Writing a Clinical Research Paper
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Before You Write

Organize Your Initial Thoughts

• Why did you do this study?

• What kind of a study was it?

• Who constituted the study population, and where did they come from? How were they selected?

• For a prospective study, what was your hypothesis?

• What is your primary outcome of interest and how did you define it?

• What are your secondary outcomes of interest, if any, and how did you define them?

• What interventions were used, if any?

• What data did you collect for the primary outcome? Secondary outcome?

• How did you collect these data?

• How do you plan to report your results (what data will go into tables and figures and what data will go into the main text)?

• What is your main message (50 words or less)?

• What are the clinical implications of your study?

• What does this study add to the literature on your topic?
Have a Publication Plan

“Do not expect a clear message to emerge as you write!!! This is like putting a pile of bricks together and expecting a house to arise. There is only one way of ensuring that your writing is focused on one simple message, and that is by defining this message carefully before you start.” Tim Albert in *Winning the Publications Game*

- Match your message/study type to a target journal
  - Who will be interested in my paper?
  - Which journals do these people read?
  - Where have other authors published?
  - What journals do your colleagues/co-authors/mentor recommend?
  - Query the journal if needed

☑️ Try to avoid making this decision based *solely* on a journal’s *impact factor* (the number of times articles from a particular journal have been cited in the literature within the past year).

- Choose your co-authors, define responsibilities, and determine author order

  A. Who is an author?

  Generally, an author is considered to be someone who has made substantive intellectual contributions to various aspects of a published study.

  Biomedical authorship is defined by the International Committee of Medical Journal Editors (ICMJE.org) in their document, Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications (last updated April 2010):

  - “Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
  - When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript (3). These individuals should fully meet the criteria for authorship/contributorship defined above, and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms. When submitting a manuscript authored by a group, the
corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name. Journals generally list other members of the group in the Acknowledgments. The National Library of Medicine indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript; it also lists the names of collaborators if they are listed in Acknowledgments.

• All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
• Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.”

All publications from Cleveland Clinic trainees must have a staff member listed as a co-author. Such publications include meeting presentations of original research. In these situations, the staff author must be prepared to meet the ICMJE authorship criteria.

B. Who should not be listed an author?

According to the ICMJE guidelines, which have been accepted by the governance body at Cleveland Clinic,

• Acquisition of funding, collection of data, or general supervision of the research group as a major activity does not meet the criteria for authorship.

Although supervisors, department chairs, and mentors used to be routinely added to the author list (a practice referred to as “guest” or “honorary” authorship), this custom is no longer acceptable “because it devalues the meaning of authorship” (American Medical Association Manual of Style, 10th ed) and minimizes the role of junior authors.

Researchers who primarily perform the following duties but do not meet all three authorship criteria described above should also not be listed as an author:

• Contribute patients to a study/trial/database
• Review a manuscript
• Provide data from a database or patient chart(s)
• Sit on a research committee, even though the committee may review research proposals and offer advice for improvement
• Assist a trainee who is performing research by acting as his/her program director

C. Who should be listed in the acknowledgments?

All contributors to a study who do not meet the ICMJE authorship criteria should be listed in this section. Examples of those who might be acknowledged include a person who provided purely technical help or writing assistance or a department chair or senior staff who provided only general support or a manuscript/protocol critique. Financial and material support should also be acknowledged. Groups or persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under a heading such as “clinical investigators” or “participating investigators,” and their function or contribution can be described—for example, “served as a scientific advisor,” “critically reviewed the study proposal,” “collected data, or “provided and cared for study patients.” Because readers may infer their endorsement of the data and conclusions, all persons listed in the acknowledgments must give their written permission to be named.

Depending on their level of involvement, statisticians can meet the ICMJE criteria for authorship and if so, should be listed as an author on the paper.

D. How should authorship order be determined?

There is no specific formula for determining the order of authorship, but it should be a joint decision of all co-authors and ideally discussed at the onset of the research project.

According to the American Medical Association Manual of Style (10th ed):

“The first author has contributed the most to the work, with other authors listed in descending order according to their levels of contribution. (Note: some groups of authors choose to list the most senior author last, irrespective of the relative amount of his or her contributions.)”

