

Fundamentals of clinical research 4: Writing and publishing an original research article

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ABSTRACT

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SUMMARY

In this article, the last of the "Fundamentals of clinical research" series, we will discuss how to prepare and publish an original research article. We will cover how to: write scientifically, design a manuscript, display research results, select a journal for publication, and find greater success in the peer review process. In the process of reviewing these topics, we will be finishing our stepwise framework for conducting and publishing research. The depth of these topics has been curated to provide the reader with the general idea, clear up popular misconceptions and elucidate how the reader might deepen their knowledge.

Key words: Clinical Research; Research writing; Evidence-based Medicine

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SERIES INTRODUCTION

This series of articles is meant to provide the reader with a framework from which to efficiently conduct research. The content presented is intended to be of benefit to both junior and senior researchers, as a firm understanding of the fundamentals is essential to performing at the highest level.

The Importance of Clinical Research

Danielson L. Anaesth Pain & Intensive Care 2017;21(3):289-291

Fundamentals of clinical research 1: Selection of a suitable and workable research proposal

Danielson L. Anaesth Pain & Intensive Care 2017;21(4):485-488

Fundamentals of clinical research 2: Designing a research study

Danielson L. Anaesth Pain & Intensive Care 2018;22(1):131-138

Fundamentals of clinical research 3: Designing a research study (continued)

Danielson L. Anaesth Pain & Intensive Care 2018; 22(2):268-278

Fundamentals of clinical research 4: Writing and publishing an original research article

Danielson L. Anaesth Pain & Intensive Care 2018;22(3):401-408

Arriving where we started

This series began with a quote from T.S. Elliot, it is only fitting that its ending begins with one as well.¹

We shall not cease from exploration, and the end of all our exploring will be to arrive where we started and know the place for the first time. – T.S. Elliot

The step 0 of this series advised the reader to begin by developing their research question and recommended accomplishing this via a literature review. Now, here we are, at "the end of our exploring", and we have arrived at the point where we must write the literature for others to review. Now, before we discuss the actual writing of a manuscript, we should discuss the mindset we should approach the task with.

THE MINDSET FOR SCIENTIFIC WRITING

In the "Selection of a suitable and workable research proposal",2 we introduced the idea that writing research manuscripts is similar to having a conversation with the research community, where our published words are heard by the individual reading our manuscript. We then covered how our knowledge of the spoken word could be applied, via this metaphor, to improve our writing. We began by noting that our research must say something that is worth listening to and suggested achieving this by pursuing a research question whose answer translates to real clinical value. We then noted that our research must speak to the audience, with words tailored for different groups of readers and presented in a format that they would know how to read in the manner most beneficial for them. And we touched on the importance of speaking with impact, captivating our audience and leading them to the appropriate conclusion. We concluded with an allusion to areas where this metaphor broke down and how taking those areas into account would further increase the quality of our manuscript.

One area where the metaphor breaks down is the work of communication. With spoken word, the work of communication is split between the speaker and the listener and how it is split can change fluidly as the conversation progresses. But for written word, the writer should strive to do 100% of the work of communication as the words can't be later adjusted for the reader's sake. This begs the question: What is the "work of communication?" The work of communication refers to both how well the idea has been developed and how well the idea has been expressed with words, based on the speaker's or writer's: word choice, sentence structure, and appropriate use of grammar. Well expressed ideas are understood by the reader clearly, unambiguously and with a certain sense of familiarity. When the writer does all the work of communication, there is no work left for the reader to do. The reader must only read the words on the page to perfectly understand the idea the writer is trying to convey.

The purpose of doing 100% of the work is two-fold. First, by requiring less effort to interpret the writer's ideas, the reader is better able to think critically about the ideas. Second, there are differences between speaking and writing. Scientific writing is a sort of one-way conversation. When work is left for the reader to do, it becomes possible for the writer's idea to be misunderstood. When speaking, the speaker can

notice when a listener is becoming confused and can adjust what they say next to help bring the listener along, but a writer lacks this luxury. A writer cannot know when a reader gets confused and cannot adjust their text for a confused reader after publication. Once a reader is confused, there are three things that can happen: the reader may be able to correctly piece together the writer's idea, they may misinterpret the idea, or they may simply stop reading the article. The only option that ensures that the reader understands the writer's idea, requires the writer to do 100% of the work of communication. The writer must not leave anything to be assumed and they must provide the reader with everything they could want to know about the topic, without overburdening them with information.

