

PUBLISH OR PERISH

**STEPS TO AVOID PITFALLS
WHEN PUBLISHING RESEARCH**



EVERYTHING THAT CAN BE THOUGHT AT ALL
CAN BE THOUGHT CLEARLY.
EVERYTHING THAT CAN BE SAID
CAN BE SAID CLEARLY.

— *Ludwig Wittgenstein*

INTRODUCTION

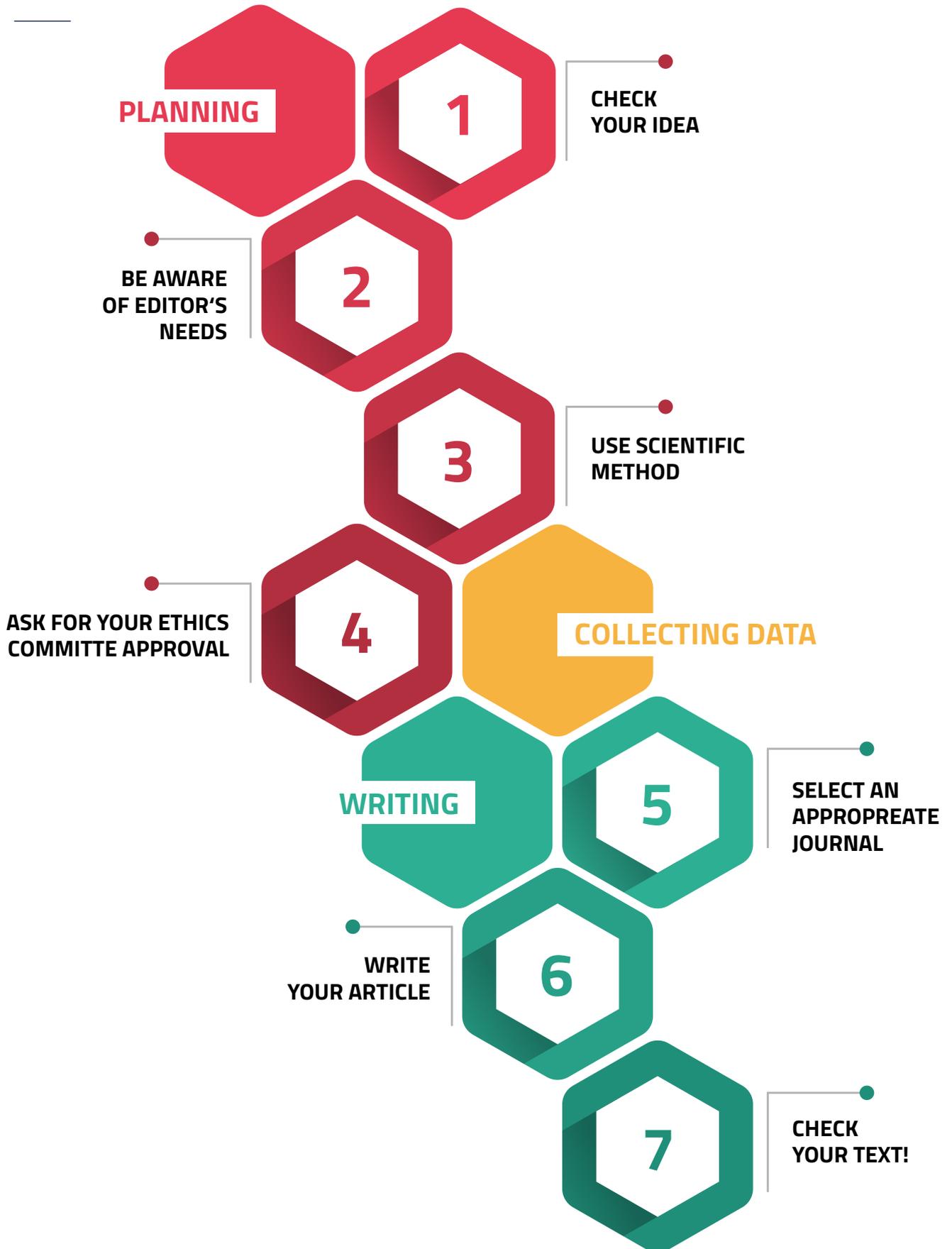
Most researchers have a hard time getting their manuscripts published in the beginning, yet success is achieved by learning from mistakes and criticism. Among the most common reasons for having an article rejected, we find:^{1,2}

