

A “how-to” guide for effectively writing a publishable research manuscript

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Abstract

Nuances for preparing a publishable manuscript in an efficient and productive manner are often learned experientially and over many years. The purpose of this “how-to” guide is to assist new practitioner pharmacists, as well as pharmacy residents and students, with effectively writing a research manuscript for publication. General considerations for scientific writing are presented, including target journal selection; the intentional process of writing fast, bad, and wrong; editing with a focus; and methods to convey messages in the most unambiguous and accurate ways possible. Then elements and nuances to writing the common manuscript sections (ie, introduction, methods, results, discussion, conclusion, and abstract) are elucidated. Finally, guidance on documents that accompany a manuscript (ie, cover letter and response to reviewer comments) is provided.

KEYWORDS

manuscript, pharmacist, research, writing

Clinical pharmacists bring distinct and unique perspectives to clinical research because of their expertise in various aspects of pharmacology and pharmacotherapy.¹ Despite the challenges associated with performing clinical research, most health-system pharmacists have participated in these activities.² While most hospitals and health systems do not require their clinical pharmacists to have a minimal level of involvement in clinical research, most pharmacy faculty members are expected to publish original research to varying degrees based on their school of pharmacy, time and effort allocation, and tenure status.^{3,4} Furthermore, completing a clinical research and/or quality improvement project is a requirement of any American Society of Health-System Pharmacists accredited residency program.⁵ This requirement exposes many clinical pharmacists to the process during their training as a resident and then subsequently as preceptors and/or mentors to residents for this learning experience.

Common barriers to participating in and publishing clinical research as identified by pharmacists and pharmacy residents include a lack of time, minimal research experience or mentorship, minimal support from their employer, and inadequate communication with team members (most commonly past residents).^{2,6,7} Additionally, the primary means for performing research for most health-system pharmacists are single-center, prospective or retrospective, observational, cohort studies with student and/or resident co-investigators.^{2,8} This is likely because this

research is more feasible to complete compared with more complex study designs. Furthermore, pharmacist research mentors and colleagues may have previous experiences with these types of study designs.^{2,6,9} Unfortunately, publication rates for resident research projects are between 3 and 36% and pharmacy faculty members may publish as few as 0.51 to 0.82 peer-reviewed articles per year.^{4,6,10-13} Because journal editors consistently receive far more submissions than they are able to accept for publication,¹⁴ junior researchers may feel discouraged to submit their original research to a desired journal for fear of rejection and misallocating the time associated with the eventual editorial decision. Nuances for preparing a publishable manuscript in an efficient and productive manner are often learned experientially and over many years. The purpose of this “how-to” guide is to assist new practitioner pharmacists, as well as pharmacy residents and students, with effectively writing a research manuscript for publication.

1 | GENERAL CONSIDERATIONS FOR SCIENTIFIC WRITING

The first step in scientific writing occurs before the writing has commenced. The research team should determine the target journal, and

preferably at least one backup journal, prior to preparing any aspect of the manuscript. Common strategies for identifying target journals include consulting with more experienced researchers, reflecting on journals that have published similar content (ie, retrospective observational studies with a similar sample size and rigor in their study methods), and electronic lists of peer-reviewed journals.¹⁵ It is often beneficial to prepare the initial submission for a journal that would be a “realistic stretch” to publish in, based on variables such as rejection rate (eg, realistic stretch journal, 80% vs more attainable journal, 50%) and impact factor (often 3-10 times as high for the realistic stretch journal). A common, unwritten adage espoused by many researchers is, “If your manuscript is accepted to the first journal to which you submitted it, you probably did not aim high enough.” Almost all peer review provided for a manuscript is extremely valuable, and many of the journals that may constitute a target for initial submission are rife with competent and thoughtful reviewers who are focused on promoting and developing good science. The feedback provided by these reviewers may yield insights and promote professional growth that will develop the authors into more confident and competent researchers. Selection of the initial target journals will allow the team to ensure that specific author instructions regarding content, formatting, and word count are incorporated into the writing process. Additionally, the chosen journal for submission will have a specific audience and scope to which the authors should tailor their submission. Reading published articles in the chosen journal may help the authors better identify aspects of successful submissions (eg, sentence and paragraph structure, tone, methods, and content) that can be incorporated into their manuscript.