Furthermore, the Manual states that:

These decisions should be… “reevaluated later as often as needed” and any changes (ie, order, addition, and deletion) “should be discussed and approved by all authors.”

Authors should be prepared to explain the order in which authors are listed.
It is important to decide on the author list and order before the paper is written, and ideally, before the project is started. This should be an open, transparent discussion that all potential authors participate in, and no researcher should be made to feel uncomfortable for broaching the subject.

These authorship guidelines also apply to academic posters, meeting abstracts, oral presentations, and book chapters.

- Obtain your target journal’s instructions for authors
- Estimate the length of your paper
  how many words/how much space will you have?

Your Title

The title “may be the only part of the paper that will be read, so make sure it encourages the reader to read on.” (How to Write a Paper, GM Hall, editor)

You can do that by adhering to the following principles:

1. Make the title specific and clear

“A properly constructed title will raise the odds that your paper will be read when it first appears in the journal and that it will be retrieved from a bibliographic database like MEDLINE by searchers looking for papers on its topic.” (Edward Huth, "Writing and Publishing in Medicine," 1999)

- **Comparative Study**
  - Effect of X (independent variable, intervention) on Y (dependent variable; outcome) in Z (patient population): Study Method
  - X and Y in Z: Study Method
    - Effect of Esmolol on Airway Function in Patients with Asthma: A Prospective Cohort Study

- **Study with Dependent Variable Only**
  - Y in Z
  - Y = dependent variable
  - Z = Study Population or Material
  - Microvascular Pressure in the Lungs of Premature Newborns

- **Descriptive Study**
  - Case report, Clinical Observations, Special Communication, etc.
  - X = condition being described
- Pemphigus With Features of Lupus Erythematosus

- **Methods Paper**
  - X for Y in Z
    - X = Method being described
    - Y = Purpose
    - Z = Patient Population
  - Endotracheal Flowmeter for Measuring Tidal Volume, Airway Pressure and End-Tidal Gas in Newborns
  - *If the method does not have a name, use “method,” “apparatus” or “technique”

- Some writing guidelines (CONSORT Statement for randomized controlled trials, PRISMA Statement for systematic reviews, for example) mandate that you mention the study method within the title. Generally, that is good advice for most titles. If you have completed a retrospective study and chose not to mention this in the title, however, you must do so in the abstract.

- ✓ One way to write your title is to base it on your objective statement

  Objective Statement: To assess the impact of continuous glucose monitoring on hypoglycemia in People with Type I Diabetes

  Title: Effect of Continuous Glucose Monitoring on Hypoglycemia on Type I Diabetes

- ✏ Make the title concise; it should not contain waste words within but especially at the beginning.

Examples of waste words include:

A Study of...
A Study to Determine...
Investigations on...
Notes on...
Report of a Case of...
Results of...

- ✓ Try to start the title with one of the most important study elements

  **OK example:** A Cooperative-Group Trial of Cytolysane and a New Multidrug Regimen for the Treatment of Metastatic Breast Cancer [In this
example, the most important terms, “metastatic breast cancer” and “multidrug regimen,” are far from the beginning.]

Better example: Metastatic Breast Cancer Treated with a New Multidrug Regimen or with Cytolysane: A Cooperative-Group Trial [This title puts the name of the disease and the new aspect of the paper right up front.]

Ensure that the title represents the content and breadth of the study
Most papers will be revised numerous times, so it is best to wait until the paper is completed to finalize the title. Otherwise, it may not be truly reflect the content.

Limit or avoid using abbreviations
“Abbreviations should not, in general, be used in main titles.”

Check your instructions for authors to determine if there are any exceptions. Some journals have an approved abbreviation list.

Structure the title appropriately
Titles can be worded in one of three ways:

Informative: Venlafaxine Extended-Release Capsules and Quality of Life in Nondepressed Outpatients with Generalized Anxiety Disorder: A 6-month Randomized Controlled Trial

Declarative: Venlafaxine Extended-Release Capsules Improves Quality of Life in Nondepressed Outpatients with Generalized Anxiety Disorder: A 6-month Randomized Controlled Trial

Question: Do Venlafaxine Extended-Release Capsules Improve Quality of Life in Nondepressed Outpatients with Generalized Anxiety Disorder? A 6-month Randomized Controlled Trial

Not all journals accept titles written as declarative statements and questions, so check the instructions for authors for any guidance.

