A publisher's view on RWE studies and articles

Andrea Bucceri, PhD
Dove Medical Press
(now part of Taylor & Francis – An Informa business)

Contact: Andrea Bucceri - Publications Development Manager - M: +44 (0)778 665 1501; Email: andrea@dovepress.co.uk

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- The views expressed in this presentation are those of the presenter and do not necessarily reflect those of Dove Medical Press or Taylor & Francis.

RCTs vs RWE studies

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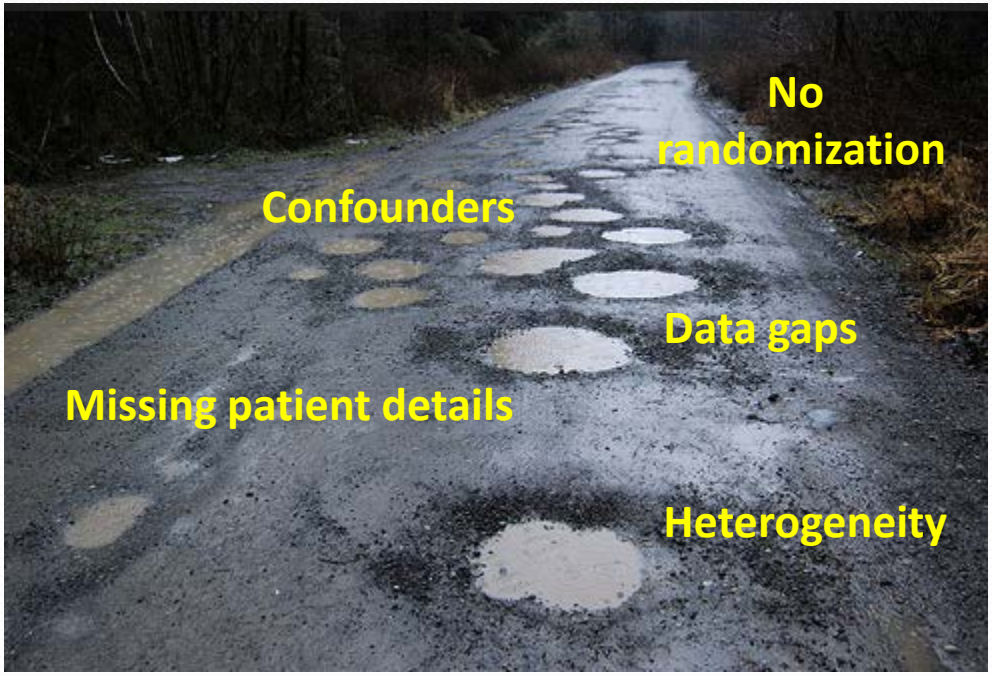

Manuscript preparation

- Clarify in detail the rationale of the study
- Make sure you fully address all the study limitations (ideally also in the abstract!) in a separate paragraph
- Describe the strengths of the study in spite of its limitations
- Discuss how you have minimised bias and confounding during the study
- In case journal enforces article length limitations, consider using supplementary material to improve readability of the article
- Follow official reporting guidelines

Feedback from Ed. Boards: The voice of the experts!

PubMed SJR OA IMPACT FACTOR

Clinical Epidemiology

COPE Member since 2011 JM07186

About Journal | Editors | Peer Reviewers | Articles

Article Processing Fees | Aims and Scope | Call For Papers

ISSN: 1179-1349

Editor-in-Chief: Professor Henrik Toft Sorensen

SJR Top 10 OA Journal

Clinical Epidemiology is an international, peer reviewed, open access journal. *Clinical Epidemiology* focuses on the application of epidemiological principles and questions relating to patients and clinical care in terms of prevention, diagnosis, prognosis, and treatment.

Clinical Epidemiology has a special interest in international electronic medical patient records and other routine health care data, especially as applied to safety of medical interventions, clinical utility of diagnostic procedures, understanding short- and long-term clinical course of diseases, clinical epidemiological and biostatistical methods, and systematic reviews.

Clinical Epidemiology endorses the PRISMA statement for the reporting of systematic reviews and meta-analyses, the STROBE statement for the reporting of epidemiological studies, and the RECORD statement for the reporting of studies conducted using observational routinely-collected health data. Authors should check the EQUATOR Network for reporting instructions and further information.

When considering submission of a paper utilizing publicly-available data, authors should ensure that such studies add significantly to the body of knowledge and that they use appropriate validated methods for identifying health outcomes.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE).

Journal Impact Factor: 3.799

PubMed ESCI

Pragmatic and Observational Research

COPE Member since 2011 JM07257

About Journal | Editors | Peer Reviewers | Articles

Article Processing Fees | Aims and Scope | Call For Papers

ISSN: 1179-7266

Editor-in-Chief: Professor David Price

An international, peer reviewed, open access journal that publishes data from studies designed to reflect more closely medical interventions in real-world clinical practice compared with classical randomized controlled trials (RCTs).

Classical RCTs are designed to maximise internal validity and to establish an unequivocal cause-and-effect relationship between an intervention and an outcome. Classical RCT populations represent only minority groups of real-life patients and are thus limited in their extent. Complementary data from studies designed to reflect more closely the nature of real-world patients and medicines usage are required to inform guidelines and extrapolate research findings across the broad heterogeneous patient populations encountered in everyday clinical practice.