Once the authors are ready to begin the writing process, we recommend the primary author write “Fast, Bad, and wRong” (FBR).^{16,17} The hallmarks of this process are an intentional focus on writing in phases that helps the author to focus his or her energies on a particular aspect of the writing process in a non-judgmental and optimistic manner. When one expects his or her initial manuscript drafts to possess a quality of refinement of thought and an execution of focus and flow that bears any resemblance to published articles, expectations are likely set too high and may negatively affect efficiency and confidence in and desire for writing.¹⁷ At its core, this strategy focuses on the primary author writing quickly and all members of the research team editing slowly. At every stage of the process, do not let “perfect be the enemy of very good.”¹⁷ When using the FBR approach in medical writing, we first recommend that the primary author prepare a detailed outline of the proposed manuscript with references included. All members of the research team should discuss this outline and make edits with a focus on clarity of thought, logical flow, and connecting the specific findings of the research into a cohesive big picture. After this outline has been refined, the primary author should write a first draft quickly (often called a “down draft” because the intention is to get ideas down on paper) without regard to the quality of the writing. At this stage, the writer should not get hung up on the labor intensive and focus-diminishing task of preparing formal citations for reference articles. Incorporate citations using a consistent, short-hand nomenclature that allows you to save time and maintain focus and clarity of thought while writing and facilitates being able to go back to enter formal citations

once the final draft is completed (eg, Last Name Journal Year - Hammond JACCP 2019). Eventually, references will be added. We recommend free software platforms for referencing that are online and easy to use (eg, Zotero®, Mendeley®). The focus at this stage is of getting ideas on paper in a logical manner that provides a document that can be edited to become very good. After this “down draft” is prepared in full, the primary author should execute the first round of initial edits due to familiarity with the thought process during the initial writing and as a common courtesy to co-authors in respect of their time. The second and subsequent drafts are often called the “up drafts” because the intention is to fix up the manuscript so that it begins to resemble a publishable product. These second and subsequent drafts will then go through a process of editing by co-authors, incorporation of these edits into a refined manuscript by the primary author, editing by the primary author, and then presentation of the next draft to co-authors for their edits. The senior author should shoulder the bulk of the initial editing responsibility, reviewing each draft first prior to other co-authors, because he or she is likely the most knowledgeable on this topic of the research team and is guiding the research process. Once all authors believe the manuscript is “good enough” (remember, do not let perfect be the enemy of very good) to submit to a journal, we recommend that submission be completed. Conversations with other researchers have identified that too many manuscripts remain unpublished because one or more authors believe additional, minor edits can be incorporated into subsequent drafts. As long as there are no ethical concerns with a manuscript, we recommend allowing external peer-reviewers for a peer-reviewed journal to provide their thoughts at this stage of the process.

The standard, unwritten rules for medical writing hold true for preparing most manuscripts for publication. The writer's intentions should be to convey messages in the most unambiguous and accurate ways possible. One way to accomplish this is to write simple sentences that use minimal commas (eg, 0-1 when not including a list). This will force the writer to convey single points in a succinct manner and build upon previous points with logical flow and transition words. Additionally, avoid using first- or second-person pronouns (eg, I, we, and you), passive voice, and unnecessarily fancy words when a more common and easily understood word would suffice.¹⁷ Readers who are constantly re-reading sentences or refreshing themselves on the definition of uncommon words are more likely to miss the intentions of a passage or stop reading your article. If this reader is a reviewer, their recommendation to reject or accept your publication may be influenced. If the manuscript has been published, then your reader may not gain the necessary insight into the topic to apply your work to his or her practice. Additionally, almost all sections of the manuscript should be written in the past tense. Exceptions may include the introduction, discussion, and conclusion sections when the current state of affairs or thoughts on future practice is being described. Writing in all sections should be intentional with a focus on crafting a streamlined narrative. The introduction begins this narrative with “why this topic and research matters.” The methods and results continue this narrative with “how we did the research” and “the uneditorialized findings of the research.” The discussion and conclusion bring the narrative to a close with “how to interpret this research in light of other research on this topic.” Most study designs have specific guidance for necessary

information to include. For example, for observational studies, authors may craft each individual manuscript section upon this framework of general concepts for manuscript writing to develop a final product that addresses all recommended content areas from the "Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies in a focused manner."¹⁸