Adhere to any character/word limit, as set by the journal

Usually, main words are capitalized in a title while prepositions/articles are not. But this can vary by journal, so check a recent copy for guidance.

Question: Are shorter titles better than long ones?
In one 2010 study, the authors found that longer titles seemed to be associated with higher citation rates—an association that was more pronounced for journals
with high impact factors. The bottom line: there is no right title length. As such, you’ll need to carefully balance the need for concision with the need to be as informative as possible.


How to Write Your Abstract

“Abstracts serve 3 important purposes: (1) they may persuade someone to read the article, (2) they allow busy readers to learn the main results without reading the entire article, and (3) they make it easy to capture the main results in computerized databases, such as MEDLINE, which make the results available worldwide. Given these purposes, it is worth writing an informative abstract.”


1. Determine whether you will create a structured or unstructured abstract. Most medical journals prefer the structured abstract. Check your instructions for authors for more details.

Example of a structured abstract for original research:

**Importance** Long-term data on mortality after first-ever stroke in adults aged 18 through 50 years are scarce and usually restricted to ischemic stroke. Moreover, expected mortality not related to first-ever stroke is not taken in account.

**Objectives** To investigate long-term mortality and cause of death after acute stroke in adults aged 18 through 50 years and to compare this with nationwide age- and sex-matched mortality rates.

**Design, Setting, and Participants** The Follow-Up of Transient Ischemic Attack and Stroke Patients and Unelucidated Risk Factor Evaluation (FUTURE) study, a prospective cohort study of prognosis after transient ischemic attack (TIA), ischemic stroke, or hemorrhagic stroke in adults aged 18 through 50 years admitted to Radboud University Nijmegen Medical Centre, the Netherlands, between January 1, 1980, and November 1, 2010. The survival status of 959 consecutive patients with a first-ever TIA (n = 262), ischemic stroke (n = 606), or intracerebral hemorrhage (n = 91) was assessed as of November 1, 2012. Mean follow-up duration was 11.1 (SD, 8.7) years (median, 8.3 [interquartile range, 4.0-17.4]). Observed mortality was compared with the expected mortality, derived from mortality rates in the general population with similar age, sex, and calendar-year characteristics.

**Main Outcome Measures** Cumulative 20-year mortality among 30-day survivors of stroke.

**Results** At the end of follow-up, 192 patients (20.0%) had died. Among 30-day survivors, cumulative 20-year risk of death was 24.9% (95% CI, 16.0%-33.7%) for TIA, 26.8% (95% CI, 21.9%-31.8%) for ischemic stroke, and 13.7% (95% CI, 3.6%-23.9%) for intracerebral hemorrhage. Observed mortality was increased compared with expected mortality (standardized mortality ratio [SMR], 2.6 [95% CI, 1.8-3.7] for TIA, 3.9 [95% CI, 3.2-4.7] for ischemic stroke, and 3.9 [95% CI, 1.9-7.2 for intracerebral hemorrhage, respectively). For ischemic stroke, cumulative 20-year mortality among 30-day survivors was higher in men than in women (33.7% [95% CI, 26.1%-41.3%] vs 19.8% [95% CI, 13.8%-25.9%]). The SMR was 4.3 (95% CI, 3.2-5.6) for women.
and 3.6 (95% CI, 2.8-4.6) for men. For all etiologic subtypes of ischemic stroke, observed mortality exceeded expected mortality.

**Conclusions and Relevance** Among adults aged 18 through 50 years, 20-year mortality following acute stroke was relatively high compared with expected mortality. These findings may warrant further research evaluating secondary prevention strategies in these patients.

Example of a structured abstract for a systematic review:

**Importance** Intermittent preventive therapy with sulfadoxine-pyrimethamine to control malaria during pregnancy is used in 37 countries in sub-Saharan Africa, and 31 of those countries use the standard 2-dose regimen. However, 2 doses may not provide protection during the last 4 to 10 weeks of pregnancy, a pivotal period for fetal weight gain.

**Objective** To perform a systematic review and meta-analysis of trials to determine whether regimens containing 3 or more doses of sulfadoxine-pyrimethamine for intermittent preventive therapy during pregnancy are associated with a higher birth weight or lower risk of low birth weight (LBW) (<2500 g) than standard 2-dose regimens.

