

Advice to authors for avoiding flaws in preparation of original research manuscripts

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Abstract

Preparation of manuscripts of original research for publication is the final and critical step in the conduct of clinical research. Most manuscripts are rejected because of flaws in design, methodology, interpretation, and writing. Understanding the reasons for rejection can help clinical researchers in avoiding common errors in all sections of manuscript – introduction, methods, results, and discussion. The article highlights the reasons for rejection of original research manuscripts and suggests approaches to improve the quality of the manuscript.

Keywords: errors, publication, rejection, research

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In India, academic medical institutions have increasingly focused on publication of original clinical research after the Medical Council of India (National Medical Council) made publication in specified indexed journals mandatory for career advancement and promotions.^[1] Young postgraduates, junior faculty members, and several institutions commit a lot of resources and efforts to plan and organize research and prepare manuscripts for publication.

However, they are dejected when the manuscript is rejected. For high citation impact factor journals, the rejection rates could be as high as 90%. Common reasons for rejection include flaws in design, methodology, interpretation, and writing and missing ethical aspects.^[2,3] Understanding the reasons for rejection can help clinical researchers in avoiding common errors in conducting and publishing research.

Before writing manuscript

Lack of novelty/originality in the research question itself and errors in study design are reported as some of the most common reasons for rejection.^[2,3] These errors are considered fatal study flaws, as they cannot be corrected once the study is concluded.^[3] The authors – students and their guides – should critically assess whether the research question is Feasible, Interesting, Novel, Ethical, and Relevant (FINER) before beginning the study.^[4]

Novelty means that the research could (a) contribute new information, (b) confirm, refute, or extend previous research findings, and (c) improve understanding of concepts of health and disease or medical practice or research methodology.^[4] A novel research question need not be entirely original. A thorough review of literature focusing on limitations of previous research could suggest interesting ideas: (1) whether previous results could be replicated, (2)

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whether the findings in one population would be relaxant to a different population, or (3) whether a new measurement method would help in better interpretation of findings.

Significant flaws in scientific aspects would be: ^[2,3,5]

- Poor conceptualization of problem
- Inadequate control of variables
- Biased sample
- Confounding factors not considered
- Lack of control group
- Inadequate sample size.

Important ethics-related errors would be: ^[2,3]

- Inadequate protection of human subjects – lack of ethics committee approval/written informed consent
- No registration in clinical trial registry
- Plagiarism.

Selection of the wrong journal for that manuscript is not an uncommon issue. The manuscript is likely to be rejected if (1) it is out of scope for the journal^[3] or (2) the findings are not of interest to journal readers but to specialist audience or (3) the manuscript is not prepared as per the format or instructions to authors.

During preparation of manuscripts

The format of original research article – IMRAD divided into Introduction, Methods, Results, and Discussion – reflects the process of scientific research.^[5] The articles are often not accepted because of errors/flaws in the content, most of which are observed in methods, results, and discussion sections.^[2,3]

METHODS

For the methods section, clarity about how and why a study was done in a particular way is paramount.^[5]

Description of methods covers (1) selection and description of participants, (2) technical information, and (3) statistics. This section should provide sufficient details [Table 1] so that other researchers with access to the study data would be able to reproduce the results.^[5-8]

The methods section is the easiest to write. However, this section is most frequently responsible for rejection of the manuscript.^[2] Some of the common flaws/pitfalls in writing the methods reported are: ^[2,3,6]

- Inadequate description of methodology
- Inadequate explanation of the study design/ experimental conditions
- Insufficient information about the patient population

Table 1: Methods Section

| | |
|---|------------------------------------------------------------------------------------------------------------------------------------|
| M | Materials Methods of assessments and follow-up Measurements Methods – randomization, blinding, and allocation concealment |
| E | Equipment Exposure |
| T | Technical details Transparency – registration in public clinical trial registry Therapy – intervention |
| H | Human protection Ethics committee approval Informed consent |
| O | Outcomes/endpoints – primary and secondary |
| D | Drug – dose and duration Data sources |
| S | Settings and locations Study participant selection criteria Study design Scales Sample size Statistics |

- Inappropriate statistical tests
- Mixing results with the methods.

These errors could be minimized by (a) logically organizing relevant details of methods described in the protocol,^[6] (b) following relevant reporting guidelines, for example, Consolidated Standards of Reporting Trials (CONSORT) or Strengthening the Reporting of Observational Studies in Epidemiology (STROBE),^[7,8] and (c) providing sufficient details to allow replication of the study.^[6]

RESULTS

The purpose of the results section is to inform readers about important observations of the study.