2 | GUIDANCE ON MANUSCRIPT STRUCTURE

2.1 | Introduction

A concise, focused introduction section for most studies is often between 250-500 words.^{19,20} (Table 1) Though many investigators will be tempted to use the introduction or data summary section from their Institutional Review Board submission as the introduction for the final manuscript, most investigators will discover that their

thoughts on the research topic have become more refined during the research process and this initial draft is likely too lengthy, unfocused, or does not convey the exact message needed to begin their research. We recommend outlining and then writing the introduction anew after data analysis has been performed. Key concepts that will be a focus of the discussion can be alluded to/briefly introduced in the introduction; however, these key concepts will not be apparent until the entire manuscript has been outlined.

A common strategy for formatting the introduction section is to consider it in three subsections or paragraphs. In the first paragraph, give context to the general topic or issue. Bring the reader up to speed on why the topic is important with a goal of making the reader care about the topic. This may be accomplished by beginning with mortality and/or morbidity data and transitioning into cost data, quality of life data, and any other data that can instill a desire to see an answer to the research topic. Guideline recommendations and/or society or government-focused initiatives may be described briefly. The first paragraph should crescendo to a key transition that makes

TABLE 1 Guidance on manuscript structure

Section	Word count (percentage of manuscript)	Predominant verb tense	Usual references	Order of outline preparation	Order of writing	Comments
Introduction	250–500 words (10–20%)	Past and present	8–16	Third	First	- Often 3 paragraphs - Content progresses from general to moderately specific overview to highly specific purpose statement
Methods	350–750 words (15–30%)	Past	0–5	First	Second	- Often 4 paragraphs - Enough detail to replicate is necessary
Results	250–500 words (10–20%)	Past	0	Second	Third	- Often 3–4 paragraphs - Leverage use of tables and figures to highlight findings and spare words in main text - Do not editorialize
Discussion	750–1500 words (30–60%)	Past and present	8–30	Fourth	Fourth	- Often 5–8 paragraphs - Discuss 3–5 key findings and identify their importance in the context of patient care - Present limitations in an authentic, structured manner
Conclusion	<100 words (1–5%)	Past	0	Fifth	Fifth	- Often 1 paragraph - Provide readers with a citable statement
Abstract	200–300 words (not applicable)	Past	0	Sixth	Sixth	Developed from the most relevant language in the main text
Cover Letter	Not applicable (not applicable)	Past and future progressive	0	Seventh	Seventh	- Often 2–4 paragraphs - Present the most compelling findings to the journal's target audience
Response To Reviewers	Not applicable (not applicable)	Not applicable	To be determined	Not applicable	Not applicable	- Respond to each comment with a thoughtful response - Identify exact changes to the text in the response

reader say, "This topic matters; what have people done to try to address this?" In the second paragraph, create a knowledge gap by making clear what is known and what is unknown to date on a more specific subset of the research area that relates to your specific research topic. The goal is to instill the reader with a curiosity about what is missing in this area of research. Briefly summarize findings from relevant previous literature into a high-level overview while saving the more nuanced details for the discussion section. Highlight areas where the data are unclear or unavailable to heighten this curiosity. The second paragraph should leave the reader thinking, "People have tried to resolve this, and I see a next logical step." Finally, in the third paragraph, preview your research plan by building up to a statement for how this study will fill the established knowledge gap by connecting the knowledge gap(s) to your study purpose. End with a purpose statement (eg, "the purpose of this research was to..."). This paragraph should leave the reader with no doubts regarding this research as the next logical step in resolving the research topic at hand.

