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Mr. Speice

Independent Study and Mentorship II- 3B

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Assessment 12

Subject: Medical Research

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Works Cited

Kallestinova, Elena D. "How to Write Your First Research Paper." *The Yale Journal of Biology and Medicine* 84.3 (2011): 181–190. Print.

Süt, Necdet. "Study Designs in Medicine." *Balkan Medical Journal* 31.4 (2014): 273–277. *PMC*. Web. 8 Dec. 2017.

Assessment:

To begin my original work project I am beginning by gather background knowledge to prepare myself for my overall goal, which is to begin working on the prospective research titled Mitral Valvuloplasty and Mitral Valve Replacements in Infants Less Than One Year Old. For the past couple of research assessments I have focused on gaining the medical background knowledge to understand congenital mitral valve malformations and different types of mitral valve repairs and replacements. I have also research past prospective articles on mitral valve surgery in infants to update myself with the available information presented in the medical world about mitral valvuloplasty and mitral valve replacement in infants less than one year old.

Through these various assessments I have prepared myself for the understanding of our topic of research; however, I still left with little knowledge of true medical research writing. Going into the medical field I am sure that medical research will eventually become something I will be used to, but at this point in my life the only scientific writing I have made came from lab reports in my science classes and possibly a couple ISM assessments. Going into college with a more tangible and accurate understanding of research writing could assist me in standing out as a pre-med student, and when entering into the Independent Study and Mentorship program I had always hoped to leave the program with an understanding of medical research. Before diving into the articles I had chosen to read I knew from reading several medical journal articles in my two years in the Independent Study and Mentorship Program that medical research in a very broad term, and that the information I find on these articles may not apply to the research I will be conducting with Dr. Pirolli; however, I thought it would still be beneficial to come into my next mentor visit with a deeper understanding of medical research even if it may not apply to our research specifically.

When reading these articles I was left more confused then before I obtained all this information. This is due to the fact that I am unsure of what step of the research we are at. I believe we are right now gathering and observing all the information from the past 16 years of patients, but still have not begun to write our article. Since this article speaks specifically on article writing, I am not sure how well this information will come into benefit in my next mentor visit. However, it has taught me a lot of the tedious process of article writing and the specificity with in sharing our medical knowledge that should come into benefit when we begin to write out article.

Overall, this assessment has left me with many questions that will hopefully be answered by my mentor on my next mentor visit. Now with a better understanding of my confusions within this project I can hopefully come better prepared to better understand the next steps to completing my original work. There is no doubt that my original work has allowed me to step outside of my comfort zone and strengthened my understanding of my topic and I am immensely grateful to be fulfilling my Independent Study and Mentorship goals once and for all.

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Focus: Education — Career Advice

How to Write Your First Research Paper

Elena D. Kallestinova

Author information ► Copyright and License information ►

Go to:

Abstract

Writing a research manuscript is an intimidating process for many novice writers in the sciences. One of the stumbling blocks is the beginning of the process and creating the first draft. This paper presents guidelines on how to initiate the writing process and draft each section of a research manuscript. The paper discusses seven rules that allow the writer to prepare a well-structured and comprehensive manuscript for a publication submission. In addition, the author lists different strategies for successful revision. Each of those strategies represents a step in the revision process and should help the writer improve the quality of the manuscript. The paper could be considered a brief manual for publication.

Keywords: scientific paper, writing process, revision

It is late at night. You have been struggling with your project for a year. You generated an enormous amount of interesting data. Your pipette feels like an extension of your hand, and running western blots has become part of your daily routine, similar to brushing your teeth. Your colleagues think you are ready to write a paper, and your lab mates tease you about your “slow” writing progress. Yet days pass, and you cannot force yourself to sit down to write. You have not written anything for a while (lab reports do not count), and you feel you have lost your stamina. How does the writing process work? How can you fit your writing into a daily schedule packed with experiments? What section should you start with? What distinguishes a good research paper from a bad one? How should you revise your paper? These and many other questions buzz in your head and keep you stressed. As a result, you procrastinate. In this paper, I will discuss the issues related to the writing process of a scientific paper. Specifically, I will focus on the best

approaches to start a scientific paper, tips for writing each section, and the best revision strategies.

Go to:

1. Schedule your writing time in Outlook

Whether you have written 100 papers or you are struggling with your first, starting the process is the most difficult part unless you have a rigid writing schedule. Writing is hard. It is a very difficult process of intense concentration and brain work. As stated in Hayes' framework for the study of writing: "It is a generative activity requiring motivation, and it is an intellectual activity requiring cognitive processes and memory" [1]. In his book *How to Write a Lot: A Practical Guide to Productive Academic Writing*, Paul Silvia says that for some, "it's easier to embalm the dead than to write an article about it" [2]. Just as with any type of hard work, you will not succeed unless you practice regularly. If you have not done physical exercises for a year, only regular workouts can get you into good shape again. The same kind of regular exercises, or I call them "writing sessions," are required to be a productive author. Choose from 1- to 2-hour blocks in your daily work schedule and consider them as non-cancellable appointments. When figuring out which blocks of time will be set for writing, you should select the time that works best for this type of work. For many people, mornings are more productive. One Yale University graduate student spent a semester writing from 8 a.m. to 9 a.m. when her lab was empty. At the end of the semester, she was amazed at how much she accomplished without even interrupting her regular lab hours. In addition, doing the hardest task first thing in the morning contributes to

the sense of accomplishment during the rest of the day. This positive feeling spills over into our work and life and has a very positive effect on our overall attitude.

