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INSIDE

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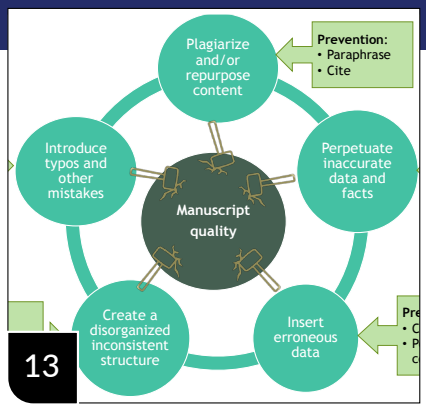

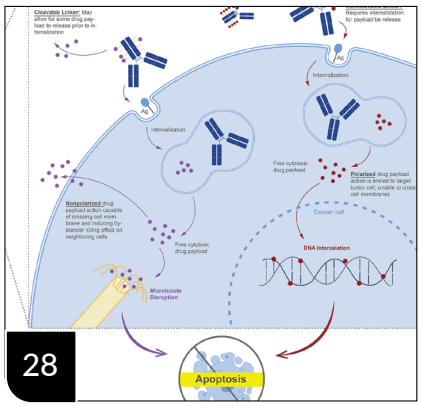

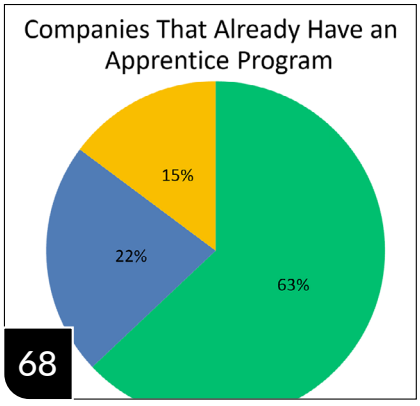

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL
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In support of the mission of the American Medical Writers Association (AMWA) and to advance the broader profession, the *AMWA Journal* publishes content that reflects the interests, concerns, and expertise of medical communicators. Its purpose is to inform, inspire, and motivate medical communicators.

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N2 / 2023

FROM THE GUEST EDITOR

Publications of Biomedical Research: Evolving Landscape and Constant Themes

Qing Zhou, PhD, ELS / Regeneron Pharmaceuticals, Inc, Tarrytown, NY

The field of biomedical research publication has undergone significant changes in the last few years. The COVID-19 pandemic catapulted forward an era of virtual scientific conferences, for which technological tools were quickly developed and established to enable the display of conference presentations and posters on digital platforms. Although conferences have returned to in-person attendance, most still use a hybrid format, enabling virtual participation and on-demand access to digital conference materials. On the front of biomedical publishing by scholarly journals, there is a similar trend toward digital content beyond the traditional 2D format. Many journals have embraced digital enhancements of journal articles to extend their reach to a wider audience. Examples include video or audio abstracts, infographic summaries, plain language summaries, and social media posts, to name a few.

Tied to the evolving format and types of publications is the evolving audience of biomedical research data. In the current digital environment and with more open access available, scientific publications now reach a much wider audience all around the world. For publications of biomedical research, especially clinical studies, the readers are no longer only the clinicians and researchers in the field. They can include investors and funders of research, payors of health care, and patients and their families. In this new publication environment, medical writers often embrace the task of completing multiple deliverables for one publication, which often means shorter timelines and more complex review and approval cadence.

The scope and depth of publications are increasing as well. Besides the traditional phase 1 to 4 clinical studies, medical writers now also work on publications of real-world data research, health economics and outcomes research, biomarker and other translational research, and preclinical research. Also, publication teams nowadays can be larger and more complex, including authors and contributors from more parties or functions (eg, academic institutions, sponsors, contract research organizations, alliance partners, and patients). With these changes, medical writers often find themselves learning new topics and collaborating with more people.

Are there constant themes in this backdrop of a rapidly evolving landscape? My answer is a definite "yes." One constant theme is the need for good medical writers who can step up to the challenges and contribute to successful publications, fulfilling authors' visions and meeting readers' needs. A good medical writer is masterful at the art and craft of medical writing. They have solid command of scientific research principles and methodologies, they understand authors' intent and readers' needs, they know journals' guidelines and requirements, and of course, they possess writing skills that deliver concise and precise prose, logical flow of information, and effective visual representation of research data. This package of knowledge and skills will always remain a core competency of any medical writer working on scientific publications, regardless of research topic or publication type. A good medical writer is also masterful at driving a project and collaborating with authors, contributors, and many other people involved in the publication process. Last, a good medical writer is a lifelong learner. Through continued education and professional development (eg, activities run by professional societies such as AMWA, the European Medical Writers Association, and the International Society for Medical Publication Professionals), they strive to keep up with advances and changes in the field and define and reflect on our evolving roles and responsibilities.

In this special issue of the *AMWA Journal*, I reflect on the rapidly evolving landscape of biomedical publications and the constant theme of achieving medical writing excellence. Two featured topics correspond with these 2 strands of thoughts.

The first featured topic is the latest Good Publication Practice (GPP) guidelines—the GPP 2022 update. First published 20 years ago, the GPP guidelines have become a cornerstone of principles and standards for publications of company-sponsored biomedical research. The latest

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iteration was published in August last year. For those who are relatively new to the latest 2022 GPP guidelines, an overview article provides a summary of key updates, a quick tour of the much-expanded document, and a discussion of changes relevant to medical writers and editors. An accompanying piece on this topic is an interview with Dikran Toroser, a coauthor of GPP 2022, on his insights into the changing field, key updates of GPP, roles of medical writers and publication professionals, and uptake of GPP guidelines.

The second featured topic is a practical guide shared by a seasoned writer, Monica Nicosia, for working on clinical research manuscripts for submission to peer-reviewed medical journals. This article offers perspectives, insights, and practical guidance on various aspects of working on a clinical research paper: how a medical writer contributes to the project at various process steps, the essential knowledge and skills, how to get started on a project, how to develop the first draft, how to avoid common pitfalls, and how to work with difficult people. Early career writers benefit from insights from experience medical writers, and as the author recognized, "our practice and ongoing learning are critical for success."

This *AMWA Journal* issue also includes summaries of 3 publication-themed open sessions from the 2022 Medical Writing & Communication Conference. These topics—"The New Normal in the Medical Publication Sector," "The Backbone of Manuscripts: Supporting Your Writing with Storytelling," and "Journalistic Approach to Writing Better Abstracts"—further add to our reflection on the evolving landscape of the field and enduring essentials of medical writing.

I welcome your feedback for this special themed issue on publications. The *AMWA Journal* recently created a section "Publication Progress" that we hope will become a forum for sharing updates, experience, insights, and ideas for those who work in the publication field. As the Section Editor for "Publication Progress," I encourage your contribution to the *Journal* and look forward to continued reflection about our profession in an evolving landscape.

Author declaration and disclosures: *The author notes no commercial conflict of interest in relation to this article. The views and opinions expressed in this article are those of the author and do not necessarily reflect the views of the author's employer.*

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Editor's Note: In our Spring 2023 issue of *AMWA Journal*, the author of "Common Grantsmanship Hurdles of Early Career Clinician-Scientists and How a Medical Writer Can Help" noted that they were missing grant information in their Acknowledgments. The individual PDF for that article and the full issue PDF galleys were updated on 7 April 2023 in order to add this information.

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THEME ARTICLE

An Overview of the 2022 Update of Good Publication Practice (GPP) Guidelines: A Medical Writer's Perspective

Qing Zhou, PhD, ELS / Regeneron Pharmaceuticals, Inc, Tarrytown, NY

ABSTRACT

This year marks the 20-year anniversary of the Good Publication Practice (GPP) guidelines, a set of principles and recommendations pertaining to peer-reviewed or peer-orientated publications arising from research funded by or conducted in collaboration with industry sponsors. Since the publication in the initial GPP guidelines in 2003, GPP guidelines have undergone several updates, with the latest iteration (GPP 2022 update) published in August 2022. The latest GPP guidelines built upon prior work and continue to strengthen principles and refine practices to reflect a rapidly evolving field of biomedical publishing. This article summarizes what is new in the latest GPP update and provide a quick document tour to help readers navigate the GPP 2022 document. In addition, a section from the perspective from medical writers and editors provides a preview of principles and practical guidance relevant to our day-to-day work. It is expected that further dissemination and discussion of the latest GPP 2022 update will continue to take place among publication professionals, medical writers, authors, journal editors and publishers, and other stakeholders, who share common goals of transparency, accountability, and quality of publications arising from company-sponsored biomedical research.

The Good Publication Practice (GPP) guidelines are a set of principles and recommendations pertaining to peer-reviewed or peer-orientated publications arising from research funded by or conducted in collaboration with industry sponsors, typically pharmaceutical, biotechnology, and medical device companies.

This year marks the 20-year anniversary of the first GPP guidelines that were published in 2003.[1] These initial GPP guidelines were developed to promote transparency and to establish standards for publication practice used by pharmaceutical companies. Since then, GPP guidelines have undergone several updates to reflect changes within the publication field and to provide additional practical guidance on publication processes and procedures. These updates include the GPP2[2] published in 2009 and the GPP3[3] published in 2013. Good Practice for Conference Abstracts and Presentations (GPCAP)[4] was published in 2019 to provide guidance specifically for congress abstract and presentations. The latest update of the GPP guidelines, the GPP 2022 update, was published in August 2022.[5] To facilitate better tracking of updates, the current and future GPP updates will carry the date of the update (instead of a version number). Table 1 summarizes GPP iterations published to date; all GPP guidelines are free to access by the public.

Table 1. GPP Iterations

GPP Iteration	Year of Publication	Citation
GPP 2022	2022	DeTora LM, Toroser D, Sykes A, et al. Good publication practice (GPP) guidelines for company-sponsored biomedical research: 2022 update. *Ann Intern Med*. 2022;175(9):1298-1304. https://doi.org/10.7326/m22-1460
GPCAP	2019	Foster C, Wager E, Marchington J, et al. Good practice for conference abstracts and presentations: GPCAP. *Res Integr Peer Rev*. 2019;4:11. https://doi.org/10.1186/s41073-019-0070-x
GPP3	2015	Battisti WP, Wager E, Baltzer L, et al. Good publication practice for communicating company-sponsored medical research: GPP3. *Ann Intern Med*. 2015;163(6):461-464. https://doi.org/10.7326/m15-028
GPP2	2009	Graf C, Battisti WP, Bridges D, et al. Good publication practice for communicating company-sponsored medical research: the GPP2 guidelines. *BMJ*. 2009;339:b4330. https://doi.org/10.1136/bmj.b4330
Original GPP	2003	Wager E, Field EA, Grossman L. Good publication practice for pharmaceutical companies. *Curr Med Res Opin*. 2003;19(3):149-154. https://doi.org/10.1185/030079903125001767

GPCAP, Good Practice for Conference Abstracts and Presentations; GPP, Good Publication Practice.

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One may wonder about the process for developing the GPP guidelines. As described in the Methods sections of the GPP guidelines (GPP2 and onward),[2-3,5] with support from the International Society for Medical Publication Professionals (ISMPP), a steering committee was invited and formed, then members of the steering committee wrote the guidelines and managed review of the drafts by selected expert reviewers or a wider range of volunteers. The steering committees (typically also serving as the author groups) have consisted of experienced professionals representing various constituencies involved in publishing company-sponsored biomedical research. For example, in the latest GPP 2022 update, the author group represents different geographic regions (Asia, Europe, and North America) and includes members from pharmaceutical, biotechnology and device companies, medical communication agencies, journal editors and publishers, and academic institutions.

It is worth noting that GPP guidelines identify best practices based on a wide range of existing guidelines. These include broader guidance on scholarly publishing by the International Council of Medical Journal Editors (ICMJE),[6] various reporting standards such as CONSORT[7] and guidelines collected by the EQUATOR Network,[8] as well as ethical principles maintained by professional organizations such as American Medical Writers Association (AMWA),[9] the European Medical Writers Association (EMWA),[10] the ISMPP,[11] the Council of Science Editors,[12] and the World Association of Medical Editors,[13] to name a few.

GPP guidelines are intended to be a living document that reflects current practice and will be subject to revisions as the field changes and expands. The sections below summarize what is new in the latest GPP update and provide a quick document tour to help readers navigate the GPP 2022 document.

WHAT IS NEW IN THE GPP 2022 UPDATE

Many principles of prior GPP guidelines remain. The GPP 2022 update[5] reflects the changes in the publication field as well as the expanding role of the publication professionals. The updated guidelines strengthen the core values of GPP such as ethics, transparency, inclusivity, accountability, and responsibility. The GPP 2022 update also includes a significantly expanded and reorganized supplement document, intended to provide more detailed guidance on day-to-day work in various process steps of publication planning, development, review, and approval.

Below is an overview of themes of changes and additions in the GPP 2022 update since the previous iteration (GPP3).[3] For a detailed list of changes, the readers can refer to the table in the main body of the GPP 2022 update.

- **Principles of GPP were augmented and strengthened.**
  - GPP principles incorporate updated references to key ethical documents, such as ICMJE recommendations and the Declaration of Helsinki. The AMWA-EMWA-ISMPP joint statement on the role of professional medical writers was also cited.
  - Updated "Ethical Principles" include a total of 23 principles (compared with 10 principles in GPP3), divided into 5 areas:
    - General principles for ethics and good publication practice.
    - Principles for protecting research and data integrity.
    - Principles to promote transparency.
    - Principles to support inclusivity.
    - Principles for authorship, contributorship, and accountability.
  - "Practical Planning Principles" were added to describe principles guiding practical aspects of work processes.
- **New topics were included to reflect changes and advances in the publication field.**
  - GPP 2022 specifies a wider scope of research (eg, translational and biomarker studies, nonclinical research, health economics, real-world evidence, and outcomes research) and reflects advances of in biomedical publishing (eg, enhanced content, plain language summaries, preprints, and social media posting about peer-reviewed publications).
  - Guidance is given regarding plain language summaries and enhanced content.
  - GPP 2022 recommends inclusivity in publication activities (eg, cultural differences and region-specific needs) and in people and teams involved in publications (eg, the composition of steering committees, author groups, and publication teams).
  - The guidelines also address the potential role of patients in publication activities.
- **The supplement was significantly expanded and reorganized.**
  - In GPP 2022, the supplement was significantly expanded and reorganized to provide more detailed guidance on various publication process steps in a logical order (see the next section for more details).

HOW TO NAVIGATE THE GPP 2022 UPDATE – A QUICK TOUR OF THE DOCUMENT

The overall format of the GPP 2022 update[5] is similar to that of GPP3;[3] main principles are presented in the main body, and more detailed guidance and recommendations are

summarized in the supplement. The updated document, especially the supplement, contains a large amount of information. It may be hard to read the entire document in one sitting or to remember all the details. The summary below provides a quick tour of the document that may help readers to get familiar with the structure of GPP 2022 so they may locate relevant information more easily.

- **Main body**
  - "Ethical Principles" and "Practical Planning Principles" are presented.
  - The main body also includes methods used for developing GPP 2022, the scope and format of GPP, how to use GPP, as well as conclusions and future directions.
  - A detailed table summarizes key changes and additions since the previous iteration.
  - Specific sections in the supplement are called out in GPP principles in the main body to aid in quick cross referencing.
- **Supplement**
  - The expanded and reorganized supplement provides detailed guidance on various process steps, organized in sections A-I (summarized in Table 2).
  - Each section of the supplement may be used as a standalone document to help explain the process and best practices to publication stakeholders. The overall supplement can be used as a tool for publication team education and for guiding the development of publication policies and procedures at certain organizations.

A PERSPECTIVE FROM MEDICAL WRITERS AND EDITORS

Many medical writers and editors, whether employed by company sponsors, by medical communication agencies or contract research organizations, or are self-employed, are involved in the development of publications of company-sponsored biomedical research. Medical writers, with professional expertise in scientific communication and in ethical publication principles, assist authors and sponsors to disclose and communicate research findings in an ethical, accurate, and timely manner.

Following on from GPP3,[3] GPP 2022[5] continues to emphasize the professional roles of medical writers. A notable update is that under "General Principles for Ethics and Good Publication Practice" in the main body text, it was made clear that medical writers should be treated ethically and enabled to follow ethical practice.

Table 2. Summary of Supplement Sections A-I in the GPP 2022 Update[5]

Section	Topic	Content (Section Headings, Titles of Supplement Tables and Figures)
A	Publication Types	- Primary and secondary publications - Reviews and meta-analyses - Scientific conferenced presentations - Other publication types - Enhanced content and plain lanuage summaries
B	Publication Professional Roles and Professional Development	- Professional roles - Professional development - Sharing best practices - Developing publications policies and procedures - Supplement Table 1. Team education: essential events and timing for clinical research publications
C	Ethical Principles: Additional Detail	- Commitment to peer-reviewed publications - Publications as scientific exchange - Special considerations for communicating with the public - Additional significant considerations
D	Publication Steering Committees	- Responsibilities - Formation and ending - Membership - Charter - Meetings and communication - Supplement Figure 1. Suggested life cycle of a publicaiton steering committee
E	Publication Plans	- Principles - Review and approval of publication plans - Supplement Table 2. Principles for publication plans - Supplement Table 3. Special considerations for the publication plan
F	Publication Working Groups	- Responsibilities - Initiation - Membership - Meetings and communication - Ending
G	Authorship and Contributorship Determination	- Principles - Author agreements - Additional considerations - Process - Supplement Table 4. Suggested author agreement contents
H	Publication Process	- Journal and conference selection - Data sharing - Working with professional medical writers - Publication kick off - Publication draft - Review and approval - Acknowledgment, disclosures, and author statements - Journal submission, peer review, and page proofs - Post publication activities - Supplement Table 6. Relevant criteria for journal and conference selection - Supplement Figure 2. Overview of the publication process
I	Documentation Guidelines	- Guidelines

In the GPP 2022 supplement, medical writers can also find relevant practical guidance on day-to-day work in several sections, including Section B "Publication Professional Roles and Professional Development," Section D "Publication Steering Committees," Section F "Publication Working Groups," Section G "Authorship and Contributorship Determination," and Section H "Publication Process."[5]

Below are just a few examples of practical guidance relevant to medical writers:

- Roles of medical writers, along with roles of authors, other contributors, and reviewers, should be defined prospectively (Supplement Section D), and the employment of professional writing support should be agreed by authors (Supplement Section G).
- Medical writers, as with all publication contributors, qualify as authors if they meet authorship criteria (Supplement Section G).
- Medical writers should work under author direction.
- Medical writers should attend relevant meetings such as kick off or data dissemination meetings so they can capture authors' views and directions (Supplement Sections F, H).
- If they are not a byline author, a medical writer should not be asked to perform final data integrity check (Supplement Sections F, H) to help ensure adherence to ICMJE authorship criteria.
- Medical writing support needs to be disclosed. Typically, the writer's name, professional qualifications, affiliation, and funding source are disclosed at a minimum, along with any other information required by the journal or conference (Supplement Section H).
- Medical writers should engage in professional development and in sharing best practices (Supplement Section B).

Medical writers are highly encouraged to keep GPP guidelines on hand as a key reference and to consult them when questions or uncertainties arise at work. Even if one may not find the exact answers for every work situation, the principles and processes described in the GPP guidelines may provide an approach for developing solutions.

Medical editors often work closely with medical writers to ensure that the publications are clear and concise, with a format and style suitable for the target audience, and meeting requirements by the journals, publishers, and scientific conferences. Editors are often knowledgeable on topics related to journals and publishers (eg, journal styles, copyright requirements, and predatory publishing). Their insights into language use can help make enhanced content and plain language summaries more effective for different audiences. For medical editors and those who work with medical editors, the detailed publication process described in the latest GPP guidelines can help identify where an editor's insights and input are needed.

For medical writers and editors, besides reading the published GPP document, there are other resources to learn about the latest GPP guidelines. For example, the ISMPP held an ISMPP U webinar "Introducing GPP 2022" on September 21, 2022,[14] and the EMWA held a webinar "Good Publication Practice 2022: Focus on Medical Writing" on March 8, 2023.[15] There are likely more discussions at various professional organizations on the latest GPP guidelines.

CONCLUSION

Since the publication in the initial GPP guidelines 20 years ago, GPP guidelines have undergone several updates, with the latest iteration (GPP 2022 update) published in August 2022.[5] Over the years, GPP guidelines have become a cornerstone of principles and standards for publications of company-sponsored biomedical research. The latest GPP guidelines built upon prior work and continue to strengthen principles and refine practices to reflect a rapidly evolving field of biomedical publishing.

Disseminating the newest GPP guidelines and incorporating them into day-to-day work requires continuous effort. It is expected that further dissemination and discussion of the latest GPP 2022 update will continue to take place among publication professionals, medical writers, authors, journal editors and publishers, and other stakeholders, who share common goals of transparency, accountability, and quality of publications arising from company-sponsored biomedical research.

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THEME ARTICLE

Good Publication Practice (GPP) 2022 Update: An Interview with Dikran Toroser

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INTERVIEW

AMWA: Thanks Dikran for taking the time to speak to AMWA. First, I would like to recognize the time and effort by the steering committee and authors of the GPP 2022 update. This is a major update of the guidelines since GPP3,[3] which was published in 2015. The work for the latest update started in April 2019, and the article was published in September 2022, so the entire process took more than 3 years from start to finish. ***My first question is why there was a need for this major undertaking to update the GPP, and what are the main objectives of this update by the GPP steering committee and authors?***

Toroser: The publication field has been moving and changing at an extraordinarily fast pace in the last few years. For example, with the emergence of various enhanced content, publications are no longer just black-and-white pieces in a journal. The COVID pandemic was an incredible catalyst for many of the changes. Because people were not traveling to attend scientific conferences in person, there has been a huge need for digital enhancements, such as audio and video recordings, to be accessed virtually and on demand.

Another important factor is that the audience for scientific publications is evolving. The audience is no longer limited to a select few who are technically minded in the same field. Today's audience includes those who are not experts in the same field, who are not experts at all, who are short of time, or who are from other parts of world. The changes in the audience and their needs are another force in shaping the changing publication field. These are among many reasons to update the GPP guidelines.

The latest GPP update builds on prior iterations of GPP guidelines and reflects the latest changes and advances in the publication field. It is worth mentioning that, as with all guidelines, GPP won't be able to provide answers to all questions at work and requires day-to-day judgment calls by publication professionals to apply the principles in specific cases.

AMWA: The GPP 2022 update covers a wider scope of publications. For example, in the "Scope" section, the authors described research areas applicable to GPP guidelines: besides clinical research, the scope now includes translational and biomarker studies, nonclinical research, health economics, real-world evidence (RWE), and outcomes research.

Why should we include these additional types of research under GPP guidelines? Are there differences in planning and developing publications in these research areas other than traditional clinical research?

Toroser: A wider scope of publications reflects the increasingly complex nature of data and research in the health-

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Dikran Toroser was educated in the United Kingdom and has a PhD in biochemistry from Newcastle University in Newcastle upon Tyne. He did his postdoctoral research in the United Kingdom at the Cambridge laboratory on genetics and then moved to the United States to work as a biochemist and researcher for the US Department of Agriculture (USDA). He has an extensive background in scientific publications as well as medical writing. He has led scientific publication teams involved with preclinical, clinical, and mature product studies and publications. Dikran is one of the founding faculty for the University of California San Diego medical writing certificate and a consulting director for the program. Active in professional organizations such as the American Medical Writers Association (AMWA) and International Society for Medical Publication Professionals (ISMPP), Dikran most recently has been involved in compiling guidelines for publication professionals, including the AMWA-EMWA-ISMPP joint position statement on the role of professional medical writers[1] and GPP 2022, the latest 2022 update of Good Publication Practice (GPP) guidelines for company-sponsored biomedical research.[2]

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care space. For example, health economics and outcomes research became more important in terms of informing unmet medical needs as well as providing valuable information on health economics relevant to policy and decision-making from a payer's perspective. Research on real-world data (RWD) or real-world evidence (RWE is another area of growing interest and importance because RWD and RWE are playing an increasing role in healthcare decisions by regulatory agencies such as the US Food and Drug Administration (FDA).[4]

Publication professionals today find themselves managing publications arising from expanding research disciplines besides the traditional clinical research; therefore, it is helpful that the updated GPP now covers the work that we do. Because of the differences in the research process and methodology, the cadence in publication activities for these additional types of research may be different from those for clinical research. For publications on complex data or analyses, there are added challenges in making the publications understandable and meaningful to the intended audience.

AMWA: GPP 2022 also calls out a few new publication types, notably enhanced content and plain language summaries. Definitions for these new publication types are provided in Supplement Section A. Guidelines on the planning and developing enhanced content and plain language summaries are also provided in various other sections in the supplement, from policies and procedures (Section B) to specific process steps such as publication plans (Section E) and publication development process (Section H).

Why are guidelines important for enhanced content and plain language summaries? For organizations that have not routinely worked on these new publication types, what are some key considerations?

Toroser: The need for these new types of publications reflects the fast-changing publication field and an evolving audience. The updated GPP guidelines support the use of enhanced content (such as video, audio, or infographics) and plain language summaries to augment the publication and increase its reach. For the teams who are new to these newer publication types, they would need to collaborate with stakeholders at their organizations to incorporate good practice in day-to-day work. GPP guidelines emphasized that enhanced content and plain language summaries should be developed following the same ethical and quality principles as the main publication. It is also important to consult the journals and congresses for their policies and requirements on enhanced content and plain language summaries.

AMWA: The supplement of GPP 2022 was significantly expanded and reorganized. There seems an emphasis of making this updated GPP more usable to provide guidance on day-to-day work. For example, Section B describes the roles of publication professionals in developing publication policies and procedures as well as sharing best practices and continued professional development. Sections D through H detail various process steps in publication planning and development of individual publications, covering topics from publication steering committees to publication working groups, from publication plans to the process of individual publications.

Can you elaborate a bit more on the rationale behind the expansion and reorganization of the supplement? Is the expanded supplement in GPP 2022 intended as a tool for team training?

Toroser: Thanks for asking about the aspect of training, which had been brought up many times during this current GPP update. An important goal of the GPP document is to facilitate training of publication teams on best practices, both on principles and on day-to-day work processes.

Yes, the supplement of the GPP 2022 update was reorganized and reformatted to increase the clarity of various topics and to make the document easier to read. The supplement is a comprehensive document with a large amount of information; it will be helpful for publication teams to be familiar with the structure of the document so they can consult relevant sections to find guidance on certain topics.

AMWA: Publication professionals need to interact with a wide range of people—eg, company teams, authors, journal editors, and patients—in these various publication process steps and activities. ***Can you speak to the role of publication professionals, perhaps an underappreciated leadership role, in educating others and implementing the GPP?***

What challenges may be faced by publication professionals in adopting GPP 2022? Any insights on how to overcome these challenges?

Toroser: The roles of publication professionals are evolving along with the evolving field. We are the gatekeepers of best publication practices in a complex and changing landscape, often faced with complex questions and ethical dilemmas. We shoulder important responsibilities of ensuring that authors meet their authorship criteria, of working with statisticians and other teams to provide data and study materials to authors, and of meeting requirements from the journals and congresses.

The important roles by publication professionals are also supported by the AMWA-EMWA-ISMPP joint position

statement,[1] which calls out the responsibility of professional medical writers in achieving quality publications in an ethical, accurate, and timely manner. Publication quality suffers when these responsibilities are not met to the full stringency. From my perspective, there has been more and more appreciation of the leadership role played by publication professionals.

In terms of challenges, the global nature of publications nowadays can be a challenge to navigate cultural differences. For example, authorship practice in another culture may require more nuanced considerations, including how we ask for feedback and approval from authors. This may require a good understanding of the culture and practice in a specific region to anticipate problems and come up with solutions.

AMWA: Many AMWA members are freelance writers, some of whom provide medical writing assistance to company-sponsor biomedical research publications. ***For freelance writers who are new to GPP guidelines, are there specific sections or aspects in GPP 2022 that they may focus on*?**

Toroser: I very much appreciate the opportunity to reach out to professional medical writers in the AMWA audience, who are an extremely important part of the publication professional community. My recommendation is that freelance writers should be closely familiar with the entire GPP document, especially ethical and quality principles. I hope that the GPP guidelines become an essential reference document for all medical writers.

AMWA: Besides publication professionals and teams, it seems that the other audiences for the updated GPP 2022 include journal editors, conference organizers, academic institutions, and the wider research community and public. ***Have the authors received feedback from the wider audience on the GPP 2022 update? Is there anything we can do to promote dissemination of GPP 2022?***

Toroser: The GPP author group includes representation from the pharmaceutical industry, academic researchers, journal editors, and conference organizers. Also, the latest GPP update underwent review by volunteers from the public before it was finalized for submission. So, feedback from a wide range of perspectives was received during both the writing phase and the review phase.

GPP guidelines have already become a cornerstone for publication processes and procedures in the industry, especially at large companies. I anticipate that GPP guidelines will be more and more widely accepted by journals, congresses, and the academic research community. For example, we already built links with organizations such as the Asian Council of Science Editors in the Asia-Pacific region. ISMPP is also collaborating with various professional organizations such as the Medical Affairs Professional Society (MAPS) and Drug Information Association (DIA) to discuss and disseminate the latest GPP update.

AMWA membership is a crucial audience for GPP. I encourage AMWA members who are involved in scientific publications to get closely familiar with the GPP 2022 update. It takes continued effort to disseminate the latest GPP guidelines; we all can do our part through discussions with colleagues and stakeholders at professional development activities and in our day-to-day work.

