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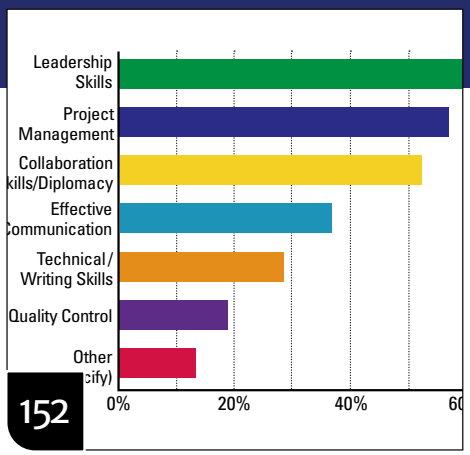

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL
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In support of the mission of the American Medical Writers Association (AMWA) and to advance the broader profession, the *AMWA Journal* publishes 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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FROM THE EDITOR

MICHAEL G. BAKER, PHD

What's Coming to the *Journal* in 2022

As 2021 winds to a close, we are excited to announce several *AMWA Journal* developments for 2022.

1. The *Journal* is going digital! We are working diligently to bring the *Journal* to you online and will continue to provide it in PDF format. The online version will allow you to search issue contents and access individual articles. DOIs and Crossref will be enabled, making journal content easy to find and cite. Further details will be conveyed in our spring 2022 issue.
2. Issues will be theme-based, led by guest editors. We will rally around themes of particular interest to AMWA members, starting with Digital Revolution in the spring, followed by Communicating Science in the summer. Diversity and Inclusion will be the theme for fall, with the winter issue addressing Global Medical Communication. Although we are implementing theme-based issues, we will continue to feature content of ongoing interest to AMWA members, led by our terrific section editors and regular contributors.
3. We are adding new regular sections on topics of ongoing importance to our AMWA audience, including Technology Talk, addressing the digital platforms used by medical communicators, and Progress in Publications, in recognition that a substantial proportion of AMWA's members are focused on the development of scientific publications.

We hope you share our enthusiasm as the *Journal* continues to evolve to best serve our audience.

As always, we welcome contributions from our AMWA members, which you can submit directly to me at journaleditor@amwa.org.

Yours in medical communication excellence,
—Michael

FEATURE

Optimizing the Value of Regulatory Medical Writers

Dylan Harris,[1] Lisa Chamberlain James,[2] Julia Forjanic Klapproth,[3] Brian Bass,[4] and Angela Russell Winnier,[5] on behalf of the AMWA Value of Medical Writing Working Group / [1]Takeda Pharmaceutical Company Limited, Lexington, MA, USA; [2]Trilogy Writing and Consulting, Cambridge, United Kingdom; [3]Trilogy Writing and Consulting, Frankfurt, Germany; [4]Bass Global Inc, Fort Myers, FL, USA; [5]Pfizer, The Woodlands, TX, USA

ABSTRACT

An expanding need for clinical documentation and regulatory health authority interactions during drug development has drawn increased attention to the role of the regulatory medical writer. This role is frequently misunderstood and poorly recognized. The American Medical Writers Association (AMWA) formed a working group in 2020 dedicated to defining the value that regulatory medical writers contribute. The purpose of this article is to demonstrate the value that regulatory medical writers bring to the drug development and approval processes and to explore the ways in which efficiencies in regulatory writing can be increased. Current models for success provide guidance on training to help medical writers achieve their full potential, but obstacles and barriers to medical writing efficiency and document quality remain. Surveys developed by the AMWA working group revealed that (1) regulators who review clinical documents believed that regulatory writers improve document quality and (2) writers are frequently recognized for leadership and collaboration. Maximizing medical writing value requires thoughtful leadership and investment in training that includes both technical knowledge and soft-skill proficiency.

INTRODUCTION

Expansion of the biopharmaceutical industry has given rise to many jobs with very specialized skills sets supporting both the conducting and reporting of clinical trials. One of these specialized jobs is that of the medical writer. There are now several types of medical writers: those who focus on clinical data publication writing, those who support medical education and conference materials, and those who primarily prepare regulatory documentation supporting ongoing clinical trials (eg, clinical study protocols, investigator brochures, investigational new drug [IND] applications) and the reporting and submission of trial results to regulatory agencies (eg, clinical study reports and Module 2 clinical summary documents for marketing applications). Writers in this latter category have been termed "clinical writers," "regulatory writers," or "clinical–regulatory writers," and exploration of the value of their role is the focus of this article. For purposes of the current discussion, these writers will be referred to as regulatory writers.

Companies engaged in the development of new medicines have a high need for expert communicators and devote substantial budgets to ensuring that documentation supporting clinical trials and regulatory submissions is accurate and of high quality. However, because company structures and team structures vary significantly, expectations of the role of the regulatory writer may also vary. Full exploitation and harnessing of the writer's skills and value requires members of the clinical project team to have a common understanding of the writer's role. As this proposition regarding the value of the regulatory writer has become a prominent topic in the medical writing community, the American Medical Writers Association (AMWA) has formed a working group focused on understanding and communicating the value that regulatory writers bring to project teams. The remit of this working group included developing a series of surveys designed to gather information about the value that regulatory writers represent, as well as a thorough review of the literature to identify articles that address this topic. This article aims to demonstrate the value that regulatory writers bring to the drug development and approval process and to explore both common obstacles to efficiency and ways we can increase efficiencies in regulatory writing, including through improved training of medical writers industry wide.

CURRENT MODELS FOR SUCCESS

A Medical Writing Competency Model was developed by an industry-wide group of medical writers to provide guidance

on how to assure quality and consistency in the medical writing function.[1,2] It also serves as a tool to describe the value and contributions of medical writers to drug development and medical communications. The model defines the essential knowledge, skills, abilities, and behaviors (KSABs) necessary for medical writing competency. It is purposefully designed to include the scope and breadth of the medical writing profession, and it is applicable to both medical writers and managers of medical writers.[1] The Competency Model establishes 5 core competency domains through which the KSABs applicable to medical writing can be assessed and a medical writer's competency can thus be certified.[1,3] These 5 core competency domains are gathering, evaluating, organizing, interpreting, and presenting.[3] They are the backbone of medical writing certification and the foundation of the Medical Writer Certified (MWC) examination.[1,4] In addition to defining and facilitating assessment of the core competencies that contribute to a medical writer's value, the Medical Writing Competency Model and MWC examination inherently provide guidance on training to help medical writers achieve their full potential.

OBSTACLES TO EFFICIENCY

Notwithstanding the training and competency models currently available, there are still substantial obstacles and barriers to efficient medical writing to be recognized, acknowledged, and overcome. These obstacles have a significant and direct impact on submission timelines, success, and ultimately the speed of delivery of new medicines to patients.

Lack of Adequate Writing Skills and Strategy

Documents prepared without using lean writing techniques take longer to write, review, approve, and therefore submit. They also slow down the regulatory review and approval by agencies. Thus, not only the sponsors but also, ultimately, the end users of new drug treatments are affected by these documents that hinder readability and comprehension.[5] Oshiro et al surveyed registrants of 12 noncompulsory workshops on scientific publishing, in which respondents were asked what they found most difficult about preparing a manuscript.[6] Two of the most common barriers to manuscript publishing included uncertainty about how to organize. Lean writing techniques and technical skill in writing help give a writer clarity in structuring thought and organizing it into a meaningful order with a good thought flow. When a document is structured to present data in a manner that builds ideas, the reader can more easily follow what the intended messages are and can more readily understand the conclusions.

Insufficient Time

A key barrier to efficient medical writing is having sufficient time to craft the documents. Writing is an iterative process and writing the scientific documents that medical writers prepare is also a collaborative process involving multiple stakeholders, all of whom bring different perspectives that are relevant to the totality of the storyline. This means that timelines for the writing activities need to allow for sufficient time to pull a large amount of information together from multiple sources and weave it into a cohesive document. Timelines need to permit teams the bandwidth to strategically review the ideas and data presented. Complex documents with many interrelated topics may require multiple reads, with adequate timelines supporting this activity.

In addition, the time available for medical writers to focus on the data presentations and honing of the messaging is often reduced because they are not given the right tools and processes to optimize their writing time. For example, in the absence of good templates, medical writers need to spend time on predefining headings, styles, and formats, which means that less time is available to spend on the scientific content.[7] They might be given PDF files as source documents, which means they must spend time reformatting content taken from these files; or the team might insist on not using a lean approach to presenting the data, and the medical writers are asked to produce long, unwieldy documents full of bulk. Because timelines are rarely extended to accommodate these extra activities, adequate checks for scientific rigor are foregone, errors may be overlooked, and the relevance of interrelated data points may not be captured.[8] As writers face ever-accelerated looming deadlines, they are working longer hours, resulting in increased errors and an overall loss of quality. A study on quality metrics for clinical study reports found that for medical writers whose work rate exceeded the standard work rate by 1.5 times, it was more likely that major sections of the draft clinical study report required reworking than for medical writers whose work rate did not exceed the standard.[9]

Insufficient Training

Good and continued training is crucial to ensuring that these regulatory documents are being written by medical writers who have the lean writing skills to present the data with a structure that improves readability and guarantees they are fit for purpose. Training is needed not only on communication of clinical messages but also in interpretation of the data in the first place. Sharma highlighted that the key barrier that medical writers from India face in producing quality regulatory documentation is training because of a lack of a standardized training curriculum.[10] Lack of training can result in flaws in connecting the results to the conclusions, leading to claims that are not adequately supported or are erroneously reported.[8] Diong et al conducted an analysis on research

papers and found poor statistical reporting, including implied or gross spin, use of standard errors or the mean to calculate data variability, and lack of P value reporting for primary analyses.[11] This demonstrates a clear lack of understanding on how to be reporting this information, which could be avoided if medical writers had adequate training in this area.

