

An integrated approach to research and manuscript development

MARY ROEDERER, MACARY WECK MARCINIAK, SHANNA K. O'CONNOR, AND STEPHEN F. ECKEL

In his 1985 Harvey A. K. Whitney Award Lecture, Fred Eckel¹ described the advancement of the pharmacy profession and pharmacy practice as requiring “a renewed appreciation for the role of research—the quest for new knowledge and the development and evaluation of new services.” Almost 30 years later, pharmacists continue on this quest to document, through peer-reviewed literature, the successes, failures, and best practices of medication therapy and the pharmacy profession.

Despite the need for an expanding knowledge base about best approaches for patient care, only a few pharmacy school curricula include courses on how to plan, do, and write about research.² Graduates of schools of pharmacy who seek a pharmacy residency or fellowship are required to complete research projects, and many postgraduate programs require the generation of a manuscript that details the project prior to matriculation.³ Unfortunately, many of these projects do not result in publication

Purpose. A stepwise process for planning, writing, and submitting a research manuscript to a peer-reviewed journal is described.

Summary. The research project and writing-related activities should be conducted concurrently along a clear timeline developed with input from all members of the writing team. Issues of conformance to standards of scholarly publishing (e.g., ordering of the author list, contributor acknowledgments, disclosure statements) should be resolved and agreed on by all authors before manuscript development begins. After deciding on an appropriate hypothesis or research question, members of the writing team should meet to craft a detailed manuscript outline and identify a target journal. In addition to writing or coordinating the writing of the various manuscript sections, one designated team member (typically the lead, or primary, author) should be responsible for

ensuring consistency of data presentation and overall article cohesion. Before submitting the manuscript to a journal, the writing team should solicit internal and external review and feedback from colleagues with expertise in statistical analysis and the research topic. Once an article is accepted by a journal, the corresponding author has primary responsibility for communicating with editors and coordinating the team's response to peer reviewer concerns and requests for revisions.

Conclusion. The process of writing and securing journal acceptance of manuscripts should proceed along a well-defined pathway integrating all research and writing tasks. Close adherence to the target journal's instructions for authors and prompt response to reviewer comments help avoid delays in the publication of accepted articles.

Am J Health-Syst Pharm. 2013; 70:1211-8

in the peer-reviewed biomedical literature.^{4,5} When practitioners enter the work force, advancement in practice and obtaining recognition

from peers as an expert in a particular knowledge area often require the publication of research results in the peer-reviewed literature.

MARY ROEDERER, PHARM.D., BCPS, is Adjunct Assistant Professor, Division of Practice Advancement and Clinical Education, and Institute for Pharmacogenomics and Individualized Therapy, UNC Eshelman School of Pharmacy, University of North Carolina (UNC) at Chapel Hill, Chapel Hill, NC. MACARY WECK MARCINIAK, PHARM.D., BCACP, BCPS, FAPHA, is Clinical Associate Professor, Postgraduate Year 2 Community Pharmacy/Academia Residency Program Director, and Postgraduate Year 1 Community Pharmacy Residency Program Assistant Director, Division of Practice Advancement and Clinical Education, UNC Eshelman School of Pharmacy. SHANNA K. O'CONNOR, PHARM.D., BCPS, is Faculty Fellow, Kelley-Ross Pharmacy, and Assistant Professor, School of Pharmacy, University of Washington, Seattle; at the time of writing, she was Visiting Professor, UNC Eshelman School of Pharmacy. STEPHEN

F. ECKEL, PHARM.D., M.H.A., BCPS, FASHP, FAPHA, is Clinical Associate Professor and Vice Chair, Division of Practice Advancement and Clinical Education, UNC Eshelman School of Pharmacy, and Associate Director of Pharmacy and Director of Residency Programs, UNC Hospitals.

Address correspondence to Dr. Marciniak at the UNC Eshelman School of Pharmacy, University of North Carolina at Chapel Hill, 115 Beard Hall, Campus Box 7575, Chapel Hill, NC 27599 (macarymarciniak@unc.edu).

The authors have declared no potential conflicts of interest.

