Reading Material for “ICMJE Guidelines for Writing a Medical Research Paper” Webinar

Medical and healthcare researchers strive to adapt the best practices to improve the quality, credibility, transparency, and accuracy of medical publications. Several leading biomedical journals recommend authors follow ICMJE (Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals) guidelines for accurate reporting of research methods and findings.

- **What are Medical Guidelines?**
  Simple, structured tools (recommendations, checklists, flow charts, etc.) developed meticulously to provide directions for accurate reporting of research methods and findings

- **Healthcare & Medical Editorial Associations**
  Healthcare and medical associations promoting best practices for reporting medical research—ISMPP, ICMJE, WAME, EQUATOR, COPE

- **Purpose of ICMJE Recommendations**
  o Developed to implement best practices and ethical standards while conducting, reporting, and reviewing medical research
  o Helps authors, editors, and peer reviewers share information that is accurate, clear, reproducible, and unbiased

- **ICMJE Recommended Sources for Reporting Guidelines**
  o EQUATOR Network
  o NLM’s Research Reporting Guidelines and Initiatives
  Examples of reporting guidelines:
    o PRISMA is a set of guidelines for reporting systematic reviews and meta-analyses.
    o MOOSE is a set of guidelines for reporting and enhancing the utility of epidemiological meta-analysis.

- **The methods section should include:**
  o Selection and Description of Participants: observational or experimental participants, eligibility criteria, exclusion criteria, source of the population,
  o Technical Information: methods (new and modified), equipment, procedures, reference to established protocols and statistical methods, drugs and chemicals used
  o Statistics: statistical methods, indicators of measurement error, statistical software package(s) and versions

- **The results section should include:**
  o Data that directly corresponds to your research
  o Description of how the methodology was applied and key findings
  o High-quality figures and tables in the most appropriate format

- **The introduction section should include:**
  o Appropriate background of the topic
  o Previous attempts to solve/address research problem
  o Specific objectives of your research
• The discussion section should include:
  o Summarize the main findings
  o Emphasize the new and important aspects of your study & implications of your findings for future research
• Abstract and Title page
  o Abstract should be a miniature article that includes key points from the background, rationale, methodology, results, & conclusions.
  o The title page should include elements such as author information, disclaimers and sources of support, word count, number of figures and tables, and disclosure form.
• References – Do’s & Don’ts by ICMJE
  o When citing, provide direct references to original research sources.
  o References to papers accepted but not yet published should be designated as “in press” or “forthcoming”.
  o Do not use references for the promotion of self-interests.
  o Do not cite articles published in predatory or pseudo-journals.
• ICMJE Recommendations for Authorship
  o Substantial contribution
  o Drafting the work/Revising it
  o Final Approval
  o Accountability
• ICMJE provides a form for ‘Disclosure of Conflicts of Interest’ that serves to facilitate and standardize author disclosures.
• Protection of Research Participants
  o Planning, conducting, and reporting human research should be following the ‘Helsinki Declaration’ as revised in 2013.
  o Patients’ right to privacy should not be violated without informed consent.
• Protection of Animals Rights
  o Authors must follow the ‘International Association of Veterinary Editors’ Consensus Author Guidelines on Animal Ethics and Welfare’ for animal research ethics.
• Preservation of Research Data
  o Primary data and analytical procedures should be maintained for a minimum of 10 years in data repositories.
  o Raw data should be made publicly available at the time or after the publication.
• ICMJE Recommendations for Overlapping Publications
  o Authors must not simultaneously submit the same manuscript.
  o Authors must provide proper attribution of the overlapping publications.
  o Authors must mention the overlapping publications in the submission letter.
  o Authors must inform the journals.
• ICMJE Rules for Secondary Publications
  o Permission from both journals (primary & secondary publishers)
  o Publication interval
Secondary publication intended for a different set of audiences
- Includes authors, data, information, and the interpretations of the primary version
- The secondary version informs its audience that the paper has been published.
- Title should indicate that it is a secondary publication

• **Submission Requirements**
  - Mention all submissions and previous reports that might be regarded as redundant publication.
  - Mention financial or other relationships and activities that might lead to a conflict of interest
  - Authorship
  - Contact information
  - Mention any concerns raised regarding the conduct of the research or if corrective action has been recommended

• **ICMJE’s Clinical Trial Registration Policy**
  - Clinical trials are registered in a public trials registry at or before the time of first patient enrolment.
  - ICMJE accepts publicly accessible registration in any registry that is a primary register of the WHO International Clinical Trials Registry Platform (ICTRP) or in ClinicalTrials.gov.
  - Secondary data analysis of primary (parent) clinical trials should not be registered as separate clinical trial.
  - Statement indicating that results have not yet been published in a peer-reviewed journal