A publisher’s view on RWE studies and articles

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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
RCTs vs RWE studies

- No randomization
- Confounders
- Data gaps
- Missing patient details
- Heterogeneity
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!
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

2. PRECIS-2 toolkit: https://www.precis-2.org/Help/Documentation/ToolkitDownload
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. Include a priori planning of data collection and analyses,
  2. identification of appropriate database(s),
  3. proper outcomes definition,
  4. study registration with commitment to publish,
  5. bias minimization through matching and adjustment processes accounting for potential confounders, and
  6. sensitivity analyses testing the robustness of results

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 effect¹⁻⁷
- 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 bias⁸

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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)
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

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