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To encourage professional publishing, collaborations among pharmacy researchers are often developed through practice-based research networks.⁶⁻⁸ Also, the website of the American Society of Health-System Pharmacists Research and Education Foundation highlights key articles and online tools for completing successful research projects.⁹⁻¹³ Several pharmacy organizations have created daylong or weeklong conferences and even yearlong programs to educate practitioners about completing research.^{14,15} However, many pharmacy learners and practitioners lack the time and resources to attend seminars and other educational programs. The purpose of this article is to describe a pathway of basic steps to expedite the process of developing a research manuscript and securing its acceptance for publication in the peer-reviewed literature.

The planning stage

Creating an article development timeline. The writing of the manuscript should begin in tandem with the development of the research plan. Specific aspects of developing a

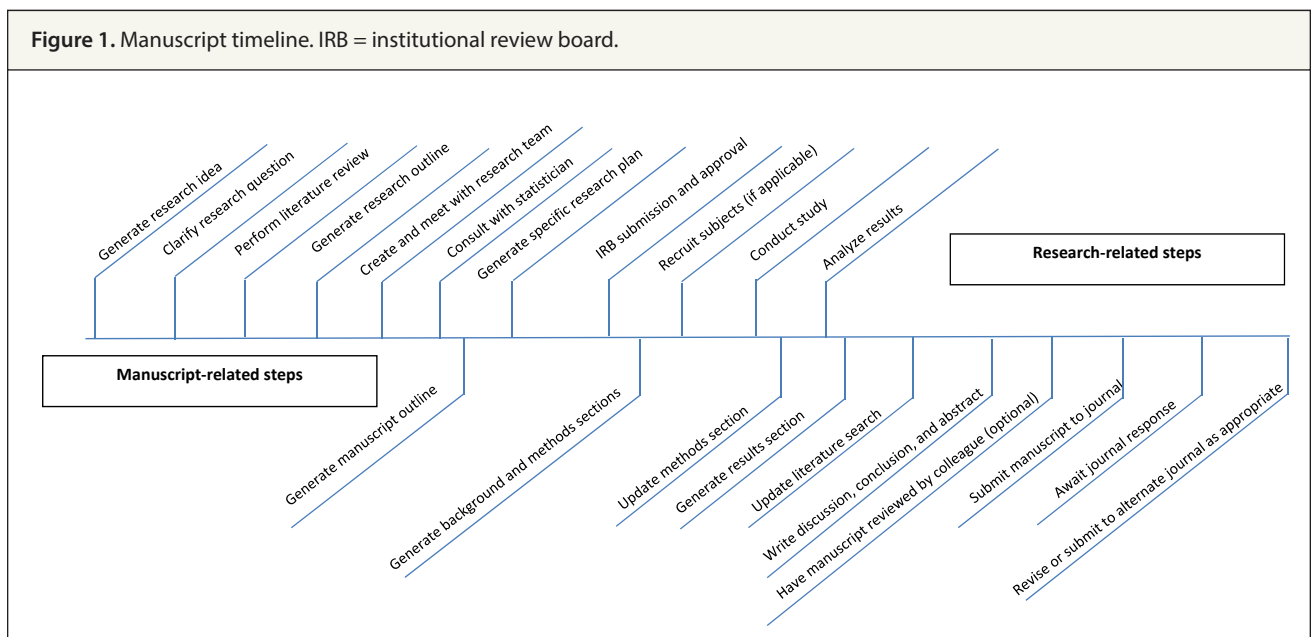
research project, such as identifying a research question, defining the null hypothesis, and obtaining institutional review board (IRB) approval, are addressed elsewhere and are beyond the scope of this paper.^{9,12,16} However, the stages of manuscript writing can be integrated with the various stages of the research project along a comprehensive timeline (Figure 1). For example, the methods section of the IRB application or study protocol will be fairly similar to the methods section of your manuscript.^{11,17} Therefore, once the IRB has approved the study, the application materials provide a foundation for beginning the work of writing the manuscript.