Barriers to Document Quality

Given that regulatory documentation is critical for drug approval, these documents need to be of a high quality and accurately reflect the data supporting the proposed indication. Review of regulatory documents by subject matter experts during the authoring process ensures that the data have been correctly interpreted and that key messages are supported; however, getting reviewers to provide the necessary input can be challenging. As a result of competing priorities, they often do not have sufficient time for their review, which results in inadequate checks of methods, results, or conclusions and can contribute to the introduction or oversight of errors.[8]

Inconsistencies, both between documents in a submission dossier and between documents and their source data, hinder review by regulatory agencies, resulting in unnecessary questions and responses. Li et al provided an example of the review of an IND submission in which a discrepancy in a definition of a key term, which on the face of it may seem relatively minor, confused a regulatory reviewer who questioned the sponsor in the regulatory response.[12] This error, which would have been simple to correct during document review or quality control, led to wasted time and effort on the sponsor's part and was a fully avoidable delay to approval.

OPTIMIZING EFFICIENCY: IMPACTS OF LEADERSHIP AND TRAINING STRATEGY ON MEDICAL WRITING VALUE

Maximizing medical writing value requires investment in training and thoughtful leadership. How a medical writing department utilizes its writers may impact the value potential of the team. Managers who encourage specialization in a specific document type or phase of development (ie, the creation of functional silos) are working toward short-term efficiencies only. Functional silos can result in inefficiency and employee dissatisfaction.[13] Avoiding those silos is critical for establishing an environment of flexible and creative problem-solving, and writer overspecialization can lead to reduced knowledge, collaboration, creativity, and confidence.[14] This does not mean that medical writers should never work on the same document twice in a row. Indeed, a writer needs to write any one document type several times to become truly confident in the unique features of that document and understand its needs. But by allowing writers to work on multiple document types, in different therapeutic areas, they gain a broader understanding of how the documents relate to each other and how they need modifications for different settings. This broader oversight makes them better able to advise teams and construct documents that are more fit for purpose. Building an agile, broadly experienced team also positively impacts employee satisfaction and career development as it gives the writers more options to work in areas that better fit to their personal character (some writers enjoy writing about pharmacokinetics and others prefer safety topics), which keeps them engaged and gives them growth potential.

Effective leadership thus requires investment in cross-training and broader development of writing staff; in other words, it requires seeking to create medical writing "generalists" rather than "specialists." The value of generalists over specialists is known from other industries, and David Epstein, author of *Range: Why Generalists Triumph in a Specialized World*,[15] describes the benefit of more generalized training like this: "The more varied your training is, the better able you'll be to apply your skills flexibly to situations you haven't seen."[16] This book describes many examples of the impact of broader education on the ability to solve problems creatively. The generalist trainee is not constrained to understanding the same repetitive pattern of working.[15] Likewise, a writer who has written for all phases of development and across a variety of regulatory and clinical document types will have a breadth of experience that lends itself to valuable and creative contributions to document strategy.

Beyond training at the document level, building a strong writing team requires leadership that combines informed hiring decisions with day-to-day demonstration of desired behaviors. When regulatory writers were surveyed, the skills they were most recognized for on their teams were leadership and collaboration skills (see The Regulatory Writer's Perspective on page 152), indicating that these soft skills are a critical dimension of the regulatory writer's role. The survey also revealed leadership skills, collaboration skills, and project management as the top areas in which writers desire more training. Managers need to hire staff with the curiosity and team spirit needed to form a solid working group. The managers themselves then need to lead by example of the desired traits that solidifies a team. This includes showing a willingness to ask the right questions and to collect varying viewpoints on a problem (Table 1 on next page). It also includes encouraging horizontal relationship-building with other functional areas so that the medical writing team has a shared vision and understanding of goals with those other functions.[17] Teammates who learn to collaborate across functional boundaries gain skills faster and increase business efficiencies.[18]

Multiple studies describe a link between employee satisfaction and effective training.[19] A study of human resource

Table 1. How to Ask Good Questions

Common Pitfalls	Effective Inquiry
Start With Yes-or-No Questions.	Start with open-ended questions that minimize preconceptions. ("How are things going on your end?"; "What does your group see as the key opportunity in this space?")
Continue Asking Overly General Questions ("What's on Your Mind?") That May Invite Long Off-Point Responses.	As collaborations develop, ask questions that focus on specific issues but allow people plenty of room to elaborate. ("What do you know about x?"; "Can you explain how that works?")
Assume That You've Grasped What Speakers Intended.	Check your understanding by summarizing what you're hearing and asking explicitly for corrections or missing elements. ("Does that sound right—am I missing anything?"; "Can you help me fill in the gaps?")
Assume the Collaboration Process Will Take Care of Itself.	Periodically take time to inquire into others' experiences of the process or relationship. ("How do you think the project is going?"; "What could we do to work together more effectively?")

Adapted from Edmonson et al.[18]

employees showed a statistically significant impact of training and development on employee satisfaction and concluded with a recommendation to provide training oriented not only to work tasks but also to the developmental goals of the employee (eg, more generalized training opportunities).[20] Not only do generalist skills aid writers' development, but these skills can also help them to progress in their career. The progression from individual contributors to managers to enterprise-level leaders requires multiple "seismic shifts" in thinking, including a willingness to train as a generalist as opposed to a specialist.[21] Supporting this idea, a survey conducted in 2013 revealed that 60% of respondents felt their manager was a "good generalist" with broad transferable skills in people management and leadership, which are necessary for more senior positions in an organization.[22] Broad training strategies, then, need a company's attention for both improving problem-solving as well as positively impacting employee satisfaction and development into more senior roles, all of which elevate the value of the medical writing organization.

SOFT SKILLS THAT INCREASE EFFICIENCY AND ADD VALUE

Soft skills, in addition to technical knowledge, are essential for medical writing success.[1,2] These skills are increasingly recognized as an important contributor to competent job performance in a wide range of fields.[1,2,23-36] A recent survey was conducted with human resources and learning development specialists, including C-level executives, senior managers, and managers/supervisors, at companies ranging in size from <1,000 to >50,000 employees in a variety of industries, including technology, manufacturing financial services, health care, retail, hospitality, telecommunications, and education.[36] The survey found that across industries, the need for soft skills is nearly as difficult to fill as the need for hard skills.[36] The most in-demand soft skills identified by survey participants were critical thinking, communication, and creativity.[36]

However, as the need for soft skills grows, they are only briefly mentioned within the context of medical writing.[1] The Medical Writing Competency Model includes a list of soft skills in a supplementary table of general abilities that are applicable to all medical writers, regardless of their area of specialty.[37] These soft skills include assertiveness, compromise, decisiveness, kindness, conflict resolution, flexibility, leadership, resilience, negotiation, and openness.[37] Many of the soft skills listed in the Competency Model are mentioned in other articles on medical writers and medical writing.[1,2,23-35] Many of these authors identify additional soft skills they believe are also crucial for medical writer and manager competency (Table 2).

Table 2. Important Soft Skill–Based Competencies Not Listed in the Medical Writing Competency Model[1]

Soft Skill	Cited in:
Project Management	Pal 2019,[24] Limaye 2020,[25] Saleh 2020,[27] Guillemard 2014[28]
Time Management	Heisel-Stoehr and Schindler 2012,[23] Flaherty 2014,[26] Nice 2016[30]
Multitasking	Heisel-Stoehr and Schindler 2012,[23] Pal 2019,[24] Nice 2016[30]
Critical Thinking	Flaherty 2014,[26] Guillemard 2014[28]
Cultural Competency	Heisel-Stoehr and Schindler 2012,[23] Flaherty 2014[26]
Ability to Work Independently	Heisel-Stoehr and Schindler 2012,[23] Pal 2019[24]
Work Ethic	Heisel-Stoehr and Schindler 2012,[23] Flaherty 2014[26]
Attention to Detail	Heisel-Stoehr and Schindler 2012,[23] Nice 2016[30]
Networking	Heisel-Stoehr and Schindler 2012[23]
Self-Motivation	Pal 2019[24]

Many of these soft skills are relevant to the competency, and ultimately to the value, of all medical writers. An analysis of regulatory medical writing job opportunities posted on the European Medical Writers Association website between 2009 and 2011 ranked the behavioral and social soft skills required of medical writers by the frequency of their appearance in job posting advertisements (Table 3).

Table 3. Top-Ranked Soft Skills in EMWA Job Ads for Regulatory Medical Writers: 2009–2011[23]

Behavioral Skills	Percentage of Ads	Social Skills	Percentage of Ads
Leadership, Team Working	62	**Communication**	47
Networking	56	**Interpersonal**	22
Organized	33	**Work Independently**	18
Time Management	30		
Detail-Oriented	27		
Multitasking	15		
Conflict Management	10		

Ads, advertisements; EMWA, European Medical Writers Association.

Medical writers are recognized by drug development stakeholders, including study sponsors and government agencies, as valuable contributors to drug research and regulatory processes.[32] Part of that value lies in their technical understanding of how to craft thought and their regulatory understanding of the needs of the various documents. Yet their soft-skill competency is an equally important aspect of their value for their ability to pull teams together and keep stakeholders focused on messaging, timelines, and collaborative work ethics. Their ability to manage projects brings an essential value to their role. As noted by Ohms, a good project manager shepherds their projects and understands the interplay of the different functional areas involved.[38] Ohms points out that the 4 features of an exceptional project manager are (1) respecting others earnestly, (2) knowing when to speak and let others speak, (3) understanding the details driving the project, and (4) taking the time to self-assess and maintain focus. All of these features typify the skills that a good medical writer needs to have to successfully complete their projects on time and with a well written document.