2.2 | Methods

A concise, focused methods section is often between 350-750 words.^{21,22} Many junior investigators may falsely believe this section is the easiest section to write; however, the challenge of presenting adequate detail that would allow another competent researcher to reproduce your work at their institution while providing all relevant information and avoiding the tendency to explain ad nauseum is not straightforward. Explain key definitions and outcomes with referenced materials whenever possible. Ensure all outcomes presented in results are mentioned in methods and vice versa. Methodological decisions that could be controversial need to have cited reason(s). Finally, avoid presenting any data in this section. This section is the recipe for the meal so no sampling of the dishes is allowed.

A common strategy for formatting the methods section is to consider it in four subsections or paragraphs. The first paragraph introduces the study design and setting (eg, "This was an observational cohort study performed at a single tertiary care center with X beds of which Y are intensive care unit beds..."). Any policies, procedures, or protocols that are relevant to the care study patients received may be mentioned in this paragraph. The second paragraph may be focused on qualities and characteristics of the patients. This is the paragraph in which the study inclusion and exclusion criteria may be presented as well as the study timeframe. The third paragraph may focus on study outcomes and data collection. All study outcomes should be presented with the primary outcome designated as such. If any subgroup analyses were performed, these should be listed as well. Definitions for any study variables that may be controversial or essential to comprehending the study should be provided and appropriately referenced. The fourth paragraph may focus on data analyses that will be performed. List the manners in which the data will be described (eg, means, standard deviations, percentages, etc.), the tests that will be performed for each type of data (eg, "nominal variables will be compared using Chi-square tests"), and if any tests will be performed

to determine normalcy of data (eg, "Shapiro-Wilkes tests were performed and skewness and/or Kurtosis were evaluated"). If any regression analyses were performed, describe how candidate variables were selected and entered into the model(s). As applicable, state if time-to-event analyses was performed for the primary outcome. Though the necessity of an a priori sample size calculation based on desired study power is controversial, most journals will expect this to be provided.¹⁴ Free, online resources are available to assist with this calculation.²³ A pilot study for which there are no reasonable prior data on which to base a sample size calculation and a sample of convenience is used may be acceptable for some journals. Finally, state that the research was approved by an institutional review board.

2.3 | Results

A concise, focused results section is often between 250 and 500 words (10-20% of manuscript length) exclusive of tables and figures.^{24,25} The presented information should proceed in a logical progression without editorializing. Point estimates and precision/confidence surrounding those estimates (eg, odds ratio 1.78, 95% confidence interval 1.04-2.56) tell a more robust story when available than presenting a probability alone (ie, will help readers remember information that can be incorporated into their knowledge base and compare and/or contrast to other research in the area). Tables and figures should be used to reduce the word count in the main text while presenting the most vital findings in a manner that is easier to digest, locate, and share with colleagues than the written word.²⁶⁻²⁸ Avoid significant duplication of information in text and tables/figures. Ideally, blank shells of the tables that were developed prior to beginning the research can be adapted and then filled in with the study results. Because many readers will review a study's tables and figures preferentially to other components of a manuscript, the utmost care should be given to these elements. Appropriate and clear titles and legends with only essential acronyms should be used. Additionally, grayscale is often the most cost-effective way to design figures because most journal have charges for color figures. The most appropriate ways to present data are usually two significant figures after the decimal for *P*-values and point estimates/variability in estimates (eg, odds ratio 1.78, 95% confidence interval 1.04-2.56, *P* = .024) and one significant figure after the decimal for descriptive data (eg, 69.6 years). Finally, additional results that exceed journal limits (eg, tables presenting results from subgroup analyses) should be provided in a supplemental Appendix S1.

A common strategy for formatting the results section is to consider it in three to four subsections or paragraphs. The first paragraph may present the basics of the study and its sample. The sample size and patients' allocation to study groups are most frequently provided in a figure alongside the reasons for study exclusion. The study exclusion information is an essential element that allows readers to determine the study's external validity and applicability to their patient population.^{24,25} Demographic information for the overall sample and/or study cohorts should be presented in full in a table. Key aspects of the demographics (eg, age, race, sex, etc.) should be