Convening the manuscript team. It is likely that many of the individuals who constitute the research team will also serve on the manuscript writing team. In order to ensure that all prospective contributors are “on the same page” from the outset, it is helpful to arrange a meeting of the group. While many aspects of research and collaboration can be conducted online and via e-mail or document sharing, setting specific

meeting dates at key points along the manuscript development timeline can be a motivator for team members to accomplish specific tasks.^{11,18}

Determining authorship. Issues of conformance to accepted standards of scholarly publishing should be resolved early in the manuscript development process. The International Committee of Medical Journal Editors (ICMJE) has recommended criteria whereby authorship credit is 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.¹⁹ All persons listed as authors must meet all three criteria.

In most cases, all investigators will make major contributions to the research and the actual writing of the manuscript, as described by the ICMJE guidelines. However, in some instances, a more senior scientist or author may serve as a major editor rather than the writer of the first draft. Still, the senior author must have made a substantial impact on



the conception of the study, interpretation of the data, and final approval of the publication to be deemed an author according to the ICMJE criteria.^{19,20} In fact, many journals, beginning with *The Lancet* in the late 1990s, now require authors to sign a “contributory statement” regarding the submitted manuscript and the research contribution of each person involved.²¹ While some research team members may not meet the strict criteria for authorship, it is professionally appropriate to note significant contributions in the acknowledgment section of the manuscript.²²

The apportionment of writing duties and the ordering of the author list are other important issues best resolved early in the manuscript development process. Baerlocher et al.²³ proposed a schema for authorship order in which the primary, or first, author is the contributor who plans the study, executes the study, drafts the manuscript, ensures the accuracy of data, is able to explain all results, and fulfills the criteria for authorship. For novice writers, it may be helpful to identify a senior team member to serve as a writing mentor for the manuscript. The senior author, sometimes listed as the last author, assumes the same responsibilities as the primary author, with the exception of providing revisions to rather than the initial draft of the manuscript. Contributing authors (i.e., all authors listed between the primary and senior authors) remain responsible for fulfilling the ICMJE criteria of authorship.

There are various opinions regarding the ordering of author lists. In many journals, including the *American Journal of Health-System Pharmacy* (AJHP), it is customary to list the authors in descending order of contribution, from most involved to least involved²⁴; this would suggest that the senior author would be the second or third person listed depending on the extent of his or her

involvement in research and writing. When preparing the manuscript, it may be helpful to contact the target journal to determine if it has policies or recommendations on authorship and the appropriate ordering of the author list.

The research team should determine who will serve as the corresponding author for the manuscript. The corresponding author serves to communicate with the journal regarding publication decisions, revisions, and galley proof approvals and receives comments and questions from the scientific community. While the first author or a senior author often serves as the corresponding author, selecting a corresponding author with permanent contact information versus a trainee likely to change positions allows for other researchers and the journal to have a consistent contact person before, during, and after publication.

With authorship and order of authorship defined, it is helpful to obtain or verify author-specific information such as affiliations and contact information. In addition to contact information, each author should provide disclosures in preparation for eventual manuscript submission. Disclosures related to conflicts of interest are meant to clearly indicate if an author has a personal or financial relationship that may introduce bias into the research or manuscript.²¹ Failure to appropriately disclose any conflicts of interest may lead to postpublication problems. Journals now often require extensive information about each author, including name, title, address, e-mail address, disclosure of any potential conflicts of interest, and awarded grants and other funding sources.²⁵

It can be uncomfortable to initiate a discussion on authorship after the writing begins.²⁰ Therefore, it is best to be explicit about authorship (i.e., determine who will be listed as an author and ordering of the author

list) early in the research project and manuscript development.

Developing the manuscript outline. It is best to begin with a general, written outline for the manuscript. If (as is usually the case) the article will have more than one author, this outline serves to ensure that all participants are in agreement with how the paper will move forward while defining the responsibilities of each author. A timeline should be integrated into the manuscript outline.^{11,17} This timeline needs to be flexible given that unforeseen difficulties can arise, but it is extremely helpful in tracking the progress of the multiple components that comprise the manuscript. The timeline should clearly delineate deadlines for grants, abstract submissions, and conference presentations as well as for writing manuscript sections; in this way, the research team is kept on track and aware of the overall goal of the plan. Even if the research project or the manuscript is delayed by months, the timeline includes all major pieces, so that no area is neglected, forgotten, or delayed.