Given that most of our readers will have many articles to read, we cannot assume that our reader will spend a significant amount of time trying to understand our research. For this reason, we should write with the belief that we will have only one shot to impress upon the reader the importance of our research. To not lose this one opportunity, we should strive to write clearly and simply. Ideally, our words and graphs should be both easy to understand and hard to misunderstand.

Our writing should have a flow to it that compels the reader to keep reading. Flow in writing is most easily achieved by presenting all the information that a reader needs to understand the idea and guiding them from point to point such that the conclusion that the writer wants them to draw is the same one they have already come to before the writer has stated it. Simply put, flow in writing provides the reader with a feeling about what will come next.

Flow can be lost when ideas are not presented in a mentally-digestible manner. The ideas we present are easiest to understand when only one idea is presented per sentence and each group of ideas is its own paragraph. The previous sentence presented two ideas, this can be done sparingly without disrupting the flow of the writing. But try rereading that sentence once again as it was written and again imagining that it ended before the "and", and then ask yourself which version of the sentence you preferred reading. The structure of a sentence can also be tweaked to improve its flow, using that same sentence as an example: The ideas we present are easiest to understand when only one idea is presented per sentence and one group of ideas per paragraph. This version of the sentence presents two ideas, but it presents them as subtle variations of each other and, as such, the sentence flows a bit easier.

SCIENTIFIC WRITING

Before one can write scientifically, one must be able to write in general. And it's not enough to simply be able to write, one must be able to write well. As masters of your own craft, you know how important the fundamentals are to your trade, and the same is true of good writing. Good writing requires excellent usage of the most basic principles. Alas, these basic principles are easy to forget, especially if you haven't kept up with them. Improving one's ability to write starts with paying attention to what one feels is good or bad writing and identifying what makes them different. The types of questions one should ask oneselfinclude: How do "good" authors structure their arguments? How do they structure their sentences and paragraphs? How do they use punctuation? For multilingual writers, it is important to remember that English is an SVO language. This means that the subject of a sentence must be mentioned first, and it is then followed by the verb that relates said subject to the object of the sentence. While there is no formal rule regarding sentence word length, sentence clarity is maintained by minimizing the number of words used in between the subject, verb and object.

Scientific writing requires the use of the scientific terms appropriate for the context in which one plans to publish. The point of these words is to present information clearly and unambiguously, as such, while technical terms should be used, unnecessary jargon should be avoided. Scientific writing should be written in a formal and impartial manner. There is disagreement over whether scientific writing should be written in an active or passive voice. There is a certain amount of consensus that scientific writing should be formal and easy to understand. To this end, one should only sparingly use the terms "I" or "we" in their manuscripts. Additionally, one should use an active voice when a passive voice would lead to ambiguity of what is being described.³

PEARLS TO BETTER WRITING

Even if one does write well, engaging in certain behaviors can help further improve the quality of one's writing.

1. The first is to not edit what one has written until they've completed the first draft. This is to say the purpose of the first draft is simply to put one's ideas into words and the work of making sure the words chosen are the "right" words should be reserved for subsequent drafts. If one is struggling to write their first draft, O'Connor and Holmquist's algorithm for writing a scientific manuscript may be of use to you.⁴

