Reporting Research & Evaluating Studies

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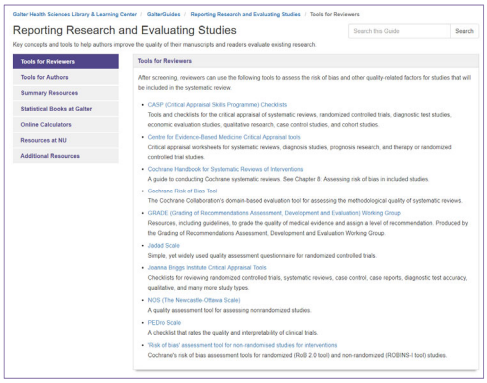
About this Class

- 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

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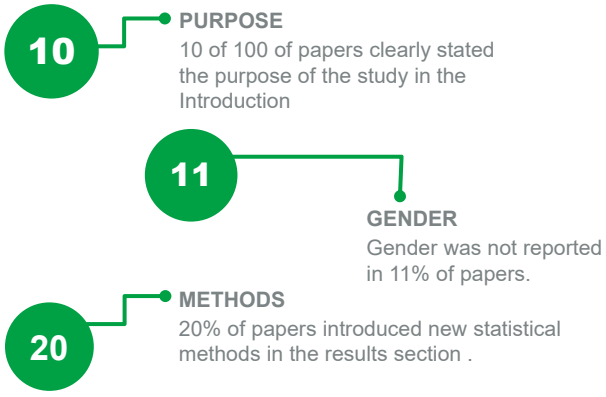
Writing & Research Resources at NU

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

3

Poor Reporting

- Missing Information
- Ambiguity
- Misrepresentation



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

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4

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

Reporting Methods

The PICO framework is a great tool for identifying key methodological information

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

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

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

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

7

What to Report
Results

Estimates
Strength of the associations or relationships

Relative risk (RR), Odds ratio (OR)

Inferences
Demonstrate statistical significance

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

Adjustments
Account for differences between groups

Stratification, Multivariate models, Logistic regression, Linear regression

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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”

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11

Reporting Guidelines

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

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Reporting Guidelines
Benefits

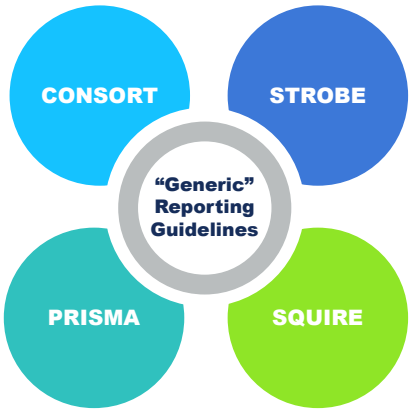
- Improve accuracy and transparency of research
- Promote replication by researchers
- Improve efficiency of literature searching
- Enable readers to critically appraise the study
- Help clinicians apply research to clinical decision-making

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*

Section/Topic	Item No	Checklist item	Reported on page No
Title and 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	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	

STROBE

STrengthening the Reporting of OBservational studies in Epidemiology

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	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*) 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
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	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
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

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17

PRISMA

Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	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.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	
METHODS			
Protocol and registration	5	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.	
Eligibility criteria	6	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.	
Information sources	7	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.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	
Risk of bias in individual studies	12	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.	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	

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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

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

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

The EQUATOR mission is to achieve accurate, complete, and transparent reporting of all health research studies to support research reproducibility and usefulness.

