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MAIN PRINCIPLES OF SCIENTIFIC PUBLICATIONS' PREPARATION ACCORDING TO THE STANDARDS OF HARVARD MEDICAL SCHOOL

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ABSTRACT: The article is written for young researchers, who constantly face many problems with Manuscript writing due to unknowing or ignoring of main rules of good preparation of scientific publication. All sections of this methodological paper are mostly based on Harvard Medical School's lectures for participants of the on-line Course "Principle and Practice of Clinical Research".

Content of the article has been guided by IMRAD – a modern algorithm for relevant placing of all information to be included in the publication – Introduction, Methods, Results, Assessment, Discussion, including tips on writing style. There have been given brief recommendations on Authorship issues according to ICMJE (International Committee of Medical Journal Editors) Also there is "Tips for authors" by Caren Solomon, Chief-editor of the "New England Journal of Medicine", which has one of the highest impact-factor among the medical periodicals in the world, that has been given in Application 1. There is specific guidelines for proper arranging of research paper depending on the Study's type, have been given in Application 2.

We expect the article will help young researchers to prepare and arrange their papers properly, according to Harvard standards of Manuscript writing.

Key words: *Manuscript writing; scientific publication; peer-reviewed journals; publishing; research design; research methodology.*

This article has been prepared mostly on a basis of Harvard Medical School's lectures developed for participants of the Course "Principles and Practice of Clinical Research".

As an Introduction, we would like to cite the Course Director, Dr. Felipe Fregni, which defined Manuscript writing as an Art, and explained relevance of this kind of the Art in this way:

"Papers are one of the most important components in the life of a scientist. It is the tool that the scientist uses to take his/her discoveries to the scientific community and the world. It is also one of the most important outcomes to measure the scientist's productivity and capacity. It is the scientist's most important currency, and is essential for receiving grants and for the promotion process in academia. Although the impact of a paper depends highly on the research idea, methodology and research design, a poorly written manuscript will certainly not go far and will be rejected by journals with high impact factor where the competition is so high that editors and reviewers will quickly reject when other well-written papers are submitted. In addition, the reader now has easy access to a wide range of manuscripts through online access, and therefore will quickly ignore a paper that is difficult to read and understand even if the science is outstanding. In fact, physicians and other health care professionals do not usually like writing a paper mainly due to the fact that they often do not know how to write. Some of them quickly give up as they consider themselves to not have the talent that is essential for the process. Although talent is helpful, writing as with any other skill comes from intensive training. Certainly talent helps, but talent without training is equally useless. In fact, physicians might have additional difficulty as they spend years in medical school and residency without getting formal training in manuscript writing. One difficult aspect in the training of manuscript writing is that, unlike other disciplines, **there is no recipe for writing**. Some fundamental principles need to be followed and can help, but writing needs to be viewed as an art

in which creativity, previous knowledge, and a considerable effort are important ingredients to write an outstanding paper” [1].

First section of any scientific publication is **Abstract**, which contains brief information through the whole article, often being the most widely read part of the article by both those who scrutinize the journal, as well as those who just perform electronic literature searches[2]. To be laconic and attractive, that is necessary for any Abstract, author has the opportunity to use concise language to summarize his/her paper by following 2 principles:

- 1) the abstract should be clear enough to be understood by a reader who may not read the rest of the article,
- 2) the abstract should not be too long (word limitation varies from journal to journal, approximately 150-250).

For instance, the abstracts for “New England Journal of Medicine” need to be of no more than 250 words [3]. Anyway, all Abstracts should include four mandatory subheadings – **background or objectives, study design, results and conclusions**.

A convenient algorithm for any research paper is **IMRAD**, which was established in 1950s, and by 1980s most of prestigious journals such as BMJ, the Lancet, NEJM completely adopted it.

Introduction: Any Introduction should include the following points [4]:

- statement of the problem
- clinical relevance
- review of literature
- rationale and theoretical framework
- specific purpose and hypotheses (or guiding questions).

By Donald Halstead’s lecture [5], any Introduction should consist of three main steps:

1 step is – *Establishing the overall research area*, that provides the reader with general background and on context on the overall health issue here. In other words, all included here information is KNOWN, with nothing controversial here, and answers the “SO WHAT?”.

2 step *identifies the GAP of knowledge*. This step focuses on the issue of population studied, which was nested within step 1 and reviews the pertinent existing literature (still KNOWN). In the whole, flow of the Introduction culminates in identifying the GAP of knowledge, or critical area of “NOT KNOWN”, you are going to investigate. Consequently, optimal placement of the GAP is at the end of step 2, and flow of the Introduction should be accordingly continued by using of “HOWEVER statement”, which sends a powerful signal to readers. Namely “HOWEVER statement” clearly explains to readers your intentions.