- Once a first draft has been finished, one can edit it to produce the second draft. Tips to improve your editing process include reading sentences aloud and reading each sentence individually, from last to first. If one is unsure if a particular phrase they have written is grammatically correct, one can perform a web search of the phrase using quotation marks. A high number of returned results may imply correctness. It can also help to search alternative versions of the phrase (e.g. versions utilizing different prepositions) to see how the number of results changes. This method can lead you astray but can also be helpful when used appropriately. If doubt remains, the problematic phrase can be avoided by rewriting the sentence.
- 3. Once one has created their second draft, they should leave it alone for a while, this period should last between 2 days and a month. After this period has passed, one should reread the manuscript and further edit it. After finishing the second draft, it is advisable to have a colleague review the manuscript for content and readability. One should not expect to be able to make a perfect manuscript on their first attempt, the peer reviewers that review your manuscript will find something to comment on, but this shouldn't stop one from presenting the peer reviewers with the best manuscript one can produce.
- 4. Many word processors include grammar checks and these checks should be utilized. Applications also exist to help writers with the content of their scientific writing. For example, SWAN is an application designed to assist writers in utilizing scientific writing practices.⁵

WRITING THE ABSTRACT

No original research manuscript is complete without an abstract. Writing a high-quality abstract is important as most readers will use the abstract to decide whether the article it accompanies is applicable to their interests.

There are varying schools of thought on what should be written first, the abstract or everything meant to follow it. One can write the abstract first and then add information and details to create the rest of the paper. Or one could write the paper and then remove information from it to create their abstract. This author's suggestion would be to start by making a "pseudo-abstract" for the purpose of essentially outlining and clarifying one's thoughts for manuscript. From this pseudo-abstract, the main

paper can be written such that the flow of ideas is clear for the reader. As the process of writing the paper will undoubtedly help the writer further develop the ideas they are presenting, the flow of ideas in the main text will likely differ from that of the pseudo-abstract. For this reason, this method suggests that, after producing the main text from the pseudo-abstract, one produce their abstract by removing information from their main text. This version of your abstract should be less than one page in length. When it is the time to submit your abstract, you'll likely have to revise it again to fit the conference's or publication's word limit. As different venues can have different word limits, this author suggests starting with an abstract that has a length of less than one page and reducing its word count only when the time comes to submit it somewhere.

Abstracts feature five distinct sections: title and author information, introduction, methods, results, and conclusions.

- 1. The title of your abstract (and manuscript) should clearly identify your research's purpose and scope. The title should be short and it should leave the reader thinking that your project is important, relevant and innovative. The American College of Physicians has a strategy for designing "winning" titles. They advise making a list of up to 10 key words found in your abstract and using those words to make a list of sentences. Once you have a sentence that essentially describes your project, make the sentence a tad shorter and that's your title.⁶
- 2. The list of authors and their respective institutional affiliations should only include the people that made significant contributions to both carrying out the research as well as the creation of the manuscript. People who made contributions not qualifying for authorship can be thanked for their assistance in a separate section at the end of the manuscript.
- 3. The "Background" or "Introduction" section should explain why your research is important and provide a context for the work that you've done as well as the study's a priori hypothesis.
- 4. The "Methodology" section needs enough detail to empower the reader to assess the validity of the study. Examples of appropriate details to mention include: research design; research setting; number of patients enrolled, brief patient selection criteria, outcome variables recorded, and the statistical methods used to analyze the data.

- of your research in 2 to 3 sentences. A table can be used in this section if the venue accepting the abstract allows tables in abstracts. Any numerical result mentioned must include standard deviations or 95% confidence limits as well as the level of statistical significance. If listed results were not statistically significant, then the power of the study should also be mentioned.
- 6. The "Conclusion" or "Discussion" section should explain the implication of your study's findings. Any conclusion mentioned must be supported by the data you gathered. If space allows, include how generalizable your results are to other populations and mention any weaknesses of your study.

Any acronym used in the abstract or main text must be written in full the first time it is mentioned. Note, any acronym used in the abstract must be written in full again the first time it is used in the main text. Abstracts should be fully self-sufficient and as such they should not contain citations. Given that the abstract is essentially an incredibly focused version of the main text, every idea that appears in the abstract should also appear in the main text of the manuscript.