Author declaration and disclosures: *The interviewee (D.T.) and the author (Q.Z.) note no commercial associations that may pose a conflict of interest in relation to this article. The views and opinions expressed in this article are those of the interviewee and the author and do not necessarily reflect the views of their employers.*

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N2 / 2023

THEME ARTICLE

A Medical Writer's Guide: Working on Clinical Research Manuscripts for Submission to Peer-Reviewed Medical Journals

Monica Nicosia, PhD / Nicosia Medical Writer LLC, Bryn Mawr, PA

ABSTRACT

Prompt publication of clinical trial results in peer-reviewed journals is essential to advance clinical practice and improve patient outcomes. The involvement of professional medical writers (PMWs) in the preparation of these clinical research manuscripts can enhance their quality and shorten publication timelines. Research manuscript projects can be daunting, especially for early-career PMWs who could benefit from insights provided by experienced PMWs. In this guide, first I share my perspective on how PMWs contribute to such projects and the essential skills and competencies we should provide. Then, I describe my tactical approaches to initiating these projects, developing the first draft of a detailed outline or manuscript, and avoiding some common pitfalls that can undermine the quality of a manuscript. Finally, I share some tips for working with challenging personalities.

There are many types of biomedical research manuscripts (Figure 1).[1] Research manuscripts that report the results of clinical investigational studies are among the most impactful articles published in peer-reviewed biomedical journals. Prompt publication of clinical trial results is essential to facilitate discussion of their implications for clinical practice and any potential improvements in patient outcomes. However, because clinical investigators need to balance clinical, research, and other responsibilities, they usually have limited time to prepare manuscripts for journal submission. Their junior medical colleagues often have even less time and less training in writing scientific manuscripts. The involvement of professional medical writers (PMWs) in the preparation of research manuscripts can improve their quality and shorten publication timelines.[2-4] In this context, PMWs lay the groundwork for building a submission-ready manuscript like specialist nurses or physician assistants do for physicians treating patients.

For early-career PMWs, working on research manuscript projects can be a daunting challenge. In this guide, I share my perspective on the role of PMWs in such projects, our key functions and responsibilities, and tactics and tips that have helped me excel at these projects.

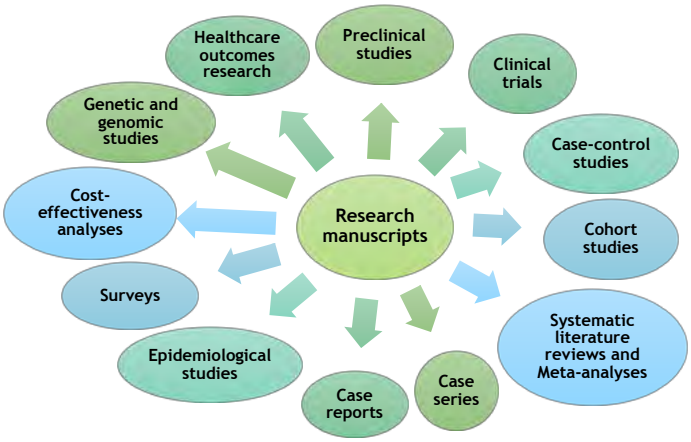

Figure 1. Types of biomedical research manuscripts.

HOW MEDICAL WRITERS CONTRIBUTE TO RESEARCH MANUSCRIPT PROJECTS

In collaboration with the lead clinical investigators/authors and under their guidance, PMWs can contribute to various aspects of manuscript preparation (Figure 2, next page). As a freelance PMW, I have sometimes been asked to prepare only a partial or complete first draft. Other times, I have supported research manuscript projects from conception and through various revisions, until readiness for journal submission. Occasionally, I have been tasked with revising the work of others for submission to a different journal.

The work of PMWs on research manuscript projects must reflect guidance provided by professional ethics,[5-8] standards for best practice,[9-13] applicable health research reporting guidelines,[14] and journal-specific instructions for authors (Figure 3, next page). In light of this guidance, my main goal as a PMW is to produce a succinct, clear, well-organized, and accurate draft document that reports the results of a study and the authors' interpretation while adhering to the guidelines for the target journal. By producing a high-quality, data-supported work, I maximize the chances that the

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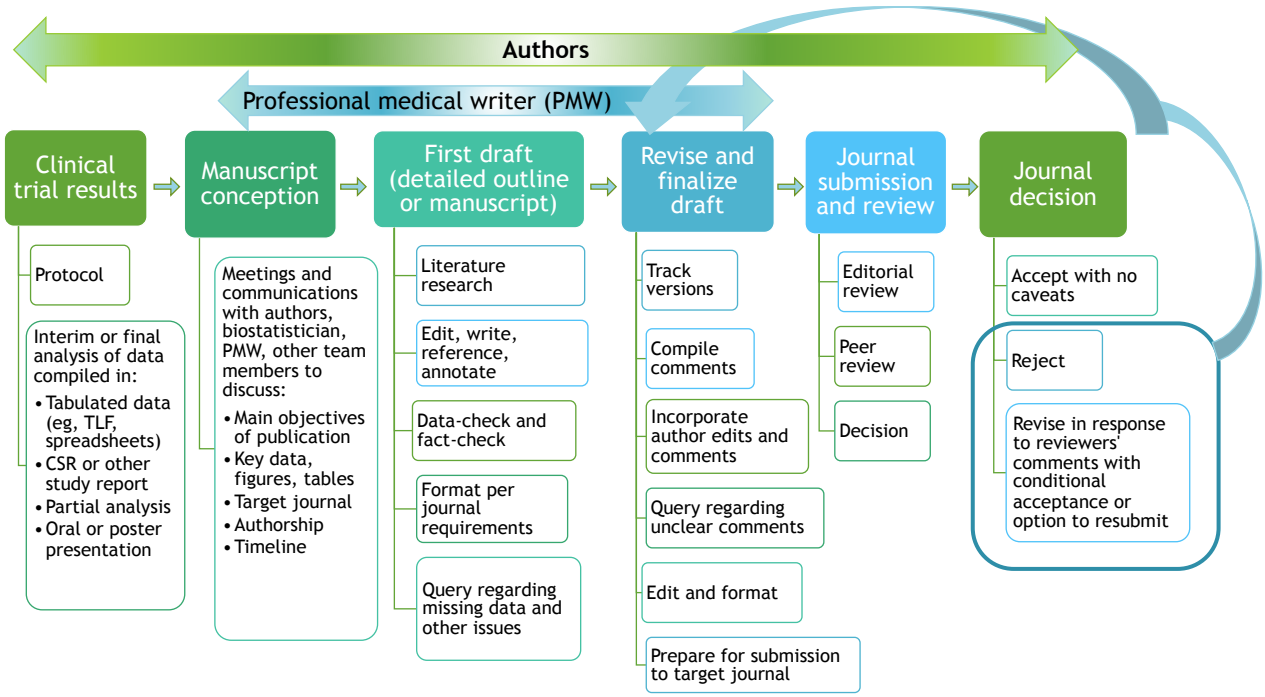

Figure 2. How a PMW might contribute to the preparation of a clinical trial research report for submission to a peer-reviewed journal.

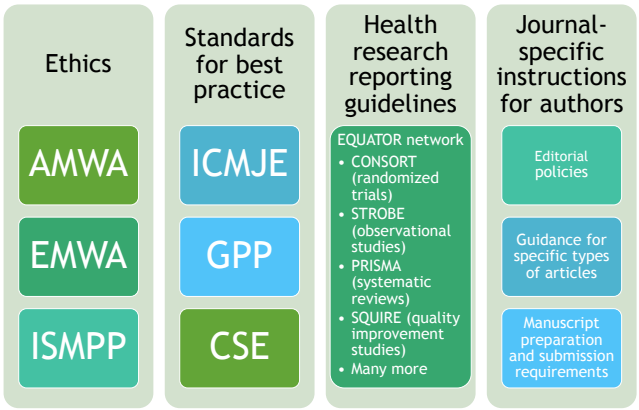

Figure 3. Key sources of guidance for PMWs working on research manuscripts. AMWA, American Medical Writers Association; CSE, Council of Science Editors; EMWA, European Medical Writers Association; GPP, Good Publication Practice; ICMJE, International Committee of Medical Journal Editors; ISMPP, International Society for Medical Publication Professionals; PMW, professional medical writer.

manuscript will be accepted for publication and minimize the work required of others (eg, authors, editors, other collaborators, colleagues).

As a PMW of a research manuscript, I am usually not considered an author because my contributions do not meet all 4 of the International Committee of Medical Journal Editors (ICMJE) criteria for authorship (Figure 4).[9] Per ICMJE standards, journal guidelines, and other best practices, manuscripts must acknowledge the contributions of PMWs and medical editors along with the source of funding for their work.

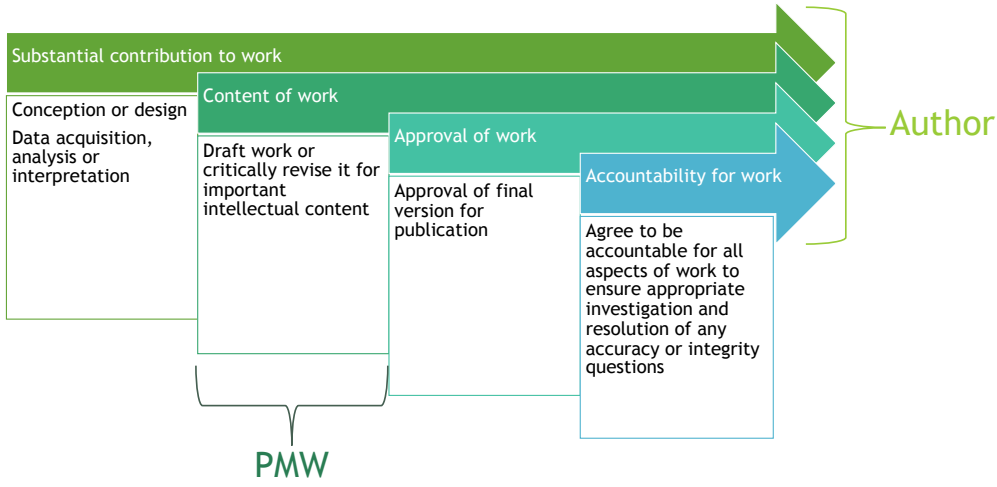

Figure 4. How ICMJE authorship criteria usually apply to PMWs working on research manuscripts.

ESSENTIAL SKILLS AND COMPETENCIES FOR WORKING ON RESEARCH MANUSCRIPTS

PMWs must have a variety of skills and high-level competencies (Figure 5). It is not a hobby that can be casually picked up—it's a profession. For example, being considered a good writer as an undergraduate, earning a doctorate in a life science field, doing postdoctoral research, and being an author of several nonclinical research manuscripts did not automatically make me a good medical writer. I was fortunate to be hired as an entry-level medical writer at a medical communication company. While there, I developed my medical writing and editing skills through AMWA workshops and seminars, diligent practice, reading good medical writing, and receiving constructive criticism and feedback from medical editors and other experienced colleagues. When I started my own freelance business, I continued to expand these skills by always striving to improve.

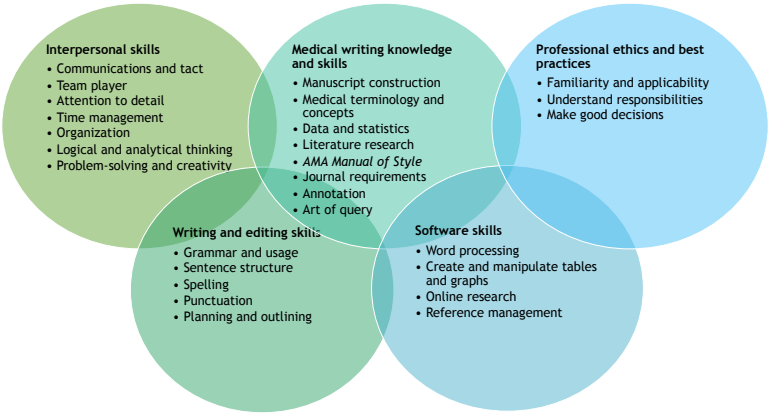

Figure 5. Essential knowledge and skills for medical writers working on research manuscript projects.

Mastering the craft of medical writing is key to successfully completing a research manuscript project. The *AMA Manual of Style*[1] is an important resource for PMWs who work on manuscripts for submission to American medical journals. Most of these journals base their style and format on the *AMA Manual*. When I work on a manuscript for submission to a peer-reviewed journal, I apply the *AMA Manual* guidance (for examples, see Table 1) along with guidance provided by the journal's

Table 1. Selected Recommendations for Good Medical Writing of Research Manuscripts Reporting Clinical Trial Results

Topic	Applicable Statements From *AMA Manual of Style* 11th Edition	My Recommendations
Active Voice Versus Passive Voice	"In general, authors should use the active voice, except in instances in which the actor is unknown or the interest focuses on what is acted on …"[1,a] "If the actor is mentioned in the sentence, the active voice is preferred over the passive voice."[1,a]	Use a judicious mixture of active voice and passive voice. Active voice makes the writing clearer and more concise. It also emphasizes the authors' ownership of their work. Too much passive voice makes the writing boring and verbose, causing the reader to lose interest.
Patient or *Participant* Instead of *Subject* or *Case*	"Some consider *subject* (as in study subject) to be impersonal, even derogatory, as if the person in the study were in a subservient role. Similarly, the use of *case* is dehumanizing when referring to a specific person."[1,b]	Use the term patient if the study *participant* is being treated for a medical condition. Use the term *participant* or *volunteer* if the study participant is healthy and/or is not being treated. Keep in mind that the study participants or their loved ones might read the publication. We must show respect for their personhood and contributions.
Sex and Gender	Use sex-neutral terms when applicable. For example:[1,c] • *Chair* or *chairperson* instead of *chairman* or *chairwoman* • *Layperson* instead of *layman* • *Humankind* instead of *mankind* "When reporting the sex of participants in a table, include both sexes, as identified in the study, regardless of the ratio. Do not use "white" and "male" as the default."[1,d]	Report data on sex and gender in an equitable, inclusive, and consistent manner. Don't report only the data for the majority group. When sex/gender is irrelevant, reword the sentence to use they as singular or plural. This is an evolving area; read on the topic,[15,16] attend an AMWA talk about it, and research the latest trends.
Race and Ethnicity	"… be sensitive to the designations that individuals or groups prefer. Be aware also that preferences may change and that individuals within a group may disagree about the most appropriate designation."[1,e]	Report data on race and ethnicity in an equitable, inclusive, and consistent manner. Don't report only the data for the majority group. Be as specific as possible when reporting data by race and ethnicity (eg, include definition of "other" category).
Terms for People With Conditions, Disorders, or Diseases	"Avoid labeling (and thus equating) people with their disabilities, or diseases (eg, the blind, schizophrenics, epileptics). Instead, put the person first."[1,f] "Avoid describing persons as victims or with other emotional terms that suggest helplessness."[1,f]	Some of my preferred phrasing: • *Patient with cancer* instead of *cancer patient* or *cancer victim* • *People with obesity* instead of *the obese* • *Persons (or people) with COVID-19* instead of *COVID-19 patients (or cases)* • *Older patients (or patients ≥ 65 years of age)* instead of *the elderly*

[a]Page 431, [b]page 513, [c]pages 543-544, [d]page 544, [e]page 546, [f]page 547.

manuscript preparation instructions. Doing so improves the consistency and clarity of my work and helps me educate other collaborators (eg, authors, clients, colleagues) on best practices in medical writing.

HOW TO GET STARTED ON A CLINICAL RESEARCH MANUSCRIPT PROJECT

As I work on these manuscripts, I am especially cognizant of the second principle from the AMWA code of ethics, which states that "Medical communicators should apply objectivity, scientific accuracy and rigor, and fair balance while conveying pertinent information in all media."[5] As PMWs, we must keep this principle at the forefront when we synthesize information and data from various sources (Figure 6) to produce cogent and accurate drafts for authors to develop.

Once I receive a research manuscript assignment, I take several steps to ensure that I start the project efficiently (Table 2). First, I review and organize the provided assignment document(s), background information, and other materials. As a freelancer who is usually not bound to a company's internal processes, I have developed my own system of 5 main electronic folders (named Background, Communications, Paperwork, References, Text), each labeled with a client and project code. I make sure that I understand the project specifications, the team's roles and

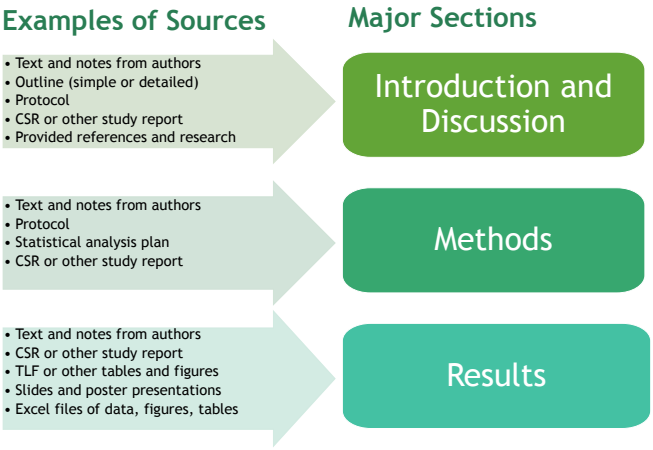

Figure 6. Examples of information and data sources for the major sections of a clinical research manuscript. Notes from authors can come from meetings, emails, and phone calls. CSR, clinical study report; TLF, Tables, Listings, and Figures.

Table 2. Key Steps and Tips for Starting a Manuscript Project for Submission to a Medical Journal

Step	Tips
1. Study and organize materials, and keep them organized.	• Organize project materials into standardized electronic folders. • Keep emails and notes of kick-off and follow-up phone conversations and live/online meetings (start and maintain a paper trail to document everything).

2. Determine what else is needed, keep notes on the project, and proactively communicate issues.	• Take notes regarding project-related questions and issues that arise.
	  ○ If issues can't be resolved by digging deeper in material, send queries via emails to a key contact.
	  ○ Keep track of queries and responses (eg, save emails in project subfolder).

3. Review author manuscript preparation instructions for target journal.	• Find examples of recent articles from journal.
	• Take notes on requirements and stylistic preferences:
	  ○ Word counts for abstract and main text.
	  ○ Limits for numbers of tables, figures, and references.
	  ○ Types of headings.
	  ○ Data format (eg, *P* values, significant digits).

4. Set up Word manuscript file.	• Follow the author manuscript guidelines for the target journal. • Modify the heading styles to outline and organize your draft. • Include a statement acknowledging contributions as a medical writer/editor and the source of funding for this work. • Use the Quick Access toolbar, keyboard shortcuts, Navigation Pane, and split screen option (View panel) to work efficiently.
5. Set up reference management library (eg, EndNote).	• Import citations from PubMed, other databases, and journal websites. • If needed, correct EndNote style to match current format used by journal.
6. Use easy and consistent naming formats for reference PDFs.	• My preference: First author's last name, journal abbreviation, year of publication (eg, Smith et al J Clin Oncol 2023) • Don't name files by their title (it's too long, and that's not how papers are cited) but do consider including a short phrase summarizing the title (eg, Smith et al J Clin Oncol 2023 [phase 3 drugX melanoma]).
7. Use a file naming system that promotes version control	• Name files in a consistent manner (eg, "smith phase2 ms d1.0"). • Have reviewers add initials when they send in their comments or rename the file yourself when you receive it (eg, "smith phase2 ms d1.0_MN").

PDF, portable document format.

responsibilities, the format for required deliverable (eg, outline, manuscript), and the timeline. When I work with a new group, I also need to confirm the lines of communication (eg, who will answer queries, who will provide portable document format (PDF) files for reference articles).

Second, I identify what else I need to start the project and decide on my next steps (eg, what questions to ask; what to research). Typically, the initial questions I need answered are:

- What sources of materials (eg, protocol, study report, key references) do I have to write and/or revise the draft?
- What is the target journal?
- What is the deadline for my first deliverable?
- Does the client want me to highlight sources and annotate the first draft? If yes, do they require a specific format?
- Which, if any, reference management software may I use?

Third, I study the journal's manuscript preparation instructions. To help structure and format the manuscript, I find 2 or 3 studies published in the target journal that are similar to the one that I am working on. I also try to find a few recent publications by the lead author(s) to get a general idea of their writing style.

Fourth, I set up the Word document. Unless a client requires me to use their template, I structure my Word manuscript to comply with the manuscript preparation instructions. I like to modify the style headings to help me outline and navigate the draft.

Fifth, I set up a reference management library for the project. I use EndNote. Other options include Mendeley and Zotero. A reference management software program is an essential time-saving tool for PMWs to manage references, create citations, and generate reference lists that conform to the target journal style.

Sixth, I use a consistent naming format for my reference PDFs so that I can easily access the correct reference as I develop a draft outline or manuscript. I used to print reference articles and other key sources, but I no longer do that. I work from the PDFs, keeping them side by side with my draft and highlighting and annotating as I go.

Seventh, I use a simple file naming system that promotes version control to minimize confusion during reviews. Of course, sometimes the lead author or client renames files using their own system. I stick with what they decide and keep detailed notes to keep track of versions and author responses.

HOW TO DEVELOP THE FIRST DRAFT OF A CLINICAL RESEARCH MANUSCRIPT

Similar to the approach recommended by other PMWs,[17] I start by drafting the Methods and/or Results, which are the most straightforward sections of a typical clinical research manuscript (Figure 7). This approach helps me familiarize myself with the study and avoid writer's block. Sometimes, perhaps because a section is tedious, I alternate working on different sections. Clinical trials tend to have similarly organized Methods section, unlike in vivo and in vitro experimental studies which have varied methodologies even within the same research area.

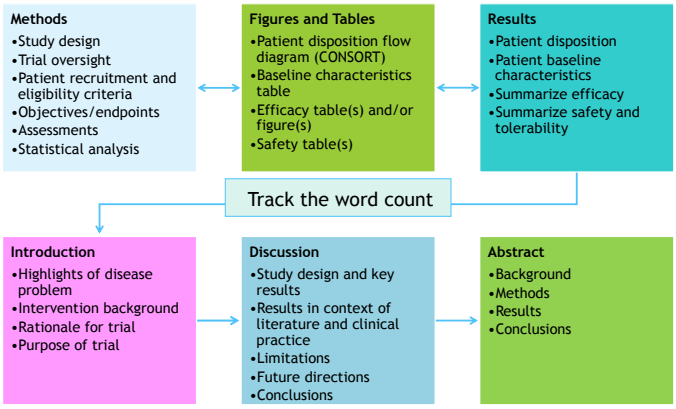

Figure 7. Sequential approach to building a research manuscript reporting clinical trial results.

After I have drafted the Methods and Results sections, I work on the Introduction and sketch out a discussion for the authors to modify and expand. The abstract is usually the last section I work on because I tend to build it by cutting and pasting key sentences from the main sections and then editing the text to fit the required word count. Once, a lead author asked that I start with the abstract to help him organize his thoughts at the onset of the manuscript. Luckily, I only had to update and edit an abstract that the authors had presented at a conference.

As I research and write the first draft of a detailed outline or manuscript, I highlight references and annotate corresponding PDFs (Figure 8). In comment boxes or within brackets in the text, I include notes and queries regarding any potential issues (eg, missing or unclear methods, inconsistent use of terms) (Figure 9). I also compile small batches of queries that require prompt attention because they impact how I proceed in my work and email them. It's important to resolve issues sooner rather than later. I absolutely do not want to submit a draft peppered with queries that should have already been resolved.

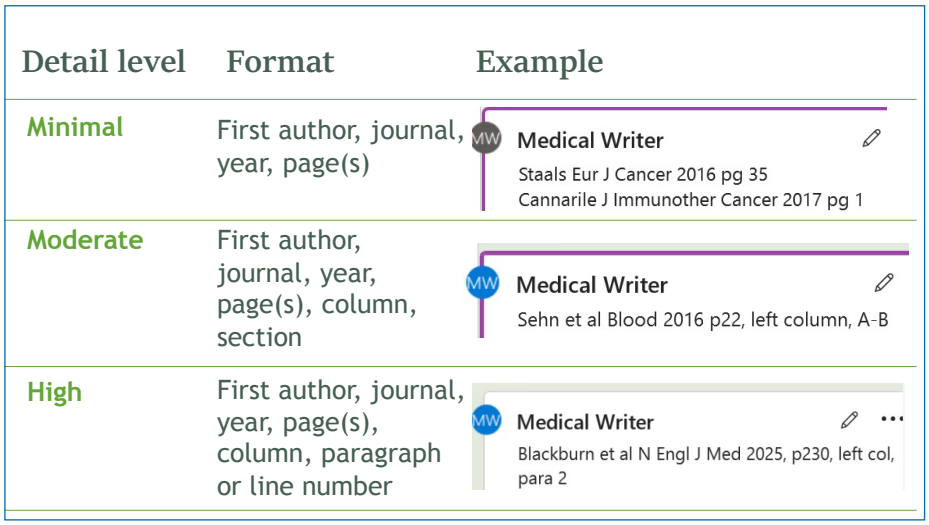

Figure 8. Examples of reference annotation formats.

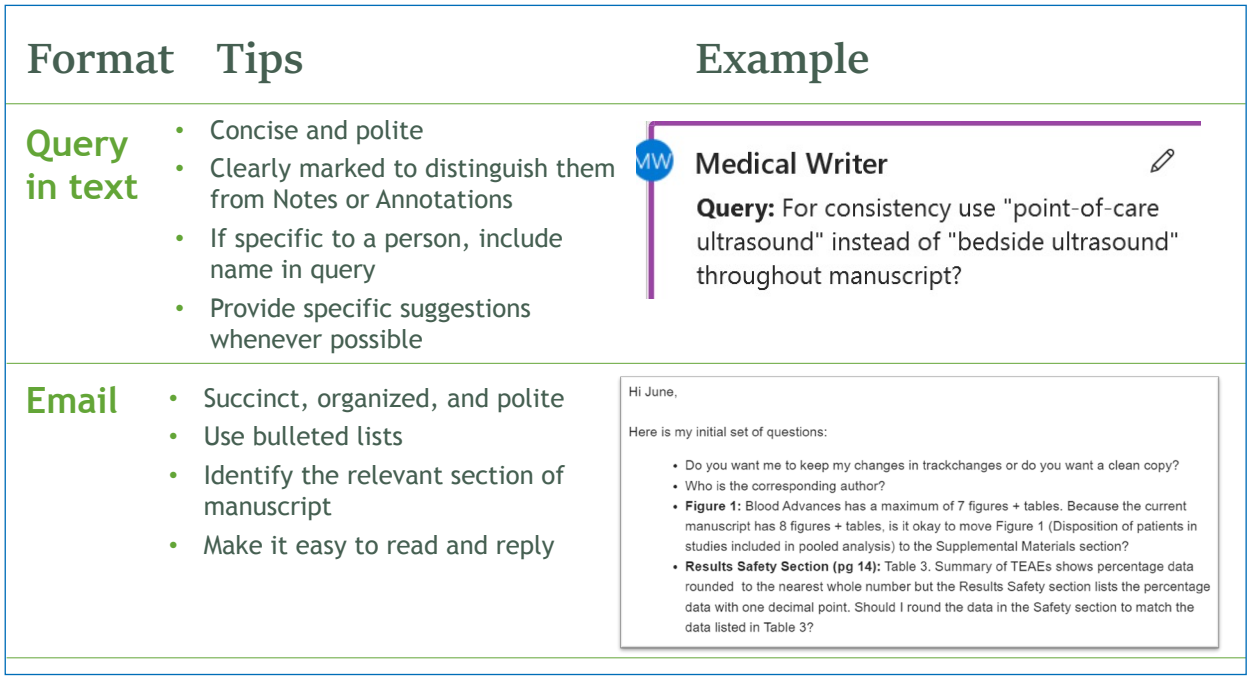

Figure 9. Tips and examples of in-text and email queries.

Throughout this work, I keep track of the word count (which for some journals can be quite stingy). Before I send any draft for review, I make sure to update the word counts for both the main text and the abstract. One of the tasks we have as PMWs is to help the authors comply with the word count requirements. This can be challenging during the draft revision process. When authors exceed the word count limit, I suggest edits in track changes to retain the meaning while reducing verbiage. Sometimes, I suggest that they move certain sections to an online supplement.

HOW TO AVOID COMMON PITFALLS

Common pitfalls of writing research manuscripts include accidentally plagiarizing published information and/or repurposing unpublished content; perpetuating inaccurate content; inserting erroneous data; creating a disorganized, inconsistent manuscript structure; and introducing typos, spelling mistakes, and poor grammar (Figure 10). Most of these errors are unintentional and are caused by taking shortcuts. I employ several tactics to avoid these pitfalls. If medical editors are on the project team, they will also check for these issues, but they might not be involved until later, and we should give them and the authors a well-written and organized draft to work on.