3 step *responds directly to the GAP*. This step demonstrates that your study addressed the GAP using appropriate methods that are robust enough to advance knowledge on the issue investigated. The essence of this step is “THEREFORE statement” that presents overview of the study design, data and other information that methodologically “fit” the GAP and clearly states objective, outcome, hypotheses and etc.

It’s very important to revise your Introduction by using Intro checklist which should contain the following questions:

- why research needed to be done?
- why you used those methods?
- are the health problem and its importance clear?
- is GAP - HOWEVER statement explicit and in right place?
- is narrative flow clear with “THEREFORE statement” following logically?
- does the flow lead reader to Methods section? [5].

After your Introduction has passed the checklist successfully, you may start “Methods” section.

Methods: According to Caren Solomon [3], this section may be the longest one: appr. 4-5 sheets of the whole 15 in average, or $\pm 30\%$. Donald Halstead [5] in his lecture speaks the same and advises to make it as concise as possible. Methods section should consist of the following paragraphs:

- study design
- criteria for and methods of subject selection
- description and number of subjects
- measurement methods and data collection techniques
- data analysis procedures.

As a matter of fact, this section should contain the algorithm PICOT which facilitates formulation of clinical issue (Patient; Intervention; Comparison; Outcome; Time). This part of work should begin by describing the subjects, including how many, what criteria were used to recruit them, how were they assigned to groups. Moreover, most journals require a statement

documenting that subjects read and signed an “Informed consent form” and the appropriate committees approved the project (IRB – Institutional Review Board). It’s necessary for any study in order to respect important ethical principles according to Human rights. The section continues with a description of equipment and data collection procedures, presented in chronological order so that the reader can follow the procedural flow of the project (Intervention part, strictly speaking). It’s mandatory to supply this section with Operational definitions for all variables, so that **any other researcher could replicate the data collection procedures easily** (very important point). It would be relevant to develop a written protocol for this purpose. It’s very pertinent also to summarize some variables in a table or diagram in order to shorten verbal component of the work. Photographs of a unique procedural setup would be the best solution in this direction.

In the whole, the Methods section purpose is to demonstrate *how* you investigated the GAP/unknown. Papers are mostly rejected namely because of errors or lack of clarity in writing up this section.

Results: This section is not less important than previous one, and fully dedicated to show what you found (letter “O” from PICOT). Remember, report of results only, without any long comments or explanations, which will take their place in the next section. The outcomes of statistical tests must be included to demonstrate or support the statement of results. Although the inclusion of calculated values, degrees of freedom, and the significance level is important, but this section should emphasize the variables of interest rather than just statistics. Two major principles should guide the structure of the Results section:

1) Tables and figures should not duplicate the narrative portion of the section. It means, any reader should be able to understand the results without referring to the tables and should be able to understand the tables without referring to the text.

2) Authors should not discuss the results in this section (4).

In relation graphs, photographs, diagrams, tables any author must remember that their superfluous number could entirely complicate understanding of the work. In average, no more than 3-4 tables or graphs are assumed as pertinent, except some specific cases.

Assessment: This part implies assessment of the results or methods and often being divided between two sections or relates fully to the Discussions or to the implied section. Practically the section is not being mentioned in the IMPAD.

Discussions: The Discussion section is the heart of a research report [4]. This is a part of the paper, where author can express opinions. The author should comment on the importance of the results, limitations of the study, suggestions of the future research and clinical implications.

The section must include the following paragraphs:

- interpretation of statistical outcomes
- discussion of clinical significance of outcomes
- importance of the work
- comparison of results with works of others
- how results support or conflict with theory
- critique of the study limitations and strengths
- suggestions for further study.

According to Donald Halstead [5], the section consists of three steps of Inductive Discussion Pathway:

Step 1: *Findings and Evidence.*

It’s recommended to begin by summarizing main findings and answering research question which has been formulated in the GAP (Introduction section). It’s desirably to set a new baseline for the Discussion in order to avoid repeating previous content (research question, methods, significance, etc). In this step we can interpret our main findings by claiming what we think they mean.

Step 2: *Put your study in perspective.*

Compare your findings to most pertinent literature, accounting fairly for differences. State any unexpected findings, if any, including any surprising hypotheses or models from your findings. Turn the critical lens on your own work and identify key limitations that could be threats to validity of your results. Consider your study design: what other explanations might there be for your results? Take into consideration possible inadequate blinding, selection bias, recall bias, loss to follow-up, low response rate, unmeasured confounders and etc. What we can do for that? Address and resolve probability for bias.