mentioned in the text with a focus on areas of difference between groups and overall as well as those that relate heavily to study outcomes. The second paragraph may present characteristics of the clinical care patients received, including variables that are compared between study groups. These characteristics are also frequently presented in a table. The intention of this paragraph is to assist the reader in appreciating the similarities and differences in the care patients received. Key aspects of the clinical characteristics may be presented within the text to avoid extensive duplication. The third paragraph is the ideal place to begin presenting study outcomes. If there are minimal outcomes, the primary and secondary analyses may be included in this paragraph. However, if the outcomes are extensive, then the third paragraph may be reserved for the primary outcome and other findings that relate directly to this outcome, such as a time-to-event analysis and/or a multivariable regression analysis for variables associated with occurrence of the primary outcome. The primary and secondary outcomes are frequently presented in a combined table. If the entirety of paragraph three was focused on the primary outcome and related advanced analyses, then paragraph four may focus on the secondary outcomes and any ancillary analyses. If the ancillary analyses are extensive (eg, propensity-score and/or regression analyses), they may be predominately presented in a table either within the manuscript or in a supplemental Appendix S1). Because study results are being presented without editorializing, the average number of references for the results section is zero.

2.4 | Discussion

A concise, focused discussion section is often between 750-1500 words (30-60% of manuscript length).^{29,30} The first paragraph is likely to be one of the most read paragraphs in the entire manuscript. As such, the authors should strive to grab the attention of the reader with a statement of the study's importance (eg, "This is the first study to...") and most important findings. This is the ideal place to begin describing the results of the primary outcome analysis in such a way that their relevance to the care of this patient population is evident. Other findings that will be most relevant to the care of patients in the study's population may be mentioned as well as the implications of these findings. All subsequent paragraphs in the discussion, other than one or two paragraphs that will be discussed in the next paragraph, are likely to be most impactful if they each focus on a key finding from this study, relate that key finding to other studies, and make suggestions on the implications of that finding on patient care. The authors should strive to leave the reader with three to five important nuggets of information from their research that can be incorporated into the reader's understanding of the study topic and/or patient care. Guide the readers to thoughtful interpretations of your study findings and their incorporation into patient care without overstating their impact or editorializing too much. A common method for accomplishing this is to begin a paragraph with a key finding from the study's results. Subsequent sentences may clarify or elaborate on the finding and relate the finding to ones observed in other studies. The final

sentence of the paragraph may suggest the impact of this finding on patient care and/or outline the next steps in future research to establish this impact. It is also imperative that findings that are unexpected, non-significant, or not in line with other study findings are not ignored or covered up in the discussion section. Help readers evaluate your research by explaining the biological, physiological, and/or statistical rationale behind findings and the cautions that must be considered. Additionally, match language for the results to confidence in the findings (ie, "may" or "might" when a finding has a wide confidence interval around a point estimate as compared with "demonstrate", "establish", and/or "suggest" when the confidence interval is narrow and unlikely to be due to chance alone). We also caution authors to avoid strongly causal language (eg, "prove") if they have performed a single-center, observational study because of the many inherent limitations in this design and instead to use softer language that describe correlations (eg, "associated").

The one or two paragraphs in the discussion section that will differ from the structure described previously pertain to: (a) the physiological basis of a study finding (often needed but not always essential) and, (b) a study's limitations. The paragraph on the physiological or pathophysiological rationale for a study result is often presented in a more descriptive manner with the threads of the logic woven in a stepwise manner to the final conclusion. The paragraph on study limitations is often presented as more of a complex interaction between study methods and determination of their impact on interpretation of study results. The limitations that are of the greatest benefit to readers are those that seamlessly move through the steps to provide the limitation, describe how the limitation was mitigated (if possible), and present the most likely effects of the limitation on the study results. If this paragraph is navigated well, readers will feel more confident with their interpretation of the study's findings and their place in patient care. An average number of references for the discussion section is 8 to 30.^{29,30}

2.5 | Conclusions

A concise, focused conclusions section is often less than 100 words. The authors may leave the readers with a citable statement and/or call to action for future research. The language of the citable statements should match the confidence in and strength of the study results with an emphasis on not overstating the significance of study findings. The focus in this short section is on the key takeaway(s) of the research and future directions.