Cite and Paraphrase Content

Because plagiarism is unethical and infringes on intellectual property rights, PMWs should know how to paraphrase

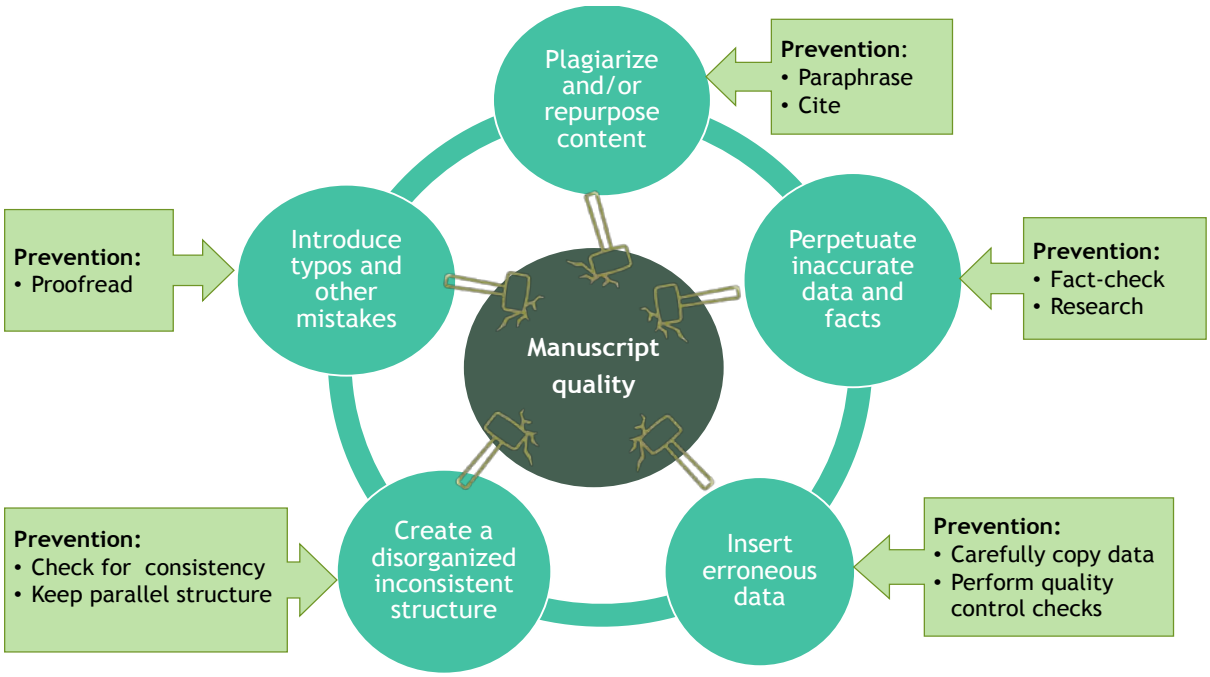

Figure 10. Common pitfalls and how to avoid them.

content and properly cite its sources. We should not succumb to the temptation of copying text from study protocols, clinical study reports (CSRs), and other unpublished documents. The writing style of such documents is often unsuitable for a journal article because it may be passive, formulaic, and verbose. It's better to paraphrase the material, pay attention to active and passive voice, and avoid using archaic terms like *subject* and *Caucasian*. I am also cautious about copying whole or parts of tables across files because disruptive formatting codes might transfer to the manuscript.

I would not use any content generated by an artificial intelligence program like ChatGPT. Several leading journals have published editorials discussing this controversial, still evolving technology and limiting or prohibiting its use in manuscripts submitted for publication.[18-21]

Verify Data and Facts

Another common pitfall in writing clinical research manuscripts is incorporating data and information cited in other documents (eg, protocols, CSRs, published articles) without factchecking the accuracy of each citation. I check the cited reference (often using the PDF search field to quickly find specific numbers or terms) to determine if it does indeed provide the information. Also, when the cited information is older than 1 to 2 years (depending on the field's pace of research), I do literature searches to identify more recently published sources. This is especially important for rapidly advancing fields like oncology in which, for example, the American Cancer Society publishes new statistics every year.

Even when not required by project specifications, I highlight references and annotate the detailed outline or first draft of a manuscript to keep a record of the sources of any included information and data. This documentation step does not take long, and it saves time and headache during the review/revision process in addressing questions regarding data accuracy, conflicting information, and other issues that might be raised by authors and other project participants.

I have noticed, when factchecking others' work, that some writers cite a published research manuscript as the source of information referred to in the Introduction or Discussion sections of the cited publication. This is a misleading use of a citation. For example, the Introduction section of a hypothetical phase 2 study by Smith et al on a new adjuvant drug for people with resectable pancreatic cancer mentions a range of reported median progression-free survival (PFS), citing 3 sources. Instead of taking the shortcut of inaccurately citing the Smith et al study in my manuscript, I would cite the primary sources for the PFS data or a reputable review. I would cite the Smith et al paper if I were discussing the results or conclusions of their study.

Avoid Inserting Numerical Errors

The compilation of data in tables and figures is one of most tedious tasks of a research manuscript project. It's challenging to keep track of and accurately copy numbers from large tables that were prepared for CSRs, Tables, Listings and Figures (TLFs), and other study reports. These are the steps I take to avoid losing track as I copy numbers:

- Place documents next to each other on a large screen.

- Enlarge source and recipient documents.
- Copy (cut/paste or retype) and round (if necessary) small batches of numbers at one time.
- After copying the numbers, highlight the data in the source document (to mark my place).
- Every 2 to 3 rows of copied numbers, backtrack and double-check the values to correct any typos.

The data in tables from CSRs, LTFs, and other statistical/mathematical outputs can be difficult to read because of the multiple digits to the right of the decimal (eg, 45.567% vs 45.6% or 46%). Often these digits are not scientifically significant, especially when they were generated to calculate percentages or mean/medians. As noted in the 11th edition of the *AMA Manual of Style*[1(p1010)], "When numbers are expressed in scientific and biomedical articles, they should reflect the degree of accuracy of the original measurement. Numbers obtained from mathematical calculations should be rounded to reflect the original degree of precision." The *AMA Manual* has a helpful section summarizing rounding rules.[1(p1011)] In addition to being scientifically accurate, rounded numbers are easier to read. However, before doing any rounding, it's important to verify with the authors how many significant digits they would like to use throughout their manuscript.

Create an Organized Consistent Manuscript

To create a well-organized and easy to read manuscript, PMWs must ensure the consistent use of terms, abbreviations, and data across the different sections of the manuscript (ie, abstract, main text, tables, figures, online materials). For example, the definition of an outcome measure described in the Methods and Results sections should match the definition used in a table. For numerical data, inconsistencies might especially occur whereby numbers are rounded in one section of the manuscript (eg, the Results text) but not in another (eg, a table, figure, or abstract). I use the Word Split screen option (Window submenu in the View bar) to help me verify that numerical data are reported in the same way across sections.

We should also use parallel structure in subheadings, paragraphs, and sentences that are discussing similar information. For example, the presentation of information in the Methods section should match the sequence and content of data discussed in the Results section.

Although some of these tactics may appear subtle, together they improve manuscript clarity and maintain reader's interest.

Proofread Your Drafts

As I work on a draft in Word, I turn on the Spelling and Grammar checker under the Proofing submenu of the Review tab. Despite this and careful writing, errors slip through. Thus, even if other people will review my work, I proofread it before sending any draft to the next step in the process. The point of proofreading is to catch and correct any mechanical errors, not to second-guess myself and rewrite.

It's challenging to proofread your own work because when you are immersed in writing a draft, your eyes tend to skim over words they have seen repeatedly, allowing errors to become invisible. To reset and refresh my eyes and brain after I finish a draft, I wait for several hours or, preferably, until the next morning before proofreading it.

I proofread on screen, zooming in to enlarge text 15% to 25% of my normal writing mode. Early in my writing career, I proofread printed drafts. I switched to working onscreen years ago because it works well for me and reduces paper waste. Other tips for proofreading onscreen include changing the background color, reading text aloud, and pointing at words as you read them. An interesting tactic Hope Lafferty, ELS, spoke about during her excellent AMWA 2022 Annual Conference education session entitled "Editing Your Own Work (After You've Read it 1,000 Times)" is to read text backwards, word by word or sentence by sentence.

TIPS FOR WORKING WITH CHALLENGING PERSONALITIES

Some authors and clients are easy to work with in a collaborative manner. Others might pose challenges. For example, they could be unresponsive, set in their ways, condescending, overly demanding, and inexperienced. Regardless, as PMWs we have to remember that the authors have the final say and responsibility for the content of their manuscript. We can offer suggestions and provide education, but all final decisions are theirs.

Patience and tact are essential for working with challenging individuals. For example, when I must respond to an irritating email, I draft a response and then step away from it for at least several hours before editing (usually to tone it down) and clicking send. Sometimes it might help to discuss the matter with a trusted colleague before further communicating with the difficult person.

During a project, I routinely keep all my emails in an organized fashion so that I can verify prior responses (keeping that paper trail documentation mentioned earlier). This is especially helpful when someone tells me to do one thing one week and something completely different a week later, doesn't respond to several polite emails asking for clarification or further instructions, or demands their draft earlier than agreed.

Other tactics for working with different personalities include:

- Be clear, concise, and tactful in all forms of communication (ie, email, queries in the drafts, voicemail).
- Suggest concrete solutions for issues regarding their writing—for example, instead of saying that text is unclear, I reword it into what I think it means and ask the authors if my edited version is correct.
- Use information from the *AMA Manual of Style*, journal author guidelines, and examples from articles published in the same journal or in more prestigious journals to educate about formatting and style decisions you implemented in a manuscript—for example, sometimes authors spend their valuable manuscript-review time to change "ie or eg" to "i.e. or e.g." They don't understand that I purposely used the unpunctuated abbreviations to follow the journal style (even though I noted on the first page that the manuscript is formatted per a specific journal). In these cases, I don't accept the author changes and explain my rationale, citing the appropriate style manual or manuscript preparation instructions.
- Try alternative ways of communication—some people who don't respond to emails might be reachable through a phone call or by first speaking with their administrative assistant or another member of the project team. Online meetings to share the screen and do edits live might work well for authors who never find the time to review drafts and send their comments via track changes.

FINAL WORDS

Being a PMW is rewarding and humbling. We should take pride in the ways we contribute to the clear and timely publication of research findings. It is gratifying to hear from authors how much they appreciate our work. However, we also have to accept feedback and corrections from editors, authors, and other stakeholders involved in the project. When we make mistakes, we should take responsibility, apologize, and learn. These actions help us grow as professionals and maintain good working relationships with authors, clients, supervisors, and colleagues. Regardless of whether a PMW works on research manuscripts or other types of projects, practice and ongoing learning are critical for success. To keep up with progress in our profession and in the therapeutic areas we work on, PMWs must continue to broaden our knowledge base and skill sets throughout our careers.

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TOPICAL FEATURE

PART 1 IN A 3-PART SERIES

The Business of Medical Writing: Understanding the Value Proposition and Successful Business Models

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ABSTRACT

A high-performing medical writing team begins and ends with talented writers, editors, and leaders who understand their mission and their business. A panel of writers comprising the authors convened virtually on October 28, 2021, at the American Medical Writers Association National Conference to discuss this topic. The topics of value proposition and business models, communication and leadership, and financial acumen and corporate responsibility will be reprised in this 3-part series, along with thoughts from the authors looking to the future of the business of medical writing, including what we can do in the medical writing community to introduce these topics earlier in the medical writing career path.

A high-performing medical writing team begins and ends with talented writers, editors, and leaders who understand their mission and their business: the value proposition, the finances that drive strategy and decision-making, the financial goals, and effective communication. To execute the organization's goals, leaders must orchestrate resources and often have to balance dynamic variables including budgets and governance that provide bidirectional input into the business strategy.[1]

A panel of writers comprising the authors convened virtually on October 28, 2021, at the American Medical Writers Association (AMWA) National Conference to discuss this topic.[2] The authors felt the topic was apropos given that they themselves have experienced—and often hear from other writers—that business-related topics in medical writing are learned on the job, mid- to late-career, when writers are expected to be able to analyze and synthesize knowledge across the business portfolio of assets,[1] often in high-stress and rushed circumstances without the benefit of prior observation.

The panel members shared their own journeys as business leaders and the methods they used to strengthen the business acumen of their teams. Discussion topics included identifying and defining a compelling value proposition; models to teach financial understanding and oversight; business leadership skills, anchored by simple, clear communication, to keep teams motivated and engaged with their mission; collecting data to measure the effectiveness of teams and prioritize and allocate resources in support of business goals; and communication styles to support critical business drivers such as team focus and engagement.

The topics of value proposition and business models, communication and leadership, and financial acumen and corporate responsibility will be reprised in this 3-part series, along with thoughts from the authors looking to the future of the business of medical writing, including what we can do in the medical writing community to introduce these topics earlier in the medical writing career path.

The authors' collective experience comprises the following medical writing work environments:

- Freelance business
- Small business/vendor
- Department leadership of small- to mid-size biotech company and large-sized pharmaceutical company

The moderator's (Joan Affleck - JA) prompt is provided for each topic, followed by each perspective on the topic. In some cases, text from the session has been paraphrased for optimal clarity in this medium.

DEFINING VALUE

Value Proposition

JA: Let's start today with a fundamental question for each of us. We often hear the buzz phrase "value proposition." That's the idea that there's a service or product that is attractive and valuable to a customer or end user.[1] In my regulatory medical writing department, our value proposition, in brief, is that we develop documentation to support the research and development objectives of a much larger organization. ***So, what does your value proposition mean in your organizations, and why is your value proposition important in the big picture?***

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Jeanette, could you start?

Jeanette Towles (JT): I'll start by saying what our value proposition is: "We apply our years of experience and current regulatory and technical knowledge to help deliver important new therapies to patients in an expedient manner. We are a best-in-class firm and take pride in our operational excellence." For me, a value proposition means: 1) what we bring uniquely to the table if a customer wants to work with our company; 2) what we stand for; 3) what challenges we solve; and 4) what gains we offer (Figure 1). Hopefully, by convincing the customer [that] we can use our years of experience, we make the sale—and the company not only chooses us but also keeps coming back to us. We strive to leave the impression with our customers that we should really be their go-to to get things done. This proposition also translates well to the in-house setting.

Figure 1. Defining a value proposition.

JA: ***Dom, is that something that resonates with you, being in Big Pharma?***

Dominic De Bellis (DD): Being the go-to to get things done always resonates with me! It's important to understand that, regardless of whether [you're] independent or in-house, your goal is really the same: to provide [an] excellent product to the client. For the freelancer, that will be another organization, and for the in-house medical writer, that's your clinical team or your document development team. You're a smaller piece of a bigger organization if you are in-house, but the requirements from the writers' or teams' perspective are very similar; it is a question of how you manage the team to affect the success of the document as a whole.

JA: ***And Brian, in the freelance context, what's that like?***

Brian Bass (BB): In the freelance world, value is paramount. If we are not bringing value to the table, we are not going to be able to make a living wage and ultimately keep our clients. The value proposition from the freelance standpoint is to remember that first and foremost we are problem-solvers. Clients come to freelancers when they do not have someone on staff (or another freelancer they have worked with) who can get the job done. Especially when clients reach out to you as a new freelancer, they are coming to you with a problem, and our job is to solve that problem. We happen to do it by medical writing, but what we need to understand is what is driving the client's need to reach out to us. They need us to be confident, and they need to be confident in us. They need to know that we are going to make their job easier. And that's how freelancers ultimately put forth their value in making their clients' lives easier.

JA: ***Have any of you run into challenges with defining or clarifying that value proposition with your customers? Any situations [in which] they didn't quite understand what it was you were bringing to the table or perhaps misinterpreted it?***

JT: This comes up fairly often, to be honest—and earlier in my career this was surprising, but it no longer is. I enter each client relationship and document saying I need to prove myself to this client continually for them to keep coming back to me—for example not only that we can execute a clinical study report but also that we can execute a supplemental new drug application in its entirety. Needs, requests, and the regulatory environment change over time, so I have personally faced continual challenges. I also worked with an organization that was in such a funding situation that we kept getting questions about every dollar and

cent. So, I said to myself that I need to have a conversation with this customer to walk them through what goes into this work. That exercise ended up building trust; they came to understand how many hours went toward producing a particular type of document and all the steps that went into it. In the long run, we received fewer questions, and the tone shifted to a more trusting partnership. If you are having challenges, it is worth having a conversation about them.

JA: Interesting that trust is something we don't usually think of as being part of a business plan—but you and Brian have both pointed out it most definitely is: trust and confidence.

> Trust is something we don't usually think of as being part of a business plan, but it most definitely is: trust and confidence.

BB: I find that clients often don't realize what I strive to deliver to them makes their job easier because I anticipate where other freelancers go wrong: not staying in touch and on top of projects, calling at the last minute to say they are behind schedule, things like that. All of those mistakes really are so easy to avoid if you focus on them. But many clients don't expect that, and they are naturally very pleased. As a matter of fact, I just received an email this morning from a client who said, "you are everything that so-and-so said you were." And to me, that is the proof of why I work hard to deliver that value proposition.

JA: ***Dom, when you are embedded in a company, do you still have the same challenge—do you have to keep proving yourself to customers?***

DD: It's very much the same, you are only as good as your last document. That maxim holds true in-house in the same way. The problems we solve may differ: we may be more focused on navigating complex internal processes on behalf of the team, we may be more aware of certain regulations that may be more relevant, and we have to keep our finger on the pulse of those changes. But from a document development and writing standpoint, it's the same thing: quality is expected, and we need to provide that level of service. I think of our teams as our clients, so there's "client education" to get the team to understand what's involved in the work you are doing. Everyone learns to write, which is wonderful, but not everyone writes the way we need them to write for a particular document or in a way that's applicable to the audience you're writing for. There are many nuances to the craft, and it's necessary for us to explain that to the client or team as we build trust and get them to see the value proposition.

BUSINESS MODELS

JA: OK, so you've got your value proposition—this is the value we bring. But then you have to have a way to operationalize that—you've got to have a business model that hooks up with your value proposition. Let's talk a little bit about the kind of business model you have today. Is it a group, one person, [a] freelancer, in-house employees? ***What are some factors you consider as a business leader when you're building a business model? Brian?***

BB: I was an independent freelancer for the first 15 years or so of my business. Since the early 2000s, I have been bringing in other freelancers who subcontract with me, including both medical writers and medical editors. My business model had to evolve because I was no longer just responsible for paying attention to how I delivered for my clients in terms of the value I bring to the table. I had to make sure that the other people on my team understand that as well and take that to heart as much as I do. Therein lies the challenge for any manager; even though I'm not operating a big department within a large corporation, I am still operating my own department. I am ultimately responsible for any project and any person on my team who is working on it. So, I had to adapt my model to consider the amount of time it takes me to manage the projects, to work behind the scenes with the writers and editors to make sure they are delivering the way I need them to deliver. One way that I am perhaps a little unique compared with other freelancers who bring in subcontractors is that the people on my team are as qualified if not even more qualified than I am, so they are all at the top of their craft. I find that by starting with the very best people, it takes away some of the challenges you might run into with people who have less experience and are still learning their way through the processes. That is what has been working for me.

JA: I like how you talked about thinking of your group as your own department because I do just the opposite. I say, okay, I have a department within a large corporation, but I think of it as my own business. So, I like that cross-pollination.

BB: Clearly it must work if we are both approaching it that way; we are doing the same thing, just from a different direction!

JA: Exactly, and we are borrowing across each other's worlds! Jeanette, I bet that with your value proposition and that quality element, you, too, must spend a fair amount of time in your business model making sure that other people who are delivering on behalf of your company's name are doing it at the very highest level and in the way you want them to deliver. Is that true?

JT: That is absolutely right. "Operational excellence" is part of our pitch, and we make sure we deliver on it. Similar to what Brian was saying, if you are going to pitch yourself as a best-in-class firm, you really need people who have the experience behind that. And not just on paper—we administer a test to make sure, pragmatically speaking, that they live up to the basic standards, that they are focusing on the right things if they have a short period of time to do something. Something we introduced recently was a pathway for people who don't have as much experience in industry; and the reason we did that is two-fold: 1) our resource pool is finite by nature, which COVID emphasized because there was a lot of competition for really great talent; and 2) a sense of corporate responsibility to help people coming in at a lower level to work up to where they could eventually do tasks on their own. So, we created a Medical Writing Operations group, and we have folks come in through that pathway, learn what it's like to be in this function, learn what it's like to manage a project day-to-day, and approach it that way. By learning the basics in a lower-pressure environment, they have the opportunity to really learn and get exposure to items so they could eventually live up to those same standards that we have to offer on the medical writing side.

JA: It's really interesting that Brian and Jeanette both touched on resourcing; the care, feeding, and development of medical writers and medical communicators; and the search for top talent all as part of the business model. ***Dom, is it the same in your space?***

DD: I may be repeating myself, but yes, it is in the sense that we also need top people here on our team to do the same kind of work. The finite resource pool is a known challenge for all of us; however, we have to provide the right environment—whether it be training, resources, infrastructure, or established process: these are the things we offer as an in-house environment versus someone who may start out freelancing independently or work with someone more established. It's the same need for personnel, and the one difference we have in-house is we have the resources available to us to develop and put plans in place or put opportunities in front of people for them to have a broad experience and to become marketable across the industry in medical writing, rather than to become pigeonholed in one particular skill set or document type. We need the same high-quality people. We may have an advantage in what we can offer in terms of training people and developing them, but again, we cannot do that at the expense of quality or the work that has to be done, so it's a delicate balance.

LOOKING TOWARD THE FUTURE

As the moderator of this AMWA Business of Medical Writing discussion noted, this panel was an initial dialogue meant to "kick off a broader discussion of the many aspects of business leadership as it applies to our work as medical communicators."[2]

Learning about business is part of regular training in adjacent fields in industry, for example, for regulatory affairs professionals (Figure 2).[1,3] The business acumen domain of the Regulatory Affairs Professionals Society (RAPS) competency framework, for example, as a cross-functional domain, is characterized as representing "knowledge content that is broadly relevant to those employed as regulatory affairs professionals."[3] The domain descriptor is the "ability to leverage systems and processes to successfully operate a regulatory function to manage product and organizational risk," and the topics covered include industry-specific, operational, project management, quality management, and continuous improvement knowledge.

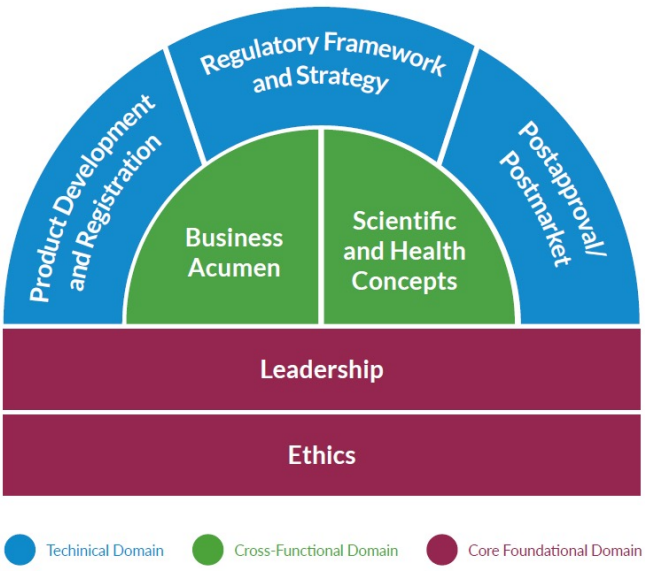

Figure 2. Regulatory professional competency framework, including business acumen domain. Source: Regulatory Affairs Professional Society (RAPS). Regulatory Competency Framework Model Concept. 2021.[3]

The similarity of the regulatory framework's business domain description to what medical writers encounter in their daily job function—for example, leveraging systems and processes to manage risk—is striking. What is

equally remarkable is that the business domain is considered "broadly relevant" to all in the job function—not just for those considering being in a management position. In this framework, leadership and ethics are "the foundational domains, providing the underpinning for professional success" and are considered as additional skills separate from the business acumen domain, whereas the panelists for the Business of Medical Writing discussion considered them within the same overall umbrella of business skills but placed them with the same level of importance in terms of contribution to overall professionalism.

Although the DIA medical writing competency model references the need to deliver to business objectives and interact with business partners to meet customer needs as part of the writer's regular functions, tasks, and activities,[4-6] it is not clear what business literacy skills medical writers should acquire to prepare them for such interactions. In fact, this model not only prescribes key activities like mapping of a "product's key messages to customer needs, critical success factors, medical/scientific objectives, clinical plans, and data results across phases of development and global regions," but assumes that the writer is familiar with how to create important business documents like a business continuity plan. So, the question remains—what content from these disparate sources is most relevant in the medical writing context?

Furthermore, managers of medical writers are expected to understand many tenets of business interconnectivity, management principles, innovative concepts and organizational theories, finance and budget management, resource and performance management, vendor management, strategic planning, change management, metrics, and more.[6] The AMWA Recommended Training Outline for Regulatory Writers, although acknowledging that the skills in the outline are but some of the skills and proficiencies needed for professional success and are subject to regular review and update, similarly does not distinguish business knowledge as a separate training topic and broadly covers the topics of analytical skills, self-management, people skills, and personal development across 2 primary categories that make up the competency along with a third category for document-specific training.[7] Having a comprehensive business curriculum would benefit the writer in these circumstances toward the goal of developing a strategic mindset while learning fundamental business topics.

Realizing a value proposition that solidly complements the now-accepted medical writing competencies requires a pathway whereby medical writers can readily learn the skills needed to demonstrate leadership while also participating in decision-making activities earlier in their careers. Along with such a pathway is the need to develop the infrastructure of their departments that supports the development of business-savvy medical communicators.

The panelists of the Business of Medical Writing discussion (the authors) hope to use the momentum of the interest and enthusiasm of the medical writing community on this topic from the national conference to propel our community forward into further discussions about how business literacy can be incorporated into our training curricula and our practices and processes—and ultimately, perhaps our competency frameworks—so that it becomes an intentional element of training for all writers, enabling them to best support the needs of their organizations and businesses.

Author declaration and disclosures: *J. Affleck and D. De Bellis are employed by Merck & Co, Inc, and are shareholders. B. Bass and J. Towles note no commercial associations that may pose a conflict of interest in relation to this article.*

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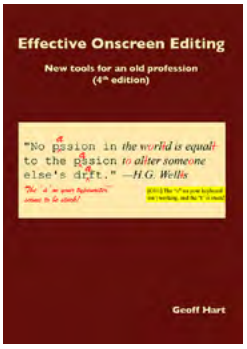
TOPICAL FEATURE



Effective Onscreen Editing: New Tools for an Old Profession (4th ed.)

Alba I. Cid, MSc / Quincy, MA

It's highly unfortunate, but for a large majority of people, their writing and editing software is basically a typewriter: most shortcuts, symbols, or things like automatic find and replace, for example, don't exist. This is where *Effective Onscreen Editing* stands out: it will make you aware of the software editing tools you have available at your disposal. It will teach you how to use them to the best of your abilities to make your work more accurate and efficient. There is a lot of content, so even if you know some about the workings of the software, you are bound to learn some very good tips. Mr Hart has decades of experience as an editor and was willing to share them in his book.

The text is not organized around Microsoft Word but around editing functions within a word processing program. Therefore, the book should be useful to those using other programs as well. However, Word is still the most often used program for editing, so you will see the most about it. Take a look at what is covered: A detailed table of contents is available at http://geoff-hart.com/books/eoe/detailed-TOC.html. Perhaps you will need a boost from your search engine to verify how to properly set a function up in an alternative software, but the practices introduced within the book are extremely effective regardless because they introduce the general principles and how to use them. The book also takes into account Mac users and points out differences in protocols if necessary. The book covers Word 2016, so anyone who orders it will also receive for free a copy of Hart's more recent book *Write Faster with Your Word Processor*, which contains updated information on changes in Word 2019. It also has a website to add updates to the content.

The portions of this book I found most valuable were those that deal with tailoring your word processing program to suit your preferences when displaying documents, strategies for maneuvering quickly through a document, how to select text quickly and accurately, track changes, how to use styles and templates, using AutoCorrect to fill in text, leveraging find and replace tools, discussion of macros, and style sheets. Additionally, Hart gives good advice on adding explanatory comments to a document to communicate with the author. Although learning how to use these tools properly can take a long time, it can lead to greater accuracy and efficiency in the long term, which is critical in medical writing and editing.

The book also provides other advice not directly related to word processing software. The author discusses important issues such as document access, contracts, and pay rates. He also provides advice on working in teams and equipment that promotes healthy ergonomics. Details on editing graphics, video, and multimedia files—mediums that are becoming increasingly common—are also discussed. The book is a very useful colossus, including its appendix of shortcuts.

As a bonus, Mr Hart cares about keeping the book updated as word processing functions change, and he provides links to the book's webpage. The book has a website that includes images and further information and can be regularly updated. You have access to these new explanations if you own the book. Previous editions of *Effective Onscreen Editing* are available to users of earlier versions of the Microsoft Word program.

Further, the book is reasonably priced and is substantially discounted for groups, students, and members of professional organizations (http://geoff-hart.com/books/eoe/onscreen-book.htm#buy). The book is available in print, EPUB, and PDF formats. A digital version would be recommended so that the links in the text, as well as the clickable index and table of contents, can be easily used. A compressed version of the webpages for the book, with links to all the images and procedures, can also be downloaded so that you can work offline if you're travelling.

The book has made an impact and is now on its fourth edition. The European Medical Writers Association gave the prior edition a very good review, with the review author saying, "This might just be the most useful book I have ever reviewed. Anyone who does any kind of editing work or who wishes to use Word more efficiently should strongly consider buying it." It's true that it takes a lot of time and effort to read the book and apply its precepts, but there are many good ideas worth incorporating into your work. It's easy to open the book to learn how to deal with a particular issue and save time with a solution. The savings in time and the increase in accuracy should be considerable, so I highly recommend the book as well.

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Antibody-Drug Conjugates: Understanding Associated Drug Design and Pharmacology

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ABSTRACT

Antibody-drug conjugates (ADCs) are currently among the fastest growing drug classes in oncology, combining the specificity and targeting capabilities of monoclonal antibodies (mAbs) with the potent cytotoxicity of small molecule drugs. Considered the "biological missiles" of cancer therapy, ADCs are composed of 3 key elements: (1) a mAb framework that selectively binds to an antigen on the tumor cell surface, (2) a cytotoxic drug payload, and (3) a chemical linker attaching the 2 entities. Because each of these components can vary widely among ADCs, the associated drug design is relatively complex, with subtle differences leading to immense diversity in the overall drug structure and associated pharmacological and clinical properties. As medical communication experts, it is essential to have a basic understanding of the various components of ADC design and their potential impact on drug efficacy, safety, and capability in targeting certain degrees of antigen expression and tumor types. This review aims to provide a basic understanding of each component related to ADC design and the role they play in defining the pharmacological properties of a particular ADC.

