

Study summary

1. Publication Ethics

- **ICMJE Authorship Criteria:** According to the International Committee of Medical Journal Editors (ICMJE), an individual must meet all four of the following criteria to qualify for authorship:
 1. **Substantial Contribution:** Must contribute to the conception, design, execution, or interpretation of the research.
 2. **Drafting the Work:** Must participate in drafting the article or revising it critically for important intellectual content.
 3. **Final Approval:** Must give final approval of the version to be published.
 4. **Accountability:** Must agree to be accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity are investigated.
- **Disclosure of Conflicts of Interest:** Authors must disclose any financial or personal relationships that could influence their work. This includes funding sources and other affiliations.

2. Good Publication Practices (GPP)

- **GPP4 Guidelines:** The Good Publication Practice (GPP4) guidelines, published in *Annals of Internal Medicine*(2022), outline the best practices for publication of company-sponsored biomedical research. Key points include:
 - **Transparency:** Ensure all research results, whether positive or negative, are published.
 - **Authorship:** Ensure that all authors meet the ICMJE criteria and that contributions are clearly defined.
 - **Sponsorship Disclosure:** Clearly state the role of the sponsor in the study design, data collection, and manuscript preparation.

3. Medical Writing Process

- **Key Steps:** The medical writing process typically includes:
 1. **Planning:** Define objectives, timelines, and target audiences.
 2. **Drafting:** Write the initial manuscript, adhering to the chosen journal's guidelines.

3. **Review:** Gather feedback from co-authors and stakeholders.
4. **Revisions:** Incorporate feedback and refine the manuscript for clarity and accuracy.
5. **Submission:** Prepare for submission, ensuring all required documentation and disclosures are included.

4. Scientific Reporting Guidelines

- **CONSORT Statement:** Familiarize yourself with the Consolidated Standards of Reporting Trials (CONSORT) which provides a 25-item checklist to improve the reporting of randomized controlled trials (RCTs).
- **PRISMA Guidelines:** The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines help authors ensure the transparency and completeness of reporting in systematic reviews.

5. Metrics and Impact Assessment

- **Altmetrics:** Understand the alternative metrics (altmetrics) used to assess the impact of research articles beyond traditional citation counts. Altmetrics include social media shares, news mentions, and downloads.
- **Article-Level Metrics:** Know how to evaluate metrics that assess the performance of individual articles, including the number of citations, views, and downloads.

6. Submission and Review Process

- **Peer Review Types:** Familiarize yourself with different types of peer review:
 - **Single-Blind:** Reviewers know the authors' identities, but authors do not know the reviewers.
 - **Double-Blind:** Both authors and reviewers remain anonymous to each other.
 - **Open Review:** Both authors and reviewers know each other's identities.
- **Responding to Reviewers:** Learn the best practices for addressing reviewer comments, including providing a point-by-point response and showing gratitude for constructive feedback.

7. Role of the Medical Affairs Professional

- **Key Responsibilities:** Medical Affairs professionals ensure scientific integrity, facilitate communication between researchers and stakeholders, and manage the dissemination of medical information.

8. Emerging Trends

- **Open Access Publishing:** Understand the significance of open access models in increasing accessibility to research findings.
- **Digital Engagement:** Familiarize yourself with how digital platforms are used for publication dissemination and audience engagement, including webinars, social media, and online repositories.

Practice Questions

1. ICMJE Authorship Criteria

1. Which of the following is NOT one of the ICMJE criteria for authorship?
 - a) Substantial contribution to the research
 - b) Drafting the manuscript
 - c) Obtaining funding for the study
 - d) Accountability for all aspects of the work
2. According to the ICMJE, an individual must meet how many criteria to qualify for authorship?
 - a) 2
 - b) 3
 - c) 4
 - d) 5

2. Good Publication Practices (GPP)

3. What is a key principle of GPP4 guidelines?
 - a) Only publish positive research results
 - b) Ensure all authors have made substantial contributions

- c) Avoid disclosing funding sources
- d) Limit authorship to senior researchers
- 4. **What should be clearly stated in a publication regarding sponsorship?**
 - a) The author's institution
 - b) The sponsor's role in the study
 - c) The author's previous publications
 - d) The financial status of the authors

3. Medical Writing Process

- 5. **What is the first step in the medical writing process?**
 - a) Drafting the manuscript
 - b) Planning
 - c) Submission
 - d) Review
- 6. **Which of the following best describes the revision step in the medical writing process?**
 - a) Incorporating feedback from reviewers
 - b) Gathering data from clinical trials
 - c) Finalizing the manuscript for submission
 - d) Planning the timeline for writing

4. Scientific Reporting Guidelines

- 7. **The CONSORT Statement is primarily concerned with the reporting of which type of study?**
 - a) Observational studies
 - b) Systematic reviews
 - c) Randomized controlled trials
 - d) Qualitative research
- 8. **What do PRISMA guidelines help authors achieve?**
 - a) Improve citation rates
 - b) Enhance transparency in systematic reviews
 - c) Streamline the peer review process
 - d) Increase journal impact factor

5. Metrics and Impact Assessment

- 9. **What is the main purpose of altmetrics?**
 - a) To measure the quality of peer reviews
 - b) To assess the impact of research beyond citations
 - c) To quantify the number of authors on a paper
 - d) To determine funding amounts for studies
- 10. **Article-level metrics can include which of the following?**
 - a) Total number of authors

- b) Number of social media mentions
- c) Journal impact factor
- d) Author affiliation

6. Submission and Review Process

11. **In a double-blind peer review, which of the following is true?**
- a) Reviewers know the authors' identities, but authors do not know the reviewers.
 - b) Both authors and reviewers know each other's identities.
 - c) Neither authors nor reviewers know each other's identities.
 - d) Only the editor knows the identities of the authors and reviewers.
12. **What is an effective strategy for responding to reviewer comments?**
- a) Ignore minor comments
 - b) Provide a point-by-point response and thank the reviewers
 - c) Only respond to positive feedback
 - d) Submit the manuscript without revisions

7. Role of the Medical Affairs Professional

13. **Which of the following is NOT a responsibility of a Medical Affairs professional?**
- a) Ensuring scientific integrity
 - b) Managing clinical trials
 - c) Facilitating communication with stakeholders
 - d) Disseminating medical information
14. **How do Medical Affairs professionals enhance stakeholder engagement?**
- a) By limiting information distribution
 - b) By using digital platforms for communication
 - c) By avoiding direct communication
 - d) By focusing solely on peer-reviewed publications

8. Emerging Trends

15. **What is a significant benefit of open access publishing?**
- a) It increases the cost of publication.
 - b) It limits the audience to subscribers only.
 - c) It enhances accessibility to research findings.
 - d) It reduces the visibility of research articles.
16. **Digital engagement strategies in publication dissemination may include which of the following?**
- a) Using print media exclusively
 - b) Hosting webinars and using social media
 - c) Avoiding interaction with the audience
 - d) Limiting the use of online platforms

Answer Key

1. c
2. c
3. b
4. b
5. b
6. a
7. c
8. b
9. b
10. b
11. c
12. b
13. b
14. b
15. c
16. b

These questions should help you reinforce your knowledge and prepare effectively for the CMPP exam. Good luck with your studies!