Step 3: *Generalizability, Significance, Implications, Conclude.* The following questions must be answered in this step:

What are the implications of the work? How generalizable the findings are and what is their significance for research and practice?

Conclusions need to be very carefully worded and indicate levels of certainty and generalizability. Recommendations for further study or discussions of clinical implications must be thoroughly evidence-based. Paper should be ended with justifiable

conclusions with reminding the importance of the project for people's health.

Writing style, being one of the main tool for attraction of reader's attention, is crucial for any paper. Researchers should not rely only on the scientific content of their work, if they want their articles to have been read and cited by colleagues.

With regards to the topic on writing style, it would be relevant to cite a witty article of Dr. Paul W. Merrill "Principles of poor writing": "To do a consistently poor job, however, one must grasp a few essential principles:

1. Ignore the reader.
2. Be verbose, vague, and pompous.
3. Do not revise" [6].

Conversely, Donald Halstead, Instructor and Director of Writing Programs of Harvard School of Public Health, in his Lecture for PCR students, offered Four Main Principles for writing English clearly and concisely[5]:

1 Principle: Focus on actors and actions.

In other words, clear sentences should focus on actors-action. To do that, one should place main actor (what sentence is about: grammatical subject) in topic position, and the "topic position" comes at the start of any "discourse unit". For example:

- A woman who is infected at least one of the HPV genotypes, has an increased risk of cervical cancer.
- The risk of developing cervical cancer increases in a woman who is infected at least one of the HPV genotypes.

Whose story is it?

So, follow the 1-st Principle, and you will find, which sentence is more relevant.

2 Principle: Avoid unwanted nominalizations.

For instance, compare this: "We conducted an examination of..." instead "We examined..." Which sentence sounds better? Undoubtedly, second option looks much more attractive because of its brief essence. Even the most difficult topics which have been described in the article, should not seem cumbersome.

So, be pertinently laconic!

3 Principle: Prefer Active to Passive voice.

We can easily observe that using of passive voice is the most frequent mistake in scientific papers. Actually, a sentence written in active voice is more powerful and concrete, and on the contrary, passive voice tends to make sentences ponderous. Besides, passive voice often creates too many prepositions. But scientific writing has special nuances, and sometimes emphasis becomes a crucial factor. Passive voice may be appropriate when the subject of the sentence is unimportant or the object or action should be emphasized.

One important point is worth to be discussed – the use of first - person active voice. Nowadays the use of active voice is found to be more acceptable. Nonetheless, researchers should avoid overuse of "we", for it can be quite intrusive.

So, use active voice, but without overuse, and remember about strong features of passive voice, especially when proper emphasis to be needed!

4 Principle: Information flows best from old-new, simple-complex, short-long, known-unknown.

In other words, start with familiar topic information first, then introduce new, complex info. By Donald Halstead, writers should understand that when they begin sentences with unfamiliar and complex information, they force readers to do the extra cognitive work of mentally reconfiguring the sentence. When the new and complex info is placed at the end, it's easier for readers to digest it there. To improve flow, link the new information at end of one sentence to the beginning of the next.

So, revise written text for flow for several times to make it as easier to understand as possible.

Finally, there is the most important principle for all writers – Our patients are people first! It means we have to respect this basic human issue in all our publications. It would be preferable to say "children with learning disabilities" instead of "learning-disabled children". Emphasis to people-first language implies an underlying respect to our patients.

There are some examples of using more simple words instead of cumbersome expressions:

accounted by the fact that = because

are of the same opinion = agree

as a consequence of = because

at the present moment = now

due to the fact that = because

during the time that = while

if conditions are such that = if

in (my, our) opinion it is not an unjustifiable assumption that = (I, we) think

in close proximity to = near

it has been reported by Jones = Jones has reported.

A few words about Authorship:

Authorship has historically been one of the most significant indicator of any researcher's professional success, and includes the following issues:

- Disputes on authorship on rise - the earlier the better;
- Honorary or guest authorship is unacceptable;
- Ghostwriting is illegal;
- Failure to recognize responsibilities of authorship is the most frequent problem.

Here are recommendations for authors on a regulatory basis (from ICMJE – International Committee of Medical Journal Editors):

- 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.
- When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript.
- Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.
- 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 [7].

Conclusions: the work is developed with didactic purpose for young researchers to help them to avoid rejection of their papers by editors and related disappointments.

According to Caren Solomon, Chief-editor of the NEJM, initial rejection of all sent papers happens in 60.5 %, and reject after peer-review happens in 33.8 %. It would be logically to assume unhappy destiny of the rest 6.7 %.