**Data Sources and Study Selection** ISI Web of Knowledge, EMBASE, SCOPUS, PubMed, LILACS, the Malaria in Pregnancy Library, Cochrane CENTRAL, and trial registries from their inception to December 2012, without language restriction. Eligible studies included randomized and quasi-randomized trials of intermittent preventive therapy during pregnancy with sulfadoxine-pyrimethamine monotherapy.

**Data Extraction** Data were independently abstracted by 2 investigators. Relative risk (RR), mean differences, and 95% CIs were calculated with random-effects models.

**Results** Of 241 screened studies, 7 trials of 6281 pregnancies were included. The median birth weight in the 2-dose group was 2870 g (range, 2722-3239 g) and on average 56 g higher (95% CI, 29-83 g; \( I^2 = 0\% \)) in the ≥3-dose group. Three or more doses were associated with fewer LBW births (RR, 0.80; 95% CI, 0.69-0.94; \( I^2 = 0\% \)), with a median LBW risk per 1000 women in the 2-dose group (assumed control group risk) of 167 per 1000 vs 134 per 1000 in the ≥3-dose group (absolute risk reduction, 33 per 1000 [95% CI, 10-52]; number needed to treat = 31). The association was consistent across a wide range of sulfadoxine-pyrimethamine resistance (0% to 96% dihydropteroate-synthase K540E mutations). There was no evidence of small-study bias. The ≥3-dose group had less placental malaria (RR, 0.51; 95% CI, 0.38-0.68; \( I^2 = 0\% \), in 6 trials, 63 vs 32 per 1000; absolute risk reduction, 31 per 1000 [95% CI, 20-39]). In primigravid plus secundigravid women, the risk of moderate to severe maternal anemia was lower in the ≥3-dose group (RR, 0.60; 95% CI, 0.36-0.99; \( I^2 = 20\% \); in 6 trials, 36 vs 22 per 1000; absolute risk reduction, 14 per 1000 [95% CI, 0.4-23]). There were no differences in rates of serious adverse events.

**Conclusions and Relevance** Among pregnant women in sub-Saharan Africa, intermittent preventive therapy with 3 or more doses of sulfadoxine-pyrimethamine was associated with a higher birth weight and lower risk of LBW than the standard 2-dose regimens. These data provide support for the new WHO recommendations to provide at least 3 doses of intermittent preventive therapy during pregnancy at each scheduled antenatal care visit in the second and third trimester.

Example of an unstructured abstract for a narrative review:

Frailty has important implications for the care needs of older adults and how those needs are met. By recognizing frailty and measuring it objectively, clinicians can better engage patients and their loved ones in difficult discussions about treatment plans and prognosis, and ultimately deliver better palliative care.
Most abstracts can contain no more than 250 words (check your instructions for authors for the exact word limit). That’s not a lot of space to discuss the background/objective, methods, results and conclusion. To ensure you cover the full range of information that is presented in your article, write the rough draft using the 10-sentence method:

- Background or rationale for the study—1 sentence. Be sure to answer the question, “Why is my research important?”
- State the objective or hypothesis—1 sentence.
- Describe your methods and patient population—3 sentences.
- State your results—3 sentences. Be sure to focus on the primary comparison(s).

“This section describes the most important findings in the same order as the methods that produced the data. It is important that each result has a method and that each method has a result, even if the result was not one that you expected or wanted.”


- State your conclusions—1 to 2 sentences.

Do not end with “more research is needed.” Why? Because this phrase does not answer your research question! Rather, answer the question and then place the answer into the appropriate context.

For example:

Among healthy term infants in Belarus, an intervention that succeeded in improving the duration and exclusivity of breastfeeding did not prevent overweight or obesity, nor did it affect IGF-I levels at age 11.5 years. [conclusion] Breastfeeding has many advantages but population strategies to increase the duration and exclusivity of breastfeeding are unlikely to curb the obesity epidemic. [implication]

For ways to reduce the word count in your abstract, see chapter 5 (How to Write an Abstract) in Lang TA. How to Write, Publish, & Present in the Health Sciences. Philadelphia: American College of Physicians, 2010.

State your results, do not promise that they will be included in the paper.