Each section of the manuscript outline should have subpoints to remind the authors of topics to cover and the general flow of the planned article. These subpoints are vital when a research project involves multiple authors. Obtaining the approval of the outline by the entire research team helps to prevent rewriting due to differing views regarding the intent of the article or the article flow.

Selecting a target journal. Early in the manuscript development process, the authors should identify the most appropriate journal to which to submit the final manuscript. The choice of journal relies on the content, professional focus, or educational focus of the manuscript. The key to journal selection is matching the research work to the aims and scope of the journal. It is helpful to review the aims of the journal as well as pub-

lished volumes or issues to determine if the submission is similar to previously published studies. For example, if your research is about pharmacy education and the journal's focus is pharmacy practice, a different journal may be a better choice. Although some journals do not encourage the practice, an author may consider e-mailing a journal's editors in advance to confirm their interest in a particular research topic or knowledge area. The primary author, with input from the research team or writing team, typically chooses a journal and assumes responsibility for ensuring that the manuscript is formatted according to the journal's author guidelines.

Decisions regarding article submission are often influenced by the "impact factor" of each journal under consideration by the writing team. A journal's impact factor is a mathematical representation, or quantification, of how often articles from the journal are referenced or cited over a period of time. For most journals, this information can be obtained from the online database Journal Citation Reports (Thomson Reuters, New York), which allows users to search for specific journals in key content areas.²⁶

The use and interpretation of impact factors are controversial, and the European Association of Science Editors recommends the cautious use of the information only as a measure of the relative influence of a journal—not of individual articles or researchers.²⁷ The impact factors of pharmacy-focused journals are generally in the range of 1.5 to 3.0, whereas those of major medical journals can be as high as 50. General guidance on interpreting impact factors is available at the *AJHP* website.²⁸

At times, authors may be less concerned about the journal impact factor when their priority is to present their research to an intended audience with the goal of changing practice. As an example, pharmacist researchers

who have conducted research that involved the care of geriatric patients may pursue publication of their work in a popular nursing-focused journal with a relatively low impact factor because they believe it is critical that nurses caring for this patient population learn about the research to improve care.

Other considerations when selecting a journal might include whether it is peer-reviewed, whether its articles are indexed in PubMed or MEDLINE, and whether the journal offers methods to increase the availability of the content (e.g., author podcasts, mobile access for smartphone users, ahead-of-print availability for important topics). When journal selection is difficult, consider consulting a medical librarian to formulate a plan for journal selection and manuscript preparation and rely on your most senior author for advice on the best journal.

Constructing the manuscript

The article title. Although the title of a research project manuscript can—and often is—changed when the results are incorporated, a title gives impetus to the writing process and reminds the authors that the end goal is the publication of a journal article. Generally, article titles should be concise, should not lead the reader to a biased conclusion, and should be informative regarding the nature of the research.²⁹

It is prudent to review the author guidelines of the target journal to ensure that a proposed title fits the requirements for publication; it can also be useful to evaluate the titles of other research articles published in the journal for general guidance.

The introduction. When writing a research manuscript, it is important to recognize that a formal (i.e., scientific) writing style should be used. Even though many authors might contribute to different sections, the entire manuscript needs to flow smoothly, as if only one person

were the author. A productive way to begin the manuscript is to complete the introduction (or background) and methods sections prior to initiating the research. With research that involves human subjects or animals, IRB approval is required. During the process of submitting a research plan to the IRB, the background and methods are assembled.¹¹ Many resources are available to enhance the research and manuscript writing process (appendix).

In situations where IRB approval is not required, writing the introduction and methods is helpful in ensuring that a sufficient literature review is conducted and a sound methodology is followed. A summary of the referenced articles that is written soon after the literature review is completed is much more accurate and detailed and requires less frequent revisiting of material than a summary written after data analysis is completed.

Brevity is valuable when writing the introduction. Although it may be tempting to offer a lengthy summary of the information known regarding a particular subject, such an introduction will be unwieldy and likely unacceptable to a journal's editors. In general, an exhaustive description of the disease, clinical problem, or other topic of interest may not be as useful as answering three simple questions: What is known? What is not known? What questions need to be answered? The introduction section should typically consist of one or two paragraphs that set the stage for posing the research question that will tell readers what is not known but needs to be known. From the presentation of the research question, the authors can move into the methods used to find the answer.