- Failure at technical screening (the article does not follow the instructions for authors, it is incomplete, the level of English is insufficient for the peer review process, etc.).
- It does not fall within the aims and scope of the journal, it lacks relevance (thus, the journal readership would not be interested).
- It is not complete (e.g., it discusses findings in relation to a study, yet it ignores other important work in the literature).
- Flaws in methodology and analysis.
- The conclusions are not justified by the article's previous sections.
- It is not an original article (e.g., it is an extension from a paper already published by the same authors; it lacks novelty, originality and presents an obsolete study).
- It is hard to understand (presents problems regarding the level of language used, structure, figures, etc.).
- It is boring.

Before moving from an idea to a manuscript, there are several steps that should be followed to avoid pitfalls: from planning and designing your research study to evaluating a potential editor's needs when reading the first draft of your manuscript, from ethical approval of your study protocol to the choice of the right journal for your paper and, lastly, writing a manuscript that reviewers will evaluate and take into consideration before deciding on its publication.

Good reading!

STEPS



INDEX

Introduction	3
Steps flowchart	4

I. Planning **6**

A. Choosing a research question that is relevant	6
B. Authorship	7
C. Methodology	7
D. Ethics Approval	10
E. Preparing to write a publishable paper	11

II. Collecting data **12**

III. Writing **13**

A. Title page	13
B. Abstract	13
C. Introduction	14
D. Methods	15
E. Results	16
F. Discussion	16
G. References	17
H. The cover letter	17

IV. Appendixes **19**

A. Reporting guidelines	19
B. Improving your writing	19
C. Understand what reviewers consider a "good" article	20
D. Ode to a Multiauthorship: A Multicentre, Prospective Random Poem	21
E. References	23

I. PLANNING

A. Choosing a research question that is relevant

How are you supposed to select a topic for a research study? Your interest and passion for a research topic should be prime motivators. However, given that you are also planning to publish your results, it is important to understand the publishing process to ensure that the chosen topic is relevant, that is, your research topic should be **timely, important and interesting**.

First, consider the target audience by asking yourself three questions:

Timely:

Is it the right moment to address and publish this research question?
Has this specific question been adequately answered previously in the literature?

Important & Interesting:

Is my research question interesting enough for readers in and around the particular research or clinical community in question, and
Is it of importance to patients?

The topic's importance is the key to getting your study published. A common reason for rejection is simply lack of importance.

So, at the very beginning conduct a thorough literature search to identify knowledge gaps. By studying the literature carefully, you may also identify publications that are flawed, underpowered, or outdated. By reading in detail the literature, you may often be able to design a study that is superior to those already published, yet make sure that your work does not duplicate other studies. Moreover, another benefit that a literature review gives the prospective author and research team is an idea of:

- What style of writing and presentation is common to the field and particular journals?
- The scientific benchmark, is it achievable in the settings available to the researcher?
- What is topical/a current trend, and what seems to get published?
- The potential target journal before you begin to write your paper (consider the following factors when selecting a journal: reader interest, impact factor, circulation, acceptance rate, publication speed).



There are some very interesting tools to run literature searches, other than PubMed, one of which is called **Jane**, that is Journal/Author Name Estimator <http://jane.biosemantics.org/>



Jane is a **freely available web-based application** that, based on a sample text (e.g., the title and abstract of a manuscript), can both suggest journals and experts who have published similar articles. It first searches for the 50 articles that are most similar to your input. For each of these articles, a similarity score between that article and your input is calculated. The similarity scores of all the articles belonging to a certain journal or author are summed to calculate the confidence score for that journal or author. The results are ranked by confidence score. Jane may also help you identify the right Journal to submit your paper.³

Note:

Last but not least, before moving from an idea to a manuscript ask yourself this: **do I have the resources to answer my research question?**

B. Authorship

The authorship of publications can be troublesome: discuss it early in the research process!

Authorship needs to reflect work done, or contributions of varying kind.^{4,5}

The '*Ode to a Multi-authorship: A Multicentre, Prospective Random Poem*' in Appendix D illustrates this issue.