MANUSCRIPT DESIGN

In the "Selection of a suitable and workable research proposal", we discussed how scientific writing has three groups of non-mutually exclusive audiences: the general research population, those actively publishing on your topic and peer reviewers. We noted that keeping these three groups in mind was important for tailoring our manuscript for each of them. The important thing to note here is that we won't be tailoring our words for each group, we'll simply be tailoring the structure of our manuscript to fit the expectations of each group, such that they will know how to find the information that they are looking for. In this way, each group will know how to read the manuscript in the way that provides them the most value.

Introduction:

The introduction section should contain the baseline knowledge that is needed to understand the research precedent, nothing more and nothing less. Your introduction should serve to provide the context that surrounds the research question you plan to answer. Providing a general review of a subject is inappropriate for an original research manuscript as the additional information distracts the reader from the importance of what your manuscript will investigate. The details

included in the introduction should be presented in a manner that makes the purpose and importance of the research clear to the reader. The introduction should conclude by defining the study question as well as the researcher's hypothesis. The information presented should clearly support the author's hypothesis. While a truly balanced establishment of the research precedent can be expected to leave some room for uncertainty, the information provided must favor a particular outcome. This predicted outcome must be clear to the reader and it must be consistent with the writer's hypothesis.

As a rule of a thumb, if the introduction represents more than 1/6th of the total length of the manuscript, then it is too long. It should be written in such a way that any intelligent high school student can read it and understand the research precedent almost as well as the writer themself. This is not to say that every aspect of the research precedent needs to be explained in great detail, indeed it is the opposite. As the research precedent is what is known about the subject, it should be possible to summarize the research precedent in a manner that can be easily understood, and the author must strive to do this. It should be noted that the introduction can be drafted concurrently with the literature review. However, it is also important to re-review the literature when it comes time to writing the main paper as sometimes a great length of time can pass from when the literature was first reviewed and when the manuscript is being prepared for publication. To do our part in shortening the time between research discovery and clinical benefit, one should ensure that the research precedent in their manuscript is the current research precedent and not the research precedent from one to five years ago.

Methodology:

The methodology section should contain everything another group would need to perfectly replicate your study. One should mention the type of study performed, where it was conducted, and the duration of the study and how the results were analyzed. The description of this analysis should include the name and version number of the statistical software used as well as the statistical tests that were chosen for the analysis. If an obscure statistical test was chosen, then a reference for this test should be cited.8 Any assumptions made by your study should be detailed in this section. For example, when calculating the number of patients required for a study, one has to know the size of the difference that they expect to find, and this value needs to be stated in the methodology section and it must also be backed up with additional information about how the value was derived — typically either via a literature review or by doing a small study beforehand to find an expected value. This section must also mention that ethical clearance was granted by your institution's review board and that patient consent was appropriately sought and obtained.

Results:

The results section is where one will describe the results of their study. As this section deals with facts, it must be fully objective, and no subjective statements can be made. The goal of this section is to present all of the facts plainly and in a logical manner by summarizing the characteristics of one's data in such a way that said characteristics are easy to understand and meaningful. Note, all research findings, whether statistically significant or not, should be presented. The data presented should have the appropriate number of significant figures. This is to say, if one can only measure a particular value to the tenths place, then one should not report an average value at the hundredths place, as the data used was not specific enough to quantify that level of accuracy. The section should be written in the past-tense. While one should not discuss the results in the results section, one can use statements that draw attention to the novelty or context of certain results, e.g. "Unique to the research precedent, we found..." as this can help the reader hone in on importance of certain results prior to their discussion in the discussion section.⁷

It can help to look to how other researchers in your field have published their results as their articles can serve as an example as to how one can present their own data.

It is important to remember that your text should contain all the information you intend to convey, while tables, charts and graphs are simply used to make that information easier to understand. Not all data needs an accompanying visual aid, instead visual aids should be reserved for one of two purposes, either: to make complex findings easier to understand or to provide emphasis for simpler findings that one wants to ensure the reader notices. One should also aim to design their visual aids to be easily understood when printed in either color or gray-scale; your future readers that print in gray-scale will thank you for this.