FEEDBACK FROM REGULATORY AGENCIES ON THE VALUE OF MEDICAL WRITERS

The AMWA working group's survey designed for regulators who review documentation prepared by medical writers gave some valuable insights into how the agencies perceive the role of medical writers and the value they bring to regulatory documents (see The Regulator's Perspective on page 145). Regulators recognized and acknowledged the value that medical writers add to the regulatory documents they work on. They believe that medical writers improve document quality, which, unsurprisingly, is extremely important for regulatory reviewers. They confirmed that poor document quality can hamper the ability of the reviewer to provide an assessment, which in turn delays the drug approval process and in some cases can even sensitize reviewers to subsequent submission documents from the same sponsor.

These survey results provide meaningful data to support how we present ourselves within our organizations and how we should develop our medical writers—quality is clearly highly valued by regulators, and the regulators' feedback illustrates the need for a sufficient supply of highly trained writers. Ultimately, the regulatory reviewers made it clear that they are looking for lean but fully developed documents that make the scientific rationale clear and show how it is supported by the data. When training medical writers, we must equip them to lead teams to create documents that are concise and clearly present the message. There is also a clear need to focus on team management and soft skills that enable writers to lead and guide the authoring teams.

We can conclude that many regulatory reviewers understand the role of medical writers and believe that they make the job of the reviewer easier. Medical writers are clearly valued and respected by regulatory agencies, and these take-home messages should empower the medical writing profession and help to shape the ongoing training of medical writers.

OPTIMIZING THE ROLE OF THE MEDICAL WRITER

To optimize the role a medical writer plays on cross-functional teams, we need to understand the skill set that these writers require to play this role well. Ultimately, a good medical writer must master 3 main areas: writing skills, understanding the regulatory needs of the documents they are writing, and interpersonal skills to effectively manage projects.

Writers need to have excellent writing skills to effectively communicate the thoughts and vision of the document from their teams. This involves not only knowing how to structure thought in well-formed sentences but also how to structure the document in such a way that a reader comprehends how the various data points build on each other to form the intended messages. Developing a good medical writer, therefore, must begin by having someone who already has a talent and passion for writing and then must progress to guiding them to hone

their craft. Like any talent, writing skills get better with training. Teaching a writer to write better requires having someone who already has the skills to take the time to review and revise the text of the learning writer to show them how to improve. This is an investment of more than just giving them a well-written document and asking them to emulate it. It needs a trainer who will pull apart what the writer wrote, reconstruct it, and then take the time to explain why and how. People learn by making mistakes, and it is only when we are shown those mistakes and understand how to avoid them that the learning process takes place.

Writers also need to understand the unique purpose of each type of regulatory document. Many of these documents contain similar information, but the intention of each document differs. Some are meant to communicate to investigators, others are meant to communicate to regulatory reviewers, and all of them need to tell a slightly different part of the story for different purposes. Medical writers not only need to learn the theory of the regulatory requirements specified by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use and other agency guidelines that define what each document is meant to do but also need to be given sufficient guided practical training to see how teams build, discuss, and craft these documents. This includes having the opportunity to see feedback from agency reviewers on different types of documents and be part of teams who revise the documents in response to this feedback. Think of the difference between learning to fly a plane by reading the instruction manual and spending 10,000 hours in the air with a coach. Only the latter produces a seasoned pilot. This is an instance in which the concept of a generalist compared with a specialist becomes salient. Ensuring that a writer has practical experience on a broad spectrum of documents across a clinical development program gives them more depth of knowledge and makes them more versatile overall. It means they can truly advise teams on what fit for purpose looks like for different document types and that they help teams achieve that.

Finally, to optimize the value of a medical writer, we need to ensure that writers can train on the soft skills identified previously. This requires creating a safe environment that empowers them to challenge their boundaries as they learn how to assert themselves and corral teams. This training should come initially through demonstration, as novice writers witness experienced writers steering their teams and collaboratively working alongside other functional areas to develop documents. As writers develop, they must be granted increasing responsibility for running simpler meetings with an experienced writer there to support them, if needed. The acquisition of soft skills can be the most challenging dimension of writer development. Many writers are not extroverts by nature, and gaining the confidence to speak up and challenge subject matter experts often means overcoming their natural tendency to sit back and let others lead. By creating a situation in which writers first learn by example, writers are then allowed to execute within a safe environment and finally function independently once they have the necessary skills. We must give them the encouragement and security to grow without fear of embarrassment or risk of failure. In this way, we nurture strong, confident writers who have the wherewithal to collaborate with even the most demanding teams. Through training and development with a focus on both technical and soft skills and identification of growth opportunities for new and developing writers, we can continue to address the challenges discussed here and foster the next generation of regulatory writers.

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Value of Medical Writing: The Regulator's Perspective

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ABSTRACT

In 2020, the American Medical Writers Association established a working group to assess the value of the contribution of medical writers across the health sciences industry, including a subgroup tasked to gather data on the regulatory agency's perspective. We invited reviewers at regulatory agencies to participate in an anonymized survey to evaluate the effect of document quality on the regulatory review process, assess awareness among document reviewers of the contribution of medical writers to the quality of regulatory documents, and identify current strengths and opportunities to optimize document quality. This article shares the survey results and discusses their implications for document quality, their impact on the regulatory review process, and the skills medical writers need to develop to bring value to this process.

INTRODUCTION

Medical writers bring value across the health sciences, taking the lead and driving efficient approaches for the delivery of high-quality medical communication documents targeted at diverse audiences including regulators, payors, physicians, and patients.[1,2] However, the value of medical writing is not consistently recognized, and medical writers often still need to justify why they should have a seat at the table and be part of the team earlier in the process. Medical writing departments can also be faced with insufficient budget and resource to do their best work due to a lack of understanding of the role's value. Given the many settings in which medical writers work and the variety of documents produced, it can be challenging to identify specific indicators of value. To address this issue, the American Medical Writers Association (AMWA) Executives Advisory Council established a taskforce to define and quantify the value of medical writing. The taskforce has 3 main areas of focus: (1) perceptions of medical writer value among medical writers and their employers, (2) key topics related to medical writer value, and (3) how the regulatory agencies view document quality and the value of medical writing.

This article presents the work of the regulatory agency subgroup to evaluate the effect of document quality on the regulatory review process and assess awareness among regulatory agency reviewers of the contribution of medical writers to the quality of regulatory documents. By understanding the regulator's perspective, we hoped to demonstrate how medical writers bring value to documents submitted to regulatory agencies, to identify and refine the training needs of medical writers, and to identify areas for action for the medical writing profession and for colleagues in the biopharmaceutical industry.

SURVEY DESIGN AND OBJECTIVES

We employed an online survey format (SurveyMonkey), targeted at participants who were actively responsible for document review at a regulatory agency, were managers of regulatory agency reviewers, or who had worked in a regulatory agency review role in the past 6 months. Participants were eligible regardless of the specific types of documents they reviewed. We identified potential participants via contacts in our own networks, via our colleagues (eg, company regulatory department), and via contacts of the AMWA Executives Advisory Council. Participants were also encouraged to forward the survey to other eligible individuals within their organization. We reached out to the United States Food and Drug Administration, Health Canada, the European Medicines Agency, the Medicines and Healthcare products Regulatory Agency, the Bundesinstitut für Arzneimittel und Medizinprodukte, the Pharmaceuticals and Medical Devices

Agency, the National Medical Products Administration, and the Australian Therapeutic Goods Administration, although the agencies of those who actually participated are not identified, as the survey was anonymous. AMWA provided an official invitation letter and cover email to explain that the survey was being conducted on behalf of AMWA, its objective, and how the results will be used and to provide confirmation that the responses remain anonymous.

Being cognizant of limitations on the regulators' availability for such a survey, we made significant effort to develop a set of 25 survey questions that we believed would capture key points from the regulators' experience with document quality and medical writing. Most of the questions were multiple choice. The survey also included a checkpoint question to eliminate participants not involved in document review, and participants were invited to take part in a follow-up interview. For the follow-up interviews, we prepared 7 questions to elaborate on the survey results. For example, some questions included "none of the above" as a response option. If many participants selected this option, we requested additional information during the follow-up interviews.

After beta testing, the survey opened in April 2021 and was open through early August 2021. Interim views of the data were done in May/June to confirm adequate participation. Follow-up interviews were conducted during August 2021.

PARTICIPANT PROFILE

We received 32 responses to the survey. Although this was considerably higher than the anticipated response rate, the response rate was not uniform across all questions, and it was agreed that the sample size was appropriate for descriptive analysis only. In the following sections, we have highlighted where we believe the data should be interpreted with caution due to a lower response rate.

The data on agency tenure and time spent reviewing documents indicated that the survey was completed by participants meeting the target profile. Most had been employed at their current agency for over 5 years (Figure 1) and spent at least 10% of their time reviewing documents (Figure 2). Participants were also asked to indicate their department or division (omitting information that could identify them or their employer). Based on these responses, we were reasonably confident that we had engaged with the right people at the regulatory agencies for the purpose of this survey.

IMPACT OF QUALITY ON REGULATOR ASSESSMENTS

Medical writers will be familiar with how the work of internal and client teams is hindered when the documents they are given are poorly constructed. The survey results confirmed

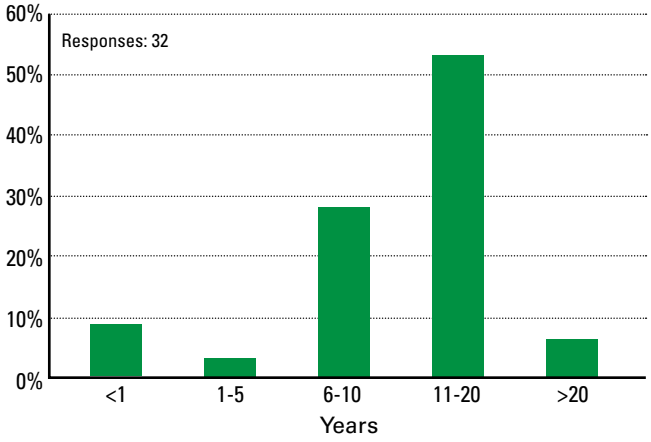

Figure 1. How long have you been employed at your current agency?