Some of the common flaws reported in this section are: ^[2,3,9,10]

- Illogical sequence of data presentation
- Inadequate, unoriginal, predictable, or trivial results
- Inappropriate or inaccurate data
- Errors in data analysis
- Improper statistical tests/analysis
- Reporting observations of parameters that have not been included in the methods section
- Not reporting observations of experiments that have been included in the methods section
- Failure to report data pertaining to the primary objective
- Describing conclusions or interpretation of the study
- Mixing results and methods.

Errors in presentation of data are:

- Repetition of data in text, tables, and graphs
- Inappropriate presentation of data^[11-13]
- Tables – not cited in the text, data discrepancy between tables and text, inaccuracy in numbers/totals
- Graphs – wrong type, lack of legend or data labels, not plotted to scale, misuse of three dimensions
- Figures – annotations small/illegible
- Images – identity of patients/participants not masked, technical and resolution problems.

The most important step in writing the results is to decide which data are relevant to the research question and are essential to present and which data need not be presented.^[9,10]

The presentation of data should be as per the reporting guidelines.

- STROBE guidelines: ^[7] Reporting of observational epidemiological studies requires (1) participant flow, preferably depicted in a diagram, (2) descriptive data, (3) outcome data, (4) main results, and (5) other analyses
- CONSORT guidelines: ^[8] Reporting of randomized control trials requires description of (1) participant flow, preferably depicted in a diagram, (2) recruitment, (3) baseline data, (4) numbers analyzed, (5) outcomes and estimations, and (6) ancillary analyses.

A systematic, logical, and sequential approach in writing results can help the authors in avoiding common errors.

DISCUSSION

The discussion section is the most important section as it describes the importance of study findings, and puts them in appropriate perspective, and describes the significance of the study.^[14] However, it is the most difficult section to compose as it requires logical thinking, while other sections require orderly and logical writing.^[14] Hence, major flaws in writing this section are common.

Some of these are: ^[2,3,7,14,15]

- Conclusions not supported by data
- Confounding factors not considered
- Overstating the importance or generalizability of the results
- Incomplete or biased assessments of the results and their implications
- Incorrect interpretation of the results
- Avoiding discussion on unexpected findings

- Inadequate discussion – recent articles/evidence not discussed
- Wrong conclusions
- Insufficient discussion of limitations
- Discussing results not reported
- Describing/repeating results in detail
- Repeating information from introduction
- Omission of important and relevant references
- Interpretation too long, meandering, or verbose.

The authors should plan and compose the discussion by having a well-thought focused approach. The authors can adapt the following approach for writing components of the discussion section: ^[5,7,8,14,15]

Key results

- Give summary of the main findings with respect to study objectives
- Emphasize new and important findings
- Explore probable mechanisms of the findings.

Interpretation of results

- Give cautious overall interpretation considering objectives and limitations
- Compare and contrast the findings and interpretations with major, relevant, and currently published evidence
- Identify and explain conflicting, contradicting, or unexpected findings.

Limitations of the study

- Sources of imprecision
- Potential bias due to confounding variables.

Generalizability (external validity) of results

- Explain the implications of the study findings in the context of the totality of the relevant evidence
- Explore the implications of the findings for future research or clinical practice or policy
- Provide a concise conclusion.

INTRODUCTION

The purpose of the introduction is to provide scientific background and explanation of rationale and state-specific objectives or hypotheses.^[7,8] This section should allow researchers or readers to understand the study's context and evaluate its potential contribution to current scientific knowledge.^[7] The authors should avoid mistakes of (1) providing an exhaustive literature review and critique of previous work, (2) not describing the hypothesis with clarity, (3) describing data or conclusions, (4) extensive citation of references, and (5) writing a lengthy introduction.^[2,5,16,17]

OTHER ERRORS

The authors should pay attention to other aspects of manuscript preparation which can lead to revision or rejection.

- Length – Most journals publish around 3000 words for IMRAD sections and up to 3–4 tables and figures. According to a recent analysis by Heßler *et al.*, major medical journals publish 30 paragraphs divided into introduction 3, methods 10, results 9, and discussion 8 paragraphs.^[18] Long discussion and introduction and many tables/figures may invite revision of the manuscript.
- Language – poor grammatical writing and poor flow of ideas.
- Abstract – As the abstract is the only section of the main article indexed in many electronic databases, and the only content most readers browse, the authors should ensure that it accurately reflects the content of the article.^[5]

After submission of manuscript

Editorial review and peer review are the important processes after submission of the manuscript.