BACKGROUND

First proposed by Paul Ehrlich in the early 1900s, the foundational concept of a "magic bullet" as a way to selectively transport cytotoxic drugs to a specific target tissue has become an ever-closer reality, passing through key milestones over the last century.[1,2] The development of chemotherapy in the 1940s was a first major step in the transition from concept to reality.[3] However, the lack of high-level specificity and targeting capabilities with cytotoxic agents led to a high degree of systemic toxicities and has remained an ongoing challenge. The advent of hybridoma technology and the development of monoclonal antibodies (mAbs) in the 1970s established a highly effective method for targeting specific antigens expressed on the tumor cell surface.[1,4,5] This led to the development of targeted therapeutics that have become an attractive method for improving tumor selectivity and reducing the systemic toxicity associated with traditional chemotherapy.[6] Combining these 2 technologies enabled the development of the first antibody-drug conjugate (ADC). In recent decades, ADCs have become a rapidly expanding therapeutic drug class specifically designed to overcome the shortfalls associated with chemotherapeutic agents.[6,7] Currently, there are 13 ADCs that have received US Food and Drug Administration approval for various hematological and solid tumor cancers.[1,8-20]

ADC MECHANISM OF ACTION

ADCs are a group of tripartite drugs made up of a tumor-specific mAb conjugated via a stable linker to a potent cytotoxic payload.[21,22] The core concept of an ADC is to use the specific recognition between an antibody and antigen to selectively deliver cytotoxic drugs to the tumor site, after which the payload is released in the tumor via a specific release mechanism.[23] The general mechanism of action for an ADC can vary depending on the inherent design (Figure 1, next page).

ADC DESIGN

The clinical success achieved with a particular ADC is contingent upon several key factors: (1) target antigen, (2) antibody framework, (3) method of conjugation, (4) chemical linker, and (5) cytotoxic payload (Table 1, next page).

Target Antigen

To achieve a favorable therapeutic index and reduce the potential for off-target toxicity, the selected target antigen should be tumor-specific or tumor-associated with a high level of expression in tumor cells and minimal to no expression in healthy tissues.[24,28] Following ADC binding, target antigens should internalize efficiently via endocytosis to enable ADC entry into the cell and subsequent cellular transport and payload release.[1,21,29] The target antigen should also undergo efficient recycling or replenishment on the cell surface with no associated antigen shedding into

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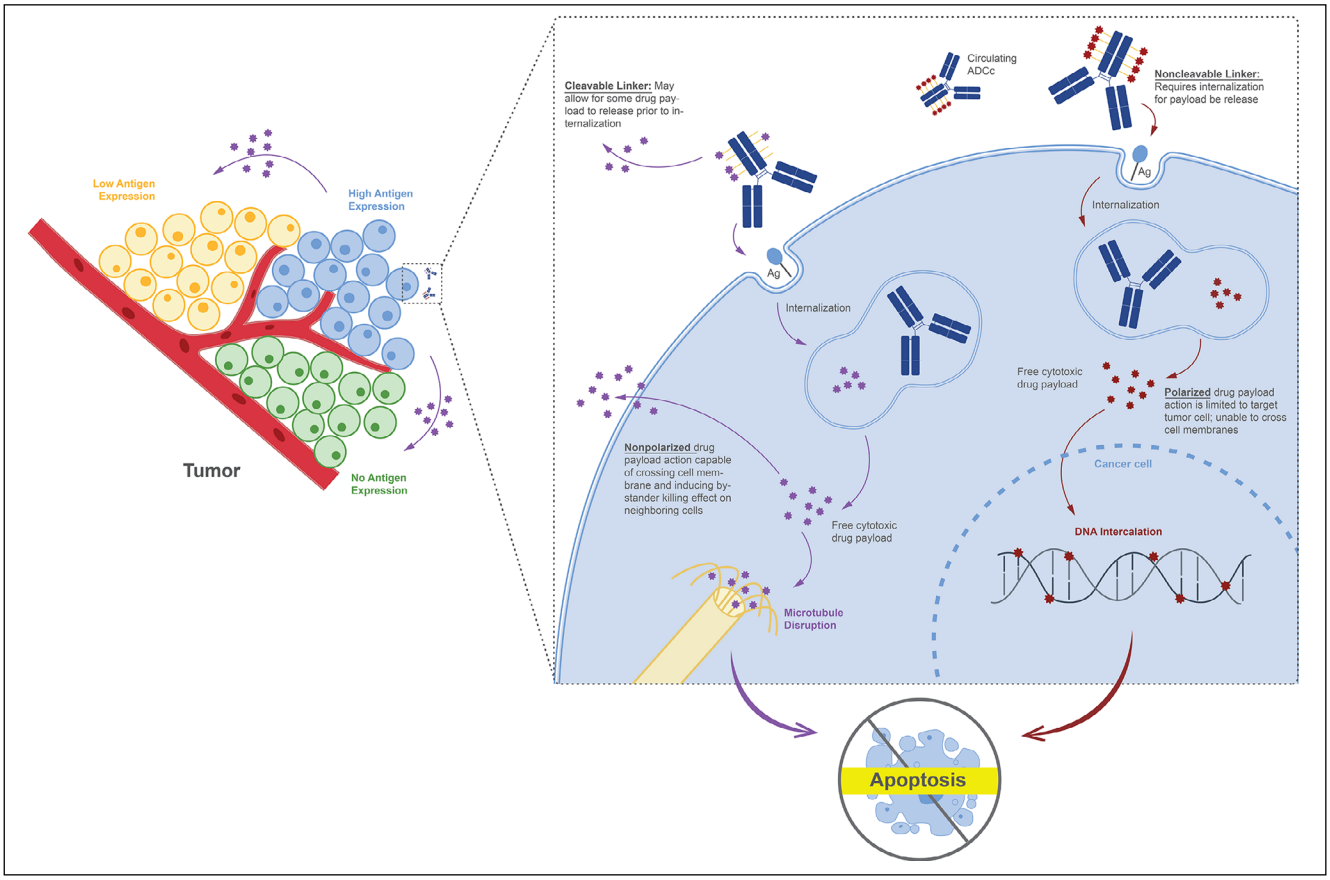
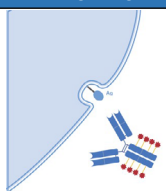
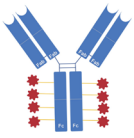
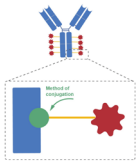
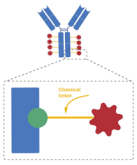
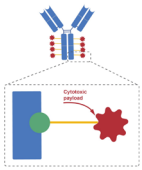


Figure 1. General mechanism of action of ADCs with and without bystander killing effect.[5,21-23] Following introduction of the antibody-drug conjugate (ADC) into the plasma circulation by intravenous injection, the target antigen is recognized on the tumor cell surface, leading to subsequent binding and formation of an antigen–ADC complex (ADCc). The complex is then internalized via receptor-mediated endocytosis. For ADCs with cleavable linker design, some initial release of drug payload may occur prior to internalization. Once inside the cytosol, endosome, or lysosome, the chemical characteristics of these environments (eg, low pH, high glutathione/thiol levels, proteolytic enzymes) allow for further payload release. In the case of ADCs with noncleavable linker design, compete degradation of the ADC is typically required for payload release. The resulting free cytotoxic drug payload then exerts its cellular destruction via a pathway-specific mechanism (eg, microtubule disruption, DNA intercalation). Hydrophobic or nonpolar payloads are capable of crossing cell membranes, thereby exerting a so-called bystander effect. The bystander killing effect involves the diffusion of free drug across cell membranes from the target tumor cell and into neighboring tumor cells, thereby expanding antitumor activity to tumor cells with low or no target antigen expression, or those that are less accessible directly from the circulatory system, eg, solid tumor cells. Ag, antigen.

Table 1. Components of ADC Drug Design[1,7,25,26]

Target antigen	Antibody framework	Method of conjugation	Chemical linker	Cytotoxic payload
				
Ideal characteristics • Highly expressed in tumor cells • Homogeneous expression in tumor cells • Minimal presence in circulation and healthy cells	**Ideal Characteristics** • Minimal cross reactivity with healthy tissues • Low immunogenicity • Strong binding affinity for the target antigen • Long PK half-life	**Conventional/stochastic** • Lysine sites • Reduced cysteine sites **Site-specific** • Engineered reactive cysteine residues • Disulfide re-bridging • Unnatural amino acids • Enzyme assisted ligation • Glycan remodeling and glycoconjugation • pClick technology	**Cleavable linkers** *Chemically cleavable* • Acid sensitive • Glutathione sensitive *Enzymatically cleavable* • Peptide based (protease sensitive) • B-glucuronide based • Phosphate based **Noncleavable linkers** • Thioether (SMCC) • Maleimido propionyl • Maleimido caproyl	**Tubulin Inhibitors** • Auristatins (eg, MMAE, MMAF) • Maytansinoids (eg, DM1, DM4) • Tubulysins (eg, tubulysin A) **DNA damaging agents** • Calicheamicins (eg, ozogamicin) • Duocarmycins (eg, duocarmazine) • Pyrrolbenzodiazepines • Camptothecin analogues (eg, govitecan, DXd) **Immunomodulators** • TLR agonists • STING agonists

Abbreviations: Ag, antigen; DM1, mertansine; DM4, ravtansine; DXd, deruxtecan; Fab, fragment antigen binding; Fc, fragment crystallized; MMAE, monomethyl auristatin E; MMAF, monomethyl auristatin F; PK, pharmacokinetic; SMCC, sulfosuccinimidyl 4-(N-maleimidomethyl)cyclohexane-1-carbocylate; STING, stimulator of interferon genes; TLR, toll-like receptor.

circulation to improve tumor cell targeting and reduce the risk of toxicity.[30,31] Solid tumors present a challenge in terms of both the drug accessibility and intratumoral heterogeneity of the target antigen. Therefore, certain characteristics of ADC design, such as cleavable linkers or nonpolarized payloads, which permit the release or distribution of drug to neighboring tumor cells with low or no antigen expression (the so-called bystander effect), may be advantageous in ADCs targeting these tumor types.[31]

Antibody Framework

The antibody framework used in the ADC structure is essential for facilitating selective binding of target antigens and can significantly influence the overall efficacy, therapeutic index, and pharmacokinetic and pharmacodynamic characteristics of the end drug product.[1,21] Ideally, the selected mAb should possess a strong binding affinity with high target specificity and minimal cross-reactivity with healthy tissues.[24] The selected mAb should also facilitate efficient internalization, demonstrate low immunogenicity, and have a long half-life. Among the 5 major subtypes of human antibodies (eg, immunoglobulin [Ig]A, IgD, IgE, IgG, and IgM), IgG antibodies are most often used for ADC development because of their plasma stability and strong binding affinity for the fragment crystallized (Fc) receptor.[1,21,32] Moreover, because of their decreased potential for immunogenicity, humanized or fully human mAbs are typically favored in ADC design as opposed to murine or chimeric mAbs.

Method of Conjugation: Conventional

The method of conjugation in ADC design refers to the approach used to connect the linker and payload to the mAb framework.[1] Historically, conventional conjugation methods have been the most widely used in ADC design. Conventional conjugation entails either the alkylation or acylation of lysine side chains or the reduction of disulfide bonds to liberate cysteine residues for conjugation sites.[21,33] Notably, mAbs such as IgG contain a natural abundance of lysine (80-100) and cysteine (32-40) residues, which offer ideal sites for linker attachment via conventional conjugation involving coupling reactions.[1,27,33-36]

Conventional conjugation using lysine and cysteine residues is stochastic. This can lead to heterogeneous mixtures of ADC species with varying sites of conjugation and drug-to-antibody ratios (DARs), defined as the number of drug payloads conjugated to each mAb.[37] DARs associated with ADCs produced by conventional conjugation methods often vary, ranging from 0 to 8 or more.[38] DAR-associated variability can potentially impact certain ADC characteristics, such as hydrophobicity, charge, polarity, pharmacokinetics, and thermostability of mAbs.[38-40] In some cases this may result in insufficient stability, causing premature payload release and increased potential for off-target toxicities.[1] Elevated DARs can also lead to aggregation, increased metabolism, or disruptive coupling within the antigen binding region of the mAb.[21,41,42] Because lysine residues are distributed throughout both heavy and light chain regions of the antibody, coupling reactions resulting in payload conjugation near antibody–antigen recognition sites could interfere with ADC target binding.[1,39] Moreover, ADCs with cytotoxic payloads conjugated to heavy chain regions of the mAb have lower in vivo efficacy compared with light chain conjugates.[24,44] Consequently, novel site-specific conjugation strategies have been developed that produce more homogeneous ADC products with favorable pharmacokinetic and antigen binding properties.[1,37,41]

Method of Conjugation: Site-Specific

Site-specific conjugation strategies are categorized according to their associated methodology and generally include the following: (1) engineered cysteine residues, (2) disulfide rebridging, (3) engineered unnatural amino acids, (4) enzymatic assisted ligation (5) glycan remodeling/glycoconjugation, and (6) proximity-induced antibody conjugation method (pClick) technology.[1,21,45,46] Site-specific cysteine residues are commonly engineered using THIOMAB technology, which allows specific positioning of conjugation sites within both heavy chain and light chain regions of the antibody.[47] Drug conjugates created using THIOMAB technology are typically referred to as THIOMAB-drug conjugates and are shown to have improved safety and therapeutic indexes.[46]

Disulfide rebridging is a process in which 4 interchain disulfide bonds in an IgG antibody are reduced and subsequently treated with a cysteine-selective cross-linking reagent.[48] This rebridging process enables simultaneous reattachment of polypeptide chain and installation of drug molecules or function groups that may be further modified. Genetically encoded unnatural amino acids, such as *p*-acetylphenylalanine and *p*-azidophenylalanine, are other site-specific conjugation methods that have demonstrated specific advantages in terms of optimizing physical properties of the ADC, and improved associated efficacy, pharmacokinetic, and safety profiles.[41,49] Compared with conventional cysteine conjugated ADCs, those using unnatural amino acids for site-specific conjugation demonstrate superior *in vitro* selectivity and efficacy, particularly in low antigen expressing tumor cells.[50] Enzyme-assisted ligation techniques use enzymes such as transglutaminase to conjugate specific amino acid sequences or tags that are genetically engineered and artificially induced to express in the antibody.[1,21,51] Glycan remodeling or glycoconjuga-

tion methods exploit naturally-occurring glycosylation sites at the N297 residue in the CH2 domain of IgG antibodies.[52] However, relative to other site-specific conjugation approaches, glycan remodeling has limited control over site placement. A site-selective conjugation method using pClick has more recently emerged and uses a proximity activated crosslinker to covalently attach to a specific antibody site, which eliminates the need for additional antibody engineering or post-synthesis treatments.[53]

Chemical Linker

The primary function of chemical linkers in ADC design is to effectively bridge the mAb to the cytotoxic drug payload.[1] ADC specificity, potency, safety, and overall activity are greatly influenced by the associated linker chemistry.[24] Linkers are generally designed to remain stable in circulation and release the drug payload once the ADC has reached the target tumor site.[2,24] Chemical linkers commonly employed in ADC design are classified into 2 main categories: cleavable and noncleavable linkers.[1,24]

Cleavable Linkers

Cleavable linkers are designed to exploit cancer-specific cellular conditions and are generally divided into 3 primary categories: acid or pH sensitive, glutathione or redox sensitive, and enzymatically cleavable (eg, protease sensitive).[21,24,28] Acid-sensitive linkers, such as hydrazone, are designed to release the drug payload within acidic environments, such as lysosomal or endosomal cellular compartments, while remaining stable within the blood's neutral pH environment.[1,31] Glutathione-sensitive or disulfide linkers exploit the high levels of glutathione and other thiols present in the cytosol of cancer cells, thereby enabling selective cleavage of the cytotoxic payload at the tumor site.[24,28,54] Protease sensitive or peptide-based linkers most often consist of dipeptide linkers (eg, valine-citrulline), which require enzymatic cleavage of peptide bonds for payload release.[28,31,55] Compared with chemically liable linkers (eg, hydrazone and disulfide), peptide-based linker technologies allow for greater control of drug delivery, with improved systemic stability and rapid enzyme-mediated release of the drug payload within the target cell.[31]

Noncleavable Linkers

In contrast with cleavable linkers that rely on tumor-specific cellular conditions for payload release, noncleavable linkers require internalization via antigen-mediated endocytosis and lysosome-mediated proteolytic degradation for payload release.[24,31,56] Generally, noncleavable linkers are associated with greater plasma stability, longer half-lives, and pose a reduced risk for off-target side effects. However, the actions of ADCs with noncleavable links are typically restricted to the target tumor cell. Moreover, amino acid-drug metabolites resulting from the drug payload release tend to be more hydrophilic and have greater intrinsic polarity, which reduces bystander effect. Commonly used noncleavable linkers in ADC design include the thioether linker succinimidyl-4-(N-maleimidomethyl) cyclohexane-1-carboxylate or maleimide moieties, such as maleimdopropionyl and maleimdocaproyl.[25]

Cytotoxic Drug Payload

The drug payloads employed in the design of ADCs are typically 100 to 1,000 times more potent than the cytotoxic agents used in traditional chemotherapy.[24,57] Cytotoxic payloads are generally subdivided into 2 main categories: (1) DNA-damaging agents, including calicheamicins, duocarmycins, pyrrolobenzodiazepines and camptothecin analogues; and (2) anti-tubulin agents, including auristatins, maytansinoids, and tubulysins.[1,24,28]

Calicheamicins (eg, ozogamicin) were first isolated from the actinomycete *Micromonospora echinospora* in the mid-1980s, and act by binding the minor groove of DNA, causing site-specific, double-stranded DNA breaks.[31,58-60] Notably, calicheamicins are highly hydrophobic, which limits the DAR or number of payload molecules able to be attached per mAb. Duocarmycins are potent alkylating compounds derived from the bacteria species *Streptomyces zelensis*. Duocarmycin and its derivatives, such as duocarmazine, act by binding to and alkylating adenine within the minor groove of DNA, leading to subsequent DNA strand cleavage and cellular apoptosis.[61-64] Pyrrolobenzodiazepine (PBD) dimers, such as tesirine, are DNA-damaging agents derived from anthramycin, an antitumor antibiotic isolated from Streptomyces.[65-68] PBD dimers bind the DNA minor groove, forming covalent interstrand DNA crosslinks within tumor cells that lead to cytotoxicity and cell death.[28,69,70] The formation of crosslinks resulting from PBD activity, which occurs rapidly and with minimal DNA distortion, is thought to contribute to their persistence and evasion of DNA repair mechanisms. Campothecin is a pentacyclic alkaloid isolated from the stem wood of *Camototheca acuminata*, a tree indigenous to China.[71-73] Campothecin and its derivatives (eg, govitecan, deruxtecan) act by inhibiting topoisomerase I enzyme activity, which results in double-stranded DNA breaks and subsequent cell death.[72-75]

Auristatins commonly used as ADC payloads include monomethyl auristatin E and monomethyl auristatin F, which are both synthetic analogues of dolastatin 10, a naturally-occurring antimitotic drug isolated from the sea hare *Dolabella auricularia*.[28,76,77] Auristatins inhibit tubulin polymerization by attaching to the same binding site as vinca alka-

loids (eg, vincristine, vinblastine), which are frequently used as traditional chemotherapy agents.[78-80] Maytansinoids are benzoansamacrolides derived from the bark of an African shrub, *Maytenus ovatus*.[81] Similar to auristatins, maytansinoids bind at or near the vinca-binding site, thereby inhibiting microtubule assembly and inducing mitotic arrest.[31,82] Maytansinoids commonly used in ADC design include 2 thiomethyl derivatives of maytansine: mertansine and ravtansine.[1,31,83] Tubulysins comprise a family of more recently discovered cytostatic peptides isolated from the myxobacteria species, *Archangium gephyra* and *Angiococcus disciformis*, that act by inhibiting microtubule polymerization during mitosis, thereby inducing apoptosis.[28,84,85]

DISCUSSION

Rapid advances in molecular and genomic technologies over the last several decades have ushered in a new era of precision medicine and led to the increased use of these technologies as important clinical tools for the diagnosis, classification, and treatment of disease.[86] As the use of precision-based treatment strategies has expanded, biomarker testing has become an increasingly important prognostic and predictive tool to improve disease management and enabled the development of numerous targeted therapies.[88,89] The effect of precision-based approaches on the treatment landscape has been especially profound in the oncology space, as reflected the growing number of biomarker-driven clinical trials, which increased from 15% in 2000 to 55% in 2018.[89] Although targeted therapies have led to major improvements in progression-free and overall survival, acquired drug resistance has led to associated therapeutic limitations and the need for other treatment options.[86] ADCs in particular represent a unique treatment approach that combines precision-based technology used in targeted therapy approaches with chemotherapy-based strategies using cytotoxic agents with greater potency.

Since the approval of the first ADC in 2000, continued technological advancements have led to an explosion in the number of ADCs under clinical development over the last few decades. As of 2022, a total of 12 ADCs with 9 associated biomarker targets have been approved for use in the treatment of both solid tumor and hematological malignancies.[7,90] In addition, over 80 ADCs are currently being evaluated in clinical trials, suggesting that utilization of these novel agents will continue to increase.

Most recently, the clinical development of novel ADCs has had a profound impact on the treatment landscape for solid tumors. The DESTINY series of clinical trials, investigated the human epidermal growth factor receptor 2 (HER2)-directed ADC, trastuzumab deruxtecan (T-DXd) in a number of solid tumor types.[91] Resulting data from these trials, led to approved indications in HER2-positive metastatic breast cancer (mBC), HER2-low mBC, and gastric or gastroesophageal cancer, as well as accelerated approval in non-small cell lung cancer.[16,92-95] Notably, DESTINY trial data surrounding T-DXd in mBC were not only unprecedented, but also transformative, and have played a major in reshaping how HER2 expression in tumors is assessed and managed. Historically, HER2 expression assessed via immunohistochemistry methods has been associated with a binary classification, namely HER2-positive or HER2-negative.[96] Early targeted therapies directed toward the HER2 receptor only demonstrated efficacy in HER2-positive mBC, with no effect in those with HER2-negative status.[96] However, the unique ADC design associated with T-DXd and the resulting bystander effect have expanded observed therapeutic responses to patients with lower levels of HER2 expression.[97]

CONCLUSION

As the incidence of cancer increases worldwide, growing demand for safer, more personalized cancer therapies with fewer side effects will undoubtedly propel further advances in ADC technology. Over the last 5 years alone, 39 clinical trials have investigated over 19 ADCs.[98,99] Given the pace at which ADC therapeutics are being introduced, the need for clear and accurate communication of information regarding these sophisticated treatments will also continue to grow. We as medical communicators must make it our mission to educate ourselves and our readers so that they can approach the literature critically and make informed decisions about their use.

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EVERYDAY ETHICS

The Patient-Physician Relationship in the Context of Physician-Targeted Violence From the Perspective of a Medical Student

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ABSTRACT

The tragedy that transpired at a hospital in Tulsa, OK, in June of 2022 highlights the issue of physician-targeted violence in the United States.[1,2] The shooting in Tulsa had occurred after a patient, dissatisfied with their back pain despite it only being 2 weeks after spinal surgery, attacked one of the few Black orthopedic surgeons in America, Dr Preston Phillips.[1] Dr Phillips' murder is not an isolated incident. In 2015, Dr Michael Davidson, a cardiothoracic surgeon at Brigham and Women's Hospital in Boston, MA, was shot and murdered by the son of a patient that the surgeon had operated on the previous year.[3] Dr Davidson had spent a significant portion of time answering questions from the disgruntled son who would eventually murder him. The 2 tragedies, separated by over 7 years, center around physician-targeted violence. Both surgeons had operated on a patient and were murdered as a result. Both cases beg the question: what went wrong, and how could they have been avoided?

These 2 cases represent examples of a greater trend of increasing violence toward physicians exacerbated by the COVID-19 pandemic.[4,5] Figures from the US Bureau of Labor Statistics estimate that the rate injuries from attacks against medical professionals grew by 67% from 2011 to 2018.[6] US hospitals reported an increase in assaults and threats mirroring the global trend during the COVID-19 pandemic.[7] Violence against physicians is symptomatic of a large issue: the deteriorating patient-physician relationship and the illusion of what the physician is. At the core of health care is the patient-physician relationship.[8]

Four models of the physician relationship have been described.[8,9] The paternalistic relationship has the physician creating decisions on behalf of the patient. The interpretive relationship requires a physician to figure out a patient's goals and values and subsequently offer options to achieve them. An informative relationship has the physician providing information and allowing patients to decide for themselves. Finally, in a deliberative relationship, the physician and patient collaborate as equals and work together to achieve a goal.

Historically, the paternalistic model predominated, in which the physician's main duty was seen to protect patients even at the expense of their autonomy.[10] This has contributed to the expectations that physicians are miracle workers and if they fall short, they should be blamed. In line with a paternalistic model, physicians often avoid talking about poor prognoses to be protective or kind; however, research shows that patients end up feeling isolated with their concerns, and the inability to discuss poor outcomes adds to the illusion of perfectionism.[11,12] The paternalistic model has contributed to the deterioration of the patient-physician relationship by disrupting communication for the sake of the patient.

Part of the problem has been the portrayal of physicians by the media.[13] Physicians are seen as wanting to maximize profits, seemingly pushing medications unnecessarily.[14] Historical events have contributed to that perception. In the past, the medical field acted against the best interest of already marginalized patients through experiments like the Tuskegee Syphilis Study conducted from 1932 to 1972, which withheld vital treatment from Black men diagnosed with syphilis.[15] Actions to correct the matter only took place after it had come to light, resulting in regulations requiring researchers to obtain voluntary informed consent and the Institutional Review Board's approval.[16] Historical events have created a gap between specific marginalized populations and physicians.

Although institutional change is necessary to bridge the mistrust that exists within marginalized communities, individual physicians and medical students can take steps to help address the issue. Physicians can start at the bedside by showing that they want the best for patients, and breaking down mistrust begins at the medical education level.[17] Understanding the historical origins and source of the mistrust would provide context to physicians in navigating interactions with patients. Physicians use a historical lens to understand the decisions of patients and allow that

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knowledge to guide their responses. Decreasing the amount of discrimination experienced by patients would minimize the mistrust felt by patients and work to support the idea of physicians as true patient advocates. Physicians can begin to decrease the amount of discrimination through removing stigmatizing language in patients' medical records that end up influencing future interactions.[18] Similar to how one negative experience can paint a patient's view of future interactions, a positive one can create a favorable view of the medical field. Over time, the accumulation of positive interactions would go a long way to mend the general patient-physician relationship.

Trust remains low in the general population, partially a result of the affordability of health care and the lack of transparency in decisions made.[19] This perception of the physician has contributed to an "us versus them" mentality between the patient and physician. No longer are physicians seen as always doing the best for the patient.[13,14] Decisions are analyzed through the lens of potential ulterior motives. Likewise, patients who end up distrusting their physicians are labeled as "noncompliant" even if they have legitimate reasons not to trust them. The relationship has been strained in both directions.[20] The way the health care system is built up does not help the issue. Physicians have limited time with each patient.[21] The lack of time has fed into the discontent felt by many patients. And so, when the health care system fails to meet the needs of the patient, it is the physician who is blamed.

Fixing the issue remains a complex and convoluted process that requires moving away from a paternalistic model toward a more deliberative relationship that encourages partnership between physician and patients. First, change needs to occur at the level of medical education. Students should not be discouraged to broach conversations surrounding failure.[22] A degree of perfectionism is required to make it to medical school, but it is important to allow medical students to fail. Fostering an environment where students can learn from their mistakes would go a long way toward removing the veil of perfectionism. Students and medical professionals should be encouraged to approach tough conversations about prognoses earlier rather than later. Physicians often feel inadequate in their training conducting these conversations, and starting from medical school would work to alleviate that.[23] Research shows these conversations do not harm patients and potentially strengthen the relationship between physicians and patients.[12,24] Through discussions, patients will eventually realize that physicians, although trying their best, are not miracle workers. When failure arises, there should be steps to prevent it from occurring again; however, normalizing failure would allow patients to understand that it is a possibility.

Relationships go two ways. Patients need to realize the limitations that exist in medicine. The success of a procedure or diagnosis depends on numerous factors. Fostering a deliberative relationship model and allowing discussions of failure would work to allow patients to recognize that. Ultimately, physicians have limitations. Medicine is a science, not a miracle, even though it may seem like it at times. The issue can only be resolved as patients realize that physicians are on their side, and that requires a mindset shift with the public. As America once again deals with another tragedy, the medical field needs to work to address the discontentment. Creating an environment that strengthens the patient-physician relationship is essential to ensure that these tragic events do not happen again.

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FREELANCE FOCUS


Brian Bass


Sherri Bowen


Cathryn D. Evans


Phyllis Minick

Jam Session for Seasoned Freelancers

Our Freelance Forum contributors—Brian Bass, Sherri Bowen, Cathryn D. Evans, and Phyllis Minick—have provided their own unique insights into topics raised during the open session during the educational session moderated by Cyndy Kryder, MS, MWC — "Jam Session for Seasoned Freelances."