Rule 1: Create regular time blocks for writing as appointments in your calendar and keep these appointments.

Go to:

2. Start with an outline

Now that you have scheduled time, you need to decide how to start writing. The best strategy is to start with an outline. This will not be an outline that you are used to, with Roman numerals for each section and neat parallel listing of topic sentences and supporting points. This outline will be similar to a template for your paper. Initially, the outline will form a structure for your paper; it will help generate ideas and formulate hypotheses. Following the advice of George M. Whitesides, ". . . start with a blank piece of paper, and write down, in any order, all important ideas that occur to you concerning the paper" [3]. Use Table 1 as a starting point for your outline. Include your visuals (figures, tables, formulas, equations, and algorithms), and list your findings. These will constitute the first level of your outline, which will eventually expand as you elaborate.

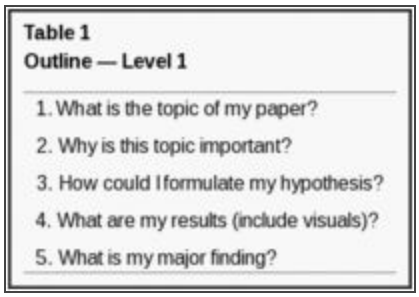

Table 1
Outline — Level 1

1. What is the topic of my paper?
2. Why is this topic important?
3. How could I formulate my hypothesis?
4. What are my results (include visuals)?
5. What is my major finding?

Table 1

Outline — Level 1

The next stage is to add context and structure. Here you will group all your ideas into sections: Introduction, Methods, Results, and Discussion/Conclusion (Table 2). This step will help add coherence to your work and sift your ideas.

Table 2
Outline — Level 2

Introduction
1. Why is your research important?
2. What is known about the topic?
3. What are your hypotheses?
4. What are your objectives?
Materials and Methods
1. What materials did you use?
2. Who were the subjects of your study?
3. What was the design of your research?
4. What procedure did you follow?
Results

Table 2

Outline — Level 2

Now that you have expanded your outline, you are ready for the next step: discussing the ideas for your paper with your colleagues and mentor. Many universities have a writing center where graduate students can schedule individual consultations and receive assistance with their paper drafts. Getting feedback during early stages of your draft can save a lot of time. Talking through ideas allows people to conceptualize and organize thoughts to find their direction without wasting time on unnecessary writing. Outlining is the most effective way of communicating your ideas and exchanging thoughts. Moreover, it is also the best stage to decide to which publication you will submit the paper. Many people come up with three choices and discuss them with their mentors and colleagues. Having a list of journal priorities can help you quickly resubmit your paper if your paper is rejected.

Rule 2: Create a detailed outline and discuss it with your mentor and peers.

Go to:

3. Continue with drafts

After you get enough feedback and decide on the journal you will submit to, the process of real writing begins. Copy your outline into a separate file and expand on each of the points, adding data and elaborating on the details. When you create the first draft, do not succumb to the temptation of editing. Do not slow down to choose a better word or better phrase; do not halt to improve your sentence structure. Pour your ideas into the paper and leave revision and editing

for later. As Paul Silvia explains, “Revising while you generate text is like drinking decaffeinated coffee in the early morning: noble idea, wrong time” [2].

Many students complain that they are not productive writers because they experience writer’s block. Staring at an empty screen is frustrating, but your screen is not really empty: You have a template of your article, and all you need to do is fill in the blanks. Indeed, writer’s block is a logical fallacy for a scientist — it is just an excuse to procrastinate. When scientists start writing a research paper, they already have their files with data, lab notes with materials and experimental designs, some visuals, and tables with results. All they need to do is scrutinize these pieces and put them together into a comprehensive paper.

Go to:

3.1. Starting with Materials and Methods

If you still struggle with starting a paper, then write the Materials and Methods section first. Since you have all your notes, it should not be problematic for you to describe the experimental design and procedures. Your most important goal in this section is to be as explicit as possible by providing enough detail and references. In the end, the purpose of this section is to allow other researchers to evaluate and repeat your work. So do not run into the same problems as the writers of the sentences in (1):

1a. Bacteria were pelleted by centrifugation.

1b. To isolate T cells, lymph nodes were collected.

As you can see, crucial pieces of information are missing: the speed of centrifuging your bacteria, the time, and the temperature in (1a); the source of lymph nodes for collection in (b). The sentences can be improved when information is added, as in (2a) and (2b), respectfully:

2a. Bacteria were pelleted by centrifugation at 3000g for 15 min at 25°C.

2b. To isolate T cells, mediastinal and mesenteric lymph nodes from Balb/c mice were collected at day 7 after immunization with ovabumin.

If your method has previously been published and is well-known, then you should provide only the literature reference, as in (3a). If your method is unpublished, then you need to make sure you provide all essential details, as in (3b).

3a. Stem cells were isolated, according to Johnson [23].

3b. Stem cells were isolated using biotinylated carbon nanotubes coated with anti-CD34 antibodies.

Furthermore, cohesion and fluency are crucial in this section. One of the malpractices resulting in disrupted fluency is switching from passive voice to active and vice versa within the same paragraph, as shown in (4). This switching misleads and distracts the reader.