Editorial review process

The editorial team takes initial decision about the acceptability of the manuscript for further processing. This decision is based on whether (1) the manuscript fits into the scope of the journal, (2) the manuscript complies with the style and instructions to authors, (3) the study is original or novel, (4) the study is ethical, (5) there is plagiarism, and (6) the manuscript presentation and write-up are of good quality. The decision could be – rejection, revision, or referral for peer review. Majority of original articles – over 70% – may be rejected during the editorial review.^[3] The most common reasons for rejection are out of scope, lack of originality, inappropriate study methods/design, ethical issues, and poor language/presentation.^[3]

Peer review process

Peer review process is the indispensable time-tested quality control mechanism integral to science for the assessment of manuscripts submitted to journals by experts who are unbiased and independent.^[3,5,19] During this process, reviewers critically evaluate the manuscript for: ^[19]

- Relevance of the study to readers
- Importance and novelty of the manuscript
- Validity of the research
- Strengths and weaknesses of the methods
- Important missing and/or inaccurate information
- Generalizability of findings

- Interpretation of results
- Important limitations
- Clarity of presentation.

Flaws in one or more of these aspects of the manuscript are common reasons for revision or rejection of the manuscript.

Peer review process is extremely useful for the authors as reviewers conduct critical evaluation of important aspects of methods, results, or discussion and give suggestions for improvement. The authors should respond to each general and specific comment individually in an objective manner with rational arguments supported by relevant evidence. The authors should critically review major comments, for example, flaws in study design, methodology, statistical analysis, or conclusion, and reanalyze or rewrite parts of the manuscript.^[20] The authors should also respond to minor comments, for example, minor clarifications, additional information on design, removal of unnecessary text, or some modification in the style.^[20] The authors should indicate where and what changes are made in the manuscript and highlight the changes in track mode. The authors should resubmit the revised manuscript within time limit suggested by the journal.

Manuscript processing time

After submission of manuscript, most authors would expect a quick response from journal and rapid publication. However, they need to be aware of the time required to complete critical processes: (1) editorial review, (2) peer review, (3) technical editing (4) proof corrections and (5) author's response for revision, responding to technical edits and correcting proofs. Shah *et al.* analyzed publication turnaround time of 420 original articles published in 14 Indian journals and reported a combined median peer review time of 143.5 days and a median publication time of 146.5 days.^[21] Manjunath *et al.* have reported a mean time to acceptance of 4.7–7.17 months (141–215.1 days) and a mean time to publication of 3.03–8.33 months (90.9–249.9 days) for three Indian dermatology journals.^[22]

For articles published in Perspectives in Clinical Research between 2018 and 2020, the mean time to acceptance was 75.49–111.8 days and the mean time to publication was 115.61–266.61 days. The rejection rate for original articles was 73%–88%.

The speed of publication in a journal is dependent on a variety of factors – strength of the editorial team, reviewer's acceptance and timely review, number and quality of the manuscripts, responsiveness of the authors, frequency of

the journal, and acceptance rate. The fact that the editorial team and the reviewers provide pro bono-free service to the journal and spare time from their own busy schedules could affect the time to acceptance. Most journals reduce time by electronic publication of accepted articles as ahead of print (AOP). However, AOP articles would appear in PubMed several weeks after they are available in electronic format on journal website and in printed hard copy format. Prospective authors, who desire rapid publication, should understand the complexity of manuscript processing, submit high-quality manuscripts, and respond to revisions rationally in a reasonable time frame.

MY TEN COMMANDMENTS FOR AMATEUR AUTHORS

1. Attend training in literature search, clinical research methodology, and preparation of publication.
2. Select research question which meets FINER criteria
3. Design study protocol with meticulous attention to scientific aspects.
4. Submit the protocol and informed consent form for ethics committee review and approval.
5. Register the study in a public clinical trial registry prior to initiation of the study.
6. Choose a journal for publication considering quality, indexing, frequency, and peer review process.
7. Review past issues of selected journal to understand the scope, and to scan and cite relevant articles, and to become familiar with style and format of the published articles.
8. Develop vital skills for preparing publications – organization, analysis, synthesis, logic, etc.
9. Prepare manuscript as per the instructions to authors, avoiding major flaws and errors.
10. Submit the manuscript, resubmit revised manuscript, and patiently wait for acceptance and publication. If rejected, look objectively for reasons and revise for another journal.

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Conflicts of interest

There are no conflicts of interest.

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