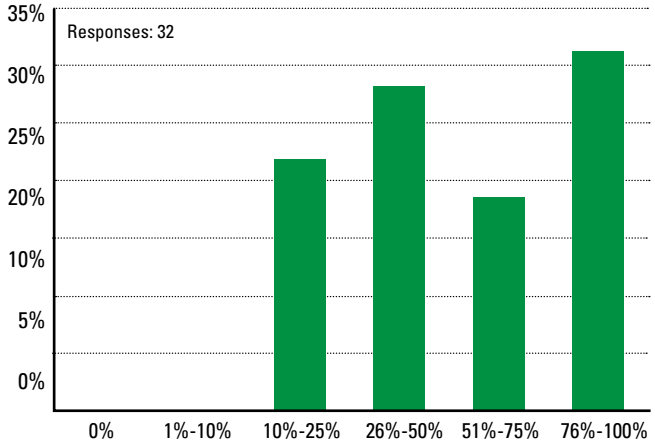

Figure 2. In your current position/role, what percentage of your time do you spend reviewing documents?

that the work of the regulatory reviewer is similarly impacted if documents submitted to the agency are not well written, and the responses provide important messages about the value of the medical writer. The following section also includes important information for colleagues in Regulatory Affairs or other functions involved in management of regulatory applications, as well as for corporate management.

The majority (87%) of the participants confirmed that poor document quality impedes regulatory assessment (Figure 3). Of note, none of the participants *disagreed* that poor quality impedes document review, and the remaining 13% had no opinion. When asked whether they encounter issues related to document quality during the review process, the same percentage—87%—reported such issues either sometimes or often (Figure 4). These results show that regulatory assessors receive poor quality documents for their review relatively frequently, and regulatory assessment of the document is thereby impeded.

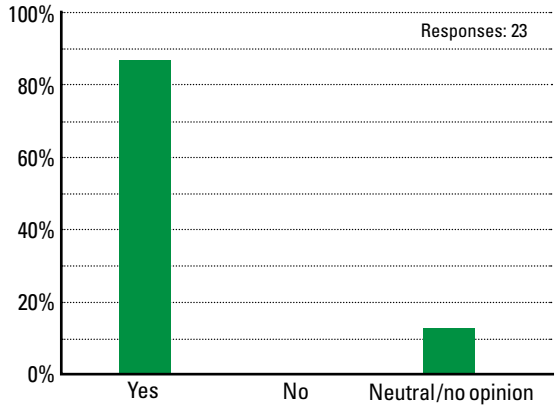

Figure 3. Does poor document quality impede your ability to provide regulatory assessment?

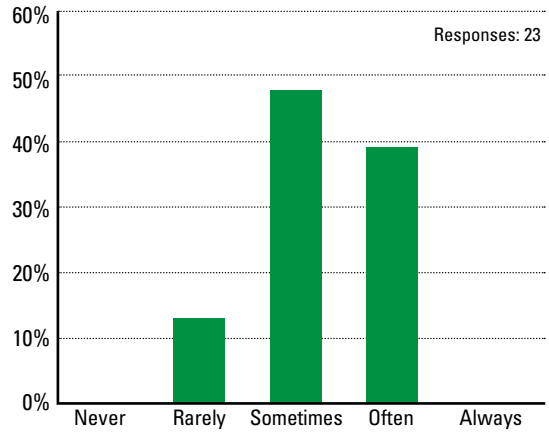

Figure 4. How often do you encounter issues related to document quality during the review process?

To gauge whether there has been any directional change in quality of documents, the regulators were asked how document quality has changed in the past 5 years. Improvement in document quality was selected by 43% of participants. This indicates that the quality of submissions is moving in the right direction. However, there is still work to be done, because almost half (48%) responded that there has been no change in quality or they were neutral/had no opinion, and 9% believed that the quality of documents submitted to their agency has declined over the past 5 years. Note that at this point in the survey the participants had not yet been provided with examples of quality issues, and so these responses likely reflect the regulators' own concept of document quality.

If documents within an application are of poor quality, the regulatory reviewer may need to send the application back with questions for clarification. Over half the participants (53%) said that they send over 10% of applications back or reject the application, with questions arising from poor document quality (Figure 5). Although 47% of participants send back or reject less than 10% of the applications, this still means that a sizeable number of applications are delayed. For applications that are ultimately approved (Figure 6), 77% of the regulatory reviewers agreed or strongly agreed that poor document quality will delay the approval process. These are clear messages on how poor document quality, which is an avoidable issue if proper processes are established and led by trained professionals, impacts the applicant's goals and, perhaps of more serious consequence, leads to patients waiting longer than necessary for new medicines.

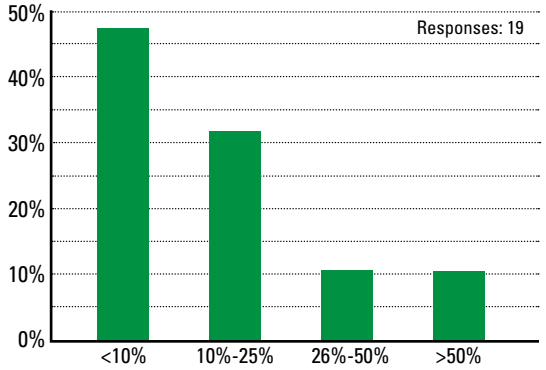

Figure 5. What percentage of applications do you reject/send back to the applicant with questions due to poor document quality?

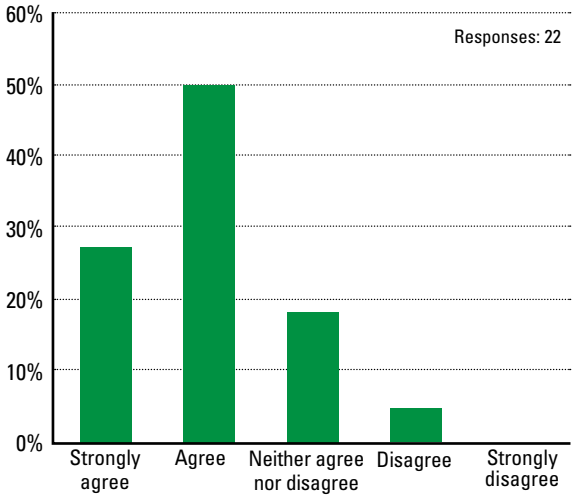

Figure 6. For applications that are ultimately approved, a poorly written document delays the approval process.

To understand whether poor quality might impact other documents in the regulatory assessment process, we asked whether a poorly written document negatively influences the review of other documents from the same applicant. Almost a third (27%) of participants agreed that poor document quality

could negatively influence their review of the applicant's other documents. It should be noted that we did not define what this means in practice, eg, whether the reviewer would be likely to review the applicant's other documents in more detail or whether this approach would carry over to documents in later submissions. The same percentage (27%) disagreed with the question, and 45% neither agreed nor disagreed. This indicates that, in some cases, poor document quality can even influence the assessor's review of the applicant's other documents.

The survey included questions around whether the regulatory agencies collect data themselves on document quality. Three participants (13%) confirmed that their agency collects such data, 35% responded that these data are not collected, and 53% did not know. When asked what the agency does with the data, one participant stated the data are reviewed, but the majority skipped the question. Most participants (90%) responded that their agency does not keep a record of applicants that regularly submit poorly written documents.

QUALITY ISSUES OBSERVED BY THE REGULATORS

Having established that document quality has a significant effect on the regulatory assessment process, it was important to understand which kinds of document quality issues are observed by the regulators. For the questions designed to identify these quality issues, participants were provided with the following response options (Figure 7).

Poor organization
Poor language usage
Lack of clarity
Poorly designed/presented tables and graphs
Data errors (eg, inconsistencies, transcription errors)
Incomplete content
Poor explanation of rationale
Excessive length, unnecessary repetition, verbose
Incorrect format/nonadherence to guidance
Broken/incorrect or insufficient crosslinks
Other
None

Figure 7. Examples of quality issues used in survey questions.

When asked to identify all quality issues encountered (Figure 8), those most frequently reported by the regulatory reviewers were excessive length/repetition/verbosity, closely followed by lack of clarity. This will not surprise most medical writers, who expend great effort working with teams to produce documents that are clear and concise with well-organized messages. However, these results do demonstrate that the effort invested in these aspects is warranted and necessary to meet the needs of the regulatory assessors. Of note, issues such as data errors, incomplete content, broken links, and poor tables/graphs were ranked relatively low in this question, which suggests many applicants have implemented processes to catch these avoidable issues prior to document submission.

In addition to the range of quality issues typically observed, we asked the regulatory reviewers to identify the one document quality issue they encountered most frequently (Figure 9). Excessive length/repetition/verbosity was ranked top here, too, closely followed by poor explanation of rationale. Once again, avoidable issues (data errors, incomplete content, poor tables/graphs, poor language) were ranked low or not at all.

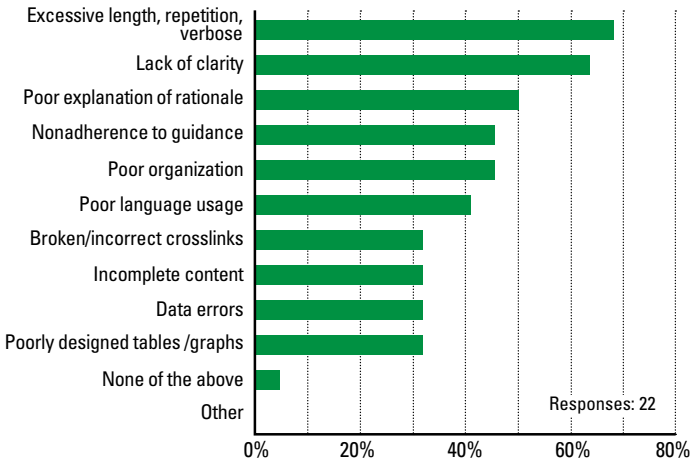

Figure 8. Which of the following issues related to document quality do you typically encounter? Check all that apply.