4. Behavioral computer-based experiments of Study 1 were programmed by using E-Prime. We took ratings of enjoyment, mood, and arousal as the patients listened to preferred pleasant music and unpreferred music by using Visual Analogue Scales (SI Methods). The preferred and unpreferred status of the music was operationalized along a continuum of pleasantness [4].

The problem with (4) is that the reader has to switch from the point of view of the experiment (passive voice) to the point of view of the experimenter (active voice). This switch causes confusion about the performer of the actions in the first and the third sentences. To improve the coherence and fluency of the paragraph above, you should be consistent in choosing the point of view: first person "we" or passive voice [5]. Let's consider two revised examples in (5).

5a. We programmed behavioral computer-based experiments of Study 1 by using E-Prime. We took ratings of enjoyment, mood, and arousal by using Visual Analogue Scales (SI Methods) as the patients listened to preferred pleasant music and unpreferred music. We operationalized the preferred and unpreferred status of the music along a continuum of pleasantness.

5b. Behavioral computer-based experiments of Study 1 were programmed by using E-Prime. Ratings of enjoyment, mood, and arousal were taken as the patients listened to preferred pleasant music and unpreferred music by using Visual Analogue Scales (SI

Methods). The preferred and unpreferred status of the music was operationalized along a continuum of pleasantness.

If you choose the point of view of the experimenter, then you may end up with repetitive "we did this" sentences. For many readers, paragraphs with sentences all beginning with "we" may also sound disruptive. So if you choose active sentences, you need to keep the number of "we" subjects to a minimum and vary the beginnings of the sentences [6].

Interestingly, recent studies have reported that the Materials and Methods section is the only section in research papers in which passive voice predominantly overrides the use of the active voice [5,7,8,9]. For example, Martínez shows a significant drop in active voice use in the Methods sections based on the corpus of 1 million words of experimental full text research articles in the biological sciences [7]. According to the author, the active voice patterned with "we" is used only as a tool to reveal personal responsibility for the procedural decisions in designing and performing experimental work. This means that while all other sections of the research paper use active voice, passive voice is still the most predominant in Materials and Methods sections.

Writing Materials and Methods sections is a meticulous and time consuming task requiring extreme accuracy and clarity. This is why when you complete your draft, you should ask for as much feedback from your colleagues as possible. Numerous readers of this section will help you identify the missing links and improve the technical style of this section.

Rule 3: Be meticulous and accurate in describing the Materials and Methods. Do not change the point of view within one paragraph.

Go to:

3.2. Writing Results Section

For many authors, writing the Results section is more intimidating than writing the Materials and Methods section . If people are interested in your paper, they are interested in your results. That is why it is vital to use all your writing skills to objectively present your key findings in an orderly and logical sequence using illustrative materials and text.

Your Results should be organized into different segments or subsections where each one presents the purpose of the experiment, your experimental approach, data including text and visuals (tables, figures, schematics, algorithms, and formulas), and data commentary. For most journals, your data commentary will include a meaningful summary of the data presented in the visuals and an explanation of the most significant findings. This data presentation should not repeat the data in the visuals, but rather highlight the most important points. In the "standard" research paper approach, your Results section should exclude data interpretation, leaving it for the Discussion section. However, interpretations gradually and secretly creep into research papers: "Reducing the data, generalizing from the data, and highlighting scientific cases are all highly interpretive processes. It should be clear by now that we do not let the data speak for themselves in research reports; in summarizing our results, we interpret them for the reader" [10]. As a result, many journals including the *Journal of Experimental Medicine* and the *Journal of Clinical*

Investigation use joint Results/Discussion sections, where results are immediately followed by interpretations.

Another important aspect of this section is to create a comprehensive and supported argument or a well-researched case. This means that you should be selective in presenting data and choose only those experimental details that are essential for your reader to understand your findings. You might have conducted an experiment 20 times and collected numerous records, but this does not mean that you should present all those records in your paper. You need to distinguish your results from your data and be able to discard excessive experimental details that could distract and confuse the reader. However, creating a picture or an argument should not be confused with data manipulation or falsification, which is a willful distortion of data and results. If some of your findings contradict your ideas, you have to mention this and find a plausible explanation for the contradiction.

In addition, your text should not include irrelevant and peripheral information, including overview sentences, as in (6).

> *6. To show our results, we first introduce all components of experimental system and then describe the outcome of infections.*

Indeed, wordiness convolutes your sentences and conceals your ideas from readers. One common source of wordiness is unnecessary intensifiers. Adverbial intensifiers such as “clearly,” “essential,” “quite,” “basically,” “rather,” “fairly,” “really,” and “virtually” not only add

verbosity to your sentences, but also lower your results' credibility. They appeal to the reader's emotions but lower objectivity, as in the common examples in (7):

7a. Table 3 clearly shows that …

7b. It is obvious from figure 4 that …

Another source of wordiness is nominalizations, i.e., nouns derived from verbs and adjectives paired with weak verbs including "be," "have," "do," "make," "cause," "provide," and "get" and constructions such as "there is/are."

8a. We tested the hypothesis that there is a disruption of membrane asymmetry.

8b. In this paper we provide an argument that stem cells repopulate injured organs.

In the sentences above, the abstract nominalizations "disruption" and "argument" do not contribute to the clarity of the sentences, but rather clutter them with useless vocabulary that distracts from the meaning. To improve your sentences, avoid unnecessary nominalizations and change passive verbs and constructions into active and direct sentences.