The article is written on the basis of Harvard lectures' materials and reminds necessity of multiple revision of the work before sending it to editors. Strict following the main principles of Manuscript writing should help to any researcher to become a good writer. These parts of the same work are not divisible.

Application 1:

TIPS FOR AUTHORS (by Caren Solomon, Chief-editor of the "New England Journal of Medicine") [3].

1. The likelihood of publication (where you would like) relates to:

- The question you set out to study
- The study methodology (design, data collection, analysis...)
- How you present your findings

2. Starting to Write: Timing

- Avoid waiting for all the data to be in and analyzed!
- Start early with Introduction and Methods
- Plan major tables/figures; prepare these once data available, followed by text of Results, Discussion, Abstract

3. General guidelines

Length – Target 15 pages or less

- Titlepage (1)
- Abstract (1)
- Introduction (1)
- Methods (~4-5)
- Results (~3)
- Discussion (~3-4)

Be concise; avoid jargon

Introduction

- Summarize briefly key background information that makes the study question important
- Final sentence(s) should make clear the aim(s) of your study
- Usual length no more than a page (+/-)

Methods

Include clear description of:

- Primary and secondary aims (Should be clearly distinguished from post-hoc hypotheses)
- Study design
- Subjects (inclusion/exclusion criteria)
- Exposures and outcomes
- How data collected (including details of assays where relevant)
- Statistical analyses (tests used; criteria for statistical significance; power/sample size calculation)
- Include statement the IRB approval and informed consent.
- For industry sponsored trials, need to be clear the role of industry. Note who (company versus non-industry authors) designed the study, collected the data, held and analyzed the data, wrote the manuscript, controlled the decision to publish; indicate explicitly whether investigators had full access to the data

Results

- Think through which results are critical to show in detail
- Present all relevant results in the results section
- Use tables and figures to summarize findings
- Include a table with subject characteristics (“Table 1”)
- Make clear main findings in the text, with reference to the tables and figures

Discussion

- Start by summarizing your main findings (1 paragraph)
- Put findings in context of relevant prior work (briefly..)
- Post-hoc findings should be acknowledged as such
- Address limitations
possible confounding or bias, small study or short follow up; limited power for certain analyses; etc.. *Where possible, note available data to suggest these are not major flaws...*

- Comment on implications (but avoid excessive speculation)
- Conclude with concise summary

Abstract

- Background –why you did the study (1-2 sentences)
- Methods– brief summary of the study design, population, what was measured (2-3 sentences)
- Results- Summarize major findings, with numbers/p values (3-4 sentences)
- Conclusions- Major take home point(s) (1 sentence)
- Overall <=250 words

3. Preparing for Submission

- Identify appropriate journal
- Follow instructions for authors
- All authors must meet criteria for authorship and must have signed off on manuscript
- Make editors aware/provide copies of related publications
- Address potential “conflicts of interest”

4. Criteria for Authorship (ICMJE)

- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Authorship (eg who will be one, and who will be senior author.) should be addressed as early as possible in the project
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article.
- Authorship based on:
 - 1) Substantial contributions to conception and design, or 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.Conditions 1, 2, and 3 must all be met.

Acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship

5. Redundant or Duplicate Publication (ICMJE)

- Definition: publication of a paper that overlaps substantially with one already published. NOT ok.
- The bases of this position are international copyright laws, ethical conduct, and cost-effective use of resources.
- Secondary publication ok only if:
- The authors have received approval from the editors of both journals.
- The priority of the primary publication is respected.
- The paper for secondary publication is intended for a different group of readers; an abbreviated version could be sufficient.
- The secondary version faithfully reflects the data and interpretations of the primary version.
- The footnote on the title page of the secondary version indicates that the paper has been published in whole or in part and states the primary reference

6. RevisionProcess

- Address all concerns of the reviewers and editors.
- Include a detailed cover letter noting each point made by editor/reviewers, followed by statement on how you dealt with it (include page number..)
- Show all co-authors revised version and give opportunity for further input.
- Aimtodoquickly

7. Summary

- Identify an interesting and focused question, for which positive or negative result of interest
- Enlist advice of others in study design
- Attend up front to feasibility, power, potential methodologic limitations
- Determineauthorshipearly
- Start writing early, and have others provide comments on drafts
- Aimforconciseandclear
- Target to appropriate journal, and be willing to revise and submit elsewhere[5].