The accepted types of contributions are outlined by some journals in their instructions to the author.

C. Methodology

Stating the problem.

When planning to publish your medical research, the two top priorities are:

- Fully conceptualizing the problem.
- Formulating a robust approach to solving the problem.

In this sense, adherence to scientific methodology is essential.



For a full description of the updated authorship standard established by the International Committee of Medical Journal Editors, see the following website:

www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html



The Clinical Study Protocol is the core document that needs to be developed to solve any research question. It represents a standard for planning and designing a research question that focuses on the study characteristics (study design, eligibility criteria) and requirements from the regulatory authorities.

The steps in the scientific method are as follows:

Step	Corresponding protocol section	Corresponding manuscript section
1. State the problem	Introduction	Introduction
2. Formulate the (null) hypothesis	Methods/Endpoints/Statistical Considerations	Methods
3. Design the study	Statistical considerations	Methods
4. Collect data	Data collection	Methods
5. Analyse the results	NA	Results/Discussion
6. Draw conclusions	NA	Discussion

NA = not applicable

Stating the problem is the first and most important step in the scientific method. You must be able to provide a clear and concise answer to the questions:

- What is the main purpose of this study?
- How will it fill an important gap in the medical literature?"^{4, 5}

The first stage of any evidence-based practice process is formulating an answerable question. This represents the foundation for any quality clinical research. A well-formulated question will ease the search for evidence and will help you in determining whether the evidence is relevant to your question.

The so-called **PICO** concept guides you through the design of an answerable question, by asking you to define the 4 fundamental parameters of your research question:

- P** > Populations/People/Patient/Problem
- I** > Intervention(s)
- C** > Comparison
- O** > Outcome



CDISC defines itself as “a global, non-profit charitable organization that develops data standards to streamline clinical research and enable connections to healthcare”.

CDISC Foundational Standards aim at enhancing the quality, efficiency and cost effectiveness of clinical research processes from beginning to end.

Read further here <https://www.cdisc.org/> to discover protocol template standards and much more!



The statement of the problem must define a specific gap in the published literature:

Example 1:

"Tibial nonunion has a high incidence and it is challenging to treat; based on the current medical literature, there are several methods that aim to achieve union and gradual deformity correction in adults."

Notes:

- The statement of the problem **should not be as vague as** "Tibial nonunion has a high incidence and it is challenging to treat".
- After such a study is completed, that problem will still exist.
- The statement of the problem must define the specific gap in the published medical literature that, at the end of your study, will be filled and thus advance science.

Example 2:

The following is an example of an **appropriately specific statement** of the problem: "It is unclear from the current medical literature whether external fixators are superior to other standard devices in achieving union and gradual deformity correction in adults 6-months after their application."

Formulating the hypothesis.

After you state the problem, the next step in the scientific method is to formulate the hypothesis, which is defined as "A tentative explanation for an observation, phenomenon, or scientific problem that can be tested by further investigation"^{4,6,7}

Some researchers prefer to start with the null hypothesis (H_0), which is a statement about chance occurrence that assumes no difference between groups or variables. Typically, this hypothesis involves an association between risk factors and outcome or a difference in outcome between patients who receive one treatment versus another.

Example:

The healing rate will not be significantly different between fractures fixed with device A and those fixed with device B.

The alternative hypothesis (H_a) is the opposite of the null hypothesis.

Analyse the hypothesis and the major objectives of the study and lay down the criteria to reject or not the null hypothesis. Journal reviewers and editors need this specific description of what you are testing to evaluate your manuscript. Regulatory authorities will also look for this information in your study protocol. If you do not include a null and/or alternative hypothesis in the statistical section of your methods, be sure to make clear to the reader what your main hypothesis is.^{4,5}

Objectives, endpoints and outcomes.

Make a clear distinction between objectives and endpoints, which are often called “outcomes”.

“Objectives” are the primary scientific questions the study wants to address by collecting appropriate data. Objectives should be clinically relevant.⁸

“End-points” are selected to address a given objective.

They should be measurable in an unbiased manner, practical and interpretable. The statistical power of the study is calculated on the basis of the primary end-point.