For example, do NOT write: “In this article, we will present the results of a comparison between X and Y.”

Present clinically interpretable results, not just P values.
For example, do NOT write: “Cholesterol levels differed significantly between these 2 groups (P=0.03).

Report all P values, not just those that are statistically significant.

1. When reporting percentages, report the numerator and denominator.

Instead of writing “50% of the patients experienced adverse side effects,” write “10/20 (50%) of the patients experienced adverse side effects.”

2. Make sure the abstract can stand on its own.
   • Thus, no references.
   • Limit the use of abbreviations (no more than 3), and always spell them out on first reference.

3. Name the type of study in the objectives or methods (even if it appears in the title).

4. When the final draft is complete, double-check it against the text and tables.

5. Because your paper may undergo numerous revisions, it may be better to write the abstract last.

6. There are three types of common errors in abstracts:
   • Inconsistencies between abstract and text
   • Information present in the abstract but not in the text
   • Conclusions not justified by the information in the abstract

Thus, it is important to have someone outside of your research group review your abstract and paper before submittal.

Question: Should I include statistical methods in my abstract?

“The statistical methods can usually be omitted from the abstract. If you present hazard ratios, rate ratios, or mean differences, it is not necessary to say in the abstract that you used proportional hazards models, Poisson regression, or linear regression. Make the study design and outcome measures clear in the abstract, and describe the statistical tools in the article.”

How to Write Your Introduction

The Introduction is crucial to readers, particularly to peer reviewers, because it helps them place the research in context. A good introduction convinces them that the research is important and interesting -- in other words, worth publishing and reading.

Answer the question, “Why did we do this study?” You can do that by using the 3-part model:

1. Describe the background to your question, or the general problem at hand. For example, this section could describe current therapies for an illness.

2. Describe the gap in knowledge that you intend to address and why it is important to address. For example, this section might describe what is wrong with the current therapies to show why a new therapy is needed. Tell readers why you posed your question research question. What good will the answer be? Will the new therapy extend survival? Improve quality of life? Decrease mortality and morbidity?

3. State your research question and, if you have one, hypothesis. Also, briefly explain how you investigated this question. Include the patient population.

Known, unknown, research question

- Keep in mind that the introduction should follow the shape of a funnel. In other words, it should start broadly and then narrow. In a hypothesis-testing paper, the introduction starts with the known and works it way to something unknown and then to the question the paper is asking. It usually ends by briefly describing the experimental approach.

- Avoid relying on the LIKA introduction to explain clinical significance. Some authors write as if the importance of their work is so obvious it need not be stated. They might begin their introduction by writing, Little Is Known About... Unfortunately, LIKA doesn’t really tell the reader why the research was done.

An introduction that follows the 3-part model:

Prompted by concerns about perioperative safety with bariatric surgery, the Centers for Medicare & Medicaid Services (CMS) issued a national coverage decision in 2006 that limited coverage of weight loss surgery to centers of excellence (COEs). These COEs were accredited by 1 of 2 surgical professional organizations: the American College of Surgeons (ACS) or the American Society for Metabolic and Bariatric Surgery (ASMBS). In addition to other structural measures and processes of care, the accreditation was based on a hospital volume threshold (>125 cases/year).
Whether the CMS restriction of bariatric surgery to COEs is associated with improved outcomes remains uncertain. Previous studies comparing COEs with non-COEs have largely failed to identify better outcomes at COEs. In contrast, studies examining outcomes before and after the CMS national coverage decision have suggested a beneficial effect of the CMS policy restricting bariatric surgery to COEs.

However, because these latter studies lacked a control group, they were unable to isolate the effect of the CMS national coverage decision from the many other unrelated factors that may have improved bariatric surgery outcomes during the same period. For example, improved outcomes could have been due to the use of lower risk procedures (eg, laparoscopic gastric banding), increasing surgeon experience, fellowships for advanced training in laparoscopic bariatric surgery, or healthier patients undergoing surgery due to broader acceptance of weight loss surgery.

In this study, we sought to evaluate whether the COE component of the national coverage decision was associated with improved bariatric surgery outcomes in Medicare patients. Our objective was to examine outcomes in Medicare patients before compared with after the implementation of the CMS policy that restricted coverage of bariatric surgery to hospitals designated as COEs. We controlled for secular trends using a control group of non-Medicare patients to better account for other factors that may have lead to improved outcomes with time, independent of the CMS policy.