The Jam Session for Seasoned Freelancers is always a popular session at the annual AMWA conference. The session gives seasoned professionals an opportunity to share concerns and challenges and to brainstorm and discuss solutions with experienced peers who have had similar experiences. Several topics emerged at this year's session, including the effect of COVID-19 on businesses, client relationships, subcontracting, and business plans.

EFFECT OF COVID-19

The consensus among seasoned freelancers was that COVID-19 was a boon to their businesses and their bottom lines. Not only did they receive more projects from established clients, but new clients also approached them to assist with a variety of projects, including virtual events such as advisory boards, and these relationships continue as in-person events ramp up again. In the early days of the pandemic, freelancers were viewed as experts in working remotely. Those who were experienced at creating virtual content sometimes had more work than they could handle.

The effect COVID-19 had on me is about the least newsworthy story of all time! The first vaccination required sitting in traffic for 2 hours to reach the injection station at our baseball park. The aftermath was no pain, no symptoms, and [paying] $50 for the hired driver. The follow-up second vaccine treatment was a phone call from [University of California San Diego] Health to go on campus immediately—private parking lot, 15-minute total injection/follow-up, then no pain, no symptoms, nothing else. Six months later, vaccination at local pharmacy—no pain, no symptoms, nothing else. Finally, 6 months later came the double-dose vaccine—same pharmacy, same lack of aftermath. However, during that time period, I had a bad fall, ripped open 6 inches of leg skin, was hospitalized for 6 days, became infected with [methicillin-resistant Staphylococcus aureus], underwent 2 sets of daily antibiotic infusions, [and] then [I took a] support antibiotic by mouth that made me nauseous. I tell this unrelated anecdote just so you won't think I missed all the fun with the effects of COVID-19!

—Phyllis Minick

I think everyone would agree that the whole COVID pandemic time was an amazing, unexpected, and terrible phenomenon that none of us in the whole world could have predicted or were at all prepared to deal with. I would like to think that there were a lot of lessons learned from it. There will be research in so many areas on its impact for years to come, I'm sure. What a very strange time!

For my freelance pharmaceutical regulatory writing business, though, I have to say that I was busier than ever during the main COVID period. I almost felt guilty about having so much work when so many others did not. I donated a lot of money to the local food bank. I have always worked from home, so that was not an impact on me.

I didn't work on anything directly related to COVID-19, but I had to adapt to (and teach clients about) ever-changing guidances about how to address the COVID impact on clinical trials in clinical study reports. I highly recommend looking at the US Food and Drug Administration guidance on this as well as the Transcelerate-suggested clinical study report template wording.

Buckle up if you haven't already!

—Sherri Bowen

* * *

MANAGING CLIENT RELATIONSHIPS

Seasoned freelancers have reached the point in their careers in which they only want to work with clients who treat them well, pay them well (and on time), and supply enjoyable work. When clients fail to meet any of these 3 criteria, most

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seasoned freelancers don't hesitate to end the relationship. Doing so politely and professionally requires finesse. Some seasoned freelancers prefer to say, "sorry, I'm busy," when approached about future projects. Others advocate taking a more transparent, honest approach and explain why they are ending the relationship. You should be able to identify which clients will appreciate this candor.

Your mental health is priceless. If you no longer enjoy working with a client, let them go. Reviewing your client list on a quarterly basis can help you identify clients to avoid. "Trust your gut" is a common mantra among seasoned freelancers. If intuition tells you something is not quite right about a client or a project, walk away.

One of my earliest intros to freelancing involved a film maker who wanted to position his video in a forested state park. A business friend made the introductions, and an appointment to meet onsite followed, [that is], the 2 of us alone among the trees. In about 30 seconds came the hustle. I dodged and later complained to the friend who did the intro that I felt compromised. He responded, "if you can't handle it, go back to the kitchen!" He was right! Before undertaking the next such job opportunity, I wrote out samples of opening sentences (a greeting—name, contact info, business card), then invented strategies I had rehearsed aloud, such as script ideas, scenic equipment supplies, examples of texts submitted to journals—anything just to keep talking for the next few sentences. Later, when I was more experienced, I substituted previously successful talking points and soon began such appointments with a contract in hand. Included were samples from previously published manuscripts, scheduling protocol, payment requirements, over-run charges, and always a hold harmless sentence absolving me from any lawsuit regarding, for example, a medical product or equipment function. The latter strategy has served me well through decades of employment as an in-house editor and as a freelancer for medical institutions in 6 countries.

—Phyllis Minick

Client management is full of unknowns! As a freelancer, I would like to think I have more control over choosing clients—but that doesn't mean there will be a bad apple even when everything looked so nice at first. My main recommendation when negotiating with a brand-new client is to ask as many questions as you can about the project up front before signing on. For your long-term existing clients, it's not unusual that companies you're working for may undergo changes—mergers, new management, new approaches to things….make sure you find out what impact those changes may have on you so you can decide whether to stay or go. I've been let go by clients (for various reasons), and I've also divorced clients myself (but try to do that early on or when a contract is up for renewal). Keep to commitments as much as you can, but it's absolutely always ok to put yourself first.

—Sherri Bowen

* * *

SUBCONTRACTING

Subcontracting takes a lot of time and energy. Not only do you need to find the right person for the project, but you also need to have the right client who will agree to let a subcontractor handle the work. When you subcontract, you are managing rather than doing the work yourself. Consequently, your estimate needs to reflect the added project management time. Never underestimate the time you will need to manage subcontractors and review deliverables. It takes longer than you think.

Subcontracting to other writers, editors, graphic artists, and consultants is an excellent way to increase income because you can mark up the work of others. The mark-up ranges from 20% to as much as 50%-75% (and more) by agencies. However, you can also lose a substantial amount of money by hiring inappropriate people. Even if someone claims to be an experienced writer, editor, artist, designer, video producer, photographer, proofreader, etc.—and provides samples—that person can end up being too slow, unreliable, inexperienced, etc., for you to make money. Sometimes it turns out that you not only *cannot mark up* the subcontractor's time, but *you end up taking a loss because you have to re-do the entire job and cannot possibly charge the client for all that time.*

Hiring subcontractors has been one of the most difficult aspects of my business. Today I hire subcontractors rarely, and then only those I know and trust. Several other consultants and business owners who hire contractors and subcontractors have commiserated with me on this issue—it is a common problem.

So yes, indeed, you can make more money if you have good subcontractors—but do it cautiously and be sure to check references.

—Cathryn D. Evans

I agree. If you think freelancing is tough, just wait until you start subcontracting. So why do it? Because as wonderful as it is to work for yourself, having others work for you is even better—if you do it right. That's the trick.

When you start bringing in other freelance medical writers and/or medical editors, if you're not very careful, you

can end up working harder than you've ever worked before for less money than you've earned in years. Why not just hire the people you need and put them on staff? Because then you have to pay them whether they're busy or not, deal with payroll taxes, health benefits, and vacation pay, and be tempted to force fit projects to the people you have instead of bringing in the best person for the job.

It's true that you have to manage the people to whom you're subcontracting, and that means a lot of extra work if you're lucky. You want to now be juggling more projects at the same time than ever; but with that comes more teleconferences, more estimating, more negotiating, more emails, and more bookkeeping, all of which takes time. And if you want to keep writing yourself instead of just managing, that adds a whole other level of complexity.

How you subcontract is a crucial decision point; one that may provide some relief for you either now or down the road. For example, the people who work with me on a subcontracting basis are among the very best in the business. They're deeply experienced and experts at their craft. They know what needs to be done and are self-motivated to do it. They have the confidence to make decisions and the ability to roll with the punches. For all these reasons and more, I don't have to watch over the people I subcontract to or worry about how they handle clients, timelines, or budgets. They deliver a top-quality product every time, which is why I trust them with my reputation. In contrast, some people prefer to subcontract to medical writers or medical editors who are relatively new to the profession. The advantage is being able to train them in how you want things to be done, so in the future as they gain experience, they'll deliver as you expect.

There's no right or wrong way to subcontract provided you're completely transparent about it with your clients, and the way you structure your business works for you and those you hire. As noted during the Jam Session, your estimate for a project must include the value you bring to the table managing it. That's right, but that's not all! Think of the infrastructure, the unbillable, the rare unthinkable. If all you factor into your estimates is a charge for your management time, you're missing the entire point of subcontracting. You should also be making a profit on the entire project. There are only 8,760 hours in a year, and you can't work all of them. The idea behind subcontracting is either to work less and earn as much as you did before, work as much as you did before and earn more than ever, or work less than ever and earn more than ever.

—Brian Bass

BUSINESS PLANS

Some but certainly not all seasoned freelancers have created business plans they review and revise annually. Businesses evolve over time as your skill set changes, technology changes, and your desires change. Writing a business plan helps some freelance medical writers determine how they want their businesses to evolve and grow as well. You can find templates for business plans online by searching "business plan templates." Through the Service Corps of Retired Executives (SCORE), a nonprofit resource partner of the US Small Business Administration (SBA), you can find a business expert to review your business plan. The SBA has also established Small Business Development Centers throughout the country in which you can get advice about business planning.

Every business must have a plan and it should be in writing. If you choose not to do this, obviously you are not "in business," you are a contract writer, which is okay, but it is not the same as owning/managing a business. Before writing your business plan, think carefully about your product and your market. The business plan describes the nature of the business, its objectives, projected sales and profitability, future growth, etc., over an estimated period of time. It includes a summary as well as a detailed description of the market, marketing strategy, competitors, officers, directors, and other staff, an initial organization chart (and possibly projected future charts), operational strategy, and financial projections (expenses and income) for an estimated period of time (eg, 5 years).

Most businesses require the same specific functions. There is a chief executive officer, president. or proprietor. The functions of marketing director, sales manager, director of finance and accounting, bookkeeper, secretary, public relations officer, purchasing manager, etc., must be included. Regardless of how you structure your business, someone has to perform these duties. Include an organization chart with your written plan. If you perform all duties, insert your name into every box in the organization chart.

Check out the bookstores and the Internet to see examples of such plans. I strongly recommend you take a (free) in-person workshop from SCORE (www.score.org), which is an organization of experienced business people put together by the SBA. They provide everything you need to know when starting out, including detailed information about why and how to create a business plan. Write your business plan your own way, but do it!

—Cathryn D. Evans

To address the issue of business plans, I actually referred to a 2001 publication of Selected AMWA Workshops.[1] Of course, the technologies have changed, but the basic elements not so much. Author Marilyn Citron cited some essentials of planning for a freelance career as follows:

attributes [include] independence, autonomy, free choice of working time, opportunity to develop new skills and technologies, [and] broad choice of subjects. Drawbacks [include] necessity to adjust for uneven workload and income, lack of health care insurance or retirement benefits, [and] isolation.

Recommendations for a business plan start with writing a mission statement as well as specifying client profiles, projected income, office and client locations, equipment/furniture costs and space, [and] detailed financial plan for both immediate and foreseeable long-term requirements.

In the 2023 environment of formerly unequaled variety of communication opportunities, I cannot improve on a time-worn practice: "sit down and write a paragraph describing your prospective clients – who will need you and why. Who will be best able to pay you well. Then turn to internet directories and your own contacts to find prospective employers."[1] Carefully document the advantages of a paycheck from an institutional employer [compared with] the uncertainties yet benefits of a freelance career.

—Phyllis Minick

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CE CRAFT CORNER

Continuing Education Writing: Know Your Clinician Audience

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ABSTRACT

Continuing education (CE) writing is a major field of work for medical writers and editors. To effectively write and edit CE materials, medical writers need to understand the target clinician audience, including clinical responsibilities. Physicians, nurse practitioners, physician assistants, pharmacists, nurses, clinical psychologists, and dieticians are examples of professions that often require CE to maintain licensure. With a general trend of increased funding for CE programs, medical writers and editors have opportunities to be involved in crafting deliverables such as needs assessments and other portions of grant proposals as well as various types of deliverables for educational content.

Despite the trust that should be inherent in receiving health care, how do we know those providing it are competent? We hope that the system in place helps these clinicians establish a standard of excellence based on licensing requirements. However, measures of clinician competence in clinical, cognitive, and communication skills were historically measured only at initial licensure.[1] In an effort to keep clinicians competent and updated on advancements in their field, licensing requirements for many health professions mandate continuing education (CE) to maintain knowledge of ongoing changes. From a logical and practical perspective, requiring CE—and in some cases recurring certification exams—is a necessary measure because of the rapid rate of ongoing change in medicine. This article reviews key considerations and practical tips for how medical writers can better understand our clinician audience and develop more targeted materials.

CE for health care professionals is sometimes (and often interchangeably) referred to as CME (continuing medical education). CME, however, refers specifically to CE for physicians. According to The Accreditation Council for Continuing Medical Education (ACCME), which sets the standards for accredited CME, "Continuing medical education consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession."[2] This definition can be adapted and applied to other health care professions. For the purposes of this article, we will use CE to refer to the educational activities of all health care professions, inclusive of CME and physician education.

In addition to the ACCME, CE accreditation bodies exist for other professions, aside from physicians:

- The American Association of Nurse Practitioners (AANP)
- The American Academy of Physician Associates (AAPA)
- The Accreditation Council for Pharmacy Education (ACPE)
- The American Nurses Credentialing Center (ANCC)
- The National Board for Certified Counselors (NBCC)
- The Accreditation Council for Education in Nutrition and Dietetics (ACEND)
- The Joint Accreditation for Interprofessional Continuing Education

Many medical writers and editors belong to certain groups of health care professionals. However, many medical writers also have nonclinical backgrounds such as basic science, communication, and journalism. Regardless of clinical background, medical writers may be asked to write educational content. This article is intended to give clinicians and nonclinicians alike an overview of how to tailor content to different clinical audiences.

With multiple health care professions requiring CE, medical writers often have opportunities to craft educational content for accredited activities. Some educational content that medical writers are asked to work on may also be nonaccredited. Whether accredited or not, we need to know how to adapt the content to address the needs of the target clinician audience.

THE MARKET FOR CE WRITING

Starting in 2006 and throughout subsequent years, the CE industry went through significant changes, including adjust-

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ments to methods, funding, and objectives.[3] Some professionals thought that CE would no longer exist. However, by 2012, the industry had settled into a sustainable trajectory. The industry continues to grow, with an increasing trend for income reported by CE providers from commercial support in the United States each year, apart from a setback in 2020 likely caused by the COVID-19 pandemic (Figure). This means continued opportunities for medical writers to capture a share of that funding because content creation is at the core of educational programs. Additionally, medical writers may compose needs assessments and other portions of grant proposals.

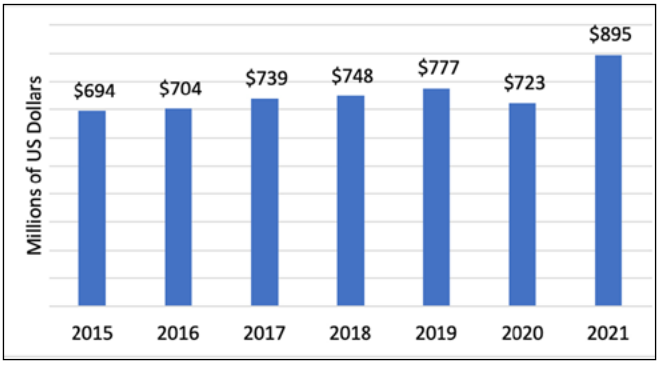

Figure. Total yearly income from commercial support reported by accredited US educational providers, years 2015-2021.[4]

Notably, commercial support of CE activities in 2021 accounted for 32% of reported yearly income by accredited US educational providers. In 2021, there were an estimated 28 million learner interactions, about 75% of which were physician interactions.[4]

Because many health care professions are required to maintain a set number of educational hours each year (Table 1), CE is not going away in the foreseeable future. Despite a large share of the market dedicated to physician education, medical writers will still be asked to create content for other clinicians. Given differences in their scope of practice, writing content for other health care professionals (eg, pharmacists, nurses) is not always the same as writing content for physicians. Additionally, physician audiences may have different specialties. For example, writing content for primary care practitioners about dementia would need a different approach than writing content for neurologists about dementia.

Interprofessional education writing often needs a unique approach as well. Interprofessional education initiatives may be focused more on concepts like communication and collaboration among team members rather than detailed medical or scientific content.

Table 1. Number of Education Hours Required by Select Health Care Professions[5-11]

Profession	Average Minimum Required Education Hours Per Year
Physician (MD, DO, MBBS)[a]	12-50
Nurse Practitioner (NP)[b]	20
Physician Assistant (PA)	50
Pharmacist (RPh, PharmD)[a]	12-20
Nurse (LPN, RN)[a,b,c]	0-15
Clinical Psychologist[a]	6-20
Registered Dietitian (RD)[a]	10-15

DO, Doctor of Osteopathic Medicine; LPN, Licensed Practical Nurse; MBBS, Bachelor of Medicine, Bachelor of Surgery; MD, Doctor of Medicine; PharmD, Doctor of Pharmacy; RN, Registered Nurse; RPh, Registered Pharmacist.

[a]*Exact number of education hours is determined by state of licensure*

[b]*Some designations may recertify by examination, which may not require CE credits*

[c]*Many states have practice hours as an additional or alternative requirement to CE credits*

HOW TO WRITE EDUCATIONAL CONTENT FOR DIFFERENT HEALTH PROFESSIONS

The foundation for understanding your clinician audience is knowing their scope of practice and role in the health care team (Table 2). For example, a nurse practitioner (NP) has a very different role than a registered nurse (RN). An educational program for RNs should not include a learning objective for prescribing treatments or making a diagnosis. However, topics covering monitoring vital signs and symptoms or medication administration would be reasonable for learning objectives for this audience.

The company you are working with to develop CE content will likely determine the target audience based on educational needs and supporter interest. The audience determines how you approach all deliverables you might be working on. This includes needs assessments for grant proposals and the educational content. As an example, if the education company or institution provides education exclusively to pharmacists, you should not identify educational gaps for physicians for the needs assessment.

If you are unsure about the specific role of the target audience within the health care system, always ask. Sometimes, your client or employer may be relying on you to determine this. In many cases, you can consult with a key opinion leader in the profession if you need more information. The American Medical Writers Association (AMWA) community is also a great resource with many clinician writers, so feel free to phone a friend!

Medical writers and editors who are familiar with creating CE content should only need to implement small tweaks in the approach to content creation. Much of the material

Table 2. General Responsibilities of Select Health Care Professionals[12-19]

Profession	Responsibilities
Physician (MD, DO, MBBS)	• Screen for, diagnose, and treat injury or illness • Perform physical examinations; take medical histories; order, conduct, and interpret medical tests • Counsel patients on preventative health care and healthy lifestyle practices • Conduct surgeries and procedure
Nurse Practitioner (NP)	• Similar responsibilities as physicians • In many states, NPs can practice independently • In some states, NPs must practice under a physician's supervision
Physician Assistant (PA)	• Similar responsibilities as physicians • Must practice under a physician's supervision
Pharmacist (RPh, PharmD)	• Offer expertise in the safe and effective use of medications • Fill and dispense prescription orders, verifying instructions from prescribers • Educate patients about their medications, disease states, and healthy lifestyle practices • Administer vaccines • In some states, pharmacists can prescribe medications under a physician's supervision
Nurse (LPN, RN)	• Provide and coordinate patient care, including conducting health assessments, medical histories, and monitoring vital signs and symptoms • Administer medications, vaccines, and medical devices and other treatments ordered by a prescriber • Operate medical equipment • Conduct patient education regarding their disease state, healthy lifestyles, and physician's instructions
Medical Assistant (MA)	• Measure and record vital signs and other patient information • Assist nurses and medical practitioners with their responsibilities • Administer vaccines • Schedule patient appointments
Clinical Social Worker	• Assist with diagnosis, treatment, and management of behavioral, mental, and emotional disorders • Provide therapy for individuals and groups • Help individuals develop and implement strategies to cope with situations or change behavior
Clinical Psychologist	• Screen for, diagnose, and treat behavioral, mental, and emotional disorders • Interview patients, administer diagnostic tests, provide psychotherapy to individuals and groups • Can prescribe medications in some states
Registered Dietitian (RD)	• Provide expertise in the use of food and nutrition to manage disease and promote health • Assess patients' nutrition needs, develop and monitor meal plans, and collaborate with the care team

DO, Doctor of Osteopathic Medicine; LPN, Licensed Practical Nurse; MBBS, Bachelor of Medicine, Bachelor of Surgery; MD, Doctor of Medicine; PharmD, Doctor of Pharmacy; RN, Registered Nurse; RPh, Registered Pharmacist.

will be similar, but your target audience will dictate where you dive deep into the details for a given CE program.

CASE STUDY – MULTIDISCIPLINARY ONCOLOGY PROGRAM

For this case study, assume that you are working with a medical education company to develop content for a multidisciplinary oncology program on non-small cell lung cancer (NSCLC). Within an oncology practice, health care professionals likely include physicians, NPs and PAs, pharmacists, nurses, and other support staff.

Imagine that the education company would like you to create several PowerPoint slides to educate each group—physicians, midlevel practitioners (NPs, PAs), pharmacists, nurses, and other support staff. The program has 4 learning objectives:

1. Describe the role of molecular testing in diagnosis and disease classification for NSCLC.
2. Apply best practices for selecting targeted therapies for NSCLC based on genetic alterations and immune checkpoint targets.
3. Manage adverse events from NSCLC treatments.
4. Employ a multidisciplinary approach to providing education on the disease state and treatment plan for patients, their families, and caregivers.

As a first step to determining the content to create, you might consider which learning objectives are relevant to each group. For oncology physicians, all 4 learning objectives apply. They are involved in testing, diagnosis, and treatment of NSCLC as well as overseeing patient education and the entire patient experience. For NPs and PAs, all 4 learning objectives also apply. NPs and PAs can diagnose and treat disease under a physician's supervision (except for NPs in certain states, who do not need a supervising physician).

For pharmacists, learning objectives 2, 3, and 4 would be relevant. Pharmacists help with treatment selection, monitoring, and patient education in many settings. They

are generally less involved with initial testing and diagnosis. For nurses, objectives 3 and 4 would be relevant. Nurses might administer medications in the clinic, call patients to assess their response to treatment, handle any questions or concerns, and provide education. For other support staff, objective 4 would be relevant. Other employees in the clinic may not be directly involved in disease management, but they are still part of the multidisciplinary team. They help educate and support patients, their families, and caregivers throughout the treatment experience.

CONCLUSION

CE writing (or CME writing) consists of conceptualizing, designing, and writing educational content for practicing health care professionals. This includes physicians, NPs, PAs, pharmacists, and nurses as well as others. Medical writers are often needed to draft needs assessments and other portions of grant proposals as well as various types of deliverables for educational content. When writing content, medical writers need to tailor the education to the target clinician audience. It is important to consider whether the program will be multidisciplinary or only focused on a specific profession. A working knowledge of the roles of clinicians on the health care team will help you create the right content for the target audience.

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CE CRAFT CORNER

Practical Strategies for Creating CME/CE Content: Insights From Adult Learning Scholarship

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ABSTRACT

Medical writers are instrumental in developing accredited continuing medical education (CME) for physicians and continuing education (CE) for nurses, pharmacists, and other health professionals. To ensure that CME/CE content meets the learning needs of health professionals, expands knowledge, and builds skills, medical writers should be knowledgeable about adult learning principles and emerging insights from the learning sciences. In this article, I review these principles and describe a suite of practical strategies that medical writers can use to write CME/CE materials that optimize learning.

Continuing medical education (CME) for physicians and continuing education (CE) for nurses, pharmacists, and other health professionals must meet standards for transparency and integrity as outlined by education accrediting bodies such as the Accreditation Council for Continuing Medical Education.[1] Medical writers are instrumental in developing accredited CME/CE materials with integrity for health professionals by ensuring balanced, valid, and unbiased content.[2] To ensure that CME/CE content also meets the learning needs of health professionals (otherwise known as learners), expands knowledge, and builds skills, medical writers in the field of CME/CE should be knowledgeable about adult learning principles (ALPs) and emerging insights from the learning sciences. This knowledge is necessary because incorporating ALPs into education content is likely to increase the effectiveness of CME/CE activities and their impact on the behavior of clinicians and patient health outcomes.[3] The Alliance for Continuing Education in the Health Professions, a leading organization that promotes best practices in CME/CE, identifies ALPs as a core knowledge domain for professionals involved in CME/CE content development.

LEARNING FRAMEWORKS AND EDUCATION FORMATS

CME/CE activities help health professionals stay current with the exponentially expanding biomedical and clinical information required to deliver optimal health care.[4] However, the relentless accretion of this information can exceed a person's cognitive capacity—our brains can only absorb a certain amount of information at a time. Clinicians compare the experience of staying current with medical sciences and clinical practice updates with "drinking from a firehose."[5] At the same time, health care professionals need more from CME/CE than just information and facts. They also need to learn how to apply that information in clinical settings, exercise analytic and diagnostic skills, and communicate and coordinate with other members of the health care team.

To better support knowledge and skills application, the CME/CE field has embraced a lifelong, continuous, competency-based approach to education.[6] Additionally, Interprofessional Continuing Education (IPCE) has emerged as an education framework in which 2 or more professions (eg, nursing, medicine, pharmacy) share a common learning process to learn with, from, and about each other. The goal of IPCE is to foster interprofessional communication and teamwork and the effective coordination of patient care.[7] IPCE differs from multidisciplinary education, which involves health professionals learning separately about patient needs within the context of their own professional roles and responsibilities.

Modes of education delivery and formats have moved away from didactic lectures toward more interactive and engaging formats that can be delivered online. Many health professionals are digital natives and increasingly expect to receive much of their CME/CE via online activities and digital platforms (eg, e-learning modules, webinars, online games, patient simulations). The COVID-19 pandemic accelerated this trend toward online learning in accredited CME/CE.[8] CME/CE now also measures learning outcomes via distinct frameworks that are sensitive to knowledge uptake, skills acquisition, and changes in clinical practice, performance, and patient outcomes.[3,9] Moore's Model of Outcomes Assessment is a commonly used learning and performance outcome framework in CME/CE.[9]

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Retrieval Practice: Before reading the next section, pause for a moment to think about the schemas or ideas you have about adult learning. Compare your schemas with the following information. What are the similarities? What are the differences?

ADULT LEARNING PRINCIPLES

Medical writers involved in developing CME/CE materials for health care professionals need to be able to incorporate ALPs into content to optimize learning outcomes. ALPs draw on legacy assumptions from twentieth-century educators and psychologists, including Malcolm Knowles, John Dewey, and others. These educators argued that teaching adults (andragogy) and adult learning differs from teaching children (pedagogy) and childhood learning. As such, adult learning requires a distinct education approach.[10]

Andragogy posits that adult learners learn best when they are self-directed in their approach to learning and intrinsically motivated to learn. Intrinsic motivation refers to the interest, pleasure, and satisfaction of learning itself.[10] Extrinsic motivation refers to outcomes associated with learning (eg, clinical practice demands, improved patient care). In addition, adult learners actively seek learning when they have specific problems to solve and want to immediately apply what they have learned to real-life situations. Adult learners also bring a rich reservoir of life experience to the learning process that provides an important context for learning and a foundation for reflection. Finally, adult learners learn best when they have control over the timing, nature, and direction of the learning process.[10] Box 1 summarizes practical applications of ALPs in CME/CE Writing.

INSIGHTS FROM ADULT LEARNING SCHOLARSHIP

Early twentieth-century adult learning theory focused primarily on differentiating adult learning from learning in childhood. A century later, adult learning scholarship now embraces cognition, memory, and brain structure and function, as well as how sociocultural, professional, and organizational contexts and social/emotional factors (eg, demographics, technology, stress) shape adult learning.[10] The learning sciences are multidisciplinary and draw on scholarship from cognitive psychology, sociology, neuroscience, anthropology, behavioral economics, and other academic disciplines.[12] What follows is a sampling of insights and strategies from adult learning scholarship that medical writers can use to create CME/CE content that enriches adult learning.

Box 1. Practical Applications of ALPs in CME/CE Writing

Adult Learning Principles

1. Adult learners are self-directed.
2. Learning should be relevant to professional needs or social roles.
3. Learning should be problem-oriented and supports the immediate application of knowledge.
4. Adult learners appreciate opportunities for feedback and reflection.
5. Adult learners prefer control over the timing and direction of learning.

Practical Applications

Ensure that content is learner-centric, problem-oriented, relevant to practice, based on educational need, and aligned with anticipated outcomes.

1. **Consult the needs assessment.** Familiarize yourself with the knowledge/skill needs and the clinical practice/performance gaps presented in the needs assessment. A comprehensive needs assessment will help you understand the clinical gaps and anticipated outcomes that the education is targeting.[11]
2. **Identify your audiences.** Who are the learners? What are their needs? What experience or background do they bring to the educational activity?
3. **Review the anticipated outcomes**. Identify the problem that the content needs to address. What do learners need to know or be able to do when they have read the material?
4. **Apply SMARTER goals to the content.** Keep the content **S**pecific, **M**easurable, **A**ction-oriented, **R**elevant to the learner, learning objectives, and anticipated outcomes, **T**ime-specific, **E**valuable, and **R**ealistic.

Cognitive Learning Theory and Science of Memory Insights

What happens in our brains when we are in learning mode? Cognitive learning theories focus on the internal dynamics of learning and how people process, structure, and retrieve information. We absorb information via the senses (ie, sensory memory), which is processed in working (ie, short-term) memory and organized into schemas of increasing complexity.[13] This processing builds on prior knowledge and is affected by cognitive load, which involves intrinsic load (the volume of information to be processed) and extrinsic load (the work required to process the information). Box 2 highlights tactics medical writers can use to manage cognitive load for learners and ease processing.