9a. We tested the hypothesis that the membrane asymmetry is disrupted.

9b. In this paper we argue that stem cells repopulate injured organs.

Your Results section is the heart of your paper, representing a year or more of your daily research. So lead your reader through your story by writing direct, concise, and clear sentences.

Rule 4: Be clear, concise, and objective in describing your Results.

Go to:

3.3. now it is time for your Introduction

Now that you are almost half through drafting your research paper, it is time to update your outline. While describing your Methods and Results, many of you diverged from the original outline and re-focused your ideas. So before you move on to create your Introduction, re-read your Methods and Results sections and change your outline to match your research focus. The updated outline will help you review the general picture of your paper, the topic, the main idea, and the purpose, which are all important for writing your introduction.

The best way to structure your introduction is to follow the three-move approach shown in Table 3.

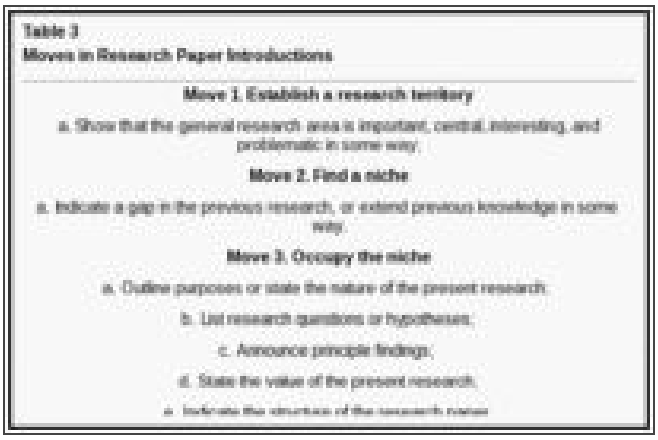

Table 3

Moves in Research Paper Introductions

Move 1. Establish a research territory

a. Show that the general research area is important, central, interesting, and problematic in some way;

Move 2. Find a niche

a. Indicate a gap in the previous research, or extend previous knowledge in some way;

Move 3. Occupy the niche

a. Outline purposes or state the nature of the present research;

b. List research questions or hypotheses;

c. Announce principle findings;

d. State the value of the present research;

e. Indicate the structure of the research paper

Table 3

Moves in Research Paper Introductions

The moves and information from your outline can help to create your Introduction efficiently and without missing steps. These moves are traffic signs that lead the reader through the road of your ideas. Each move plays an important role in your paper and should be presented with deep thought and care. When you establish the territory, you place your research in context and highlight the importance of your research topic. By finding the niche, you outline the scope of your research problem and enter the scientific dialogue. The final move, “occupying the niche,” is where you explain your research in a nutshell and highlight your paper’s significance. The three moves allow your readers to evaluate their interest in your paper and play a significant role in the paper review process, determining your paper reviewers.

Some academic writers assume that the reader “should follow the paper” to find the answers about your methodology and your findings. As a result, many novice writers do not present their experimental approach and the major findings, wrongly believing that the reader will locate the

necessary information later while reading the subsequent sections [5]. However, this “suspense” approach is not appropriate for scientific writing. To interest the reader, scientific authors should be direct and straightforward and present informative one-sentence summaries of the results and the approach.

Another problem is that writers understate the significance of the Introduction. Many new researchers mistakenly think that all their readers understand the importance of the research question and omit this part. However, this assumption is faulty because the purpose of the section is not to evaluate the importance of the research question in general. The goal is to present the importance of your research contribution and your findings. Therefore, you should be explicit and clear in describing the benefit of the paper.

The Introduction should not be long. Indeed, for most journals, this is a very brief section of about 250 to 600 words, but it might be the most difficult section due to its importance.

Rule 5: Interest your reader in the Introduction section by signalling all its elements and stating the novelty of the work.

Go to:

3.4. Discussion of the results

For many scientists, writing a Discussion section is as scary as starting a paper. Most of the fear comes from the variation in the section. Since every paper has its unique results and findings, the Discussion section differs in its length, shape, and structure. However, some general principles

of writing this section still exist. Knowing these rules, or “moves,” can change your attitude about this section and help you create a comprehensive interpretation of your results.

The purpose of the Discussion section is to place your findings in the research context and “to explain the meaning of the findings and why they are important, without appearing arrogant, condescending, or patronizing” [11]. The structure of the first two moves is almost a mirror reflection of the one in the Introduction. In the Introduction, you zoom in from general to specific and from the background to your research question; in the Discussion section, you zoom out from the summary of your findings to the research context, as shown in Table 4.