“"If you are building on scientific work already published, then it is essential to make clear how your work adds importantly to what has gone on before.”

(How to Write a Paper, GM Hall, editor)

Poor example: Several studies have shown that regular Ecstasy use creates anesthetic difficulties, and several others have shown that it does not. We report two further patients, one of whom experiences problems and one of whom did not, and we review the literature. (This only repeats what has gone on before).

Better example: Two previous studies have reported that regular Ecstasy use may give rise to respiratory problems during anesthesia. These studies were small and uncontrolled, used only crude measurements of respiratory function, and did not follow-up the patients. We report a larger, controlled study, with detailed measurements of respiratory function and two year follow up.

Keep it concise—a good rule of thumb is no more than 2.5 pages double spaced.

Question: Should I include a literature review?

When writing for clinical and laboratory journals, do not place the full literature review in the introduction. Include only a concise summary of the context or background to your research. Also, keep in mind that some journals may place a limit on the number of references you can cite in the paper, which further supports the need for concision in the introduction.

Question: What is the best way to start the introduction?
Authors generally take one of three approaches:

• “The Seminar Approach…Left-handedness is a condition affecting 10% of the population…”

• The Alarmist…Hundreds of left-handed people commit suicide each year claiming that they cannot get their scientific papers published, and the figure is rising.

• Much Discussion Recently…There has been much discussion recently about the impact of being left handed on the task of writing research papers.”


How to Write Your Materials & Methods Section

How you write your methods section will largely depend on the type of study you performed. Fortunately, there are a number of reporting guidelines that can help you write this section (as well as the rest of the paper). Here are a few:

CONSORT….randomized controlled trial
STROBE……observational study
STARD……….diagnostic accuracy study
STROBE…….systematic reviews and analyses
MOOSE………meta-analyses of observational studies
PRISMA…….systematic reviews and analyses

These guidelines usually "specify a minimum set of items required for a clear and transparent account of what was done and what was found in a research study, reflecting, in particular, issues that might introduce bias into the research." For a full list of available guidelines, go to www.equator-network.org.

Many residents and fellows begin their research careers by performing retrospective studies (medical chart reviews). Although there are no official reporting guidelines for this type of study, there are two excellent articles that discuss how to improve the accuracy of and inconsistencies in such papers:


☑ Another excellent resource that explains how to report studies based on the study method is the book:


◊ A number of general guidelines apply to many types of studies:

• Indicate whether the study was approved by the CCF Institutional Review Board or whether animal subjects were treated according to approved guidelines.

The Cleveland Clinic Institutional Review Board approved this study.

• For clinical studies of human patients, report the following:

► study setting and the source of the study participants
► time frame in which the study was conducted
► study design
► how the study groups were formed
► inclusion/exclusion criteria
► whether their written informed consent was obtained and the circumstances under which it was obtained
► interventions

If equipment or other materials are used, the name of the manufacturer, city and state, or model number is usually placed in parentheses after first mention.

“Proprietary names of drugs should not be used in scientific articles except in specific instances in which the proprietary name is essential to reproduce or interpret the study.” (AMA Manual of Style) Instead, use the generic name.

► registry number, if the trial has been registered at www.clinicaltrials.gov
how the data were collected

how the patients were monitored

study endpoints/outcome measures (primary and secondary)

Because much research involving human subjects must be conducted with their informed consent, how they are approached for their consent, by whom, and under what conditions may determine whether they participate in the study. A description of the approach will help determine whether any undue pressure or circumstances may have affected their decision to participate.

For example, “All patients granted their written informed consent, which was obtained by one of the authors (EJ) during the patients’ first office visit.”

- **Write the methods in enough detail to enable other researchers to re-create your study.** Give references to established methods and uncommon statistical methods. Describe methods that are not well known.

- **Provide operational definitions for all variables.** For example, “Patients were considered to have hypothyroidism if their thyroid stimulating hormone level was above 5 U/L.”

