ARISTOTLE UNIVERSITY OF THESSALONIKI

FACULTY OF HEALTH SCIENCES - SCHOOL OF MEDICINE

MSc Health Statistics and Data Analytics

Reporting Research Guidelines

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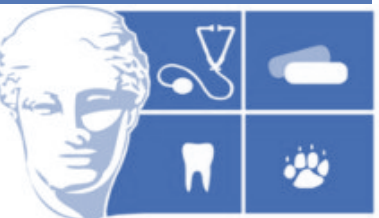


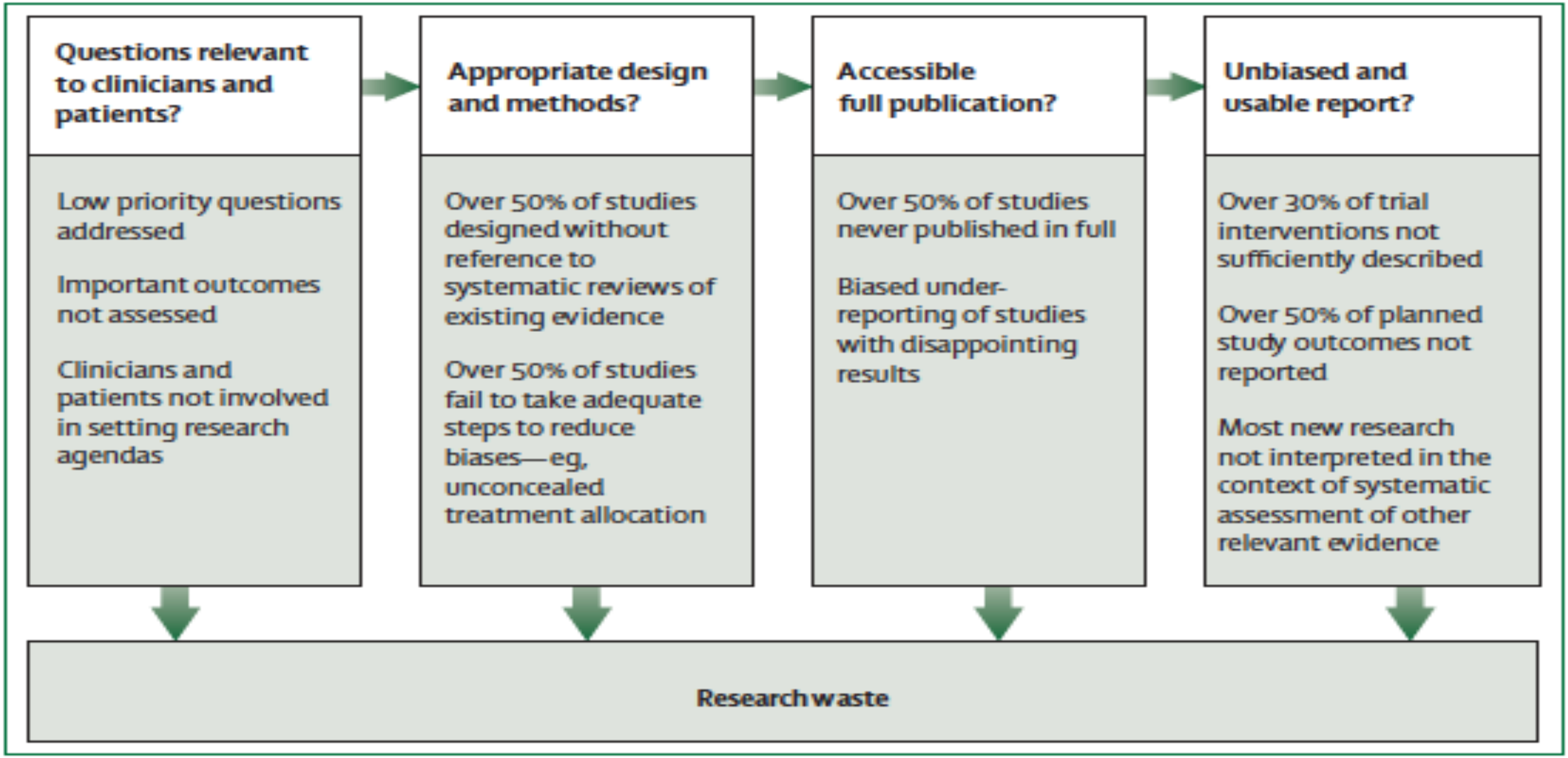
THESSALONIKI 2021-22

MSc Health Statistics & Data Analytics

Worth Publishing

- Valid research methodology
- Usable in further research or clinical practice
- Reproducible