Discussion:

The Discussion section is where you will discuss, in the context of the research precedent, the results mentioned in the results section. Only topics related to your results can be discussed. This section should

not mention any new background information. If one wants to mention new background information, do so and then move it all to the introduction section. The results should be discussed in the same order they were mentioned in the methodology and results sections, ideally from the results that are the most general to those that are the most specific.10 It is important to note that since this section is meant to be a discussion, subjective assessments can be mentioned here so long as they are appropriately qualified with a stated reasoning. Discussing one's results in the context of the research precedent requires an interpretation and judgment of the significance of said results. When one's results contrast with those of the research precedent, an explanation should be given to account for this difference.

Conclusion:

The conclusion section is where you will emphasize the knowledge that your study has created and how this knowledge should be applied (as wisdom) in the field by clinicians. Any conclusions stated must be supported by the data summarized in the manuscript. This is also the section where the author indiscriminately says that more research is needed — just kidding, please don't do that. The decision as to whether one should state that more research is needed is not one that should be taken lightly. As the author of the manuscript, you must assume the role of the subject expert, if you truly believe that more research is needed and can state what type of studies should be conducted to lead you to truly believe in your manuscript's conclusions, then you should state that more research is needed and follow it up with a description of what is needed. Whatever you do, you should have confidence in the quality of your own research and be willing to act on your research findings.

Limitations:

The limitations section should either follow the conclusions section or be a separate paragraph within the discussion section. It should list only the true limitations of the study. Now, I said "true limitations" because there are potential limitations that should not be listed. For example, questionnaire respondents may rush through their questionnaire and not answer it truthfully. This is an example of a "false limitation" as this limitation will affect all similar studies and one is supposed to design their study in such a way as to minimize the effect of the limitation. The types of limitations that should be mentioned are unforeseen circumstances that may have affected the validity of the study and that potentially could have been planned for, had they been anticipated.

By mentioning these limitations, readers are better informed about the validity of your study and future studies attempting to replicate your work will be able to avoid suffering a similar limitation.

Conflicts of Interest:

One must also create a section to describe the author's potential Conflicts of Interest. Describing one's conflicts of interest is important to maintain transparency in research, and it is paramount regardless of whether one believes that said conflicts influenced the results or conclusions of the study. Conflicts of interest can be personal, commercial, political, academic, and/or financial. If no conflicts exist, this fact should be stated.

Acknowledgements:

An acknowledgements section should be made to thank any funding agency or individuals that assisted with development of the research project or manuscript without doing enough to qualify to be listed as an author and that wish to be acknowledged in the manuscript.

References:

At the end of your manuscript, your references should also be listed in the format preferred by the journal you intend to publish with.

DISPLAYING RESEARCH RESULTS

There is indeed an art to displaying research results. Our goal should be to present the information such that it is both easy to understand and hard to misunderstand. When data has been presented in the appropriate type of graph or table, the reader should be able to draw the appropriate conclusions about the data within a couple seconds. Again, looking towards the work of others can help one figure out how to best present their data. It should also be noted that one should never complicate the data they are presenting, as such it follows that one should never use a 3D graph when a 2D graph can present the same information in a more intuitive fashion.

PLAGIARISM

Plagiarism is the hallmark of a lazy writer. If you're reading this article, then you should already know what is and is not plagiarism, so I will not go into too much detail on it. Suffice to say, if you use text or an idea from someone else's article, then you better reference them. If you use their exact words in your article, then you need to format the text appropriately to indicate this (e.g. use quotation marks), alternatively, you can restate their idea in your own

words and then add the in-line reference appropriate for the citation style you are using. Plagiarism can result in criminal charges and retraction of published articles, so it's truly in the author's best interest to appropriately credit their sources.

It is also important to note that it is possible to plagiarize oneself. If one copies parts of an old article they published and uses it unchanged in a related new article, that would be plagiarism. The word "original" in "original research manuscript" implies that it hasn't been done before, so one truly should not be copying old articles regardless of whether one authored them. Now the introduction between two similar articles may indeed still share many of the same facts and, as such, it is important to rewrite and summarize that old information for the new article. If you still doubt whether self-plagiarism counts as plagiarism, remember that when one publishes an article, the process frequently involves surrendering one's rights to copywrite, as such plagiarizing one's own words is true plagiarism as one gave up "ownership" of the words in the process of publication.