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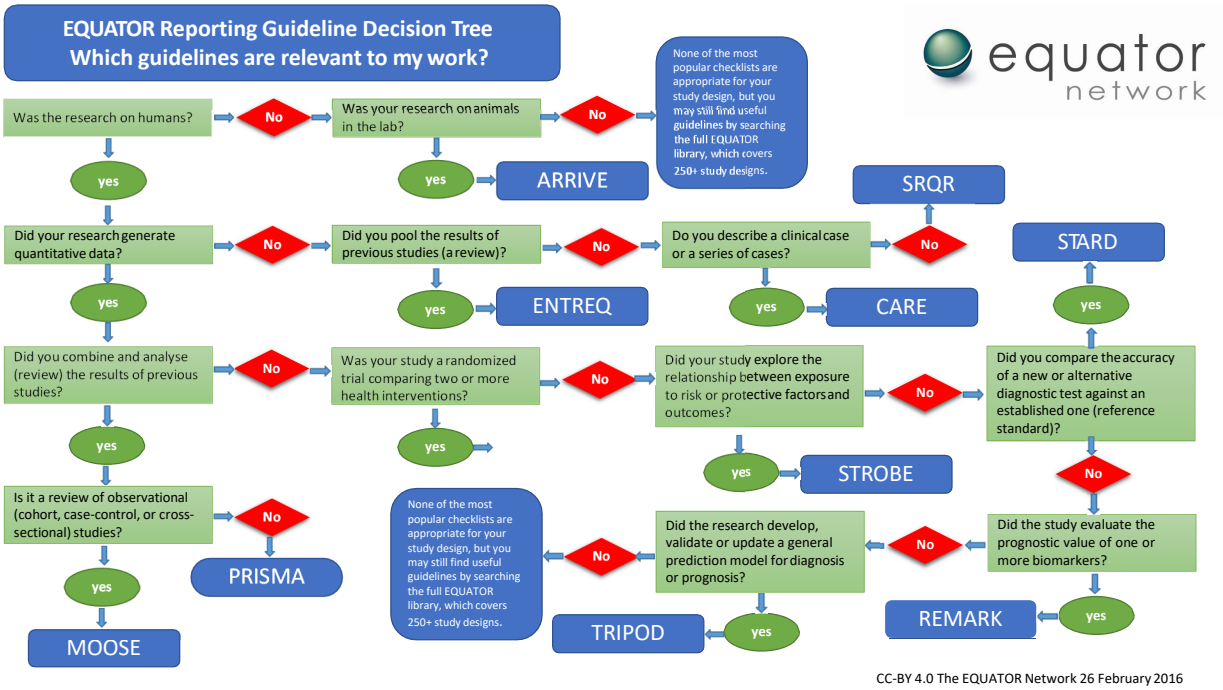
21



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.

Mhaskar R, Emmanuel P, Mishra S, Patel S, Naik E, Kumar A. Critical appraisal skills are essential to informed decision-making. Indian Journal of Sexually Transmitted Diseases. 2009;30(2):112-119.

24

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?

25

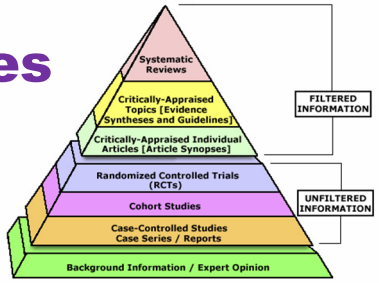
Evaluating Published Studies
Critical Appraisal

- **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	During	Post
• Selection • Allocation • Detection	• Performance • Interviewer • Attrition	• 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?

27

Critical Appraisal Checklists

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

28

Additional Resources

- **Calculators**
- **Books and articles**
- **Guide**

29

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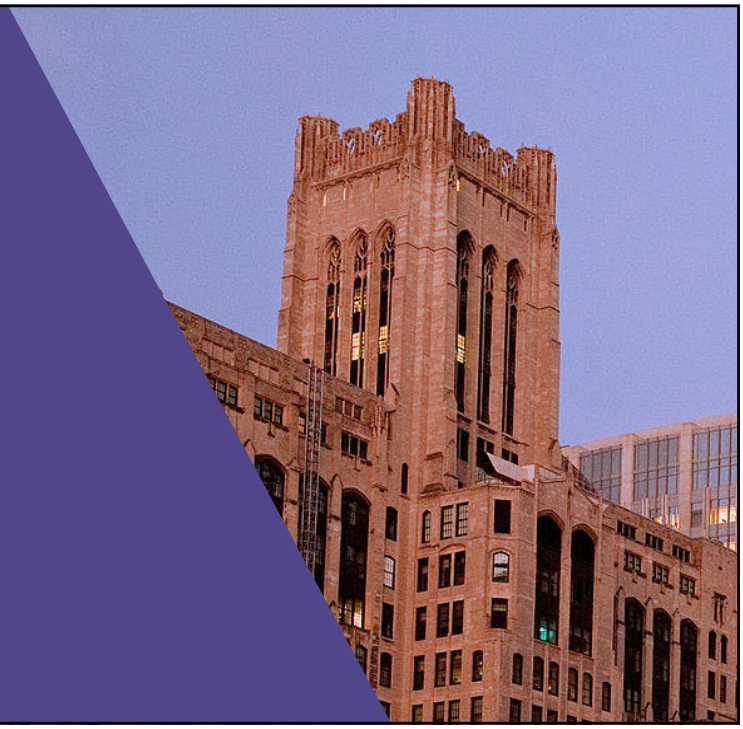

Thank you

Questions?