The journal publishes data from prospective and retrospective studies designed to evaluate outcomes associated with real-world clinical practice. Dissemination of this data and the techniques and approaches used to optimise real-world modeling allows outcome validation and improved standards and collaboration in this growing area of research.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE).

Indexed online:

- Emerging Sources Citation Index (ESCI), from 2016
- PubMed and PubMed Central (Pragmat Obs Res)
- Directory of Open Access Journals (DOAJ)
- OAIster - the Open Access initiative

RWE Reporting Guidelines

- Pragmatic Trials – CONSORT Guidelines and PRECIS-2 Toolkit [1 – 3]
- STROBE Statement[4 – 6]
  - STREGA: Genetic association studies
  - STROBE-ME: Observational studies - Molecular epidemiology
  - STROME-ID: Molecular epidemiology for infectious diseases
  - STROBE-RDS: Observational studies in epidemiology for respondent-driven sampling studies
  - RECORD: Observational Routinely-collected health Data (http://www.record-statement.org/pubs.php)
  - STROBE-AMS: epidemiological studies on antimicrobial resistance

1. Zwarenstein M, et. al. for the CONSORT and Pragmatic Trials in Healthcare (Practihc) group. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ 2008; 337;a2390. http://www.consort-statement.org/extensions/overview/pragmatic-trials
2. PRECIS-2 toolkit : https://www.precis-2.org/Help/Documentation/ToolkitDownload
3. Devereux G et. Al. JAMA.2018;320(15):1548-1559.doi:10.1001/jama.2018.14432
4. STROBE Statement. Available at: http://www.equator-network.org/reporting-guidelines/strobe/
5. BenchimolEI,SmeethL,GuttmannA, HarronK,MoherD,PetersenI,etal.(2015)The REportingofstudiesConductedusingObservational Routinely-collectedhealthData(RECORD) Statement.PLoSMed12(10):e1001885
6. Langan SM et al. BMJ 2018;363:k3532 http://dx.doi.org/10.1136/bmj.k3532

Feedback from Ed. Boards: The voice of the experts!

- **Clarify** study rationale and aims already in the introduction
- All studies that are well conducted and address an **important clinical question** are worth publishing.
  - RWE studies often cover a population that is difficult to study by 'traditional' study designs. (older and younger age groups, pregnant women, etc..)
- **Follow** quality standards and check lists for real-world research:[1 – 2]
  - Include a priori planning of data collection and analyses,
  - identification of appropriate database(s),
  - proper outcomes definition,
  - study registration with commitment to publish,
  - bias minimization through matching and adjustment processes accounting for potential confounders, and
  - sensitivity analyses testing the robustness of results

1. Quality Standards for Real-World Research. Focus on Observational Database Studies of Comparative Effectiveness https://www.atsjournals.org/doi/full/10.1513/AnnalsATS.201309-300RM (PubMed: 24559028)
2. The REal Life EVidence AssessmeNt Tool (RELEVANT): development of a novel quality assurance asset to rate observational comparative effectiveness research studies https://ctajournal.biomedcentral.com/articles/10.1186/s13601-019-0256-9

Feedback from Ed. Boards: The voice of the experts!

- **Register RWE studies** in advance of analysis
- **Be careful** when using significance testing (p-value, or confidence limits) as measure of effect[1–7]
- For studies based on existing data, provide detailed **protocol of data extraction**
  - Be ready to provide codes for statistical analysis and the datasets for the statistical review and state which author or company performed the data extraction
- If dealing with **missing data** in your study, consider using specific analysis and strategies to minimise the bias[8]

1. Significance Testing is the Reason that Scientific Results have Poor Reproducibility. Video at https://epiresearch.org/serlibrary/sertalks/sertalks-archives/significance-testing/: Society for Epidemiologic Research; 2017 https://twitter.com/i/moments/864222884000129025 (Twitter feed)
2. Rothman KJ, Greenland S, Lash TL. Modern epidemiology. 3rd ed. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins; 2008.
3. Goodman S. A dirty dozen: twelve p-value misconceptions. Semin Hematol. 2008;45(3):135-140.
4. Rothman KJ. Six persistent research misconceptions. J Gen Intern Med. 2014;29(7):1060-1064.
5. Farland LV, et. Al.. P-values and reproductive health: what can clinical researchers learn from the American Statistical Association? Hum Reprod. 2016;31(11):2406-2410.
6. Harvey LA. Statistical power calculations reflect our love affair with P-values and hypothesis testing: time for a fundamental change. Spinal Cord. 2014;52(1):2-2.
7. Wasserstein RL, Lazar NA. The ASA's Statement on p-Values: Context, Process, and Purpose. American Statistician. 2016;70(2):129-131.
8. Petersen I et al. Clinical Epidemiology 2019:11 157–167

Final thoughts…

- If you are a medical writer starting in RWE writing:
  - Work closely with experts and follow relevant working groups and conferences to gain valuable knowledge[1,2]
  - Consider pre-submission enquiries to the journal of choice
  - Be your hardest critic before submission

1. Respiratory Effectiveness Group (http://effectivenessevaluation.org/)
2. ISPOR RWE: https://www.ispor.org/strategic-initiatives/real-world-evidence

Questions...