2.6 | Abstract

We recommend preparing the abstract after the final draft for the main text of the manuscript has been completed.^{31,32} Leaving this section until the end allows the authors to fully understand the message of their manuscript prior to preparing this section. This will also allow for the authors to develop an abstract that can adapt the most

important and well-worded language from the main text into the abstract's highly abbreviated format. Most abstracts have a defined word limit (eg, 200-300 words) that requires a higher level of attention to detail with each word than the main text, although the author guidelines for the journal to which the article is being submitted should be consulted for specific requirements. This attention to detail is compounded because many readers will only read a study's abstract.³³ A structured abstract will often include a limited background and/or purpose section of a sentence or two that highlights the distinct need for this research to be conducted. The methods section presents the study design and main analyses performed. The results section is the longest section with main findings and many secondary findings being presented. Finally, the abstract ends with a conclusion section of a sentence or two.

3 | GUIDANCE ON DOCUMENTS THAT ACCOMPANY A MANUSCRIPT

3.1 | Cover letter

Although a cover letter is not required by all journals, its inclusion can only improve your submission if structured adequately. The cover letter is often a critical factor in an editor's decision for whether or not to send a manuscript to reviewers.³⁴ Articles that make it past an editor's desk to reviewers provide the authors with the opportunity to receive reviewers' comments that can improve their manuscript; this is a positive outcome with or without acceptance by the journal. A commonly employed framework to provide essential and compelling information to an editor in a succinct manner begins with introducing the project's relevance and importance in the first paragraph.³⁵ The second paragraph may begin with explaining key findings, which is often developed by blending elements of the abstract, first paragraph of the discussion section, and the conclusions section. The second paragraph may conclude by providing insight into how this submission is relevant to the particular journal to which it is being submitted and why their readership would benefit from reading this manuscript. We encourage authors to provide recommended reviewers in the cover letter if the journal's manuscript submission system does not prompt for these recommendations. These individuals do not need to be internationally recognized experts in the field but rather can be those who are familiar with the topic, possibly from past research experiences or presentation opportunities, and would encounter the information in their practice. The reviewers may include all pharmacists, though it may be of some benefit to identify a non-pharmacist or two if the journal to which the article is being submitted has an interdisciplinary readership. Because many journals rely heavily on reviewer suggestions, we recommend providing at least three reviewers to increase the likelihood that your manuscript is reviewed in a timely manner. The concluding paragraph is an appropriate place to include all required statements by the journal (eg, funding disclosures, authorship criteria met, where results were previously published in abstract form, and conflicts of interest) and thank the editor

for his or her time and consideration of the submission. A redacted example cover letter is available in the Supporting Information.

3.2 | Response to reviewer comments

An uninvited submission will almost never be accepted without revisions following the first submission.¹⁴ Consequently, the most favorable editorial decisions are the opportunity to respond to a request for minor or major revisions and resubmit a revised version of the manuscript. This response may begin by sincerely thanking the editor and reviewers for their efforts to improve the quality of the manuscript.³⁶ Then each of the reviewer's comments should be enumerated and addressed in order. This response may be formatted as a table or as a running narrative unless the journal has specific criteria for the format of a response to the reviewers' comments. Responses to each comment should at a minimum contain a thoughtful response to each component of the comment. Acknowledge the reviewer's insight when appropriate and reference the specific language added or removed from the text, table, or figure if changes have been made. This method allows reviewers to efficiently provide their second review and ensures that all points raised by the reviewers are acknowledged and the response is identifiable. Though making a change to the manuscript in response to most reviewer comments will be the most appropriate action, there will be situations in which a polite, tactful refusal to make all or part of a requested change is most appropriate. In these situations, it is essential to provide a rationale for the refusal and include any available references if the possibility that the refusal is controversial. Though a reviewer's tone may not always be as collegial as one would hope, the response should always remain gracious and non-argumentative. Remember, reviewers often receive no recognition or compensation for their services. An example response to reviewer comments is available in the Supporting Information.

4 | CONCLUSION

A semi-structured process for preparing a final, publishable manuscript has been presented. This guide serves to assist new practitioner pharmacists, as well as pharmacy residents and students, with effectively writing this type of research for publication. Following this process in an intentional manner may benefit junior investigators.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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