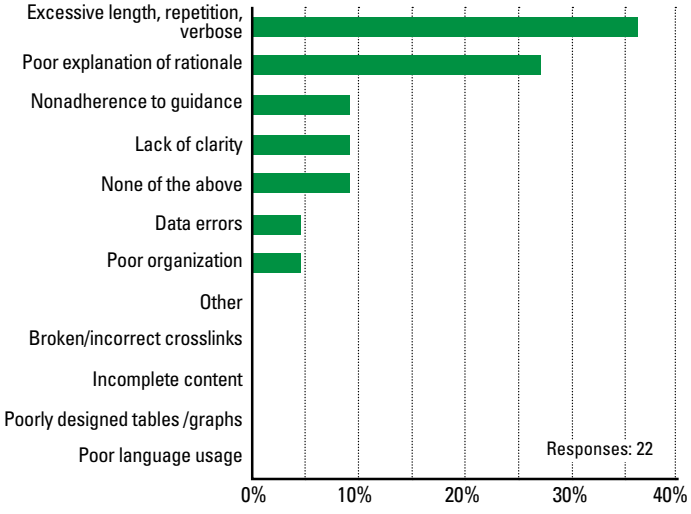

Figure 9. Which one of these issues related to document quality do you encounter most frequently?

Understanding the range and frequency of quality issues will help the medical writing profession and the industry to improve processes that support document quality and to target training and skills development for authoring teams. It is also important to understand whether specific quality issues have a greater effect on the assessor's review and application approval, regardless of how frequently they occur. Poor explanation of rationale caused the greatest negative effect on review or caused the most irritation to the regulatory reviewer, with excessive length ranked second (Figure 10). When asked to identify the one issue that has the greatest negative effect on application approval, the regulatory reviewers also ranked poor explanation of rationale at the top (Figure 11), followed by incomplete content. Poor explanation of rationale, therefore,

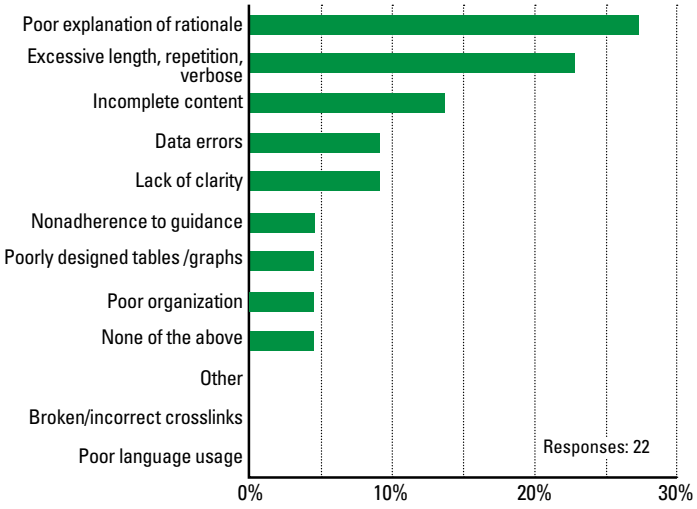

Figure 10. Which one of these issues related to document quality most negatively affects your review/causes the most irritation?

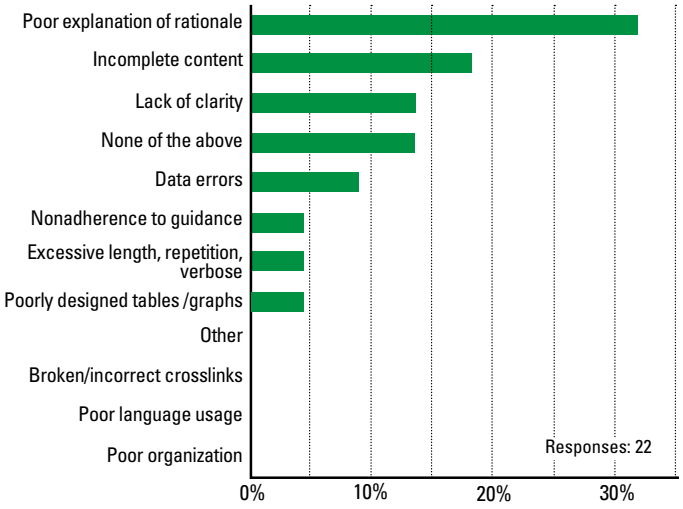

Figure 11. Which one of these issues related to document quality has the greatest negative effect on application approval?

is not only one of the most frequently observed quality issues, but also caused the most irritation to reviewers or negatively affected their review and has the greatest negative effect on approval. Clear strategic presentation of rationale supported by data should be a top area of focus for the teams responsible for documents submitted to regulatory agencies.

It is also interesting that, although incomplete content is not among the most frequent quality issues, the responses suggest it has a large negative effect on application approval when it does occur. It is therefore important for applicants to have rigorous processes to validate documents for completeness before submission. In converse, excessive length was ranked as the most frequent and was among the top document quality issues that cause irritation or have a negative effect on regulatory review, yet it is not among the top issues that negatively affect application approval.

REGULATORS' PERCEPTION OF MEDICAL WRITING

Beyond their view of the documents themselves, we wanted to understand what the regulatory reviewers thought of medical writers, their role, and their effect on the documents sent to the regulators for review.

Of those who responded, 67% were familiar with the contribution of medical writers to the documents they review. Importantly, 70% either agreed or strongly agreed that medical writers improve the quality of these documents, and a clear majority (87%) agreed or strongly agreed that sponsor companies with established medical writing functions and rigorous document development processes and standards produce higher quality submissions. Although this last question was asked before we had given examples of quality (and so the regulatory reviewers have used their own idea of a high-quality document), the responses strongly indicate that medical writers improve quality and established medical writing functions and processes produce higher quality documents.

We asked the regulators to indicate any areas where they believed that medical writers add value to regulatory documents. Over 78% identified "adherence to standards," and 71% identified "accuracy." This was closely followed by 64% for each of the following:

- Clarity
- Completeness
- Explanation of rationale
- Formatting

It is particularly reassuring that the regulatory reviewers believe that medical writers add value in the areas of accuracy, adherence to standards, and also explanation of rationale, which the previous questions had clearly identified as a key area of concern for them. However, it should be noted that this

question was only answered by 14 respondents, and so the results should be interpreted with caution.

FOLLOW-UP INTERVIEWS

Some of the participants indicated that they would be happy to give more detail about their survey answers. We arranged individual interviews to gather this information, which was anonymized and amalgamated and is presented below.

Quality Issues and Document Type

Because the survey had identified quality issues in some of the documents that the regulatory reviewers receive, it was important to understand if these were most prevalent in one document type (suggesting an issue with the template or understanding of the requirements) or were seen in all of the document types received. The regulatory reviewers confirmed that quality issues were seen generally across all document types. They explained that templates or guidance cannot address all the nuances of writing these documents and so experienced writers are needed.

"Explanation of Rationale" as the Key Quality Issue

Explanation of rationale was identified as a key area of importance for the regulatory reviewers, and they explained that this was because it can take them a lot of time to interpret what the author intended to communicate. The reviewers often go back to the sponsor for clarification, but this depends on several factors:

- The type of document being reviewed (eg, lack of clarity or other issues affecting safety are usually much more concerning than issues of lesser consequence)
- Timeline (eg, whether the reviewer has the time to work through the misunderstanding/quality issue themselves)
- Complexity (eg, whether the reviewer is able to work through the quality issue in the document compared with sending it back to the sponsor)
- Resources (eg, whether a specialist is available on the regulatory agency side to review the document to help with the quality issue)

The impact of a document with a poorly written rationale can be significant. Some regulatory agencies could interpret a poorly written rationale as lack of transparency, which could then call the entire application into question (a "domino effect"), and documents with poor rationales would likely be flagged at each review step for extra investigation, which would affect the whole application. It was widely accepted that a poorly written rationale makes the entire review process more difficult and would have a negative effect on approval.

Other Document Quality Issues

Although we asked about the most common issues negatively affecting document quality, we wanted to know if the regulatory reviewers encountered other issues that we had not specified.

Lack of transparency was identified as a key issue, particularly if the regulatory agency had experienced challenges with the sponsor or their applications previously. A lack of transparency and lack of clarity around the sponsor's objectives can raise regulatory reviewers' suspicions and give the impression that the sponsor is trying to overwhelm the reviewer with a mountain of data.

Transparency in terms of minutes from meetings with other regulatory agencies was also required, and a reluctance to provide these documents delays approval because it takes extra time to request them. The reviewers explained that it is important for them to see the concerns and requirements in other regions.

> The regulatory reviewers felt that medical writers have a "great and positive influence on document quality; they help keep documents clear, as brief as they can be, and consistent."

Medical Writers' Influence on Document Quality and Their Role

We asked what influence the regulatory reviewers felt that medical writers had on document quality and the medical writer's role. The responses were extremely heartening and reflected the aims of the medical writing profession.

The regulatory reviewers felt that medical writers have a "great and positive influence on document quality; they help keep documents clear, as brief as they can be, and consistent." They felt that there is "definitely a difference when medical writers have been involved" in document production and that they can tell if inexperienced writers have been used, as they see a lack of attention to detail and adherence to standards.

The regulatory reviewers felt that "a professional medical writer is always welcome and is always needed" and believe that the importance and value of medical writers "continues to grow," to the extent that some regulatory agencies have established their own medical writing teams.

One of the reviewers summed up the situation beautifully: "I know that it is a very specific profession needing training. [Sometimes] we cannot tell who has written what in the applications or how much medical writers have been involved—it is invisible from the regulatory agency point of view. We don't need to know, we just want something of good quality!"

Anything Else?