The problem: waste in the research production & reporting



Chalmers I & Glasziou P Lancet 2009

An example from randomized trials published in PubMed

	Δεκ 2000 (N=519)	Δεκ 2006 (N=616)
Specification of primary outcomes	45%	53%*
Power calculation	27%	45%*
Method of randomization	21%	34%*
Allocation concealment	18%	25%*
Blinding (how achieved)	40%	41%
Trial registration	-	9%

Hopewell S et al. BMJ 2010

Underreporting research is scientific misconduct

Failure to publish an adequate account of a well-designed clinical trial is a form of scientific misconduct, which can lead those caring for patients to make inappropriate treatment decisions.

Chalmers I JAMA 1990

Publication bias

- (Study) publication bias: selective publication of entire studies

- (Outcome) reporting bias: selective reporting of outcomes within published studies

The problem: summary

1. Publishing biased studies

2. Not publishing well-designed studies, because of their negative results

The solution: reporting research guidelines

equator network

Enhancing the QUAlity and Transparency Of health Research

EQUATOR resources in German | Portuguese | Spanish

Home | About us | Library | Toolkits | Courses & events | News | Blog | Librarian Network | Contact

Your one-stop-shop for writing and publishing high-impact health research

find reporting guidelines | improve your writing | join our courses | run your own training course | enhance your peer review | implement guidelines

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.

- Search for reporting guidelines
- Not sure which reporting guideline to use?
- Reporting guidelines under development
- Visit the library for more resources

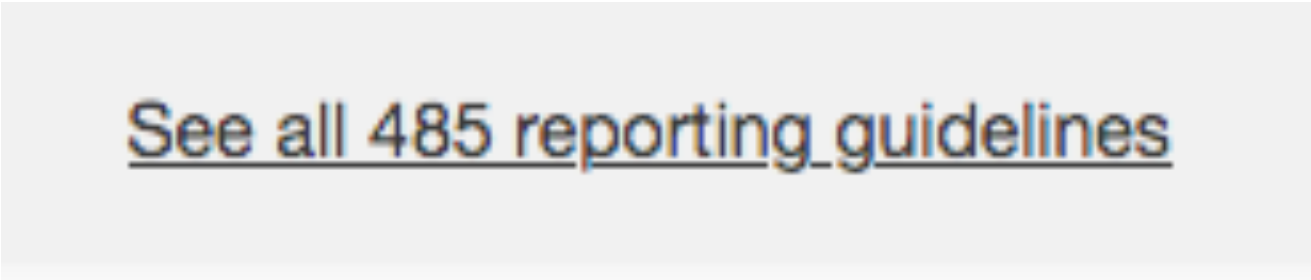
Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
Systematic reviews	PRISMA	Extensions
Study protocols	SPIRIT	PRISMA-P
Diagnostic/prognostic studies	STARD	TRIPOD
Case reports	CARE	Extensions
Clinical practice guidelines	AGREE	RIGHT
Qualitative research	SRQR	COREQ
Animal pre-clinical studies	ARRIVE	
Quality improvement studies	SQUIRE	Extensions
Economic evaluations	CHEERS	

See all 485 reporting guidelines

http://www.equator-network.org

EQUATOR: tidying chaos



http://www.equator-network.org

Aim

To publish well-designed studies and well-written manuscripts

NO MATTER their positive or negative results

An example: Cohort Study

The STROBE statement

- 22 items, which should be reported in a manuscript

www.consort-statement.org

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
		(*c*) Explain how missing data were addressed
		(*d*) If applicable, explain how loss to follow-up was addressed
		(*e*) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) Summarise follow-up time (eg, average and total amount)
Outcome data	15*	Report numbers of outcome events or summary measures over time
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for exposed and unexposed groups.

Improving reporting of my research study

- Find out about reporting requirements early, when planning your research study
- When writing up your research protocol, check the EQUATOR website for any new relevant guidelines to help improve the quality of your protocol/manuscript
- Adhere to the relevant reporting guidelines
- When not reporting on certain items, explain why
- It is important to provide enough information to allow your study to be potentially reproducible by others

Simera I et al. BMC Medicine 2010

Advantages of using reporting guidelines

- Well-design studies / less pieces of bias
- Well-written manuscripts
- Easier work for the Editors & Reviewers
- Easier published manuscripts
  - Even if the results are negative
- Papers easier to follow by the readers
- Reproducible results
- Reflection to good clinical practice
- Limit wasting time and resources (for all)

Epilogue

Reporting research guidelines: a tool towards well-performing and well-publishing but

A straightforward mind is always required