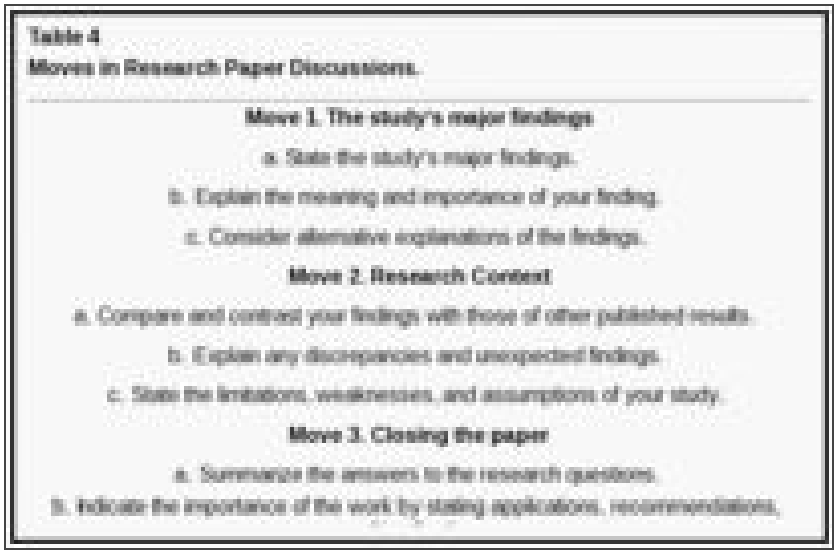

Table 4

Moves in Research Paper Discussions.

Move 1. The study's major findings
a. State the study's major findings.
b. Explain the meaning and importance of your finding.
c. Consider alternative explanations of the findings.
Move 2. Research Context
a. Compare and contrast your findings with those of other published results.
b. Explain any discrepancies and unexpected findings.
c. State the limitations, weaknesses, and assumptions of your study.
Move 3. Closing the paper
a. Summarize the answers to the research questions.
b. Indicate the importance of the work by stating applications, recommendations,

Table 4

Moves in Research Paper Discussions.

The biggest challenge for many writers is the opening paragraph of the Discussion section. Following the moves in Table 1, the best choice is to start with the study’s major findings that

provide the answer to the research question in your Introduction. The most common starting phrases are “Our findings demonstrate . . .,” or “In this study, we have shown that . . .,” or “Our results suggest . . .” In some cases, however, reminding the reader about the research question or even providing a brief context and then stating the answer would make more sense. This is important in those cases where the researcher presents a number of findings or where more than one research question was presented. Your summary of the study’s major findings should be followed by your presentation of the importance of these findings. One of the most frequent mistakes of the novice writer is to assume the importance of his findings. Even if the importance is clear to you, it may not be obvious to your reader. Digesting the findings and their importance to your reader is as crucial as stating your research question.

Another useful strategy is to be proactive in the first move by predicting and commenting on the alternative explanations of the results. Addressing potential doubts will save you from painful comments about the wrong interpretation of your results and will present you as a thoughtful and considerate researcher. Moreover, the evaluation of the alternative explanations might help you create a logical step to the next move of the discussion section: the research context.

The goal of the research context move is to show how your findings fit into the general picture of the current research and how you contribute to the existing knowledge on the topic. This is also the place to discuss any discrepancies and unexpected findings that may otherwise distort the general picture of your paper. Moreover, outlining the scope of your research by showing the limitations, weaknesses, and assumptions is essential and adds modesty to your image as a

scientist. However, make sure that you do not end your paper with the problems that override your findings. Try to suggest feasible explanations and solutions.

If your submission does not require a separate Conclusion section, then adding another paragraph about the “take-home message” is a must. This should be a general statement reiterating your answer to the research question and adding its scientific implications, practical application, or advice.

Just as in all other sections of your paper, the clear and precise language and concise comprehensive sentences are vital. However, in addition to that, your writing should convey confidence and authority. The easiest way to illustrate your tone is to use the active voice and the first person pronouns. Accompanied by clarity and succinctness, these tools are the best to convince your readers of your point and your ideas.

Rule 6: Present the principles, relationships, and generalizations in a concise and convincing tone.

Go to:

4. Choosing the best working revision strategies

Now that you have created the first draft, your attitude toward your writing should have improved. Moreover, you should feel more confident that you are able to accomplish your project and submit your paper within a reasonable timeframe. You also have worked out your writing schedule and followed it precisely. Do not stop — you are only at the midpoint from

your destination. Just as the best and most precious diamond is no more than an unattractive stone recognized only by trained professionals, your ideas and your results may go unnoticed if they are not polished and brushed. Despite your attempts to present your ideas in a logical and comprehensive way, first drafts are frequently a mess. Use the advice of Paul Silvia: “Your first drafts should sound like they were hastily translated from Icelandic by a non-native speaker” [2]. The degree of your success will depend on how you are able to revise and edit your paper.

The revision can be done at the macrostructure and the microstructure levels [13]. The macrostructure revision includes the revision of the organization, content, and flow. The microstructure level includes individual words, sentence structure, grammar, punctuation, and spelling.

The best way to approach the macrostructure revision is through the outline of the ideas in your paper. The last time you updated your outline was before writing the Introduction and the Discussion. Now that you have the beginning and the conclusion, you can take a bird’s-eye view of the whole paper. The outline will allow you to see if the ideas of your paper are coherently structured, if your results are logically built, and if the discussion is linked to the research question in the Introduction. You will be able to see if something is missing in any of the sections or if you need to rearrange your information to make your point.

The next step is to revise each of the sections starting from the beginning. Ideally, you should limit yourself to working on small sections of about five pages at a time [14]. After these short sections, your eyes get used to your writing and your efficiency in spotting problems decreases. When reading for content and organization, you should control your urge to edit your paper for

sentence structure and grammar and focus only on the flow of your ideas and logic of your presentation. Experienced researchers tend to make almost three times the number of changes to meaning than novice writers [15,16]. Revising is a difficult but useful skill, which academic writers obtain with years of practice.