Finally, we asked a very open question—were there any other comments that the regulatory reviewers would like to make concerning document quality or the role of professional medical writers?

They explained that, beyond scientific expertise, medical writers should be involved in document production to make the information understandable and usable for the reviewer. They emphasized that they cannot "transform a bad document"—if the information they are given is not understandable, they cannot reply to it, which they found very frustrating because their role is to encourage and facilitate drug development. Often, regulatory reviewers can see that there is excellent science and work behind the document, but because it has been written badly, they are forced to guess what the messages are. They believed that although the role and work of medical writers may not be immediately visible to them, it was a "major" contribution.

Their final comment was that there was "no negative in having medical writers involved in document development—their influence and contributions are always positive."

LOOKING FORWARD

The objectives of the survey were to gain an understanding of how regulatory agencies perceive the value of medical writing and to learn where to focus the training and development of medical writers to maximize the value in, and skill set for, the preparation of regulatory documents.

The survey responses showed that many regulatory reviewers understand the role of medical writers, believe that they increase the quality of the documents sent to the agencies for review, and make the job of the regulatory reviewer easier. It is unsurprising that document quality is extremely important for regulatory reviewers. Participants reiterated that poor document quality can not only hamper the ability of the reviewer to provide an assessment (delaying the drug approval process), but also has the potential to bias reviewers against subsequent submission documents from the same sponsor. There is a clear opportunity for medical writers to improve document quality, and the survey responses can also be used to inform how medical writers present themselves within their organizations—quality is clearly top of the regulatory reviewers' list of priorities and has been recognized by them as an area where medical writers add value.

Most satisfyingly, regulatory reviewers appreciated and recognized the work and importance of trained medical writers; thus, addressing regulatory reviewers' needs should continue to be a priority for the profession. Training must equip medical writers to lead teams that create documents that are concise and clearly present the message supported by the data. Perhaps even more focus should be given to team management and soft skills to allow medical writers to lead and guide these teams so that the documents supporting submissions are as concise and strategic as possible to streamline and increase efficiency of the whole clinical development process.

The fact that the regulator reviewers, who are often time-poor, chose to take the time to help us to understand the role and value of medical writers is a testament to the importance of our profession and the expertise that trained medical writers bring to the development of regulatory documents and their associated teams.

Acknowledgment

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Value of Medical Writing: The Regulatory Writer's Perspective

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ABSTRACT

The American Medical Writers Association formed a working group in 2020 focused on understanding and communicating the value that regulatory medical writers contribute to project teams, companies, and the wider research community. The working group developed a survey designed to gather information about the value that regulatory writers represent. The survey was targeted to regulatory medical writers, included 25 questions, and was administered by using SurveyMonkey. A total of 548 responses were received, and 522 of the respondents were active regulatory medical writers. The survey revealed that writers felt most valued when they were consulted or had their opinion sought (n = 154, 30.8%), contributed to patients and the community (n = 89, 17.8%), and were well compensated (n = 80, 16.0%). Writers felt that their most valuable contributions to document preparation were clarity (n = 196, 44.1%) and organization (n = 80, 18%). Although most writers indicated that their employers provided sufficient opportunities for training and advancement (strongly agree, n = 131, 29%; agree, n = 197, 44.1%), writers also indicated they would benefit from additional training in leadership skills, project management, and collaborative skills/diplomacy. This insight is invaluable for shaping the future of the regulatory writing profession.

INTRODUCTION

At its core, medical writing involves gathering, organizing, interpreting, and presenting complex information in a clear, concise, and coherent manner to a variety of audiences. Specific responsibilities can vary greatly across the industry, with roles and opportunities for medical writers constantly evolving. In this ever-changing environment, the role of regulatory medical writers is not always clear, and there is evidence to suggest that medical writers' contributions are not always fully understood or recognized.[1] To better appreciate the concrete value regulatory medical writers contribute to projects, teams, companies, and the wider biopharmaceutical industry, the American Medical Writers Association (AMWA) Executives Forum established a taskforce to define and quantify the value of medical writing. The 3 focus areas of the taskforce include writers' perceptions of their own value, regulatory agency perceptions of a writer's value, and other key topics related to the value of medical writers. This article describes the work of the subgroup tasked with determination of regulatory medical writers' perceptions of their own value. The main goals of this subgroup were to discover the views of regulatory medical writers regarding the nature of the value they contribute, identify aspects of the role that make writers feel most valued, and inquire about team feedback and dynamics. We also sought to identify additional skills, training, and opportunities for development that would benefit writers while also increasing the satisfaction of their teams.

METHODS

A 25-question survey was designed to evaluate multiple domains regarding the perceived value and contributions of regulatory medical writers. The intended time taken for respondents to complete the survey was 10 minutes, and the average duration of participation was determined to be less than 10 minutes. Many of the survey questions were multiple-choice questions, with some requesting a single answer and others allowing multiple answers (check all that apply). Additional questions allowed participants to rank their preferences. Other questions were presented in a 5-point Likert-scale format. One question was an open field that allowed participants to provide general comments on the topic at hand.

The survey was targeted to regulatory medical writers; the first question in the survey was binary (yes/no) and confirmed this status. The survey was administered by using SurveyMonkey to members of the AMWA medical writing community, the European Medical Writers Association (EMWA) medical writing community, and the DIA Medical Writing Community. Working group members also distributed the survey to colleagues who were known to be regulatory medical writers and to partner companies who had regulatory medical writing groups who agreed to participate.

The survey was completely anonymous. However, some analyses utilized the anonymized participant number to track responses to different questions from the same participants in attempting to identify trends in the data.

PARTICIPANT PROFILE

To better understand the characteristics of survey participants, several survey questions focused on demographics and work history. In response to the question, "Are you currently working (or have you worked within the past 5 years) as a regulatory medical writer?" we received a total of 548 responses, and 522 respondents (95.3%) confirmed current employment as regulatory medical writers. The second question in the survey inquired about work status. A total of 548 responses were also received for this question, and 488 (89.1%) were "employed," whereas 53 (9.7%) were "freelance or self-employed," 4 (0.7%) were "retired or unemployed," and 3 (0.5%) chose "other" as a category of employment. When asked about the type of company the respondents were employed by, a total of 518 responses were received, and the top 3 responses were (1) pharmaceutical company, (2) clinical or contract research organization, and (3) biotechnology company (Table 1).

Table 1. Analysis of Employment for Regulatory Medical Writers

Type of Employer	Responses (n)	Responses (%)
Pharmaceutical Company	261	50.4
Clinical or Contract Research Organization	118	22.8
Biotechnology Company	56	10.8
Medical Device Company	29	5.6
Medical Communication Company	23	4.4
Full Service Provider/Staffing Company	15	2.9
Other (Please Specify)	13	2.5
Medical School or University	2	0.4
Medical Marketing, Advertising, or Public Relations Agency	1	0.2

When writers were asked about the larger group in which the regulatory writing group resided, the top response indicated that medical writing stood alone as a group (Table 2). However, as this is contrary to the experience of the members of the AMWA working group, it may be suggestive of some ambiguity inherent in the question, although it may be a predictable response in smaller companies or in clinical research organizations (Table 1; 22.8% of respondents). Some of the responses in the "other" category included "Clinical Affairs," "Data Science and Safety Reporting," "Document Solutions Group," and "Regulatory Documentation and Submissions."

Table 2. Organizational Structure Housing Regulatory Writing Group

Parent Group/Organization	Responses (n)	Responses (%)
Medical Writing Stand-Alone Group/Function	198	38.2
Regulatory Affairs	115	22.2
Clinical Development	68	13.1
Clinical Operations	52	10.0
Other (Please Specify)	32	6.2
Biostatistics or Biometrics	18	3.5
Not Applicable	16	3.1
Medical Affairs	11	2.1
Strategic Operations	4	0.8
Pharmacovigilance	2	0.4
Quality	2	0.4

The tenure of the regulatory writers who responded to the survey reflected long-term experience and the longevity of their dedication to the profession. A total of 444 writers responded to our question about years of writing experience, 242 (54.5%) of whom had more than 10 years of experience in the regulatory writing profession. A total of 84 (18.9%) respondents had between 6 and 10 years of writing experience, whereas 91 (20.5%) had between 2 and 5 years of experience and 27 (6.1%) had less than 2 years of experience. More than half of respondents had either a PhD degree (n = 206, 46.4%) or another advanced degree (n = 27, 6.1%); 147 (33.1%) respondents had a master's degree, 56 (12.5%) had a bachelor's degree and 8 (1.8%) respondents specified a degree of "other." A total of 440 writers responded to a query regarding gender, with 330 (75%) writers identifying as women, 83 (18.9%) identifying as men, and 27 (6.1%) choosing "prefer not to say." Overall, professionals responding to this survey were highly educated, a high proportion were women, and most had long-term experience as regulatory writers. This is indicative of a profession that generally requires a high level of education and offers

long-term employment and development. The paucity of respondents with less than 2 years of experience (6.1%) may reflect slow recruitment of writers or a slow growth rate for the pool of regulatory writing professionals. Alternatively, it could represent our inability to reach more junior medical writers. However, if this rate is representative of the industry at large, it is concerning, given the high growth rate for medical writing needs in the biopharmaceutical industry.

ROLES AND CAREER PROGRESSION

We inquired about specific roles of medical writers to better understand how they are contributing, to learn what employers expect from medical writers, and to explore the relationship between required level of skill and the various roles of the writer. These survey questions categorized medical writing roles to reflect increasing levels of both technical skill and responsibility in order to understand the distribution of skills within the respondent pool (Table 3). The majority of respondents report involvement in activities beyond basic document preparation following a template. Most provide strategic guidance to teams and participate in some form of project management activity. Consistent with the long duration of tenure in the respondent pool, a relatively large proportion of respondents identified themselves with role C, representing a very high level of technical skill, knowledge, and responsibility.