Application 2:

Table 1 “Specific reporting guidelines” [2; 8-14]:

№	Specific reporting guidelines	Types of Study:
1	CONSORT	Randomized controlled trials
2	QUORUM	Metaanalyses; systematic reviews of randomized controlled trials
3	MOOSE	Metaanalyses; systematic reviews of observational studies
4	STARD	Studies of diagnostic accuracy
5	STROBE	Observational studies
6	STREGA	Genetic association studies
7	CARE	Case reports

The authors declare that they have no conflict of interest.

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РЕЗЮМЕ

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ОСНОВНЫЕ ПРИНЦИПЫ ПОДГОТОВКИ НАУЧНЫХ ПУБЛИКАЦИЙ В СООТВЕТСТВИИ СО СТАНДАРТАМИ ИЗ ГАРВАРДСКОЙ МЕДИЦИНСКОЙ ШКОЛЫ

Западно-Казахстанский государственный медицинский университет имени Марата Оспанова,
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Данная работа предназначена для молодых ученых, которые постоянно сталкиваются с множеством проблем в процессе написания статьи из-за незнания или игнорирования основных правил подготовки качественной научной публикации. Все разделы этой методологической статьи основываются главным образом на материале лекций Гарвардской Медицинской Школы для студентов он-лайн курса «Принципы и практика клинических исследований».

Изложение статьи руководствуется IMRAD – современным алгоритмом для соответствующего размещения всей отраженной в научной публикации информации – Введение, Методы, Результаты, Оценка результатов, Дискуссия, включая советы по стилю. Даны краткие рекомендации по урегулированию вопросов авторства на основе положений ICMJE (Международного Комитета Редакторов Медицинских Журналов).

В Приложении №1 даны «Советы для авторов» от Карен Соломон, главного редактора “New England Journal of Medicine”, журнала с одним из самых высоких импакт-факторов в мире медицинской периодики. Кроме того, в Приложении №2 даны названия конкретных руководств для надлежащего дизайна научной статьи в зависимости от типа исследования.

Надеемся, что данная статья поможет молодым исследователям в аранжировке их научных работ в соответствии с Гарвардскими стандартами подготовки рукописей к публикации.

Ключевые слова:

Написание рукописи; научная публикация; рецензируемые журналы; издание; исследовательский дизайн; исследовательская методология.

ТҮЙІН

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ГАРВАРД МЕДИЦИНА МЕКТЕБІНІҢ СТАНДАРТТАРЫНА СӘЙКЕС ҒЫЛЫМИ ЖАРИЯЛАНЫМДАР ДАЙЫНДАУДЫҢ НЕГІЗГІ ҰСТАНЫМДАРЫ

Марат Оспанов атындағы Батыс Қазақстан мемлекеттік медицина университеті,
Киото университетінің жоғарғы медициналық мектебі,
Рибейран-Претудағы Сан-Паулу университетінің медициналық мектебі

Бұл жұмыс мақала жазу кезінде сапалы ғылыми жарияланымдарды дайындаудың негізгі ережелерін білмегендіктен және мән бермегендіктен үнемі қиындықтарға ұшырап отыратын жас ғалымдарға арналған. Осы әдістемелік мақаланың барлық тараулары «Клиникалық зерттеудің ұстанымдары және тәжірибесі» он-лайн курстың студенттеріне арналған Гарвард медициналық мектебінің дәрістерінде негізделеді.

Мақаланың мазмұны ғылыми жарияланымда жинақы ақпарат - Кіріспе, Әдістер, Нәтижелер, Нәтиженің сарапшылығы, Талас-тартыс, мақам туралы ақыл-кеңестерді ішіне ала - лайықты орналастыру үшін IMRAD аталған заманауи алгоритм ережелеріне сәйкес келтірілген. ICMJE(Медициналық журналдардың редакторларының халықаралық комитеті) жағдайларының негіздемесінде авторлықтың сұрағының тәртіптеуіне қысқа ұсыныстар берілді.

Әлем медициналық басылымдарының ең жоғарғы импакт-факторлы “New England Journal of Medicine” журналының №1 қосымшасында бас редактор Карен Соломонның «Авторларға арналған кеңестері» берілді. Сонымен қатар, №2 қосымшасында зерттеу түрлеріне қарай ғылыми мақалаларды тиісінше көркемдеуге нақты басшылықтардың атаулары берілді.

Аталмыш мақала жас зерттеушілерге өздерінің ғылыми жұмыстарын әрлеуде Гарвард стандарттарына сәйкес басылымға қолжазбалар дайындауға көмектеседі деп үміттенеміз.

Негізгі сөздер:

Қолжазбаны дайындау; ғылыми жарияланым; пікірсараптан өткізілетін журналдар; басылым; зерттеу дизайны; зерттеу әдістемесі.