In contrast to the macrostructure revision, which is a linear process and is done usually through a detailed outline and by sections, microstructure revision is a non-linear process. While the goal of the macrostructure revision is to analyze your ideas and their logic, the goal of the microstructure editing is to scrutinize the form of your ideas: your paragraphs, sentences, and words. You do not need and are not recommended to follow the order of the paper to perform this type of revision. You can start from the end or from different sections. You can even revise by reading sentences backward, sentence by sentence and word by word.

One of the microstructure revision strategies frequently used during writing center consultations is to read the paper aloud [17]. You may read aloud to yourself, to a tape recorder, or to a colleague or friend. When reading and listening to your paper, you are more likely to notice the places where the fluency is disrupted and where you stumble because of a very long and unclear sentence or a wrong connector.

Another revision strategy is to learn your common errors and to do a targeted search for them [13]. All writers have a set of problems that are specific to them, i.e., their writing idiosyncrasies. Remembering these problems is as important for an academic writer as remembering your friends' birthdays. Create a list of these idiosyncrasies and run a search for these problems using your word processor. If your problem is demonstrative pronouns without summary words, then

search for “this/these/those” in your text and check if you used the word appropriately. If you have a problem with intensifiers, then search for “really” or “very” and delete them from the text. The same targeted search can be done to eliminate wordiness. Searching for “there is/are” or “and” can help you avoid the bulky sentences.

The final strategy is working with a hard copy and a pencil. Print a double space copy with font size 14 and re-read your paper in several steps. Try reading your paper line by line with the rest of the text covered with a piece of paper. When you are forced to see only a small portion of your writing, you are less likely to get distracted and are more likely to notice problems. You will end up spotting more unnecessary words, wrongly worded phrases, or unparallel constructions.

After you apply all these strategies, you are ready to share your writing with your friends, colleagues, and a writing advisor in the writing center. Get as much feedback as you can, especially from non-specialists in your field. Patiently listen to what others say to you — you are not expected to defend your writing or explain what you wanted to say. You may decide what you want to change and how after you receive the feedback and sort it in your head. Even though some researchers make the revision an endless process and can hardly stop after a 14th draft; having from five to seven drafts of your paper is a norm in the sciences. If you can’t stop revising, then set a deadline for yourself and stick to it. Deadlines always help.

Rule 7: Revise your paper at the macrostructure and the microstructure level using different strategies and techniques. Receive feedback and revise again.

Go to:

5. It is time to submit

It is late at night again. You are still in your lab finishing revisions and getting ready to submit your paper. You feel happy — you have finally finished a year's worth of work. You will submit your paper tomorrow, and regardless of the outcome, you know that you can do it. If one journal does not take your paper, you will take advantage of the feedback and resubmit again. You will have a publication, and this is the most important achievement.

What is even more important is that you have your scheduled writing time that you are going to keep for your future publications, for reading and taking notes, for writing grants, and for reviewing papers. You are not going to lose stamina this time, and you will become a productive scientist. But for now, let's celebrate the end of the paper.

Go to:

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Study Designs in Medicine

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Scientific studies can be described as "*a planned and systematic effort based on evidence for the solution of any health problems using data with high degree of accuracy*" (1). The main aims are to quantify disease prevalence, and compare interventions, predictions, association assessments or etiology assessments (2). A scientific study requires good planning including research protocol, ethical approval, data collection, data analysis, interpretation of data analysis results and publication. This study can help authors understand study designs in medicine.

Scientific studies can be classified as "Basic Studies", "Observational Studies", "Experimental (Interventional) Studies", "Economic Evaluations" and "Meta-Analysis – Systematic Review", as shown in Figure 1.

FIG. 1.

Study designs

Go to:

BASIC STUDIES

Basic studies investigate the cause-outcome relationships between a dependent variable and independent variables, such as animal experiment, genetic and cell studies. Also, method development studies investigate the development and improvement of biochemical (e.g., enzymes, markers or genes), imaging (e.g., magnetic resonance) and biometric methods (e.g., statistical methods) (3). Several checklists have been developed to guide authors in the preparing, conducting and reporting stages of their studies. The *ARRIVE* checklist supplies transparency and accuracy in the animal experiments (1).

Go to:

OBSERVATIONAL STUDIES

Observational studies can be defined as non-interventional and non-experimental (3). They do not contain any experiment or intervention methods. Investigated factors aren't controlled, repetition of events aren't generally possible and randomisation facilities are limited in these studies. However, their results are largely consistent with real life (4). They can be classified as descriptive or analytical, as shown in the Figure 1.

Descriptive studies

Health problems or events as regards a particular disease or condition are detected and identified in these studies. They seek answers to the following questions about health problems or events: *"What is it?", "Where is it seen?", "When is it seen?"* and *"Who are observed?"* Descriptive statistics (mean, rate, etc.), frequency distributions and population parameters are determined by this kind of research.

Descriptive observational studies include *case-report*, *case series* and *cross-sectional studies (descriptive or prevalence)*. Patient and disease characteristics related to some interesting and remarkable type defined in a patient are called a "*case report*". When the number of patients is more than one, this is called a "*case series*". These are the most simple research types and do not contain a control group. Case series are usually starting points of the examined hypothesis in the case-control, cross-sectional or cohort studies (5). The use of *CARE* statement in the publication of a case report supplies transparency and accuracy (6).