Example:

- Objective: Safety and effectiveness of device X.
- Endpoint 1 (to measure safety): number of adverse device reactions at 6 months from application of device X.
- Endpoint 2 (to measure effectiveness): number of non-unions at 6 months from application of device X.

D. Ethics Approval

The World Medical Association clearly states in the ‘Declaration of Helsinki – Ethical principles for medical research involving human subjects’ that any clinical study involving patients must be approved and continuously monitored by an ethics committee, as reported in the following reference:^{4,8,9}

“Research Ethics Committees

The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. (...). The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially in-



*formation about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions."*⁹

In addition, the ICMJE requires that **all medical journal editors require registration of clinical trials in a public trials registry** at or before the time of first patient enrolment as a condition for publication. Observational retrospective studies may also be registered, and although it is not yet compulsory to do so, it may soon become mandatory as the movement in favour of data sharing is becoming more and more important.

- In fact, at present, the ICMJE defines a clinical trial as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the relationship between a health-related intervention and a health outcome.

The purpose of clinical trial registration is to prevent selective publication and reporting of research outcomes, to prevent unnecessary duplication of research effort, to help patients and the public know what trials are planned or ongoing into which they might want to enrol, and to give ethics review boards considering approval of new studies a view of similar work and data relevant to the research they are considering.

E. Preparing to write a publishable paper

- Organize your material into manuscript sections as soon as you can; this will help you save time and spot any flaws in the conduction of the study. Also plan your manuscript's length. If you already know that it may be too long, consider moving some information into the appendices.^{4,5}
- You already selected a target appropriate journal when doing the first literature search.
- Read and follow your target journal's Instructions for Authors and remember to ask your team to do the same. Follow also the Publication and Reporting Guidelines (see Appendix A).
- Record your research decisions and ideas as you go, and check that all decisions made during the planning phase have also been recorded in the study file. This may save you time in the future, for example: the target journal you chose, a recent article published in the same journal that you found interesting, latest advances in the same field and any research decisions.^{4,5,8}



ClinicalTrials.gov, run by the United States National Library of Medicine (NLM) was the first online registry for clinical trials and is the largest and most widely used today.

Clinical trials registries are often searchable (for example, trials can be searchable by disease/indication, drug, device, location, etc.), so they are valuable sources for searching ongoing studies.

COLLECTING DATA

- Collect your data in a scientifically rigorous and reproducible way. Periodically monitor and critically appraise the study progress.^{4,5,8}
- Meticulously follow the eligibility criteria to be prepared for scientific and ethics reviews. If anything changes during the study, monitor and keep track of it (e.g., protocol violations).^{4,5,8}
- Record the details of interventions and patients' compliance in real time, so that there is no doubt concerning why a given piece of data is missing.^{3,4,7}
- Handle missing data using modern statistical methods (consult your statistician for advice).^{4,5,8}
- Monitor the sample size and the recruitment speed according to the protocol.^{4,5,8}

WRITING

A. Title page

Think of a concise, smart and professional tittle to hook your audience. Title should be easy to understand, describe the paper's content, be short (no more than 12 words), and you may want to begin with a keyword.

You may want to avoid stating the conclusions of the article in your title, as this may prevent your potential readers from reading the whole publication. You may instead state the subject of the study instead and thus try to entice your readers to go on.^{4,5,10,11} Nevertheless, if you obtained an impactful result, stating the finding already in the title could also be a hook for the reviewers and the journal's readership.

Example 1

Advantages of circular external fixation used in high tibial osteotomy.

Example 2

Outcomes of external fixation of tibial fractures after plate fixation failure.

B. Abstract

Most people will only read your abstract, so invest plenty of time in writing it!

An abstract should demonstrate that your findings are clinically important and that your study was carefully performed. Your target journal editors may read your abstract first to decide whether it is, or is not, in the scope of the journal.

The abstract should be specific, representative of the article and correctly structured following the instructions for authors.^{4,5,10,11}

Accurately describe the problem in the first sentence. Describe your objective afterwards. Include the null hypothesis in the methods to help your readers immediately understand what you are testing. Explain how you conducted the study. Include also any notable results and your conclusion.

The abstract should answer the following questions:

- What is the problem or the gap in the literature?
- Why is this an important problem to solve?
- What were the authors trying to do and why?
- Is this a rigorous, solid study design?
- Do the authors have a high-quality data set?

