestern Medicine
Feinberg School of Medicine
**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).

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**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.

Consists of:
- Researchers
- Editors
- Peer reviewers
- Developers of reporting guidelines
- Research funding bodies
- Other collaborators

https://www.equator-network.org/
Good reporting is not an optional extra: it is an essential component of doing good research

Vellore, 11 January 2010

Evaluating Published Studies
Critical Appraisal

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?

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?