Table 3. Analysis of Roles Among Regulatory Writers

Role	Responses (n)	Responses (%)
A. I Provide Medical Writing Support/Service to Teams That Is Mainly Focused on Document Preparation, Using Knowledge of Templates, and ICH and Other Guidance(s).	138	27.6
B. I Provide Support Described in Item A, but Also Provide Strategic Guidance to the Teams.	126	25.2
C. I Provide Support In Items A and B and Manage Submissions Documents and Lead Teams Through CTD Preparation Routinely.	171	34.2
D. Management and/or Project Management.	43	8.6
Other (Please Specify).	22	4.4

CTD, Common Technical Document; ICH, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

To better illustrate the relationship between experience and role, we analyzed the responses for each role by years of experience (Figure 1). Although there was not an exact linear correspondence in the relationship between increasing years of experience and increasingly challenging roles, there was certainly a trend for professionals with longer tenure to fill the more challenging roles. Most individuals in the management/project management category had at least 10 years of experience in regulatory writing. These data indicate that regulatory writing is a highly technical discipline, and development of the necessary expertise to assume more strategic and management responsibilities appears to require several years to develop. This also suggests that regulatory writing is a career that offers long-term progression and development.

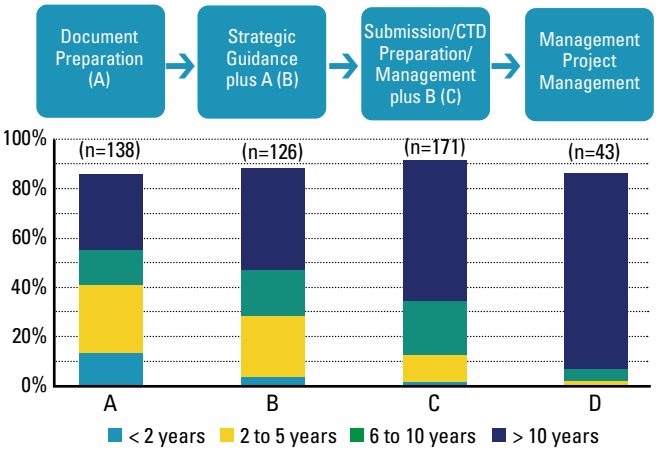

Figure 1. Relationship between experience and roles. CTD, Common Technical Document.

VALUE ASSESSED BY WRITERS AND TEAMS

Understanding and harnessing the skill set of experienced regulatory writers can keep writers engaged and make them feel satisfied and fulfilled. When writers were asked what made them feel most valued as a medical writer (and were forced to choose one answer), there was a clear leader among the options provided (Table 4). Medical writers felt most valued when their opinions were sought and when they were included in decision-making. This aspect of feeling valued was chosen by more respondents than any other aspect, including compensation and other forms of recognition. Some responses in the "other" category were (1) "medical writers have unique skills that fill a need, unmet by any other discipline involved in healthcare"; (2) "coaching and training of new or junior writers"; and (3) "authorship and being consulted; having my ideas taken seriously and acted upon."

The same question was posed with a requirement to rank these items and there was an identical response pattern, except that "autonomy/flexibility" and "recognition" switched

Table 4. What Makes Regulatory Writers Feel Valued

What Makes Me Feel Valued?	Responses (n)	Responses (%)
Consulted/Opinion Sought/ Decision-Making	154	30.8
Making a Contribution to Patients/Community	89	17.8
Compensation	80	16.0
Involvement in Scientific Research/Developing Your Own Scientific Knowledge	77	15.4
Autonomy/Flexibility	32	6.4
Recognition	31	6.2
Career Progression/Job Title/ Opportunity for Movement	28	5.6
Other (Please Specify)	9	1.8

positions in the rate of response/rank. Interestingly, "career progression/job title/opportunity for movement" remained at the bottom of the list, with only 4.7% of respondents choosing this as their top ranked item.

Many writers felt that their tactical and technical skills were fully utilized, as well as their scientific and strategic skills (Figure 2; n = 495).

Additionally, most writers felt that the teams they supported fully recognized their value and skills. A total of 265 (53.5%) respondents agreed with this statement, whereas 107 (21.6%) strongly agreed. Interestingly, only 48 (9.7%) respondents disagreed, and 6 (1.2%) strongly disagreed. Consistent with these positive responses, most writers also felt that they were empowered by management to provide clear guidance to their team regarding the document development processes and felt they were included in most necessary meetings that enabled them to remain aware of strategic decisions that could impact document development (Figure 3; n = 495).

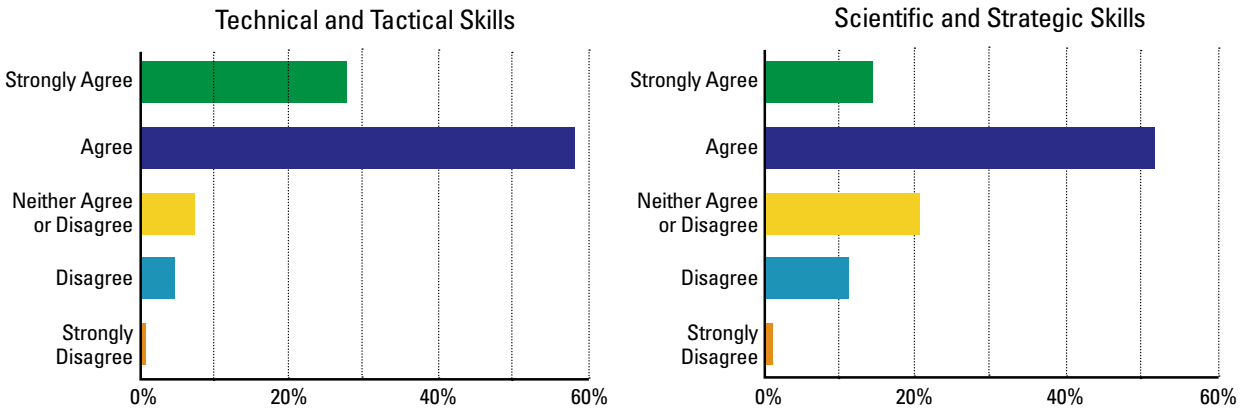

Figure 2. Utilization of skill sets.

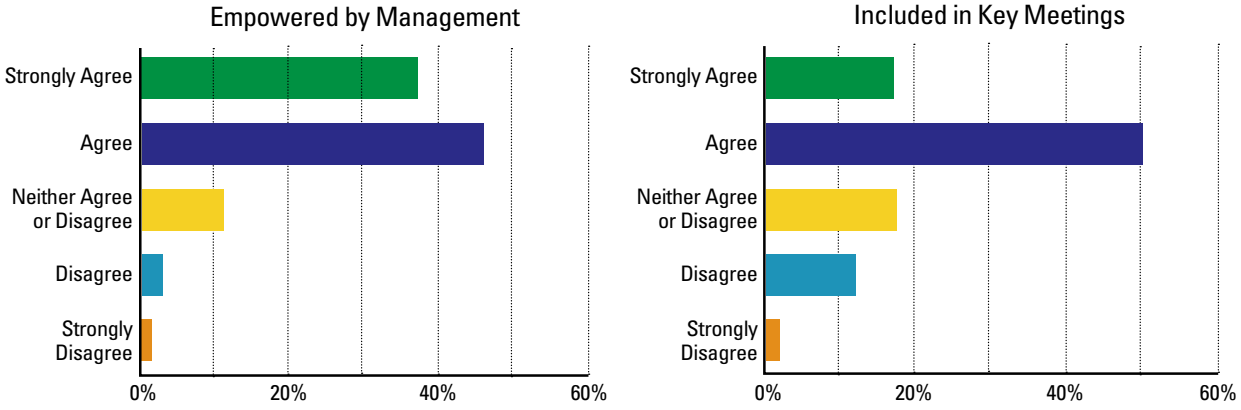

Figure 3. Key determinants of success.

Although regulatory writers provide value to teams in many ways, we sought to understand the perception of writers themselves in terms of the value they contribute. When writers were asked to select one area in which they provide the most value in document preparation, there was a clear top choice (Table 5). Writers indicated that they contributed the most value by providing clarity in documents (44.1%), followed by "organization" (18.0%), "completeness" (10.1%), "accuracy" (9.9%), and "adherence to standards" (9.9%).

When writers were asked this same question but allowed to check all areas in which they contributed value, clarity was still at the top of the list (95.3% of writers included this in their selections), and organization was still in second place (90.8% of writers included this in their selections).

Table 5. Areas in Which Writers Provide Value in Document Preparation

Area of Document Preparation	Responses (n)	Responses (%)
Clarity	196	44.1
Organization	80	18.0
Completeness	45	10.1
Accuracy	44	9.9
Adherence to Standards	44	9.9
Explanation of Rationale	22	5.0
Brevity	9	2.0
Formatting	4	0.9
Linking	0	0.0

A general comment regarding the value of medical writers was provided by 102 (18.6%) writers. Key themes in the responses were the value provided to teams to ensure that the documents will lead to a successful submission. An example is this response: "The quality and delivery time of regulatory documents improved dramatically when my employer established a medical writing department within Clinical Operations." The responses indicate that clear, well-written, and accurate messages are an important part of the medical writer's role and that this is best achieved by integration into project teams. A response that expressed this was, "Clinical–regulatory writers are critical members of the team who guide development of documents with an overall perspective for program strategy and a document that is complete, accurate, and well-written." The responses indicate that this enables the medical writer to lead team collaboration, ensure that documents support project goals, and drive the process to speed delivery and ensure high quality/regulatory compliance. A representative response was, "We take ownership and drive/lead the document through the process, and only by guiding the team do we get through it." Several writers stated that the role of the medical writer is underappreciated. Insight is provided by this response: "Much of the value can go unnoticed by management as it is difficult to measure what good clinical–regulatory writers provide to documents and the document completion process."