- Will this be a high-impact paper?
- Are the conclusions appropriate?

Avoid using the same sentences you wrote in your abstract (word-by-word) in the body of the article. The abstract should be an original 'stand-alone' text, and not a duplication of the body of the article. Always remember to check what the word-count limit of the target journal is!

C. Introduction

In the introduction, you should tell your readers why they should read the article. Go right to the essence of the argument (the gap in the literature) to hook your readers' attention and introduce the background message appropriately. Use the literature to enrich your introduction and demonstrate the specific knowledge gap your paper aims to fill.

Start your introduction with a general and concise description of the problem and reference previous publications in the literature that support your assessment of the problem. As an example, if you use the term "high risk" to define a condition or a procedure, reference it to support your use of the term. You will often need to start with a definition of the problem – try to build a sentence that is not limited to the definition itself.^{4,5,10,11}

Example 1:

Before revision:

A tibial shaft fracture occurs along the length of the bone, below the knee and above the ankle. The tibia, or shinbone, is the most commonly fractured long bone in the body.

After revision:

The tibia is the most commonly fractured long bone, the majority of injuries being sustained to its diaphysis.

Define the primary subject of your paper and any unusual terms used in the article or in the introduction itself. If you use a common term, but with a different meaning, explain why. **The last sentence of the introduction is the most important one in your paper.** With it, you should clearly state the aim of the study and thus of the paper and, no less importantly, you must convince the reviewers that the research question your study addresses is important, regardless of the answer.



The introduction must build a logical, linear case for this question without zig-zagging through the history of the field and should funnel from the broad background to your specific question.

A good rule of thumb is to keep the introduction short – no longer than one double-spaced page. Always check the Instructions for Authors for any suggestions about length and structure.^{4,5,10,11}

D. Methods

The methods section is the most straightforward section to write because it simply recounts what you have done, which is also described in your study protocol. Ironically, however, poor methods sections are a leading cause of manuscript rejection.

The goal here is to present a clear but detailed exposition of the study design. Organize and structure this section with meaningful subheadings. Always check the Instructions for Authors for specific guidance.

Example 1:

- Study design
- Eligibility criteria
- Randomization and Blinding
- Intervention and Compliance
- End Points Assessment
- Safety
- Study Oversight
- Statistical Analysis

Example 2:

- Study Design and Population
- Clinical Assessment
- Intervention
- Outcome Assessment
- Statistical Analysis

Study design: describe your study design with precise terminology (e.g., use the term “prospective” carefully).^{4,8}

Data collection methods: describe how you collected your data, who collected it, the setting of the study and the variables that enable data collection replication.^{4,8}

Eligibility: describe the study site/s (single centre, multicentre, national or international) and provide the beginning and ending dates of the study. Describe the informed consent process as well.^{4,8}

Randomization and blinding: explain your rationale for using them or not.^{4,7}

Interventions and compliance: provide specific names and brands for any devices that were tested and explain screening tests fully.^{4,8}

End points: define your primary outcome clearly.^{4,8}

Sample size: justify your sample size with reproducible detail and specify the statistical power of your study.^{4,8}

Statistical analysis: Define statistical significance and justify your choice of statistical tests.^{4,8}

E. Results

- Organizing the results:
Present your data in an objective manner and a logical order. Start with demographic and cohort data to set the scene. Describe equally well the major positive and negative findings to tell a balanced story.
- Present statistical results:
Report the confidence interval for the key variables and present the P values.

Always report results in the target journal's format and make sure you check the Instructions for Authors. Present numbers for similar variables consistently. Be careful to describe patients sensitively and diplomatically.

Also remember to carefully consider and use tables, charts, etc. and to provide them with the appropriate resolution. Always remember to check what the word-count limit of the target journal is! It is crucial to only include results here, do not include any conclusions!

F. Discussion

In the discussion, you can present your opinion on the results obtained. Follow these steps to write a successful discussion:

- Start the discussion with your most important finding, which will also entice your audience to continue reading. Remember that the most read section of your paper is the Abstract, yet the discussion is the second most read text.