In learning mode, our brains work hard to encode, organize, and consolidate perceptions and experiences so we can retrieve that material in the right context, for the right purpose.[13] Short-term and long-term memory work together with cues and context so that new information can be integrated with prior knowledge and consolidated or embedded more deeply into our internal archives or memory traces.

Box 2. Practical Applications of Cognitive Learning Theory and Science of Memory in CME/CE Writing

- **Stay on track.** Ensure that written content addresses the learning objectives.
- **Edit ruthlessly.** Reduce distractions and eliminate extraneous information.
- **Be bold.** Highlight essential points for the learner.
- **Build iteratively.** Sequence the presentation of ideas from simple to more complex.
- **Parse it out.** Chunk complex ideas into bite-sized portions of text.
- **Pair image with text.** Embed images, graphics, audio, or video clips to text where appropriate.
- **Offer opportunities for retrieval practice.** Include questions to encourage long-term memory retrieval and help learner connect new information with prior knowledge.
- **Promote active discovery.** Include exercises or activities such as matching, polling, or multiple-choice questions to help learners identify gaps between what they thought they knew and what they ought to know.

Forgetting and unlearning are also important in the process of learning new information.[13]

The multidisciplinary field of learning sciences, as described above, offers many empirically tested strategies that yield deep, durable learning.[14] An important principle that Brown et al argue in *Make It Stick: The Science of Successful Learning* is that interactivity correlates with higher learning impact. The more actively learners engage with educational content, the more likely they are to retrieve and apply information in the appropriate context.[13] To this end, instructional designers boost interactivity in e-learning by building effortful and repeated recall, recognition, and retrieval tactics into learning activities.[15] Similarly, microlearning—delivering short bursts of content that are media-rich and spaced out over time—is thought to boost interactivity and retention by reactivating memory, avoiding cognitive fatigue, and more efficiently moving new information from short- to long-term memory.[16] Box 2 summarizes tactics medical writers can use to bolster retention and augment interactivity.

Experiential, Emotional, and Social Learning Insights

Competency-based education and IPCE also benefit from insights on the experiential, emotional, and social nature of learning. In experiential learning, experience is considered an important baseline for reflection. Put simply, we encounter a problem (a concrete learning event); we take stock of our options for addressing this problem (we reflect); and we actively experiment in designing solutions to the problem (sometimes called "knowing-in-action").[17-18] Experiential learning often includes activities that involve self-appraising current practice, identifying a problem in that practice, and problem-based learning as an individual or within in a team.

Emotional learning is another important consideration in adult learning. Working in settings and situations as any kind of clinician is often stressful and, at the very least, can provoke powerful emotions. Emotions affect how and what we learn via physiologic responses to situations and subjective experience of that response (ie, mood).[14] For instance, when our mood is positive, we are more likely to absorb, retain, and retrieve information (ie, cognitive flexibility). We are more likely to see the bigger picture and apply new information to practice. Role play is an example of a CME/CE activity that might be used to explore how emotional states can impact both clinical practice and learning.

Emotional learning is grounded in social cognitive theory, which suggests that we learn more effectively when we are observing and interacting with others.[19] Social learning occurs when we belong to a community of learners or a community of practice. Communities of practice are often self-organized and emphasize participation and collaboration as the key drivers of learning. Examples of CME/CE that optimize communities of practice include journal clubs and discussions via social media groups.

In competency-based education for health professionals, learners also need to be able to develop expertise and progress from novice to mastery levels of competence. The trajectory toward mastery requires deliberate practice, a key ingredient in information processing and skills acquisition that involves effort, repetition, and feedback.[20] Deliberate practice is a common characteristic of virtual simulations or case- and vignette-based activities. Cases and vignettes are designed to mirror real-world challenges in health care and enable learners to practice reasoning, communication, and procedural skills. In online environments, patient cases are often highly interactive and are accompanied by feedback that offers insight into the consequences of learner choices, guides the learner toward an end goal, and allows room for failure and course corrections.[20-21] Examples of written feedback include expert or virtual patient commentary or notes about clinical outcomes that occurred because of decisions the learner made in the activity. Box 3 highlights tactics medical writers can use to incorporate experiential, emotional, and social learning insights into the development of CME/CE activities.

CONCLUSION

CME/CE continues to grow as a field and as a market for medical writers. Market forecasts project a 5.9% growth ($2,715.22 million to $3,830.46 million) between 2022 and 2027.[22] Health professionals are required to earn CME/CE credits as part of maintaining their professional licenses

Box 3. Practical Applications of Experiential, Emotional, and Social Learning Insights in CME/CE Writing

- **Build reflection into the text.** Use open-ended or polling questions to encourage learners/readers to actively think about how to apply the presented information to clinical practice.
- **Flex your metaphor muscles.** Metaphors can help learners integrate new information into clinical practice.
- **Emphasize context.** Where possible, describe the clinical, professional, and organizational context in which learners are expected to apply new information or skills. This helps to situate learning in relationships and communities of practice.
- **Use storytelling to engage learners.** A story-based approach to content through patient cases or vignettes promotes clinical problem-solving and deliberate practice. Storytelling also establishes learner empathy with patient experience.
- **Deliver concrete, constructive feedback.** Feedback delivered in small, digestible chunks diffuses defensiveness, minimizes negative emotional responses, and reduces cognitive load.[21]

but are extremely busy, and their in-the-moment learning capacity is affected by many factors, including specialty, proficiency level, and workplace setting. Our goal as CME/CE writers is to help health professionals process, synthesize, and apply new information effectively in the relevant context. We can help to move learners from what they know and can already do toward what they need to know and apply in practice by using ALP strategies to guide content development.

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CONFERENCE

Session Report

The Backbone of Manuscripts: Supporting Your Writing With Storytelling

Speaker
Crystal R. Herron, PhD, ELS
Managing Director, Redwood Ink, San Rafael, CA

By Allie Boman

Stories make your writing stronger and your message more engaging. Dr Crystal R. Herron uses tools and mindsets rooted in scientific observation to make her case for storytelling as the backbone of an effective manuscript.

STORIES TAP INTO THE POWER OF CURIOSITY—AND LOVE

Stories stimulate the production of love hormones. We *feel good* when we read, watch, or hear stories from others—the mechanism of this good feeling is greater levels of oxytocin. Leveraging the power of storytelling at every level of our writing helps us to connect with readers, engaging them and helping them remember what we said.

Data are like Lego building blocks, Dr Herron pointed out. Raw data are like a pile of Legos—it's all there, but it's a mess. We might sort these data by color so they're a little easier to understand. Then we might present the data in a logical way, organizing the stacks of color by height. Now imagine those blocks rearranged into a Lego house, complete with a colorful front door and bordered with flowers. A house with personality invites questions (Who lives there? Will a little Lego guy walk out the front door soon?). Storytelling generates curiosity.

USING THE STACR STRUCTURE TO STRENGTHEN MANUSCRIPTS

Although variations abound, engaging stories tend to follow a similar structure, abbreviated as STACR (which ties in well with the Legos illustration!). Dr Herron explained this structure and how to use it to keep readers reading. She also gave examples for applying these ideas to a medical manuscript and mapping STACR onto the standard IMRaD (introduction, methods, results, and discussion) structure.

S = *Setup*

- Who are the characters in this story? (proteins, compounds, disease state, device)
- Where or in what setting does the story take place? (proteins within a particular cell, disease that affects a certain organ, patients in a hospital or outpatient location)
- What problem(s) surround the characters? (prevalence of the disease, previous devices that proved insufficient, no drug available)

T = *Tension*

- What do the characters need to accomplish? How can they solve the problem you set up? (disease progression needs to be slowed; gene mutation may change protein function)
- What question do you answer in this story? (Does this drug have fewer side effects than others available? Does this device work better?)
- How does this tension connect with the problem from your Setup section? (Making this connection helps to engage readers' curiosity.)

A = *Action*

- What happens to address the questions raised in the Tension section? (What methods were used)?
- How did the characters respond to a change in the setting? (What were the results?)

C = *Climax*

- Did the characters answer the question? (What were the key findings and how did they answer the questions posed?)
- How will readers' curiosity be satisfied? (Refer to elements raised in the Tension section.)

R = *Resolution*

- How have the characters and setting changed as a result of the action? (How does this work advance the field?)
- What value does this story offer? Why does it matter? (What is the significance of the study?)

Writing a manuscript using STACR helps readers understand the importance of your work and use what they've read.

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In addition to giving a brief history of the standard manuscript structure, Dr Herron explained that the IMRaD structure follows the STACR flow fairly naturally (see Figure 1).

MICRO-STORIES STRENGTHEN YOUR WRITING FROM THE INSIDE OUT

Additionally, Dr Herron explained that the story structure can be applied to paragraphs and sentences. Using this tool on nano and micro levels, in addition to the macro level, makes your entire document strong and dynamic, like a living organism with a backbone.

At the nano (sentences) level, the story arc is compressed into *setup, tension/action/climax*, and *resolution*. Basic sentences include a subject (introducing a character is the *setup*), verb (*tension/action/climax*), and object (*resolution*—satisfying curiosity by answering what happened to the character). Dr Herron gave the following example:

- Setup: "Crystal" (what about Crystal? we are curious)
- Tension/Action/Climax: "loves" (ah, this is a positive sentence)
- Resolution: "dogs" (satisfies our curiosity about what Crystal loves)

Most of the sentences we write will be more complex than this, making it easier to create the setup, build tension, fill in the action, relieve tension with the climax, and resolve the nano-story.

Likewise, a great paragraph is made of micro-story arcs, arranged in an order that supports the overall story in the paper. Developing this structure on a paragraph level helps you ensure that each paragraph has a coherent purpose within the overarching story of the manuscript.

Ultimately, a manuscript tells the story of work that may have taken years to accomplish. Dr Herron challenged audience members to use a story structure to build and strengthen their manuscripts, enabling them to engage readers while informing them—and thereby have greater influence in the field.

For more on this topic, see "The Intrinsic Story Structure of Original Research Manuscripts," by Crystal R. Herron, in the March 2023 issue of this journal (*AMWA J*. 2023;38[1]).

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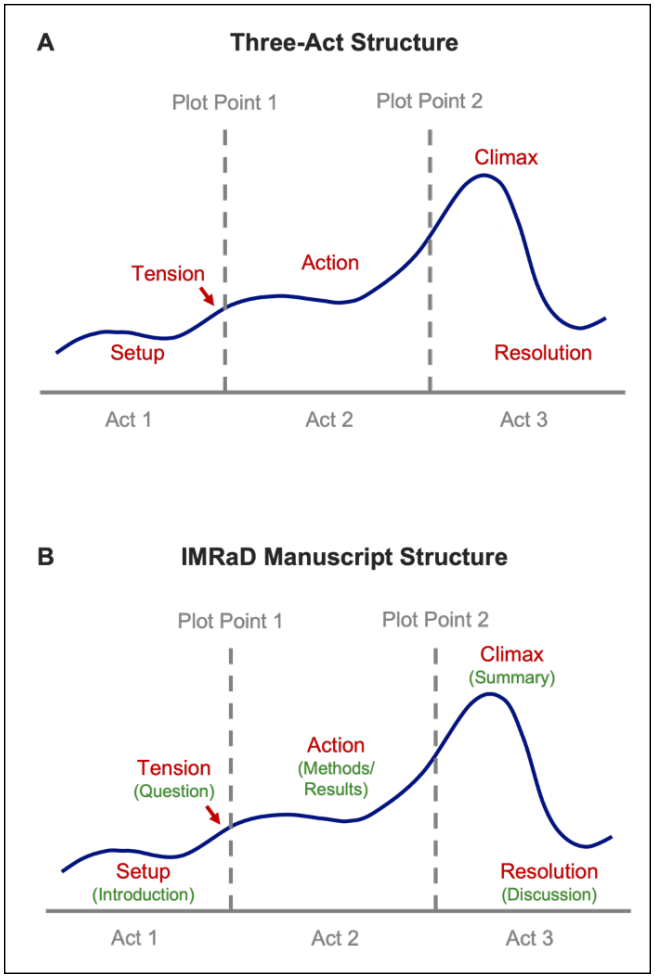

Figure 1. Three-act story structure in original research manuscripts. A. Three-act structure commonly found in stories. B. Three-act story structure found in original research manuscripts that follow the standard IMRaD (Introduction, Methods, Results, and Discussion) structure. Reprinted from "The Intrinsic Story Structure of Original Research Manuscripts," by Crystal R. Herron, in the March 2023 issue of this journal (*AMWA J*. 2023;38[1]).

AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N2 / 2023

CONFERENCE

Session Report

Journalistic Approach to Writing Better Abstracts

Speaker
Susan Aiello, DVM, ELS
Words World Consulting, Townsend, TN

By Tonya Scardina, PharmD

Dr Aiello emphasized the importance of a well-written abstract. After the title, the abstract is the most widely read part of a scientific paper. It is worth putting in the effort to ensure that the abstract grabs the attention of your audience with the key components of the scientific paper. Dr Aiello reviewed how the methods used in journalism could be adapted in the process for writing abstracts. During her presentation, Dr Aiello reviewed the purpose of an abstract, compared scientific abstracts to news stories, and provided a stepwise approach on how to apply a journalistic approach to writing a scientific abstract.

PURPOSE OF AN ABSTRACT

An abstract should summarize essential information of the scientific paper, be concise, nonrepetitive, and should be reader-focused.

FORMAT OF AN ABSTRACT

The abstract should present the sections of a scientific paper in the same order (eg, objective, methods, results and discussion/conclusion). Dr Aiello elaborated on the contents of each section of a paper, and hence the abstract. The objective of the study, or scientific question, should be in the introduction section. The methods section should state how the study was conducted. The results section should include what was found during the study. The answer to the scientific question should be in the discussion/conclusion section. The abstract should be written in a manner that the reader can understand the key points of the study without referring to the scientific paper.

The abstract should focus on the question, main methods, results, and conclusion. This can be achieved by being specific and selective. For example, the abstract may include the primary objective, the study result of the primary objective, and conclusion drawn from the study results. If space allows, any secondary objectives and their respective results can be included.

HOW TO ADOPT A JOURNALISTIC APPROACH

In journalism, the lead, defined as the first sentence of a news story, is very important. The standard news lead is typically one sentence and includes all essential information for the reader. The sentence contains the 5 W's: who, what, where, when, and why. The lead of a news story and the abstract of a scientific article have the following characteristics in common:

- The lead of a news story is the equivalent of the abstract of a scientific paper.
- After the title, the lead is the first part of a news story seen by the reader. After the title, the first part of a scientific paper that provides context regarding the study is the abstract.
- The lead and the abstract are the most read part of a news story and scientific paper, respectively.
- The lead of a news story and an abstract of a scientific paper should be able to make sense on their own.

Table 1. Comparison of the Abstract to a News Lead

Part of the Abstract	"W" of the Lead
Objective	Why?
Methods	How?
Results	What?
Discussion	So what?

Table 1 compares which key parts of an abstract correspond with some of the Ws of a lead.

DIFFERENCE BETWEEN A NEWS STORY AND AN ABSTRACT

A key difference between drafting a news story and an abstract is why the intended reader should take an interest in the presented topic. In an abstract, the discussion/conclusion section will explain why the results of the scientific paper should be of interest and contribute to scientific literature. This component is not commonly found in a news story.

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Dr Aiello provided key points on the method of using a journalistic approach to draft an abstract:

- Read the scientific paper carefully.
  - Mark key words and sentences. This will be helpful to highlight key components of the paper.
- Think about the lead technique.
  - Consider the why, how, what, and so what when drafting the objective, methods, results, and discussion sections, respectively.
- Create a list of all marked material.
- Edit to condense and refine content.

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CONFERENCE

Session Report

The New Normal in the Medical Publications Sector

Speakers
Tim Day (Moderator)
Principal/Owner, Innovative Strategic Communications, LLC, Milford, PA
Michael Platt, MS, CMPP
EVP, Managing Director, Virgo Health
Glenn S. Tillotson, PhD, FIDSA, FCCP, FISC
Consultant Microbiologist, GST Micro LLC, North, VA

By Kathleen Scogna

As we enter the fourth year of the COVID-19 pandemic, many of us have begun to look back and reflect on how much our personal and professional lives have changed since "before COVID." Like all professions, the scientific publishing world has had to adapt to a new set of expectations and priorities imposed by the global pandemic. In this talk, 3 publishing professionals give their perspectives about how this "new normal" has affected all aspects of scientific publishing, whether these changes are here to stay, and the likely impact they may have on the medical writer.

"THE GREAT RESIGNATION"

Michael Platt, MS, CMPP, executive vice president and managing director of Virgo Health, a medical education company located in New York City, focused on what has been called "the Great Resignation," when millions of workers—many of them in the healthcare and science fields—took stock of their work lives, disliked what they saw, and left their jobs for other industries. Some dropped out of the workforce altogether.

The aftermath of the Great Resignation may be positive for the medical writer who's prepared to jump through a few hoops. The demand for talent is high: 71% of life science companies plan to increase their workforce in 2022. But employers now are taking steps to check whether a candidate is committed to staying and that they can handle curveballs. Mr Platt lists 5 interview questions that candidates should be prepared to answer when applying to an agency:

1. "What is your ideal work environment?"
2. "Why did you leave your last job?"
3. "Why do you want to work for this company?"
4. "Describe a stressful situation and how you handled it."
5. "What are your immediate career goals?"

Candidates should also expect to be asked to take tests, give presentations, or write sample articles during the interview process to demonstrate their writing abilities. The savvy candidate should not only ensure that their skills are up to snuff but also develop 4 key competencies Mr Platt believes are crucial to succeeding in the current environment:

1. "Being Human"
2. Transparency
3. Accountability
4. Urgency

Although the good news is that medical writers are beginning to sense their worth and are asking for (and often getting) higher salaries and freelance rates, it's not enough to be a good writer. To flourish in this landscape, Mr Platt contends that the best candidates are lifelong learners committed to communicating data and knowledge to make a difference in the world and in patients' lives.

THE RISE OF THE PREPRINT

In the publishing space, ethics took a huge hit during the pandemic, with inevitable consequences.

Glenn S. Tillotson, PhD, a healthcare scientist in global infectious disease drug development and now editor-in-chief of *Expert Review of Anti-infective Therapy*, described the state of scientific publication in 2020 as a "tsunami" (Figure 1). As clinical trials into COVID therapeutics took off, publishers scrambled to keep up with the rising tide of publications. One solution to quickly disseminate this information was by using preprints, or posting papers on a journal's server or website "as is," without editing, peer review, or the usual checks performed by the publisher before publication. Although preprints aren't new, the number of preprinted articles increased dramatically during the pandemic. And, not surprisingly, the number of retractions increased as well.

Dr Tillotson also described a rise in plagiarized content in the manuscripts his journal receives, although it has been difficult to know whether these are deliberate instances of copying or the result of overly enthusiastic cutting and pasting. Whatever the cause, it's not difficult to conclude that the pressure to publish cutting-edge COVID research, lack of staff to oversee the publishing process,

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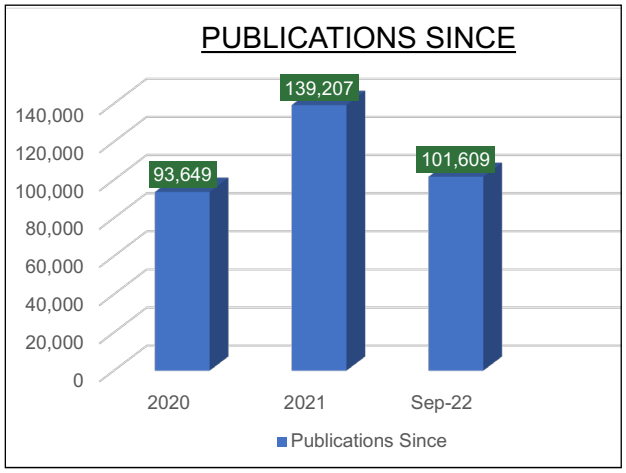

Figure 1. Number of scientific publications in 2020, 2021, and 2022.

and lowering of publication standards have created an ethical dilemma that the scientific publishing world must address in the coming years.

MENTAL HEALTH IN THE WORKPLACE

Tim Day, owner of Innovative Strategic Communications with an extensive background in pharma, spoke about the pandemic's unforeseen impact on workers' mental health. Recent surveys[1,2] found that over three-quarters of US workers experienced at least one symptom of a mental health condition in 2021, more than 80% identified their place of work as a contributor to at least one mental health challenge, and most workers are looking for workplaces that support mental health in the future.

Given these findings, moving forward in the post-pandemic era requires businesses to normalize discussions about mental health and commit to fostering the well-being of their workforce. A report published by The US Surgeon General report cited 5 essentials for achieving these goals (Figure 2).

As we approach yet another transition in the pandemic—the return of at-home workers to brick-and-mortar offices—employees and freelancers need to take stock of lessons learned over the past 3 years and apply them to the new normal in scientific publishing. Mr Day encourages staff writers to consider whether their positions are suitable for at-home work and to discuss this possibility with employers. And all employees, whether staff or freelance, should strive to develop strategies to balance work, family, and mental health. If the pandemic has taught us anything, it's that mental health in the workplace is no longer optional but essential for both the well-being of individual employees and the industry as a whole.

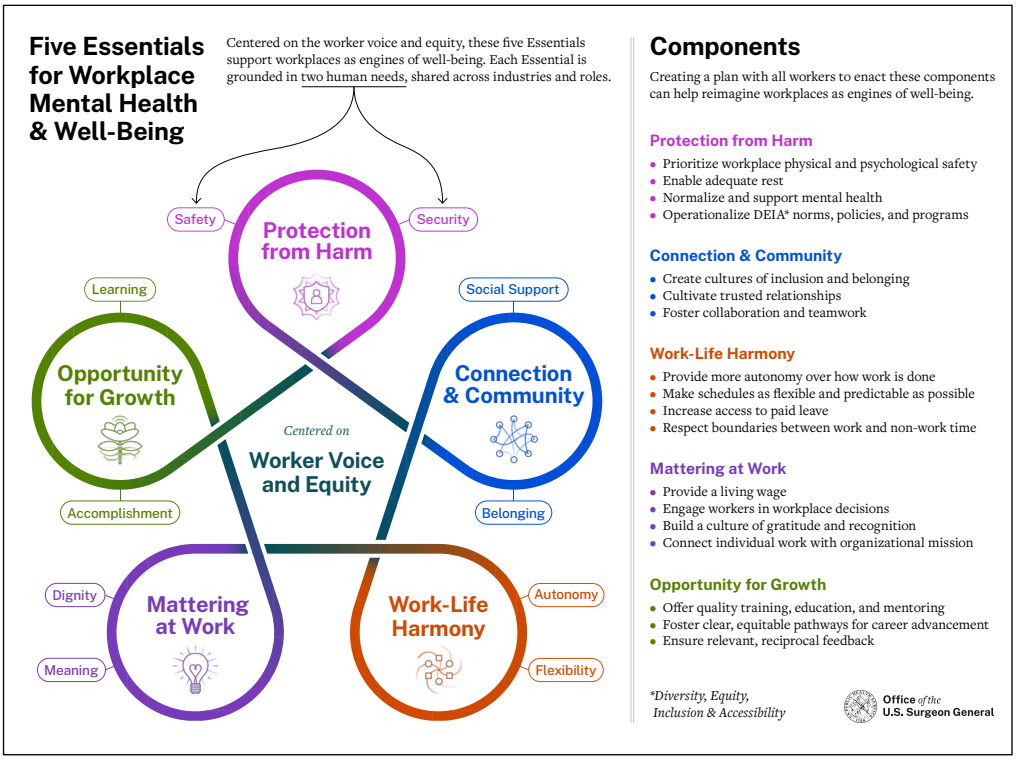

Figure 2. Five essentials for workplace mental health and well-being. From the US Department of Health and Human Services.[3]

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Author declaration and disclosures: *The authors note no commercial associations that may pose a conflict of interest in relation to this article.*

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AMWA NEWS

FROM THE PRESIDENT

Expertise and Leadership

Elise Eller, PhD / 2022–2023 AMWA President

As I write this, the AMWA Board of Directors (BOD) is preparing to meet in Rockville, Maryland, for its spring board meeting. It's always a pleasure to see my fellow board members and AMWA staff in person. I'm also excited because the AMWA BOD will review and discuss recommendations from the Diversity & Inclusion Assessment Task Force.

The AMWA BOD reviewed preliminary findings from AMWA's 2022 Diversity, Equity, and Inclusion (DEI) Survey at its meeting in January. One of the things respondents felt would be most helpful for AMWA to cultivate a more inclusive culture is to provide programs and resources on DEI topics. Providing education and resources is solidly in AMWA's wheelhouse, and I am pleased that AMWA has already begun to offer this educational content, and we plan to develop more. Our monthly webinar series has included DEI topics, and we had educational sessions, roundtables, and posters related to DEI at the 2022 Medical Writing & Communication Conference. I understand that there are several proposals on DEI topics for our upcoming annual conference in Baltimore, Maryland. I thank everyone who has stepped forward to share their expertise in this area.

Survey respondents also shared what would be most helpful to them as medical communicators. These include resources on using inclusive language in medical communication, on how to develop inclusive health communication, and on health equity and health disparities. If you have expertise in any of these topics or can recommend someone with expertise, please reach out to AMWA staff. We can use you, whether it's a webinar, online learning, or conference content. The *AMWA Journal* is another venue to showcase your expertise.

The survey respondents also indicated that AMWA should strive to have a more diverse representation in leadership and among subject matter experts (eg, *AMWA Journal* article and blog authors, conference and online education presenters). To keep our organization strong, we need to continuously cultivate new leaders and encourage a diversity of voices in our leadership.

Many AMWA leaders got their start at the chapter level—chapters always need volunteers! If you are in a chapter and would like to be more involved, consider volunteering for a task, whether it's printing out name tags for your chapter's conference, organizing a networking or educational event, or serving on a chapter committee. Members can also develop leadership skills by volunteering at the national level, such as volunteering for the *AMWA Journal* or serving on a committee, task force, or working group. As volunteers gain experience, they might want to further develop their leadership skills by chairing a committee, task force, or working group. From there, leaders might want to apply to serve on the AMWA BOD, where they will need to think strategically on behalf of the organization. In short, activities range from the operational and logistical to management to strategic, and volunteers need to consider what skills they have and want to develop further as well as the space in which they feel the most comfortable.

In addition, you can demonstrate leadership by putting yourself forward as a subject matter expert. We have many members who have established themselves as such by authoring articles for the *AMWA Journal*, presenting webinars, leading workshops, or presenting at chapter or annual conferences. Members can also serve as subject matter experts for the Education Committee. By sharing your expertise, you are investing in yourself as well as our profession.

Of course, this wouldn't be a proper president's column without me mentioning this year's Medical Writing & Communication Conference in Baltimore. I've been getting sneak peeks into the content that will be offered at this year's conference, and this year's program promises to be amazing. Our annual conference is where leaders and experts share their knowledge. This is the heart of AMWA. Come experience it this year in Baltimore and be inspired.

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AMWA NEWS

2022 Annual Business Meeting for AMWA Members

November 5, 2022, 4:00-4:30 PM MT

R. Michelle Sauer Gehring, PhD, ELS / 2021-2022 AMWA Secretary

AMWA President Katrina R. Burton called the meeting to order and provided a report about the accomplishments of the organization over the past year. AMWA has seen a growth in membership and led successful virtual and in-person events. There has been continued engagement of executives and the value of medical writing initiatives. She expressed gratitude to the Board of Directors (BOD), committee and task force members, and volunteer leaders who devoted their time and energy to lead AMWA during this past year.

On behalf of Dr Julie Phelan, Ms Susan Krug presented a financial report for the period of July 1, 2021, to June 30, 2022.

Ms Burton announced that in accordance with the AMWA bylaws, the nominating committee presented the following slate of officers for 2021-2022 to the AMWA BOD:

- President-Elect: R. Michelle Sauer Gehring, PhD, ELS
- Secretary: Kim Korwek, PhD
- Treasurer: Julie Phelan, MD, MBA

The AMWA BOD approved the slate, and the membership was notified of this slate 60 days before the annual meeting. The AMWA bylaws contain a provision for additional nominations to be made in writing and no additional nominations were received. Nominees who are unopposed are elected automatically at the annual business meeting.

Ms Burton declared the slate to be the elected officers for 2022-2023, led by Elise Eller, PhD, who as President-Elect automatically assumes the office of President.

Ms Burton passed the gavel to Dr Eller, who thanked the former President and expressed appreciation for having her leadership over the past year. Dr Eller shared highlights from her inaugural address and introduced the 2022-2023 AMWA BOD:

Officers:

- Immediate Past President: Katrina R. Burton, BS
- President: Elise Eller, PhD
- President-Elect: R. Michelle Sauer Gehring, PhD, ELS
- Secretary: Kim Korwek, PhD
- Treasurer: Julie Phelan, MD, MBA
- Executive Director: Susan Krug, MS, CAE

Chapter Advisory Council Chair:

- Jennifer Minarcik, MS

At Large Directors:

- Loretta Bohn, BA, ELS
- Sarah Dobney, MPH
- Lynne Munno, MA, MS
- Shawn Watson, PharmD, PhD, BCPS
- Joan Affleck, MA, MBA
- JoAnna Pendergrass, DVM
- Genevieve Walker, PhD

The meeting was adjourned at 4:20 PM MT.

2022-2023 BOD. Top row: Sarah Dobney, Genevieve Walker, Shawn Watson, Susan Krug, Loretta Bohn, and Kim Korwek. Middle: Jen Minarcik and Lynne Munno. Seated: R. Michelle Sauer Gehring, Elise Eller, Katrina R. Burton. Not pictured: Joan Affleck, JoAnna Pendergrass, and Julie Phelan.