The methods section. The methods section should explain the research project with sufficient detail to enable a reader to understand exactly how the research was conducted. In essence, after reading the methods

section, the reader should be able to conduct the research. Depending on the study design, the use of a specific format for the methods section may be desirable; guidance is available at the National Library of Medicine website (appendix). The Equator Network website also provides a comprehensive listing of guidelines for reporting the methods and results from research studies, as well as many other online author resources.³⁰ The methods section should provide enough detail to ensure clarity but not overburden the reader with unnecessary technical jargon. Prior to journal submission, it is prudent to ask a colleague without intimate knowledge of the topic or area of study addressed in the article to review the methodology; the goal is to ensure that a nonexpert (i.e., someone not affiliated with the project) can understand the methods without requesting clarification.¹¹

In general, the methods section should include a description of the research population or participants, including inclusion and exclusion criteria, the materials used to conduct the research, the procedures followed during the research, and the plan for data analysis. If the protocol or aspects of the protocol are well established in research, it is appropriate to cite the description of the methodology from the literature; if a new protocol is used that is complicated or cumbersome, use of an appendix may be required. The authors should consider using a supplemental table or chart if complicated procedures are described. If the research describes human or animal subjects, a mention of the IRB approval process and adherence to ethical standards should be included in the methods section. Registration information on a publicly funded trial should also be included in this section.

The results section. As shown in Figure 1, the data analysis conducted as part of the research should be completed in tandem with the

results section. The findings from the analysis need to be shared with the research team to determine if the methodology, data selected, and statistical tests were correct, as conclusions drawn from the data will be determined from the analysis.

The results section should present the data without interpretation—just a factual recounting of the data analysis. This section is often supported by relevant tables and figures. The text will mainly describe the findings. The use of reporting guidelines to select the appropriate format and content of study results enhances the presentation of data and the likelihood of approval by journal peer reviewers³¹ (other resources are listed in the appendix). Many journals have a limit on the number of tables or figures that will be accepted, so it is essential to carefully select the data for inclusion. If data are not presented in tables or figures, that information should be discussed in the text. The reader will want to cross-reference information presented in the text, tables, and figures in order to fully understand the findings, so these elements should be complimentary without being duplicative. The investigators will need to determine the order in which the results are presented: chronologically or starting with the most important finding.³² Authors must guard against the urge to include statements of interpretation and opinion when describing the results; this type of information must be reserved for the discussion section.

The discussion section. Once the background, methods, and results sections of the manuscript have been written, the focus turns to crafting the discussion. In general, the discussion section should include three major components: (1) a summary of the major findings of the research, (2) the importance of the findings, particularly as they relate to previous research, and (3) future directions for research in the topic area.³³

The discussion may simply begin with the phrase “Our study showed that . . .” The study findings should then be briefly restated and interpreted for the audience. It is important to remember that the discussion of the results should be just that—a discussion—rather than a rephrasing of what was already presented in the results. This section can be used to link the results to the research question stated in the introduction.

When reviewing the major findings of a research project, it is important to place the results within the context of other pertinent studies. The discussion should answer one key question—“What do the findings mean?”—for the reader.³⁴ It should describe how the results of the study are similar to or different from those of previously published studies, and it should identify findings that are new or unique. Among other pitfalls to avoid, authors must not inappropriately try to generalize the results of a study beyond the constraints imposed by the study methodology and study population. Clearly highlighting how the project adds to the body of knowledge in the topic area may increase the likelihood of getting the manuscript accepted for publication.³⁵

It is equally important to address the strengths and limitations of the study and, as part of this subsection, note how the limitations may have affected the validity of the results. If there are changes in the study design that could be made to improve similar studies by other researchers, this can be stated as well.