AUTHORSHIP

Not everyone that works on a research project should be credited as an author on publications related to that project. The International Committee of Medical Journal Editors recommend that authorship be awarded based on the following criteria:¹¹

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published;
 AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All potential authors and only the potential authors that meet all four criteria should be listed as authors. Potential authors that wish to be acknowledged who fail to meet all four criteria should be acknowledged at the end of the manuscript. It should be noted that the criteria are not meant to be used to exclude potential authors, as such potential authors who meet the first criteria are expected to be allowed to contribute to the process of writing the paper so that they too may claim authorship. The order of authors is at their own discretion, but it is typically in order of descending contribution, with the most senior author frequently

being listed last.

SELECTING A JOURNAL FOR PUBLICATION

Choosing the right journal to publish your research can be quite a task. The factors to keep in mind during this process include whether your article reflects the scope of the journal, whether they have peer reviewers qualified to review your article, whether their readers will be interested in your article, the journal's prestige, whether the journal is open-access or subscription-based, and whether it is cost-effective to publish with them. The process of finding a suitable journal can be narrowed down by keeping track of which journals published the articles you came across in your literature review. Selecting a journal early in the process of writing your article is important as this enables you to better target your audience when you write your article by including the information they'll be interested in knowing and the sort of "lens" that they'll view your research through. Different journals can also have different formatting requirements, hence knowing your chosen journal's requirements before writing the manuscript enables you to prepare a document that is ready for submission without substantial changes. A journal's boasts of a short timeframe from submission to decision should typically be ignored as these number are easily gamed by the journal and thus provides an author with little useful information. Likewise, one should ignore unfamiliar journals that email you requesting that you to publish with them. The SCImago Journal & Country Rank database can be used to find information regarding a journal's prestige and impact and their database is searchable by subject area, subject category, region/ country, journal type, and year. SCImago is accessible at the follow citation.¹²

SUCCESSFUL PEER REVIEW

The peer review process can take a long time, but it's much better for the review to take a while than to get a rejection back too quickly. Successful peer review will in part depend on choosing the "right" journal, as the "wrong" journal will never want to publish your manuscript. Ideally, the decision you eventually receive will come with comments on how your manuscript can be improved to prepare it for publication. These comments may at first feel discouraging, but you should do your best to understand the perspective behind them and adjust your manuscript accordingly. If you truly believe that a comment made by a peer reviewer is in error, then your resubmission must politely present additional

information to explain why this is so. In this case, one should also revise their manuscript so that eventual readers won't arrive at the same mistaken conclusion the peer reviewer did. For the most part though, the peer review process will improve the quality of your manuscript. If the journal asks for you to resubmit your manuscript with changes, one should make every effort to resubmit the revised manuscript as quickly as possible as this enables your peer reviewer to re-review your manuscript with the previous version fresher in their mind. It is also important to remember that you may have to submit your manuscript to a couple journals (sequentially, not concurrently) before finding one that will publish it. Regardless, don't give up, keep faithfully revising your manuscript and, if it's meant to be, then your manuscript will eventually find a home.

TAKING IT ALL IN

To end our discussion, I'll share the first stanza of William Wordsworth's Ode: Intimations of Immortality:¹³

There was a time when meadow, grove, and stream,
The earth, and every common sight,
To me did seem
Apparelled in celestial light,
The glory and the freshness of a dream.
It is not now as it hath been of yore;
Turn wheresoe'er I may.

By night or day.
The things which I have seen I now can see no more.

The poem goes on to describe how our gaining of experience results in that which we once thought magical now seeming normal, due to our greater understanding of it. The ode concludes that this experience and mindset enables us to love the true beauty of that which now seems normal. By this same token, I hope this series has provided you with a stronger understanding of the fundamentals of clinical research so that you too may see the process as a normal thing to be loved, not some insurmountable task. I thank you for joining me in this series and I wish you the best of luck in your future research endeavors.

Conflict of interest: Nil declared by the author.

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