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AMWA NEWS

AMWA Annual Financial Report, 2021-2022

Julie Phelan, MD, MBA / 2021-2022 AMWA Treasurer

Following is AMWA's financial report for the 2021-2022 fiscal year, which ended June 30, 2022.

This past year has been successful in many ways (membership growth, successful virtual events, continued engagement of medical writing executives, support for the value of medical writing projects, new D&I initiative, etc.) We continued to enhance marketing and social media efforts and implement new strategies to promote programs. We exceeded income for almost all our revenue-generating programs by creating valuable and timely content, resources, and member benefits. Based on the number of attendees and positive evaluation results, we had a very successful 2021 virtual annual conference. The evaluation results for this event were overwhelmingly positive, and we exceeded all income categories.

FINANCIAL PERFORMANCE

Net income from program operations was $335,422 versus a budgeted net loss from operations of ($18,700). AMWA reported a net loss for the 2021-2022 fiscal year of ($38,874) that was due to a significant investment loss of ($486,697).

REVENUES

Overall, program revenues of $1,806,892 exceeded budget expectations by 9%. This was largely because of conservative income budget estimates. Membership, annual conference, and education/certificate program income continue to be AMWA's major sources of revenue, providing 87% of AMWA's program revenue (Figure 1).

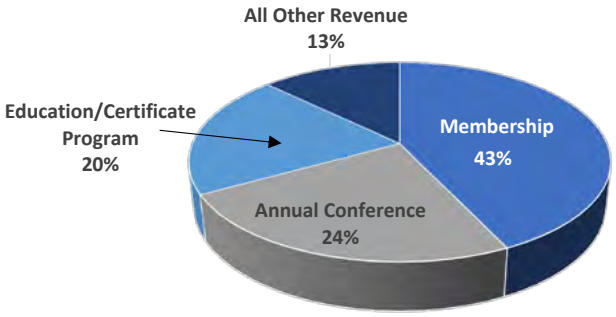

Figure 1. Sources of program revenue for the fiscal year that ended June 30, 2022.

EXPENSES

AMWA invests in programs, products, and services that bring value to members and the medical writing community. Overall, program expenses were under budget by 12% for the fiscal year. Total program expenses for the fiscal year were $1,474,826, with 32% of the expenses being used to fund membership benefits, 18% of expenses being used to produce the virtual annual conference, 16% of expenses funding educational programs including the Essential Skills Certificate Program and online education, and 7% being used to produce the journal (Figure 2).

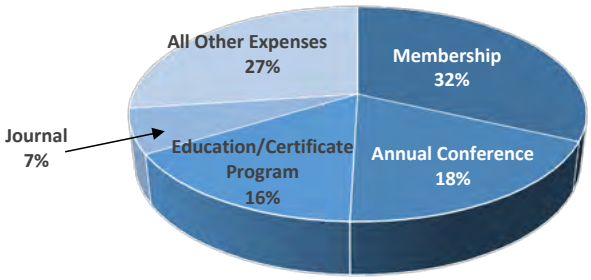

Figure 2. Sources of major program expenses for the fiscal year that ended June 30, 2022.

RESERVES

Reserves are the accumulation of funds over time that enable an organization to withstand an emergency or to invest in new mission-related initiatives. Unrestricted reserves of 6 to 12 months of annual operating expenses represent a standard target for not-for-profit organizations. Budgeted annual operating expenses were $2,236,000 for the fiscal year beginning July 1, 2022, to June 30, 2023. AMWA's unrestricted short- and long-term investment reserve level of $2,728,821 on June 30, 2022, provided sufficient reserves to cover 6 to 12 months of operations.

AMWA's restricted Endowment and McGovern funds totaled $214,906 and $172,541, respectively.

FINANCIAL POSITION

An organization's financial position is reflected in its asset and liability holdings. AMWA is well positioned to pay its obligations and plan for the future. Total assets were

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$4,172,530 as of June 30, 2022, and the organization's liabilities totaled $775,481.

FINANCIAL STATEMENT AUDIT RESULTS

Abercrombie and Associates, AMWA's independent auditors, expressed an unqualified opinion regarding their audit of the financial statements for the fiscal year that ended June 30, 2022. An unqualified opinion states that the financial statements present fairly, in all material respects, an entity's financial position, results of operations, and cash flows in conformity with generally accepted accounting principles. AMWA remains in a secure financial position as it continues expanding member benefits and resources into the next fiscal year. The full audit report is available to AMWA members upon request.

Acknowledgment

I thank Calibre CPA Group, PLLC, for providing the financial data and the members of the 2021-2022 Budget and Finance Committee for their review of reports and budgets: June Baldwin, Karen Bannick McQuoid, Alice Pappas, Whitney Smalley-Freed, Laura Town, and Christine Wogan; as well as ex-officio members: Katrina Burton (2021-22 AMWA President), Elise Eller (AMWA President-Elect), and Susan Krug (AMWA Executive Director).

Author declaration and disclosures: *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N2 / 2023

AMWA NEWS

AMWA's Fourth Medical Writing Executives Forum: Creating an Apprentice Program to Develop the Next Generation of Medical Writers

Marta Mas,[1] **Janice Worley,**[2] **Shiri Diskin,**[3] **Lynne Munno,**[4] **Robin Whitsell,**[5] **and Julia Cooper**[6] / [1]TFS HealthScience, Barcelona, Spain; [2]ProPharma, Raleigh, NC; [3]Bioforum Group, Tel Aviv, Israel; [4]Takeda, Cambridge, MA; [5]Whitsell Innovations, Inc, Chapel Hill, NC; [6]Parexel International (IRL) Limited, Dublin, Ireland

ABSTRACT

The Fourth Annual Medical Writing Executives Forum took place during the 2022 American Medical Writers Association (AMWA) Medical Writing & Communication Conference with the aim of bringing together heads of medical writing departments to discuss relevant topics in medical writing. This year's theme focused on the development of a framework for a medical writing apprentice program. The participants shared their experiences to begin laying the foundation for a successful medical writing apprentice program framework that can be customized and deployed as needed to help develop and grow the next generation of medical writers.

INTRODUCTION

In 2018, the American Medical Writers Association (AMWA) began an Executives Forum initiative with the aim to convene medical writing department heads to interact and discuss topics of interest in the medical writing field.

Against that backdrop, the Fourth Annual Executives Forum took place on November 2, 2022, in Denver, Colorado, led by Julia Cooper, Chair of the AMWA Executives Advisory Council. The Forum attendee companies, provided in Table 1, included representatives of small, midsize, and large pharma; contract research organizations; and other service providers. The theme was how to develop an apprentice program as a valuable tool to support the future of medical writing by offering an educational opportunity to the candidates as well as supporting the growth of the involved companies. The Forum began with a presentation of the results of an AMWA survey conducted in 2022 to obtain a snapshot of existing apprentice programs within the medical writing community. The survey presentation was a great starting point and provided context to Forum participants. However, the survey is not the focus of this article and will be discussed in greater detail in a separate publication.

For the main part of the Forum, participants were divided into 6 breakout groups, each addressing a specific subject related to apprentice programs, including considerations for a business case, guidance on program structure and duration, core topics, learning methods, best practices for recruitment, and defining success of the program.

This manuscript details the discussion of Forum members with the goal of supporting AMWA members in justifying, establishing, recruiting, and assessing the success of an apprenticeship program.

CONSIDERATIONS FOR A BUSINESS CASE

Apprenticeships and similar programs are an effective way to develop a pipeline of new medical writing talent. Such programs require allocation of significant time and resources to achieve the desired outcome, and in many companies, a business case is needed to obtain approval to

Table 1. 2023 Medical Writing Executives Forum Attendee Company List

- AbbVie
- Alexion, AstraZeneca Rare Disease
- Amgen Inc.
- AMWA
- Astellas Pharma
- Bannick LLC, a primary device group
- Bioforum CDMC
- Boehringer Ingelheim
- Bristol Myers Squibb
- Certara Synchrogenix
- CSL Behring
- Genmab
- Gilead Sciences
- ICON plc
- Incyte
- Janssen, Johnson & Johnson
- Jazz Pharmaceuticals
- Merck & Co., Inc.
- Moderna, Inc.
- Organon
- Otsuka Pharmaceutical Development & Commercialization
- Parexel
- Pfizer
- ProPharma
- PTC Therapeutics
- Reata Pharmaceuticals
- Regeneron Pharmaceuticals, Inc.
- RRD International, LLC
- Seqirus, a CSL company
- Spark Therapeutics
- Syneos Health
- Synterex, Inc.
- Syros Pharmaceuticals
- Takeda
- TFS HealthScience
- Trilogy Writing & Consulting
- Whitsell Innovations, Inc.
- Zentalis

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proceed. The breakout group discussed how best to present the benefits and return on investment for typical apprentice programs. It was recommended to divide the business case into financial benefits, which can usually be quantified at some level, and benefits that can be more difficult to measure, such as cultural and efficiency gains.

Examples of financial benefits include:

- **Recruiter cost savings.** It is often easy to hire entry-level employees for an apprentice program, whereas hiring at a senior level could involve expensive recruitment agencies.
- **Lower cost resource.** Although not fully trained, apprentices can often get involved in simple project work a few months into the apprentice program at a lower cost. This frees up senior-level resources to focus on more complex documents. Even if additional hours are factored in, to account for apprentices needing a little longer to complete the same task, there can still be an overall cost saving.
- **Senior-level writers hired may still need substantial training** in the company processes and (in some cases) because of misalignment between senior role expectations across companies, which could potentially cost more than trainees.
- Because of pressure on availability of senior writers in the market, **an apprentice program can allow the group to grow faster** than if only senior writers are hired.
- Apprentice programs that include an element of cross-training facilitate **scalability in line with business needs**.
- **Attrition is generally lower** among apprentices as they build strong bonds and loyalty to the company. This can be enhanced through completion bonuses or stock options to promote retention.
- Allowing senior writers to train apprentices while still working on billable activities may **reduce senior writer attrition** because experienced writers often find delivering training very rewarding. Trainers could be provided a time budget as a guide on how long to spend, and these hours should be included in the overall apprentice program budget. Reduced senior writer attrition stabilizes compensation models because frequent movement between companies drives up salaries.

Qualitative benefits include the following:

- Apprentices are **trained in the company processes from the start** (no undoing of bad habits required).
- Through a targeted hiring strategy, apprentice programs create a **larger, more diverse pool** of well-trained medical writers.
- **Sharing the work** between the apprentices and their senior colleagues (eg, through job shadowing) **forms strong bonds** and relationships in the department.
- **Apprentices provide useful support to senior writers**, allowing the senior writers to delegate some of the work and improve their own work-life balance.
- Apprentice programs provide a **forum for informal knowledge-sharing** between less experienced and senior writers.
- **Attrition among apprentices is typically lower**, which improves morale across the team.
- By developing strong, well-trained medical writers, apprentice programs contribute to **improvement in the overall quality of clinical research**.
- Apprentice programs can be an integral part of a robust **succession planning and sustainability strategy**.

When faced with the need to justify the development of a medical writing apprentice program, understanding and identifying specific internal business drivers and quantifying long- and short-term advantages will help with building a well-rounded business case.

GUIDANCE ON PROGRAM STRUCTURE AND DURATION

Once the business case has been established, the first step for any company in creating an apprentice program should be to define their goal. The breakout group acknowledged that this may vary from company to company; thus, it is important to define the *structure and duration* of an apprentice program, and the following questions should be considered:

Structure

- Is the goal to have someone write something as quickly as possible? Or is it to develop and retain medical writers with soft skills and broader context?
- Should the program be time-based, competency-based, or a hybrid?
- How many apprentices should be brought in at one time?
- If the company is small, how will the concept of an apprentice program be applied?
- Should the program include fellowships partnering with an academic institution?
- Would apprentices be hired who do not have the typical educational background or skill set that is generally sought after when hiring medical writers? If yes, how will the program be adapted?

Duration

- What is the overall recommended duration for an apprentice program cycle?

In answer to some of the above questions, the breakout group recommended the following:

1. ***Using a hybrid approach*** in which the company defines competencies based on their current and future business needs while identifying the needs and/or gaps of the individual and defining the timeframe in which those competencies should be demonstrated.
2. ***Bringing in cohorts of at least 2*** depending on the size of the company, business needs, and the availability of senior-level medical writers to train.
3. ***Using an apprentice program even if the company is small***, because it can be adapted and customized for each company, regardless of size.
4. ***Using an academic institution*** if the company has a relationship with one.
5. ***Hiring apprentices who do not fit the mold of a regular medical writer***, which can bring the benefit of diversity of thought and experience to the company. However, if this is done, a needs assessment/gap analysis should be performed and the individual's apprentice program experience tailored accordingly.
6. ***Establishing an apprentice program with a duration of anywhere from 6 months to 2 years*** depending on program structure and individual and/or company needs. The breakout group proposed a suggested duration for an example program in Figure 1. In Year 1, the medical writer works on lower complexity documents, and as they gain document knowledge and build an understanding of medical writing concepts, they move onto higher complexity documents in Year 2+. The ultimate goal of the program would be for the medical writer to independently manage a project from start to finish.

CORE TOPICS

The next step in building a medical writing apprentice program is to identify the specific content or curriculum that will form the basis of the program. Because medical writing is more than simply putting words on a page, the participants in the core topics breakout group agreed that a well-rounded medical writing apprentice program will include not only technical training on medical writing–related skills but also provide a solid foundation of broader, essential soft skills training (eg, project/stakeholder management, time management, etc.). The goal of this discussion was to identify the core topics for inclusion in the program as well as what specific content should be included within each area. The discussion centered on some of the most relevant skills that contribute to being a proficient medical writer, irrespective of what type of documents are being written, and to identify and outline core topics and suggest minimum content within each of them.

The 4 core topic areas or domains agreed upon by the breakout group for inclusion in an apprentice program are presented in Figure 2. The content of each core topic area was explored, and the participants in the breakout group agreed that within each topic or domain, the list of individual subtopics could vary significantly depending on how the program will be deployed.

Medical Writing–Related Skills and Knowledge

The participants in the breakout group acknowledged that these skills form the initial basis of a solid medical writing apprentice program. It was agreed that there is a minimum level of core knowledge that every individual needs as they embark on their journey to becoming a medical

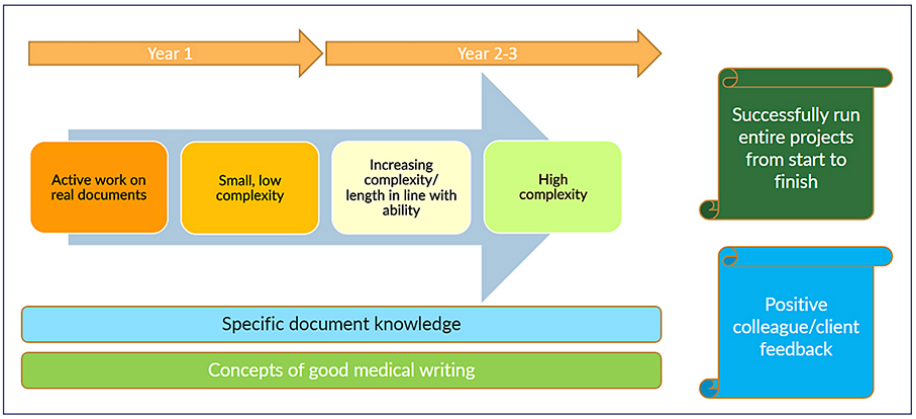

Figure 1. Suggested apprentice program duration.

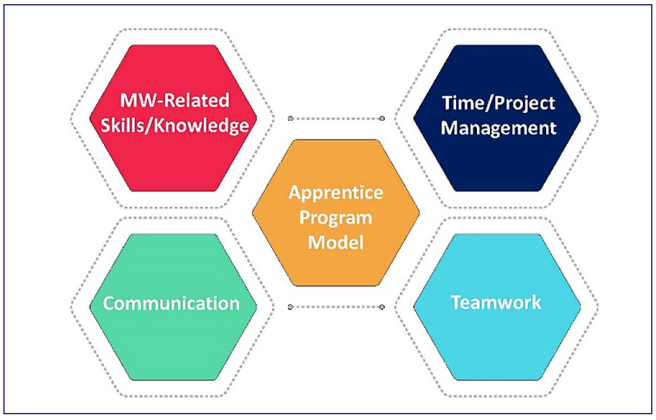

Figure 2. Apprentice program model core topics. MW, medical writing.

writer. An understanding of the drug development process, the relevant documents within the development lifecycle, and how they all relate to each other is a fundamental requirement, especially for a regulatory medical writer. In addition, the participants in the breakout group felt it was essential to instill a solid understanding of basic statistics, lean authoring, and good documentation principles. Other skills included knowledge of technology-driven tools, document preparation, and review processes as well as the use of the quality check (QC). This is not a comprehensive list of all the medical writing–related skills and knowledge, but it represents an essential starting point for establishing a solid foundation in medical writing. The group acknowledged that customizations to this core topic could include building out document and/or therapy area-specific trainings.

Time/Project Management

Within this core topic, the participants in the breakout group agreed that any curriculum for an apprentice medical writer program should include a basic education on project planning, execution, and management. This would include, at a minimum, training on timeline development and management as well as training on essential skills of negotiation, decision-making, time management, prioritization, and risk mitigation and management. The focus of the discussion centered on these topics, and the participants acknowledged that other aspects of this topic could be included but that these represented a vital primary skill set for a medical writer to master.

Communication

Medical writing at its core is about effective and purposeful communication, on and off the page. Within this subset of skills, there are many different types of training that could be implemented and deployed. However, the participants in the breakout group agreed that a robust medical writing apprentice program should include training on appropriate and effective professional communication. An important and often overlooked aspect of communication in medical writing is how to establish and align expectations, which is crucial when working with a group of cross-functional stakeholders and contributors. Another fundamental aspect of the communication skill set for a medical writer to master is effectively driving and leading team meetings. Incorporating essential training around managing and driving meetings, including how to influence without authority, was considered by the breakout group participants to be an essential facet of any medical writing training program.

Teamwork

Most medical writers operate as part of a cross-functional team and in some cases function as a process driver, driving the overall development of a medical writing deliverable. This requires a level of leadership and the ability to navigate the individual team dynamics to solve problems, mediate differences of opinion, and foster and encourage group harmony. Although these skills take time and confidence to build, the participants in the breakout group agreed that a medical writing apprentice program should include specific training to begin developing them as early as possible. Several topics were identified for inclusion such as navigating difficult personalities and interpersonal relationships, conflict resolution and problem solving, and navigating team lifecycle and contingency planning. The participants in the breakout group acknowledged that this was one core topic that could have a large variety of topics covering a broad range of soft skills.

LEARNING METHODS

Another important factor for consideration in the apprentice program model is how the curriculum will be delivered. This breakout group discussed some learning methods that have been tried in different medical writing departments and have been proven to work well as well as who should deliver the training.

The breakout group agreed that as a starting point, each person's baseline knowledge/skill set and background (Talent Assessment) should be evaluated at entry to serve as a basis for and guide the individualization of the apprentice program. This evaluation should not rely solely on self-presentation of a candidate because they could overestimate their experience or the extent to which their previous writing tasks (eg, journal articles or grant applications during graduate school) qualify them to perform regulatory writing tasks or highly complex medical communication projects.

It was also agreed by the breakout group that it was important for training to start as early as possible.

When considering specific learning methods, some of the established methods recommended by the breakout group included the following:

- Completion of the AMWA Essential Skills program
- Completion of mock writing tasks (could also be used as Talent Assessment tools)
- Implementation of simple QC findings
- Review of completed documents and team/QC comments on drafts to understand expectations from specific document types as well as learn the style guide and get acquainted with working processes
- Completion of live project work – partnering with a senior writer as a contributor (eg, writing document sections, performing QCs)

- Gradual advancement to writing full low-level, low-complexity documents
- Attending project meetings, such as kickoff meetings, data interpretation meetings, comment resolution/consensus meetings and lessons-learned meetings (even if outside the assigned teams). It was recommended to have the trainee engaged in the meeting by taking minutes rather than simply being a passive participant.
- Participation in meeting debriefings (lessons learned: how to read the room, understanding the approach and the strategy)

The breakout group also emphasized the need for soft-skill training. Some methods that can be applied to train medical writers on soft skills include the following:

- Completion of relevant AMWA courses and workshops
- Presentation to colleagues (eg, sharing learnings from attending AMWA, presenting a timeline to a team) in support of having the trainee learn and experience how to orally communicate the most important points clearly and effectively
- Shadowing a senior medical writer and observing how projects are managed and problems are solved

Ongoing assessments should be based on bidirectional periodic feedback sessions wherein managers/senior writers provide feedback on the apprentice's progress (using competency-based evaluations) and apprentices provide feedback on the program's effectiveness.

The completion of the apprenticeship or promotion to the next level in the medical writing role hierarchy would be defined by the ability to autonomously drive the development of at least one document type (predefined by apprentice program guidelines or job descriptions) with independent de novo content development.

It can be said that it "takes a village" to train a medical writer because it requires input from several different types of trainers. Internal or external subject matter experts (at all levels) often develop and deliver formal training sessions. From there, senior medical writers are often leveraged as "buddies" to provide ongoing support, guidance, and mentoring. Being a mentor and "trainer" may require specific train-the-trainer training, so the need for this type of training should be considered in an apprentice program model. In addition, this extra responsibility should be included in the senior writer's job description.

BEST PRACTICES FOR RECRUITMENT

Once the program has been designed and is ready to deploy, it's time to identify potential candidates for the program. The recruitment process for potential medical writing candidates is a key consideration for the success of an apprentice program. As previously mentioned, an apprentice program can be an effective way to develop a pipeline of new medical writing talent, which is a win-win for both the company and the candidate having a long-term career path. The participants in this breakout group discussed several topics that should be considered in the selection process of the candidates.

Process to start. The first step for recruiting candidates for an apprentice program is a successful advertisement "campaign." To that end, fostering relationships with academic institutions was seen as a particularly good option by the participants because this provides visibility into a large pool of potentially strong apprentice candidates. To do this, the interested companies can organize open sessions or webinars with graduates to explain the medical writing profession and the structure of the program they are offering. In addition to posting the job on the standard job search platforms, another potential strategy could be to leverage social media such as LinkedIn and include a brief questionnaire that allows the company to have an initial interaction with possible candidates.

Defining the right profile. Medical writing is not an academic discipline, and medical writing professionals come from many diverse backgrounds. The participants agreed that a background in the life sciences (either by training or work experience) is a good starting point for profiling prospective candidates (based on initial review of the CV and cover letter). In addition, other important skills would be a passion for communication and writing (a good cover letter and possible previous publications can be a good way to evaluate this), curious scientific spirit (that will support working in different therapeutic areas and documents), and social skills (to develop project management responsibilities).

Selection process. First, the breakout group considered that knowing how to effectively evaluate resumes, paying attention to the grammar style, formatting, and technical skills, was an important first step to start the selection process. If a cover letter accompanies the resume, a well-written one can demonstrate not only an aptitude for writing but an interest in obtaining the position. Once potential candidates are identified, one way to further screen a candidate is to administer a timed writing assessment before the interview. The participants believed this could be an effective way to evaluate a candidate's writing skills. However, this may not be allowed in some companies because of internal HR policies, so it may not always be feasible. If an assessment is used, it is important to ensure the same assessment is used

for all candidates and that a uniform, objective method to score the assessment is implemented. Finally, the participants agreed that the final pivotal piece of the selection process is a comprehensive interview to understand the full profile of each candidate and make an informed decision.

Interview questions. The participants discussed different interview questions that would be the most effective and meaningful to identify appropriate apprentice candidates. They agreed that a combination of role-specific questions, general questions related to personality and/or behavior, and questions around previous experience were good starting points for an interview. Some of the questions included:

- Why are you applying? Why this company? (Shows preparation and motivation for the role)
- What do you understand medical writing to be?
- Panel interview with behavioral questions (eg, tell us about challenges you have overcome and how)

Title within the organization. The breakout group considered the topic of possible job titles for an apprentice going through the program. Suggestions for a title included associate, fellow, or trainee. Although this can be defined in the framework of the program, the participants felt it could also be driven by or depend on the HR policies of the individual company.

Possibility of developing multiple training tracks. The breakout group also considered the possibility of having multiple training "tracks" within the apprentice program, for example, having an accelerated program (vs a standard duration or longer program) for people with advanced degrees or candidates with minimal writing experience compared with less experienced candidates.

The success of a medical writing apprentice program could depend on the quality of the candidates selected, so it is important to recruit, screen, and identify appropriate candidates.

EVALUATION OF PROGRAM SUCCESS

The participants in this breakout group discussed the best way(s) to evaluate the success of an apprentice program. Put simply, if the purpose of an apprenticeship program is to develop a pipeline of new medical writing talent, the true measure of success of the program is the ability of the program graduates to function as fully fledged medical writers. Hence, the program administrator can track the trajectory of the graduates. Were they hired directly either into the company or, if not already part of the program's plan or not feasible for those administering it, into medical writing jobs elsewhere in industry? A truly effective apprenticeship will serve as the launchpad for a medical writing career. The expectation of the apprentice program is that well-trained graduates will be able to independently work on medical writing deliverables, with the expectation that as these new writers get more experience and exposure, documents of greater complexity and/or team situations with greater complexity will be manageable.

To assess a program's success at the level of an individual apprentice, it's critical to establish evaluators, create evaluation criteria, and estimate a timeline for program completion. Competency models, such as the DIA Competency Model, create a good starting point for goals' conversations and well-defined expectations. In addition, at the program's outset, the administrator and/or mentor should define the evaluation criteria and clearly communicate those with the intern. For example, if soft skills or other "intangibles" are particularly valued, those attributes should be detailed at the outset and evaluated throughout the program to provide feedback on the intern's progression. At the completion of the apprenticeship, the level at which the company can expect the intern to perform will be contingent on the duration of the program and those prespecified goals of the apprentice and the mentor.

While the apprenticeship program is ongoing, effectiveness assessments to support continuous improvement (and adaptations, when needed) can ensure the program is working toward its goal. Alignment could be achieved by including feedback from multiple sources at multiple timepoints throughout the program. As this article has discussed, ongoing direct feedback to the apprentice from those interacting with the apprentice should be encouraged. In addition, the program administrator should seek feedback from team members on specific gaps they are observing. This could be as simple as providing additional training or expanding into other learning methods or even shifting into a different learning "track" if the program allows.

The apprenticeship program administrator should also plan specific intervals for seeking feedback from the apprentices about the program. Do they feel they are having the learning experiences and leadership opportunities that will allow them to fulfill a medical writing function upon completion? Where do they perceive gaps in their knowledge or opportunities to apply it? Do they feel the program prepared them for the next stages of their careers, and, if not, what was missing from the program?

As this paper has addressed the business case involved in creating and executing an apprentice program, this breakout group acknowledged that while apprentice programs enhance medical writing as a profession, they carry the inherent risk that a company could train someone only to have the graduate leave following completion of training.

This would have to be considered in the overall implementation of program and potentially mitigated with retention incentives, as discussed previously.

Overall, a robust apprentice program should include methods to evaluate the success of the program by defining specific criteria, identifying stakeholders who will provide feedback, and soliciting feedback from the apprentices throughout the program. A successful program provides adaptability and flexibility and ultimately results in an independent medical writer who demonstrates continued growth and development.

CONCLUSIONS

After a productive session thoroughly exploring the topics and discussions described above, the Forum participants outlined what a medical writing apprentice program could look like. Over the next year, the AMWA Executives Advisory Council will leverage these initial discussions to build out a comprehensive AMWA Medical Writing Apprentice Program framework. The goal is to provide an outline of the recommended content, structure, and duration of an apprentice program in addition to the skills and competencies achieved upon successful completion of the program. The final aim of establishing this framework is to assist companies that want to build their own program to develop the next generation of medical writers or benchmark their existing program against the industry standard.

Acknowledgment

We thank all the Forum participants for their valuable contribution to this relevant topic in the medical writing field.

Author declaration and disclosures: *The authors note no commercial associations that may pose a conflict of interest in relation to this article. The opinions expressed in this article are the authors' own and are not necessarily shared by their employers or AMWA.*

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N2 / 2023

AMWA NEWS

Medical Writer Apprentice Programs: Who Has Them, What Are They Like, and Do We Need More? Survey Results From 2022

Kim Jochman,[1] Rona Claire Grunspan,[2] Jeanette Towles,[3] Rona Vasey,[4] Linda Yih,[5] on behalf of the AMWA Apprenticeship Framework Working Group / [1]Merck & Co, Inc, Rahway, NJ; [2]ICON plc, Dublin, Ireland; [3]Synterex, Inc, Dedham, MA; [4]Trilogy Writing and Consulting, Frankfurt, Germany; [5]Parexel International, LLC, USA

ABSTRACT

In 2022, the American Medical Writers Association (AMWA) established a taskforce to develop a survey to understand the current state of medical writer apprentice programs and the desire for a standard framework to help guide the development of such programs. The survey was targeted to contributors who were actively responsible for leading and/or training and developing a medical writing team and was administered by using SurveyMonkey. A total of 78 responses were received, with the largest percentage of respondents primarily working in pharmaceutical/biotech/medical device companies (44%), followed by contract research organizations (CROs)/medical writing companies (23%), and medical writing consultancies (10%). The survey revealed that less than half (42%) of survey respondents' companies currently have an established apprentice program, and that CROs (73%) and medical writing-specific consultancies (57%) were more likely to have apprentice programs than pharmaceutical/biotech/device companies (24%). The respondents also provided details about the goals, training styles, structures, and durations of existing programs. Importantly, regardless of whether respondents' companies already have an apprentice program, the majority of respondents felt it would be useful to have a standard framework for an apprentice program either to refine existing programs or to develop a new program. Therefore, the AMWA Executives Advisory Council established an Apprenticeship Framework Working Group to develop a standard yet flexible framework for companies to use as an adaptable resource as they develop their own apprentice programs. The development of this framework is ongoing at the time of publication of this article.