The conclusion. Some journals require a conclusion section in addition to a discussion section. As the conclusion section will provide a succinct statement of the essential findings of the research project, it may be best to leave the writing of this section until all other parts of the manuscript have been finalized. A conclusion section should generally be a short (i.e., one- or two-sentence) paragraph that reemphasizes the

results found in the study and how these results apply to clinical practice; in some instances, a statement that calls on the reader to act based on the results may be appropriate. An author struggling with crafting the conclusion section might consider the following simple exercise: State the main results of the study aloud and then ask, “So what?” The brief response to this question can serve as the conclusion.

All statements and assertions in the conclusion section must be supported directly by data presented earlier in the manuscript.

Manuscript review

As a manuscript may be constructed over a period of months or even years, it is helpful to review it for cohesiveness and update references, if necessary, by repeating the original literature search. Once a first draft is completed, the manuscript should be sent to the entire research team for review. The previously established manuscript development timeline should be revisited at this point; if there were delays in research or writing tasks, a new timeline should be negotiated by the research team. All members of the research team should contribute ideas on the manuscript and have the opportunity to make suggestions for incorporation into the edited manuscript. Two goals of the editing process are to ensure a cohesive manuscript and to verify that all information included directly supports the researchers’ work in addressing the research question posed in the introduction. Furthermore, the editing process provides an opportunity to rectify differences in writing styles between different sections and ensure compliance with journal guidelines on syntax and usage (some journals specifically prohibit passive tense, for example).

It is also advisable to gain perspectives on the manuscript from colleagues not serving on the research

team. Among other strategies, the authors can request that a journal club or writing group reviews early drafts of the manuscript. As these individuals are not involved in the project at hand, they can provide new perspectives—a “fresh set of eyes”—to guide the process of final article revision. Essentially, a writing group can serve as an early form of peer review, and the feedback may help to enhance the article and the chances of its acceptance by the target journal.

It might be most efficient for one individual, perhaps the primary author, to take responsibility for making necessary manuscript edits and then recirculating the revised article to the research team for a second review.

The abstract. Many authors find it easier to write the abstract at the end of the manuscript writing process, when the final research results are available.³⁵ The abstract is typically formulated using information from each of the sections of the manuscript; thus, writing the abstract before the results and discussion are complete may not allow for the inclusion of all relevant information. It is essential to construct the abstract using the strict criteria for format and length provided by the target journal. Many journals require structured abstracts with specific headings and formatting. Most journals request that abstracts be fewer than 300 words, so brevity and clarity are key.

Selecting keywords. Author identification of keywords is requested by some journals to help with categorizing the article submission and determining appropriate reviewers. When selecting keywords, one method is to write one sentence describing the research. Take out the conjunctions and prepositions to generate a list of major concepts from your research, then search the Medical Subject Headings (MeSH) database in PubMed using these terms. MeSH headings often make good keywords because they are easily searchable

and have likely been used by other researchers.

Submitting the article

As mentioned above, selecting the target journal and reviewing the journal’s author guidelines with regard to length and formatting are important to increase the likelihood of article acceptance. Before the manuscript is submitted, the journal’s article submission checklist should be reviewed to ensure that the article is in conformance with all applicable guidelines and that the abstract, keywords, and author information are presented in the manner prescribed by the journal.³⁶⁻³⁸

One of the simplest steps to facilitate article acceptance is to follow the target journal’s instructions with regard to the formatting of reference citations. Consider using a reference management tool such as EndNote (Thomson Reuters) or RefWorks (RefWorks, Bethesda, MD), which allows for a quick change in the citation and bibliography format to match a journal’s unique criteria. Before submitting the manuscript, confirm that the journal will accept a reference manager-formatted version of the manuscript; if not, the manuscript should be converted to an unformatted document (both the formatted and deformatted versions should be saved to facilitate reference changes pursuant to editorial and peer review).

As one of the final steps leading to manuscript submission, it is wise to ensure that the list of articles referenced in the introduction and discussion sections is still complete and appropriate. In cases where originally planned research and writing timelines must be extended, new pertinent studies may have been published since the initial literature review. Although every study related to the subject need not be included, it is important that an unbiased and comprehensive picture of previously published studies is presented.

One major aspect of success in biomedical publishing is to avoid unnecessary delays in writing and editing that can render the information outdated and thus less enticing for a publisher. Executing research and writing tasks along an integrated timeline and completing both activities in tandem can help ensure that the information is timely and compelling.