Cross-sectional studies (descriptive or prevalence) can be described as prevalence studies and generally examine the prevalence, epidemiology or survey of a disease or clinical outcome. They reflect the situation of a disease or clinical outcome at a particular moment in a particular population (5).

Analytical (inferential) studies

Cross-sectional study

Analytical *cross-sectional studies are* conducted in a specific time period which does not contain follow-up and enquires: "What is happening in a specific time period?" (Figure 2) They try to explain potential causal associations between causes (exposures) and outcome (disease or clinical outcome). As a cohort study, they compare disease prevalence between exposure groups, and as a case-control study, they compare exposure between disease and healthy groups (2). Generally, they do not have a follow-up period.(5) Checklists guide the authors in preparing, conducting and reporting stages of research. The STROBE statement for cross-sectional studies is a useful guideline for this design (1).

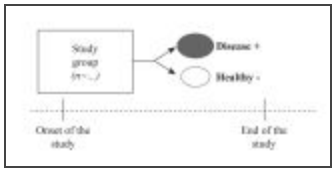

FIG. 2.

Cross-sectional study design

Case-control study

Case-Control Studies are conducted retrospectively and enquire: “What happened in the past?” (Figure 3). The cases are subjects selected according to presence of disease or clinical outcome. However, the control subjects are selected without disease or clinical outcome. The case and control groups are compared in terms of the presence of certain factors. Case group should be matched to the control group except for investigated factors. These are matched case-control study (5). *The STROBE statement* for case-control studies guides authors (1).

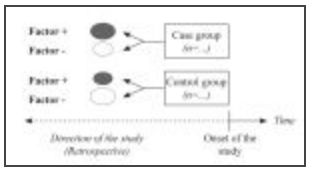

FIG. 3.

Case-control study design

Diagnostic Accuracy Studies investigate the effect of a diagnostic method (such as imaging, pathological) compared with a gold standard method (3). They are similar to case-control studies. *The STARD statement*helps authors in designing, conducting and reporting diagnostic accuracy studies (1).

Cohort study

Cohort is a special group of people who have been selected according to some defining characteristics and they have certain disease risk factors or health outcome. *Cohort Studies*, also called *follow-up* studies, are generally prospective and enquire: “What will happen in the

future?" (Figure 4) Individuals are followed over time in cohort studies, and researchers assess exposure and outcome during follow-up (2). Cohort studies investigate the effect of prognostic factors (such as age, presence of hypertension and cholesterol level) on a clinical outcome (such as disease) (3).

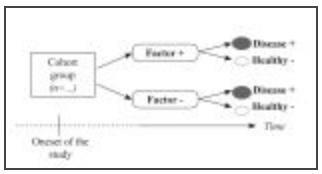

FIG. 4.

Cohort study design

Moreover, cohort studies can be conducted retrospectively; these are called *"Historical Cohort Study". Cohort Studies* produce the most reliable clinical evidence among the observational studies due to the fact that they identify clinical or health outcomes based on exposure (5). The *STROBE statement* for cohort studies helps authors (1).

Go to:

EXPERIMENTAL (INTERVENTIONAL) STUDIES

Experimental or interventional studies compare the effect of treatments or interventions with control in humans. Placebo or different treatment(s) or intervention(s) may be used as control. Experimental studies have to be transparent and evidence-based. In these studies, randomisation methods can be used, investigated factors are controlled, cause-effect relationships are evidenced

and an experiment can be repeated as much as desired. However, their results are always not appropriate for real life (4). They can be conducted in four phases (7).

Phase I study is conducted in a small number of healthy volunteers (e.g. 20–80) to determine whether a drug or treatment method is *safe*. Pharmacokinetic and pharmacodynamic measurements are done in these studies. Maximum safe dose, movement of the drug in the body and dose-response relationship are examined. *Phase II* study is conducted in a target population (75–300) to determine the treatment *effect* of a drug or treatment method. Standard treatment method has to be compared with placebo in Phase II clinical trials. *Phase III* study is conducted on many patients (e.g., 1000–2000) to determine whether the new drug is better than the standard drug. It is done in order to reveal that a drug is not only safe and effective, but also has *better* and *less adverse effects* than standard treatment. Usually, at least two RCTs are required in this phase.

Clinical trials (Phase IV) are called post-marketing product surveillance studies, which are conducted on patients in daily life; the new drug had been approved by the Ministry in this phase. They evaluate the adverse effect and various additional indications of a new drug (7, 8).

Observational Drug Studies are other forms of Phase IV clinical trials. They collect the data about a spontaneously prescribed drug from the patients with diagnosed and ongoing treatment. In these studies, additional information from a larger population may be obtained in order to compare the results of experimental clinical drug trials (4).

Randomised controlled trial (RCT)

Randomised controlled trials produce the strongest evidence among clinical trials due to the fact that patients are allocated to treatments or interventions randomly (equal chance). In these studies, two or more clinical treatments or intervention are compared. RCTs are expensive and slow, however, their level of evidence is higher due to the fact that randomisation removes the allocation bias (2). Many respected journals endorse the *CONSORT statement* in order to improve the scientific quality and transparency of RCTs. Authors should be used to the *CONSORT* statement as a guideline in RCTs (1).

When the preference of participants is not to receive a placebo or control, randomisation procedure is not applied. These studies are called *Non-Randomised Controlled Studies*. They are inexpensive especially if they are conducted as retrospective and representative sample of patients in clinical practice. However, they are open to bias (2).