Interest in the medical writing profession has increased over recent years, with candidates ranging from university graduates to those seeking a career change from within or outside the health care industry. Furthermore, demand for experienced medical writers continues to be very high, with the estimated value of the global medical writing market forecasted to more than double in the next several years (from $3.8 billion in 2022 to $8.4 billion in 2030).[1] Novel approaches are therefore necessary to sustainably develop a pipeline of new talent, and the need for structured development programs for new medical writers has emerged. Apprenticeships or similar trainee programs have been successful for some companies to bring new writers into the profession and ensure their development.

The American Medical Writers Association (AMWA) Executives Advisory Council established a taskforce in 2022 to learn more about existing apprenticeships/trainee programs. The team also sought to determine whether companies without such a program would find a framework useful, should they pursue this option. Consequently, a survey was developed to explore the above. The results of the survey were presented at the AMWA 2022 Executive Forum to kick off a full-day discussion on apprentice programs.[2]

SURVEY DESIGN AND OBJECTIVES

The survey was administered by AMWA anonymously (respondent and company names were optional) via an online platform (SurveyMonkey) and targeted contributors who were actively responsible for leading and/or training and developing a medical writing team, regardless of the types of documents they produced (eg, regulatory, publications, medical communication). To gain as much information as possible, respondents were encouraged to forward the survey to other eligible individuals within their organization. The survey was also posted on the AMWA site and promoted via social media. An option to do a brief interview with a taskforce member to gather additional details of the organization's apprentice program was included at the end of the survey.

Apprenticeships/trainee programs are referred to as "apprentice programs" throughout this article and are generally defined as programs that seek to develop entry and/or junior-level medical writers over an extended period (>6 months). Training topics for this type of program go beyond the standard training program all companies are

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required to have in place (eg, to meet Good Clinical Practice requirements).

Recognizing the limitations on respondents' availability for such a survey, we developed a set of questions that would capture key points on training programs. These questions targeted program goals, training topics, methods and structure, training source, duration, and whether a standard framework would be useful to further develop their program. Most of the questions were multiple choice and included an "Other (specify)" option where appropriate. The survey also included a checkpoint question to direct respondents who did not have an apprentice program to a set of follow-up questions regarding whether they had plans to implement such a program within 2 years and whether a standard framework would be useful as a starting point.

For those who agreed to follow-up interviews, we prepared 5 questions. These elaborated on what prompted the development of an apprentice program, components of their program, how training is structured, and overall feedback or lessons learned. After beta testing, the survey opened in late July 2022 and was available until early September 2022. Interim views of the data were done in August to confirm adequate participation, and follow-up interviews were conducted during September to early October 2022.

SURVEY RESPONDENT PROFILE

Among 78 survey respondents, the largest percentage noted their primary work setting as pharmaceutical/biotech/medical device companies (44%), followed by contract research organizations (CROs)/medical writing companies (23%) and medical writing consultancies (10%). The majority (63%) of the respondents primarily focus on regulatory writing, and most (82%) have a role in training and developing medical writers as part of their job duties (Figure 1).

Among 66 survey respondents who provided information regarding the approximate number of medical writers in their company (excluding contractors and nonwriting managers), the majority (58%) were in departments that have fewer than 20 medical writers, with an approximately equal number of respondents from companies with 20-50 (14%), 51-100 (14%), or more than 100 (15%) medical writers. Junior-level writers were largely noted to comprise up to 50% of the writers in these departments (73% of respondents), with some groups having a higher percentage of junior writers (Figure 2).

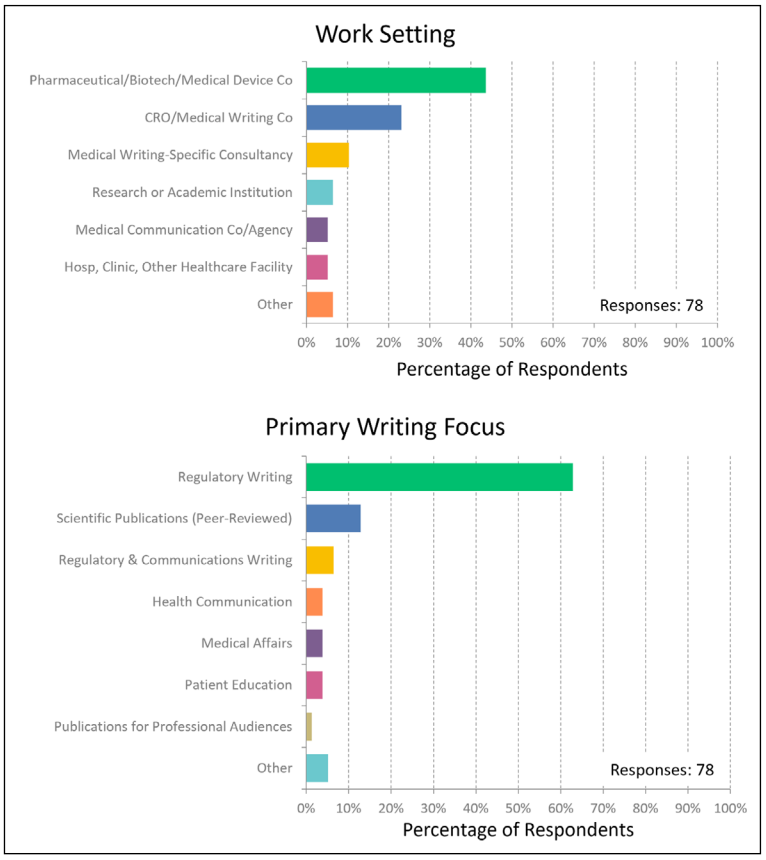

Figure 1. Survey respondents by primary work setting and primary writing focus.

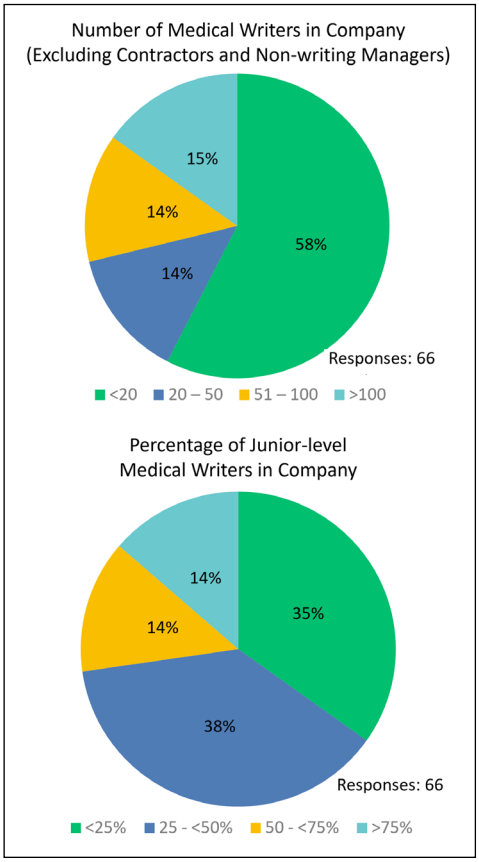

Figure 2. Approximate size of respondents' medical writing teams and percentage of junior-level medical writers within those teams.

Of note, some companies had more than 1 survey respondent; however, it was not possible to identify the exact number of companies with multiple survey respondents because the self-reporting of the organization/company name was an optional question and was only completed by 38 of the 78 survey respondents. In addition, it is possible that respondents from the same company were responding about different medical writing departments within that company. As such, all survey responses from each company were retained.

WHAT TYPES OF COMPANIES HAVE APPRENTICE PROGRAMS?

Of the 66 respondents to the question, "Does your company have an established apprenticeship or training program," 42% responded "Yes." The "Yes" responses were summarized by type of work setting, primary writing focus area, size of Medical Writing team/department, and percentage of junior-level medical writers (Table 1). The following trends were noted:

- For the most common types of work settings, CROs (73%) and medical writing-specific consultancies (57%) were more likely to have apprentice programs than pharmaceutical/biotech/device companies (24%).
- Medium (20-50 medical writers) to larger-sized (51-100 medical writers, >100 medical writers) organizations were more likely to have apprentice programs than smaller organizations (<20 medical writers).
- Medical writing organizations composed of 25%-<50% junior-level medical writers were more likely to have

Table 1. Types of Companies That Have Medical Writing Apprentice Programs

	Number (%) With Apprentice Programs		Total Number of Respondents in Category
	n	%	n
All Respondents	28	42.4	66
Respondents by Type of Work Setting[a]			
Pharmaceutical/biotech/medical device company	8	24.2	33
Contract research organization/medical writing company	11	73.3	15
Medical writing-specific consultancy	4	57.1	7
Research or academic institution	1	25.0	4
Medical communication company/agency	3	75.0	4
Hospital, clinic, other health care facility	0	0	1
Other (please specify)	1	50.0	2
Respondents by Primary Writing Focus[b]			
Regulatory writing	19	44.2	43
Scientific publications (peer-reviewed)	4	40.0	10
Regulatory and communication writing	1	20.0	5
Medical affairs	2	66.7	3
Patient education	0	0	2
Publications for professional audiences	1	100	1
Other (please specify)	1	50.0	2
Respondents by Size of Medical Writing Team/Department			
<20 medical writers	8	21.1	38
20-50 medical writers	4	44.4	9
51-100 medical writers	8	88.9	9
>100 medical writers	8	80.0	10
Respondents by Percentage of Junior-Level Medical Writers on Team/in Department			
<25%	9	39.1	23
25%-<50%	14	56.0	25
50%-<75%	3	33.3	9
>75%	2	22.2	9

[a]In order of most to least common work setting.
[b]In order of most to least common writing focus.

≥

apprentice programs than those with <25% or ≥50% junior-level medical writers.

WHAT DO APPRENTICE PROGRAMS LOOK LIKE?

The 28 individuals who indicated that their companies do have an established apprentice program were asked follow-up questions to better understand key elements of their training programs. Twenty-seven of the 28 individuals responded to these follow-up questions.

Goals and Reasons for Apprentice Programs

The primary goal of the majority (74%) of apprentice programs was to ensure medical writers have the context and skills needed to perform the role in the current landscape. The most common secondary goal was to expand the medical writing talent pool (41%) (Table 2).

In the follow-up interviews, the 8 respondents who agreed to participate were asked what unmet needs prompted their organizations to start an apprentice program. The majority of the interviewees were prompted to start an apprentice program because they recognized the challenges of finding experienced medical writers in today's environment. Interviewees also noted the desire to gain additional medical writers and to hopefully retain new talent by providing them with the tools and knowledge to succeed. By developing an apprentice program within their organizations, several interviewees were looking for gains in productivity and an overall increase of job satisfaction within their medical writing teams. Overall, the interviewees found the programs very positive in helping to resolve their unmet needs.

Training Styles and Content in Apprentice Programs

According to survey respondents, the most common core topics included in existing apprentice programs were document-specific knowledge (85%) and general writing skills (81%). Other core topics included analytical skills, technical aptitude, leadership/soft skills, and drug development knowledge (Figure 3).

Most of the respondents indicated that their apprentice programs utilized a team training approach rather than an

Table 2. Primary and Secondary Goals of Medical Writing Apprentice Programs

Goals	Number (%) Who Selected This as Primary Goal (N = 27)		Number (%) Who Selected This as Secondary Goal (N = 27)	
	n	%	n	%
Ensure writers have the context and skills needed to perform the role in the current landscape.	20	74	6	22
Expand the medical writer talent pool.	6	22	11	41
Support and champion the medical writing industry.	0	0	4	15
Development opportunities requested by writers.	0	0	4	15
Other	1	4	2	7

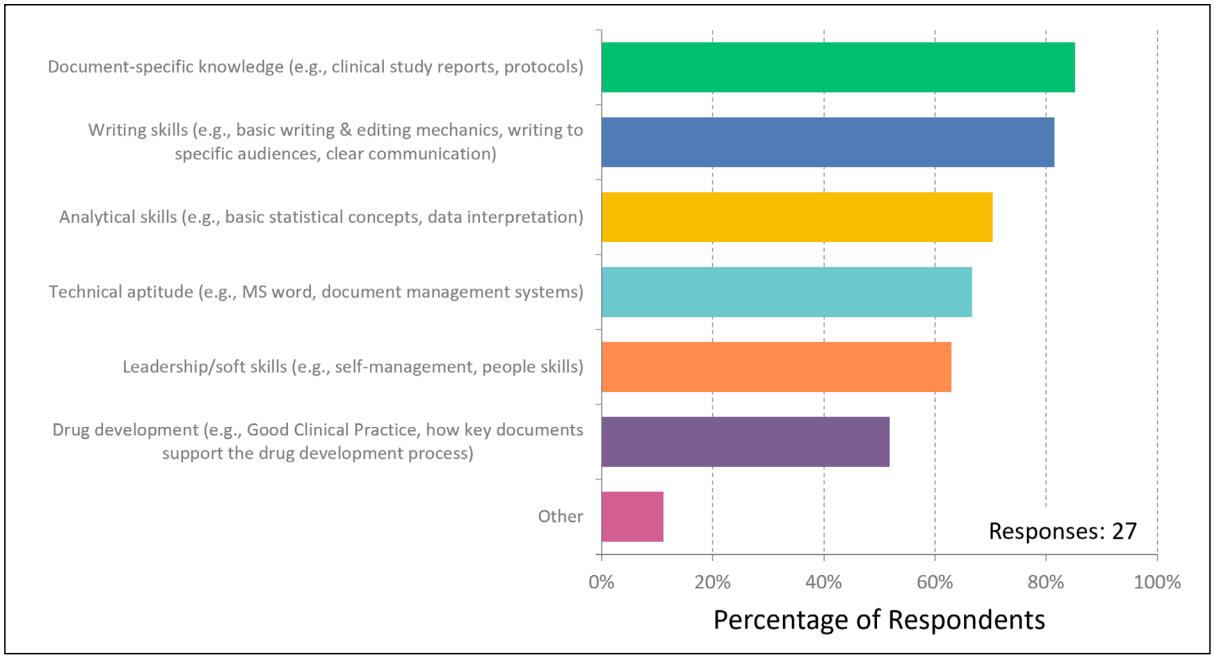

Figure 3. Percentage of apprentice programs that offer specified core training topics.

individual trainer (81%), with a mix of shadowing/coaching (93%), lecture-style presentations (85%), and self-learning (81%). Training was generally provided by other medical writers (85%) and/or medical writing managers (70%).

Based on the responses from the 8 interviewees, most apprentice programs offered a theoretical learning component (eg, classroom learning, self-serve online modules, workbooks) and a practical hands-on learning component (eg, pairing with senior writers as trainers/mentors, coaching sessions). These programs typically start the apprentice on authoring simpler document types and progress to more complicated documents as they learn. The apprentices typically receive feedback on performance and evaluation from clients, mentors, and management.

Structure and Duration of Apprentice Programs

There was a mix of time-based (26%; apprentices must complete the program in a specified amount of time), competency-based (37%; apprentices work at their own pace, but must demonstrate a certain skill level to progress), hybrid (33%; apprentices must meet time and skill requirements to progress), and other (4%) structures. The majority (67%) of program durations ranged from 6 months to 2 years (Figure 4).

There was a mix of how frequently new apprentices were onboarded into programs (ie, on a rolling basis, as a cohort) (Figure 5). Twenty-three of the 27 respondents (85.2%) indicated that program participants were brought on as regular company employees; the remaining 4 respondents indicated that participants who successfully completed the program were subsequently hired into the company as regular company employees or were offered a formal recommendation into a permanent role.

Notably, 63% of respondents whose organizations already have an established apprentice program thought it would be useful to have a standard framework in order to further develop their program (Figure 6).

WHAT ABOUT COMPANIES WHO DO NOT HAVE AN APPRENTICE PROGRAM?

Of the 66 respondents to the question, "Does your company have an established apprentice or training program," 58% responded "No."

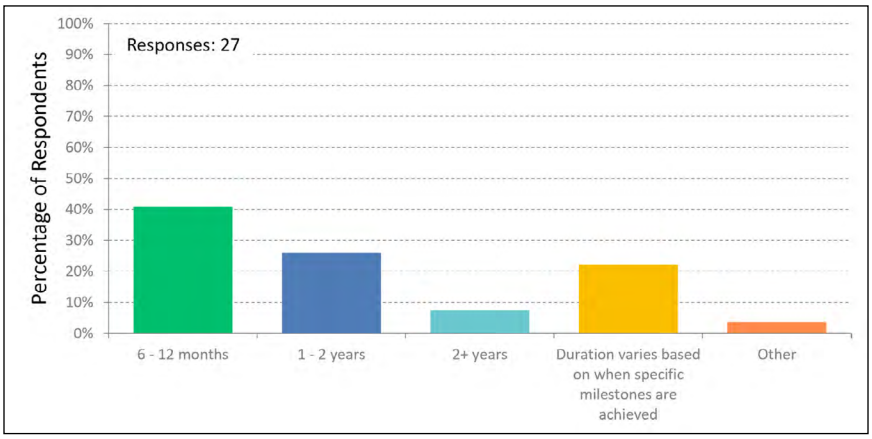

Figure 4. Duration of apprentice programs.

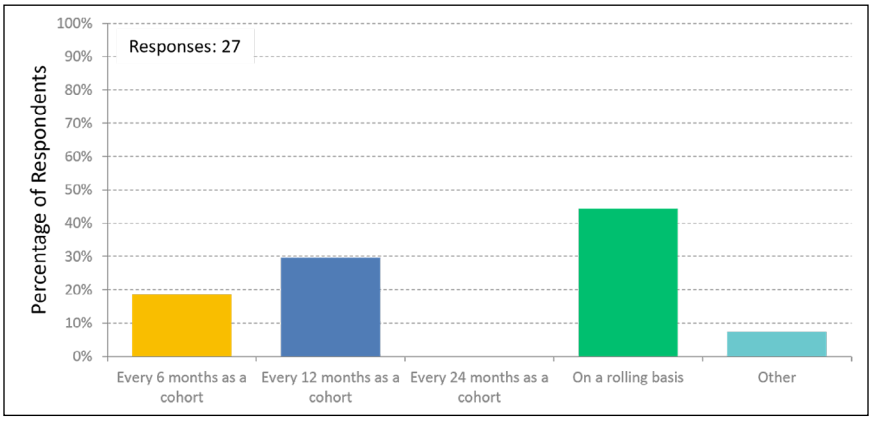

Figure 5. Frequency of onboarding new apprentices.

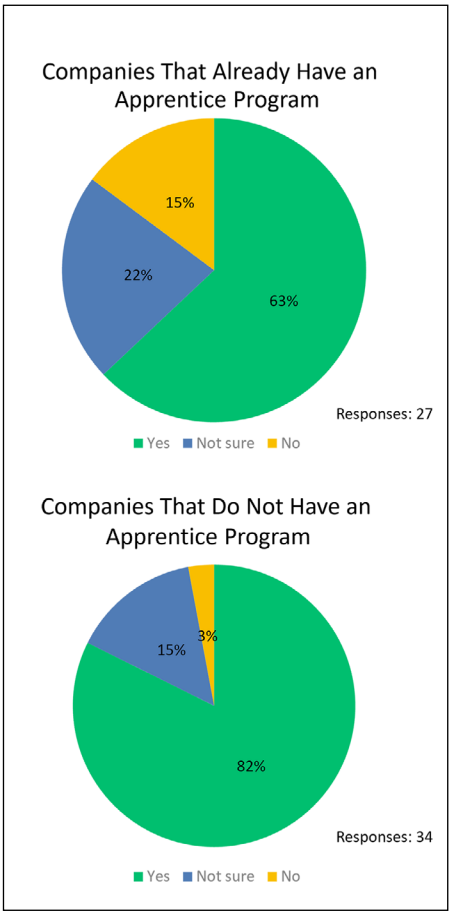

Figure 6. Would a standard framework for an apprentice program be useful?

The 38 respondents who indicated that their companies do not have an established apprentice program were asked follow-up questions to better understand why their companies did not have programs. Of these 38 respondents, 33 or 34 responded to each follow-up question.

When asked why they do not have an apprentice program, more than half (61%) said they lack the resources to provide training, and 46% said they have no to very few junior-level medical writers to train at their organization. However, 21% said their organization is planning to implement an apprentice/trainee program within the next 2 years. Most respondents (82%) who did not have an established apprentice/trainee program thought it would be useful to have a standard framework available to aid future implementation (Figure 6).

SUMMARY AND LOOKING FORWARD

The objectives of the survey were to understand how many and what types of companies currently have medical writer apprentice programs; the goals, training styles, structures, and durations of existing programs; and the desire for a standard framework to help guide the development or enhancement of apprentice programs.

The survey responses showed that less than half of the respondents' companies had medical writer apprentice programs, and that CROs and medical writing-specific consultancies were substantially more likely to have such programs than pharmaceutical/biotech/device companies. The primary goal of the majority of apprentice programs was to ensure medical writers have the context and skills needed to perform the role, and the most common reason for starting an apprentice program was related to challenges in finding experienced medical writers in today's environment.

Many existing apprentice programs include training in document-specific knowledge and general writing skills. Notably, less than two-thirds of programs include training in leadership and soft skills. In a recent survey, teams indicated that leadership and collaboration skills were the values that they perceive as medical writers' greatest contributions. However, when medical writers were asked to identify areas in which they needed more opportunities to learn, leadership skills and collaborative skills/diplomacy were 2 of the most common focus areas.[3]

The survey responses suggest that existing apprentice programs vary in terms of structure, duration, and how frequently new participants are brought into programs. Of the companies that do not have established apprentice programs, more than half indicated that they lack the resources to provide training, and 21% said their organization is planning to implement an apprentice program within the next 2 years.

Importantly, regardless of whether or not respondents' companies already have an apprentice program, the majority of respondents felt it would be useful to have a standard framework for an apprentice program either to refine existing programs or to develop a new program. As such, and in follow up to the discussions held at the 2022 AMWA Executive Forum,[2] the AMWA Executives Advisory Council established an Apprenticeship Framework Working Group to create a standard yet flexible framework for companies to use as an adaptable resource as they develop their own apprentice programs. The creation of this framework is ongoing at the time of publication of this article.

Acknowledgments

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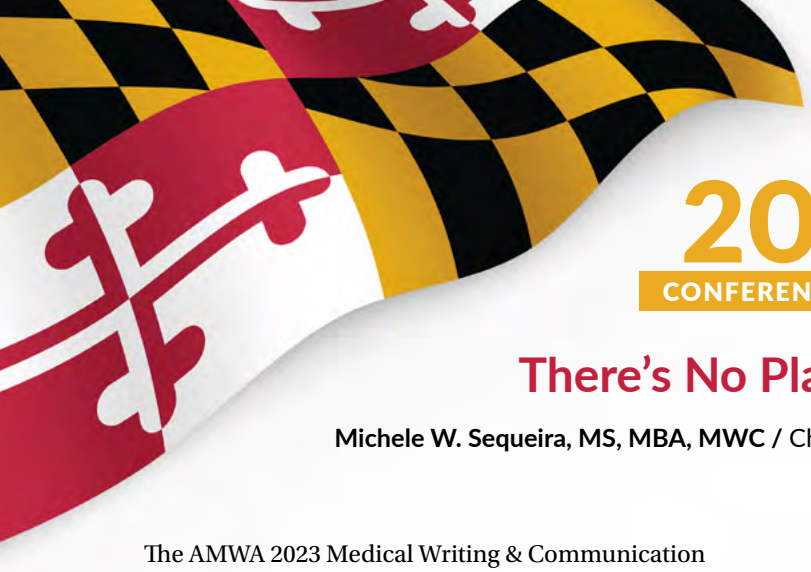

2023
CONFERENCE PREVIEW

There's No Place Like Home

Michele W. Sequeira, MS, MBA, MWC / Chair, Annual Conference Program Committee

The AMWA 2023 Medical Writing & Communication Conference will take place October 25th through the 28th in Baltimore, within an hour's drive of AMWA's home offices in Rockville, MD. The Annual Conference Planning Committee, AMWA staff, and many, many contributors have been working hard to deliver a great conference.

SESSIONS AND WORKSHOPS AND POSTERS — OH, MY!

The Annual Conference Planning Committee read, evaluated, and discussed more than 70 thoughtful and well-written proposals for educational sessions. With a packed schedule this year, we could accept only 40 of them, and we're thrilled with the ones we selected. We think attendees will be, too!

The program will have something for everyone, including sessions for beginners, midcareer, and experienced medical communicators. We're planning to have

- 9 sessions featuring core knowledge and skills
- 9 sessions on regulatory writing
- 6 sessions focused on health communication
- 5 sessions about career development
- 4 sessions on scientific publications
- 3 sessions on wellness
- And more!

In addition to the educational sessions, we'll have more than 22 workshops for deeper dives into specific topics relevant to medical communicators. As in years past, most workshops will be held on Wednesday and Saturday, the pre- and post-conference days, to minimize conflicts with the sessions. Posters will feature additional topics for learning and allow space for networking, too. MedWrite Talks, short talks given in the TEDx style, will offer thought-provoking topics important to medical communicators. And, of course, the schedule will allow time for networking, light snacks, and break time to keep attendees rested and refreshed.

FOLLOW THE YELLOW, RED, AND BLACK ROAD TO LEARNING

The annual conference offers roundtables to give attendees the opportunity to simultaneously learn and network. This year's conference in Maryland (the state colors are yellow, red, and black) will be no different. We are planning to offer several informational and participatory roundtables and will add something new, too: learning circles. We envision learning circles to include 20 to 30 attendees in a conversation about a specific topic. The presentations will be more informational, but the small group size will still allow for networking with and learning from peers.

And because technology and tools change at a breathtaking pace, we also plan to offer vendor showcases to highlight our supporters and educate attendees. These showcases will be a chance to learn more about the products and services our vendors offer, see demonstrations of their tools, and perhaps even take some for a test drive.

GET READY TO FLY (OR DRIVE) HOME

Unlike Dorothy, the central character in L. Frank Baum's The Wonderful Wizard of Oz, attendees won't be able to click their heels together to magically appear at the conference. (AI technologies aren't that advanced yet.) So, it's best to make travel arrangements and book a room at the beautiful Baltimore Marriott Waterfront hotel early to take advantage of the early bird discount. Visit the AMWA website to learn more.

And in making your arrangements, reserve some time to take in the sights and sounds of Charm City. Harbor tours, museums, historic sites, great food—Baltimore has it all. Our conference schedule will allow some time to visit the city, but you'll probably be aching for more—so, indulge yourself!

I look forward to seeing you at the conference.

Author declaration and disclosures: *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

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CALENDAR OF MEETINGS

DIA
"DIA 2023 Global Annual Meeting: Illuminate"
June 25-29, 2023
Boston, MA
https://www.diaglobal.org/en/flagship/dia-2023

International Society of Managing and Technical Editors
"Aspire 2023: Leadership, Accountability, and Growth"
July 18-20, 2023
Virtual
https://www.ismte.org/event/2023GlobalEvent

Editorial Freelancers Association
"EFACON 2023"
August 17-19, 2023
Alexandria, VA
https://www.the-efa.org/event/efa-conference-efacon/

Asian Council of Science Editors
9th Annual Meeting of the ACSE
August 20, 2023
Dubai, UAE and Virtual
https://theacse.com/2023/

Australasian Medical Writers Association
"Making a Difference"
August 24-26, 2023
Auckland, New Zealand
https://www.medicalwriters.org/events/

Council for Programs in Technical & Scientific Communication
"2023 CPTSC Conference"
September 22-23, 2023
Charleston, SC
https://conference.cptsc.org/

Plain Language Association International
"Connecting Cultures: Creating Bridges with Clear Communication"
September 27-29, 2023
Buenos Aires, Argentina
https://plainlanguagenetwork.org/conferences/2023-buenos-aires-argentina/

Society of Clinical Research Associates
"2023 Annual Conference"
September 29-October 1, 2023
Montreal, Quebec, Canada
https://www.socra.org/annual-conference/2023/2023-annual-conference-information/

Regulatory Affairs Professionals Society
"RAPS Convergence 2023"
October 3-5, 2023
Montreal, Quebec, Canada
https://www.raps.org/events/raps-convergence-2023

National Association of Science Writers
"ScienceWriters2023"
October 6-10, 2023
Boulder, CO
https://www.nasw.org/events/nasw-science-writers-national-conference-sciwri23-annual-meeting-2023-boulder-colorado

Academy of Communication in Healthcare/International Association for Communication in Healthcare
"International Conference on Communication in Healthcare"
October 22-25, 2023
Rio Mar, Puerto Rico
https://www.achonline.org/ICCH2023

American Medical Writers Association
AMWA Medical Writing & Communication Conference
October 25-28, 2023
Baltimore, MD
https://www.amwa.org/page/Conference

European Medical Writers Association
"56th EMWA Conference"
November 9-24, 2023
Virtual
https://www.emwa.org/conferences/future-conferences/

American Public Health Association
"APHA 2023 - Creating the Healthiest Nation: Overcoming Social and Ethical Challenges"
November 12-15, 2023
Atlanta, GA
https://www.apha.org/events-and-meetings/annual

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- Excellence in scientific publications
- Health communication strategies
- Preparing the next generation of medical writers
- Technology and innovation in medical communication
- Trends in medical grant writing and editing
- The medical communicator's role in diversity, equity, and inclusion

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https://www.amwa.org/conference