After ensuring that all revisions have been explicitly approved by each author, it is time to submit the final product for review by the journal of interest. In addition to the manuscript itself, the submitter must be prepared to send the editors an abstract, a list of keywords (if applicable), author information, disclosure statements, and a cover letter. The letter is submitted by the corresponding author and includes a statement of how the manuscript fits within the journal's scope and a brief description of the research completed. Again, it is essential to follow the author guidelines and provide all requested submission materials so that the article can go into peer review as soon as possible.³⁶

At the time of article submission, suggestions for potential peer reviewers may be requested by the journal. In most cases, researchers with expertise in the topic area addressed by the article can be identified during the comprehensive literature search conducted in order to write the background section. If the information presented is novel or highly specialized or if prospective reviewers are otherwise not readily identifiable, the writing team should promptly inform the journal editors so that they may begin to make inquiries and identify appropriate peer reviewers. Conversely, when authors have personal or professional relationships with experts who might be considered to serve as reviewers, it is appropriate to inform the editors of any potential conflicts of interest. Relationships that may warrant the

avoidance of an expert as a reviewer may include not only those involving close friendship, a shared funding source, or prior research collaboration but also cases in which a person is known to the authors to be averse to or otherwise unsupportive of the thrust or scientific underpinnings of the research project.

One of the hardest parts of preparing and offering research for publication is waiting for an initial response by the journal's editors, which typically comes in two to three months. When the journal responds, the decision may range from unqualified acceptance (which is rare) to rejection.³⁹ Perhaps the most likely outcome is that the submission is accepted on the condition that revisions are made in response to the editors' and peer reviewers' specific concerns. Reviewing the list of proposed revisions and promptly addressing those concerns are key, as these tasks typically must occur within a narrow time frame to avoid delays in manuscript processing. Although authors do not have to agree with every reviewer comment or acquiesce to all requests for revisions, using a systematic process to address each concern is essential; this must be done in the form of a detailed letter that systematically and in a formal way provides a response to all comments and concerns.⁴⁰ The response letter should describe the thought process for accepting or rejecting critiques and detail how the reviewers' remarks were addressed in revising the resubmitted manuscript.

In the unfortunate situation of the target journal rejecting the article submission, it is human nature to be discouraged. The authors should remember that other journals may be interested in the manuscript; if they initially chose to "shoot for the stars" and selected a journal with a high impact factor, submitting the article (either as is or in reworked form) to a less prominent journal or one with a different aim and editorial scope

may be an effective strategy. Usually, even submissions that are rejected outright are returned to the author with specific reviewer comments³⁹; authors are advised to use those comments to identify and correct areas of weakness and boost the manuscript's quality in preparation for subsequent submission to another journal.

Conclusion

The process of writing and securing journal acceptance of manuscripts should proceed along a well-defined pathway integrating all research and writing tasks. Close adherence to the target journal's instructions for authors and prompt response to reviewer comments help avoid delays in the publication of accepted articles.

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Appendix—Resources for research and manuscript development

Online resources

American Society of Health-System Pharmacists (ASHP) Research and Education Foundation. *American Journal of Health-System Pharmacy* series: Research Fundamentals www.ashpfoundation.org/MainMenuCategories/ResearchResourceCenter/FosteringYoungInvestigators/AJHPResearchFundamentalsSeries

Consolidated Standards of Reporting Trials (CONSORT) www.consort-statement.org/consort-statement/

Equator (Enhancing the QUALity and Transparency Of health Research) Network www.equator-network.org

International Committee of Medical Journal Editors (ICMJE) www.icmje.org/

National Library of Medicine (NLM) Research Reporting Guidelines and Initiatives www.nlm.nih.gov/services/research_report_guide.html

PLOS ONE
PLOS ONE Manuscript Guidelines www.plosone.org/static/guidelines

Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) www.prisma-statement.org/

Quality Of Reporting Of Meta-analyses (QUOROM) www.consort-statement.org/mod_product/uploads/QUOROM%20checklist%20and%20flow%20diagram%201999.pdf

STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) www.strobe-statement.org/Support.html

Books and book chapters

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