- Limit the discussion to your results and comparisons between other publications and your results.
- Clearly state the new information your paper provides and explain how it fills a gap in the literature.
- Your conclusions should be fully supported by your data, as these are their references.
- Describe what the limitations of your study are.
- Describe any further research needed.

G. References

You must always follow your target journal's instruction for Authors regarding which Reference system to use. [There are three major reference systems:](#)

- **Vancouver System**, Citation Order, or Citation-by-Reference: References are numbered and listed in the order in which they are cited in the text. It is the most common system for medical journals.
- **APA** (American Psychological Association), Author-Date, Name and Year or Harvard System: References are cited in the text with the last name of the primary author and the year of publication. The references list is arranged alphabetically by the authors' names.
- **Alphabet-Number System**: References are listed in alphabetical order according to the primary author's last name and cited by numbers in the text.

H. The cover letter

The cover letter represents the first contact the editors have with the authors.

[It is extremely important to write a persuasive presentation of your work.](#)

The purpose of the cover letter is to explain what you are submitting and why. It may answer the following questions:

- Why have you decided to submit your manuscript to this journal?
- Why would your manuscript be of interest to the readers of this journal?
- What is new in your paper and why should the Editor care about it?
- What are your paper's strengths?
- Which section of the target journal - if any - would be most appropriate for your paper?
- How long is your paper?



Use reference management software to help organize and format references:

EndNote, is a standard software tool for publishing and managing bibliographies, citations and references on Windows and Macintosh devices
<https://endnote.com>

Reference Manager, is a free reference manager and citation generator. It allows you to organize and search your personal library, annotate documents and cite as you write
www.mendeley.com/reference-management/reference-manager

Zotero defines itself as "a free, easy-to-use tool to help you collect, organize, cite, and share research"
www.zotero.org

Mendeley, is a software that allows you to easily organize and search your personal library, annotate documents and cite as you write
www.mendeley.com

CiteThisForMe, is an online app that helps you create perfect citations in a very short time
www.citethisforme.com

Papers is a reference management software for IOS used to manage bibliographies and references when writing essays and articles.
www.papersapp.com/

- How many graphs and tables does it have?
- Are there any appropriate reviewers you are aware of?

In case of doubts about the appropriateness of your manuscript for a given journal, you can send a pre-submission enquiry.¹³

APPENDIXES

A. Reporting guidelines

International Committee of Medical Journal Editors - <http://icmje.org/recommendations/browse/>

Study Type	Reporting Guideline	Link to the Guideline
Randomized controlled trials	CONSORT	www.consort-statement.org
Systematic Reviews Meta-analyses of controlled trials	PRISMA	http://prisma-statement.org/
Observational epidemiology studies	STROBE	www.strobe-statement.org/index.php?id=strobe-home

B. Improving your writing

Spelling

Although you may trust your spell checker, be aware that no one can deny that English spelling is complex. Even if you use a spell checker, always read your text twice before submitting your manuscript!

*I have a spelling checker,
It came with my pea sea.
It plane lee marks four my revue
Miss steaks aye can knot sea.*

*Eye ran this poem threw it,
Your sure reel glad two no.
Its vary polished in it's weigh.
My checker tolled me sew.*

This is one of the many versions that can be found online after "Zar J. Candidate for a Pullet Surprise. The Journal of Irreproducible Results, v39 #1, January/February 1994, p 13, v45 #5-6, 2000, and p 20."

Using capitals

In English, only proper nouns have capitals. *Proper noun* is the name for a person, place or organization: Richard, London, the Royal College of Surgeons. Other nouns are common nouns, and do not have capitals.

There is an erroneous belief that capital letters in acronyms always represent capital letters in the full name of the term but, for example, *ADEs* are adverse device effects not *Adverse Device Effects*.



5 complex words examined

- **Novel, innovative, innovation/new**
 'Novel' is something new and completely different from anything done or produced in the past.
 'Innovative' is something new and original.
 In today's clinical research world, most manuscripts present something that is, simply, 'new', which means that it has been recently discovered or created.
- **Alternative/other**
 'Alternative' indicates a choice of only two, although it is commonly used as a synonym of 'other'.
 Nevertheless, 'other' should be always used when there are more than two options and shorter words should always be preferred to longer ones.
- **Case/patient**
 Referring to patients as cases is dehumanizing. A case is an instance, example or episode of disease. For example, a case of osteonecrosis, should be a patient with osteonecrosis.
- **Cohort, sample/group**
 'Cohort' is a group of people with the same characteristics.
 'Sample' is a small quantity of a group.
 'Group' is a number of people which are together in one place and at one time.
- **Evaluate/examine, measure**
 'Evaluate' stands for a consideration of something to make a judgement.
 'Examine' stands for looking at something carefully.
 'Measure' stands for judging how great something is.