Self-controlled study

Self-Controlled Studies do not include an independent control group; they use the patients as their own controls. At least two measurements are obtained at different times from the same patients (e.g., preop, postop 1. month, and 6. month measurements) and the effect of treatment or intervention is determined (5).

Crossover study

Crossover Studies include both of self-control and independent groups. They are powerful, but not always possible to apply. In crossover studies, patients are assigned two groups (placebo or experimental treatment). After a time, the research is interrupted for a washout period (at least two weeks), and patients receive no treatments during this period. At the end of the washout

period, the experimental treatment group receives the placebo and the placebo group receives to the experimental treatment (5). The effect of treatment or intervention is determined by comparisons of both self-control and independent groups in *crossover* design (Figure 5).

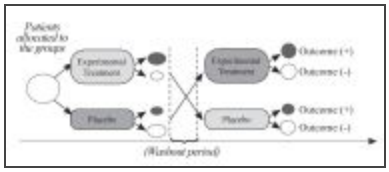

FIG. 5.

Crossover study design

Properties of experimental studies

Direction of studies

Studies can be classified as prospective or retrospective according to direction. In prospective studies, a specific sample is followed over a certain period in order to determine outcome from the reasons. The research question is: “What will happen in the future?” Retrospective studies generally compare the outcome of diagnostic and treatment methods. Data are obtained from patient records. The research question is: “What happened in the past?” (5).

Randomisation

In randomisation method the subjects or patients who will be included in the study are assigned to treatment groups with equal probability (chance) in the beginning of study. A computerized software is widely used for allocating the subjects/patients to the groups in the randomisation

processes. Studies can be classified as i) randomised or ii) non-randomised. Randomised Controlled Studies (RCTs) produce the most reliable results among all research types.

Blinding

Blinding describes that one or more of the physicians, researchers, patients and data analysts do not know which treatment subjects have received. It ensures reliable and objective results preventing bias. Blinding can be defined as three different types (single, double and triple). *Single-blind:* either subjects or researchers know which treatment subjects have received. *Double-blind:* both subjects and researchers do not know which treatment subjects have received. *Triple-blind:* in addition to the subjects and researcher(s), statisticians/monitors do not know which treatment subjects have received (5).

Confounding and interaction

Confounding can be defined as disruption of the relationships between two variables due to the effect of third variable. A confounder variable is associated both with causal and outcome variables (9). Two or higher independent variables have different effect on outcome variable to independent effect of each. This situation can be defined as *interaction*.

Go to:

ECONOMIC EVALUATIONS

Cost Analysis is an economic analysis method that estimates total cost of a particular disease or health condition on society. Direct and indirect costs attributed to a specific disease are included in this method. It is also called “cost of illness”. *Cost-Minimisation Analysis* compares two

alternative drugs' (or interventions) costs and outcomes in order to determine the least costly drug (or intervention). However, it is quite difficult to find two alternative drugs which are equally effective and safe. Thus, it is rarely used in economic evaluations. *Cost-Utility Analysis* is an economic evaluation method comparing two alternative drugs (or interventions) costs and outcomes in order to determine the most useful drug (or intervention). Outcomes in these studies are measured in preference or utility of patients, and, generally, quality-adjusted life year (QALY) or disability-adjusted life year (DALY) are used as an outcome. *Cost-Effectiveness Analysis* compares two alternative drugs (or interventions) costs and clinical outcomes in order to determine the most effective drug (or intervention). Outcomes are measured by clinical parameters. It is the most widely used economic evaluation method. *Cost-Benefit Analysis* is an economic evaluation method, in which cost and benefit of alternative interventions are expressed in monetary units. Thus, it is rarely used in economic evaluations (8).

Go to:

META-ANALYSIS AND SYSTEMATIC REVIEW

Several clinical studies (RCTs or Cohort) may be conducted in a clinical area over a period of years in different parts of the world. The results may be different and there may be different properties such as sample size and multicentre. *Meta-Analysis* combines the statistical results of different studies in a particular clinical area (7, 9). The *PRISMA statement* guides the authors in the preparation of Meta-Analysis (1).

Systematic Review evaluates and interprets the evidence of all studies conducted in a clinical area (9). The main difference from Meta-Analysis is that it combines the evidence of different studies based on interpretation instead of combining statistical results.

Evidence level of the medical studies

The evidence pyramid shows the evidence level of a scientific study in clinical practices. The evidence pyramid of scientific medical studies is shown in Figure 6. According to the evidence pyramid, the "Meta-Analysis/Systematic Review" produces the most reliable evidence, while "*in vitro* study" produces the lowest reliable evidence (10).

FIG. 6.

Evidence pyramid for medical studies

In conclusion, authors should correctly report the study design in the method section of their studies. Also, if randomisation, stratification or blinding methods are used, they should be reported in this section. Generally, studies are conducted on a sample, so sample size should be a sufficient number and representative of population in structural terms. Thus, determination of sample size, selection method of sample, inclusion and exclusion criteria should be explained in detail in the method section. Use of the checklists (*CONSORT statement* for RCTs, *ARRIVE* for

animal experiments and *STROBE statement* for cross-sectional, case-control and cohort studies, *CARE statement* for case report and *PRISMA statement* for meta-analysis) may prevent bias and guide authors in the preparation of their studies.

Go to:

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