- **For studies utilizing statistical methods, plan to include a Statistical Methods section (usually is the last section of the methods section) that specifies:**
  - The comparisons to be made (ie, what variables were compared?) and the statistical tests used to make them
  - The alpha level (eg, $P<0.05$) at which $P$ values were considered to be significant
  - The descriptive statistics used to present the results (eg, mean and SD or median and IQR)
  - The name and manufacturer of the statistical software program used to analyze the data.

When appropriate, also include:

- The sample size calculation, if one was performed (or any other rationale that was used to select the sample size)
• The statistical power of the study, if it was calculated in advance as part of the sample size calculation

• **Write the methods section using past tense.** For example, “We analyzed the data” or “Catheters were inserted in 10 patients.”

• **When organizing the methods section, consider using a chronological approach.**

• **Consider using generic subheads to break up the text and make it easier for readers to follow (eg, participants, interventions, main outcome measures, statistical methods, etc).**

  Ask your statistician to help write the statistical methods section or review it

**How to Write Your Results Section**

“The function of the results section is to provide the results for all end points and measures stated in the materials and methods (or patients and methods) section. The results section of a clinical hypothesis testing manuscript typically includes tables and figures for presenting detailed data in as compact and readily understood a form as possible and is usually devoid of references. The results section should report the results of your study only.”

MaryAnn Foote, in *The Proof of the Pudding: How to Report Results and Write a Good Discussion*

1. Whenever possible, present the main findings of the study in tables or figures/graphs.

   A table is an efficient way to show (not warehouse) lots of individual data whereas a figure or graph can be used to show trends over time.

2. **DO NOT repeat information between the text and tables.**

3. Report the results in the same order they were mentioned in the methods section, ie, study population, primary outcomes, secondary outcomes, using the same or similar subheadings from the methods section when possible.

4. Do not use percentages for small groups or samples (10 or less)

5. Report 95% confidence intervals for changes or differences in the primary endpoints
Report p values along with the data for all primary analyses
Good example: Mean BP was higher in group 1 than in Group 2 (xxxxxxxxxx)
Bad example: The difference in BP between the two groups was statistically significant (p<0.05).

Do not interpret your data in this section.

Write in the past tense.

When comparing results, use “than” not “compared with”

X was decreased compared with Y.
This could mean….
X was lower than y
X decreased more than y
X decreased but y remained unchanged

X was lower than y.

Resist the temptation to report ALL of your data. Present only those results that are pertinent to the question asked in the introduction…

…but do not omit data that contradict your hypothesis.

All methods should have a corresponding result.

Do not add extra data because you think this section “is not long enough.” Keep this section brief and uncluttered.

How to Write the Discussion

This is often the most difficult part of the paper to write. Many authors write it last.

The purpose of this section is to provide context to your results. Discuss, but do not repeat, the results.

The first sentence should briefly repeat the study question posed in the introduction

The second sentence should then answer the study question (your main conclusion)
Points 2 and 3 form the beginning of the discussion.

4 The middle of the discussion can be structured as follows:

- Describe how the results compare with what else is known about the problem: review the literature and put the results into context
  - Strengths and weaknesses of those studies
  - Differences in results

☑ “Rather than summarizing the literature in one portion of this section and interpreting your research in another section, address each point in your research one at a time. Introduce your point and then tell what other researchers have found that is relevant to this point.” Tom Lang How to Write, Publish and Present in the Health Sciences

- Discuss the implications
  - What do the results mean?
  - Discuss how the results can be used?
    - Could they lead to the development of another therapy?
  - Discuss strengths and weaknesses of your study

☑ Organize the topics “either in an order dictated by the science or in the order of most to least important to the answer.” Mimi Zeiger

5 The end of the discussion is the conclusion

- End strongly—answer the research question!
- “More research is needed” is never an answer to a research question
- Wording here should match that used in the conclusion section of the abstract

6 Never begin the discussion with background information or information repeated from the introduction.

7 One common weakness in this section is to attempt a detailed review of all research that has been published to date on the topic. Rather, “before writing this section, sort your references into those with an important message and those without. Discard the latter…Decide which of the remainder seem to have involved the strongest methods and make them the centerpiece of your historical review…” From How to Write a Paper (BMJ books)

8 The three most common problems in the discussion are:
Not answering the research question posed in the introduction
Repeating the results rather than discussing their implications
Confusing statistical significance with biologic or clinical importance

From Tom Lang in How to Write, Publish and Present in the Health Sciences