Besides spell checkers, there are many other tools that can help you write better texts:

Grammarly, at <https://app.grammarly.com/>
 Grammarly's free writing app will make sure your messages, documents, and social media posts are clear, mistake-free, and impactful.

PerfectIt, at <https://intelligentediting.com>
 A downloadable software that combined with Microsoft Word checks consistency and enforces your style manual.

Hemingway Editor, at www.hemingwayapp.com
 A readability online application that highlights lengthy, complex sentences and common errors.

C. Understand what a reviewers consider a "good" article

By learning what reviewers consider a good article, you may increase the likelihood that your paper is accepted at once. Most reviewers consider "good" articles those that are clearly written describing a well-designed study or one that makes you think "Why didn't I think of that?"



The following references are interesting reads that may help you understand your reviewers' point of view:

- Thrower, P. (2012) 'Eight reasons I rejected your article'. Elsevier. Posted on 12/09/12 and accessible here: <https://www.elsevier.com/connect/8-reasons-i-rejected-your-article>
- Ali, J. (2010). Manuscript Rejection: Causes and Remedies. Journal of Young Pharmacists: JYP, 2(1), 3–6. <http://doi.org/10.4103/0975-1483.62205>
- Garg, A., Das, S., & Jain, H. (2015). "Why We Say No! A Look Through the Editor's Eye." Journal of Clinical and Diagnostic Research: JCDR, 9(10), JB01–JB05. <http://doi.org/10.7860/JCDR/2015/17160.6699>

D. Ode to a Multi-authorship: a multicentre, prospective random poem

This poem was originally submitted to The Lancet as an article.

Horowitz HW, Fiebach NH, Levitz SM, Seibel J, Smail EH, Telzak EE, Wormser GP, Nadelman RB, Montecalvo M, Nowakowski J, Raffalli J: Ode to multiauthorship: a multicentre, prospective random poem. Lancet 1996; 348:1746.

The order of the authors is not necessarily related to specific contributions, but to the order in which each made their acquaintance with the first author. However, all have made significant contributions to the poem. The authors acknowledge their debt to Theodore Geisel.

*SIR—All cases complete, the study was over
the data were entered, lost once, and recovered.
Results were greeted with considerable glee
p value (two-tailed) equalling 0.0493.
The severity of illness, oh what a discovery,
was inversely proportional to the chance of recovery.
When the paper's first draft had only begun
the wannabe authors lined up one by one.
To jockey for their eternal positions
(for who would be first, second, and third)
and whom "et al." in all further citations.
Each centre had seniors, each senior ten bees,
the bees had technicians and nurses to please.*



*The list it grew longer and longer each day,
as new authors appeared to enter the fray.
Each fought with such fury to stake his or her place
being just a "participant" would be a disgrace.
For the appendix is piled with hundreds of others
and seen by no one but spouses and mothers.
If to "publish or perish" is how academics are bred
then to miss the masthead is near to be dead.
As the number of authors continued to grow
they outnumbered the patients by two to one or so.
While PIs faxed memos to company headquarters
the bees and the nurses took care of the orders.
They'd signed up the patients, and followed them weekly
heard their complaints and kept casebooks so neatly.
There were seniors from centres that enrolled two or three
who threatened "foul play" if not on the marquee.
But the juniors and helpers who worked into the night
were simply "acknowledged" or left off outright.
"Calm down" cried the seniors to the quivering drones
there's place for you all on the RPU clones.
When the paper was finished and sent for review
six authors didn't know that the study was through.
Oh, the work was so hard, and the fights oh so bitter
for the glory of publishing and grabbing the glitter.
Imagine the wars when in six months or better
The Editor's response, "please make it a letter".*

RPU = repeating publishable unit; PI = principal investigator



E. References

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