Pivoting to inquiry regarding the value that teams perceive as writers' greatest contributions, the skills that writers felt they were most frequently recognized for were leadership and collaboration skills (Table 6), both considered to be behavioral skills or "soft skills" rather than technical skills directly related to writing.[2]

Table 6. Skills and Contributions Recognized Most Frequently by Teams

Skill Recognized by Team[a]	Responses (n)	Responses (%)
Leadership, Including Management of the Process and Maintenance of Timelines	148	32.8
Collaboration and Flexibility	116	25.7
Providing Strategic Guidance on Document Development and/or Submissions	79	17.5
Writing Skills With Respect to Vocabulary and Sentence Structure, Grammar, Improved Readability, etc.	34	7.5
Comment Resolution and Achievement of Consensus	26	5.8
Problem-Solving	19	4.2
Quality Control and Accuracy	19	4.2
Compliance	5	1.1
Input to Study Design and Project Decisions	5	1.1

[a] *Survey respondents had to choose only one skill.*

When asked to rank the frequency of recognition of skills, the 3 top responses remained consistent, with all the other skills/behaviors ranking at least 5% beneath the third most highly ranked skill (Table 6; 17.5%, providing strategic guidance on document development and/or submissions). Interestingly, when this line of inquiry was reversed and we asked writers to provide information about constructive feedback they received from teams about areas for improvement, responses in the "other" category represented the highest proportion of responses (Table 7; n = 110, 24.4%). However, the most common entries in the "other" category open field were "none" and "not applicable," and there was no consistent trend, suggesting that inclusion of that option/field may have detracted from the precision of the data. The next 2 most

frequent responses were (1) leadership, including management of the process and maintenance of timelines, and (2) improve flexibility. Therefore, the 2 items writers felt they were most frequently recognized for doing well were also the 2 specific items for which they felt that teams requested improvement or better support. These data suggest that leadership and collaboration should be key areas of focus for writer development.

When writers were asked to rank (from 1 to 7) the 7 skills for which teams had requested better support ("other" was not included), leadership and lack of flexibility were still cited as the top areas for improvement (Table 7).

Table 7. Constructive Feedback From Teams

Skill That Needs Improvement	Responses (n)	Responses (%)
Other (Please Specify)	110	24.4
Leadership, Including Management of the Process and Maintenance of Timelines	79	17.5
Lack of Flexibility	62	13.7
Compliance With Procedures	61	13.5
Comment Resolution and Achievement of Consensus	45	10.0
Writing Skills With Respect to Vocabulary and Sentence Structure, Grammar, Improved Readability, etc.	36	8.0
Quality Control, Too Many Errors	36	8.0
Collaboration	22	4.9

TRAINING OPPORTUNITIES AND NEEDS

One of the main reasons for conducting this research was to identify potential gaps between medical writer skills and team and/or employer expectations. Although this investigation relies on information gathered from regulatory writers and not teams or employers, we can compare our results with research conducted by another group[2] as it relates to the pharmaceutical medical writing competency model.[3] According to information Heisel-Stoehr and Schindler obtained from 73 job advertisements for regulatory medical writers, "science" and the "comprehension of scientific concepts" were important technical skills cited in 78% and 92% of those job advertisements, respectively.[2] Our survey suggests that writers are not primarily recognized for such contributions during document development. Additionally, writers themselves felt that their most important contributions to document development were clarity and organization, technical writing skills that may or may not require a deep scientific understanding. On the other hand, the 73 job advertisements described by Heisel-Stoehr and Schindler cited "leadership and team working skills" as the most frequently (62%) mentioned behavioral skill/skills for regulatory writers.2 In fact, our survey results find that these are the 2 areas for which writers are most frequently recognized by teams for commendable performance (Table 6).

Although most writers in our survey felt that their employers provided them with sufficient opportunities for training and development to enable success and advancement (agree, n = 197, 44.1%; strongly agree, n = 131, 29.3%), there were others in the survey who felt neutral (neither agree or disagree, n = 78, 17.4%) and some who disagreed (n = 30, 6.7%) or strongly disagreed (n = 11, 2.5%). These results speak well of management efforts to keep writers engaged and developing. When writers were asked to identify areas in which they needed more opportunities to learn, there was a significant focus on (1) leadership skills, (2) project management, and (3) collaborative skills/diplomacy (Figure 4). Once again, the notion that behavioral skills or "soft skills" play a prominent and crucial role in the successful execution of the duties of the regulatory writer is reinforced throughout the results of our survey.

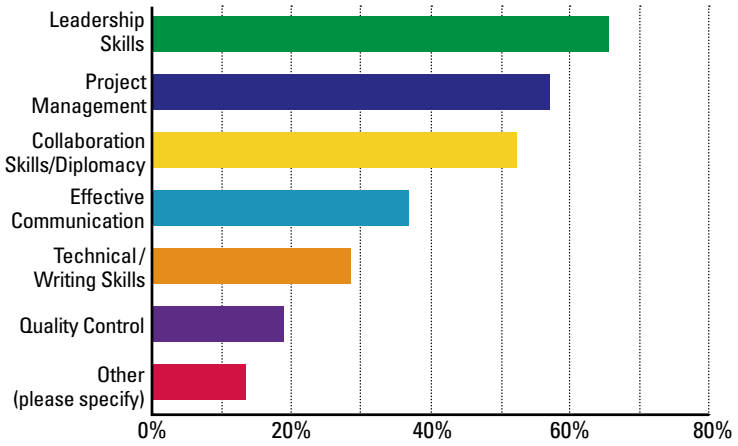

Figure 4. Areas desired for more training/learning.

SUMMARY

Results from the survey encompassing 548 respondents with regulatory medical writing experience revealed key information that is useful for understanding the value that medical writers bring to an organization and useful for further defining job responsibilities and skills needed for regulatory medical writers. Regulatory medical writers are highly educated professionals whose development to attain the skills necessary for leading regulatory submission preparation and managing projects and teams requires several years. The role requires both technical/tactical skills and scientific/strategic skills. Most regulatory medical writers report that their duties extend beyond basic

document preparation following a template to include providing strategic guidance to teams and participating in some form of project management activity. Project teams rely on medical writers for leadership and collaborative skills. Medical writers recognize these soft skills as both their key contributions and their key training needs. Data suggest that regulatory medical writers feel most valued when their opinions are sought and when they are included in decision-making.

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Effective Communication Between Medical Writers and Creative Teams: The Secret Condiment for a Flavorsome Sauce

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ABSTRACT

An impactful pharmaceutical promotional piece is an amalgam of a relatable narrative and agreeable visuals, a result of a highly synergistic relationship among medical writers, art directors, and designers. When it comes to innovation and creativity, a collaborative relationship will increase the likelihood of producing a piece that will touch the lives of the audience in a memorable way. Although the audience of pharmaceutical promotion can comprise health care providers and patients, this article will focus on the latter. A few aspects of this partnership have been shown to increase the chances of achieving that goal, such as respectful communication, alignment on the brief, mutual encouragement, and use of lay language during discussions and brainstorming sessions. Although nurturing storytelling, a strong skill of creative teams, is critical for the success of promotional medical pieces, ensuring scientific accuracy and avoiding misbranding are also key for complying with the ethical paradigms of medical communication and the US Food and Drug Administration regulations. Therefore, fine-tuning the partnership between medical and creative teams translates into a collaboration that combines freedom of creation with regulatory and scientific guardrails, as well as a strong sense of respect for each other's views and expertise.

INTRODUCTION

Over a year and a half have passed since the beginning of the COVID-19 pandemic, and we all have experienced profound changes in the way we live and interact with one another. In the realm of promotional medical education, this reality also applies. With the cancellation of congresses and personal interactions being restricted to the virtual environment, the sector has elevated digital tools and channels, creating an appetite for more involvement of creative teams in medical communication.[1,2] With that growth, we have also observed a massive migration of creative teams, such as art directors and designers, from consumer agencies, that is, companies focused on advertising products outside the realm of health care, to medical communication, bringing a fresh perspective into the sea of sameness of the industry.

With this shift, the presence of creative teams in medical communication has increasingly become more conspicuous, creating new work dynamics for medical writers, whose scientific background tends to embrace a higher focus on pure science rather than creative elements, such as visuals and engagement tools.

These new circumstances have pushed many of us, medical writers, to ask ourselves, "What is the best way to work with creative teams?"; "How can we explore the best of both worlds with such distinct trainings?"; and "How can we stir each other's motivation to accomplish the most compelling piece for our client while also ensuring scientific accuracy?"

CREATING A PARTNERSHIP

A good pharmaceutical promotional piece is an amalgam of a relatable narrative and agreeable visuals, resulting from a highly synergistic relationship among medical writers, art directors, and designers. When it comes to innovation and creativity, a collaborative relationship will increase the likelihood of producing a piece that will touch the lives of health care providers (HCPs), the audience, in a memorable way.

In the late 1950s, Bill Bernbach, founder of DDB Worldwide Communications Group, a globally renowned advertising agency, decided to integrate copywriters with art directors as a team. Because the approach worked undeniably well, other agencies gradually followed the approach. Nowadays, most advertising agency creative departments in the world comprise such cross-functional teams.[3]

By and large, medical communication agencies have also followed the approach of integrating writers, art directors,

and designers as the core team that will ideate and produce all pieces according to brand strategic imperatives and the client's direction, which are ensured to be followed by the client service team. In some agencies, the creative team is under the umbrella of shared services, as exemplified by the editorial department, whereas in others, each account has its own creative steward. The latter resembles that closer relationship between art directors and copywriters proposed by Bill Bernbach, allowing medical writers and art directors to work together throughout the trajectory of a particular brand.

Regardless of the model adopted, a few condiments have proven to be indispensable for the flavorsome sauce that is a memorable medical communication piece. One of them is building a solid relationship between medical and creative teams. According to Simon Veksner, the author of the book *How to Make it as an Advertising Creative*, "the basics are the same as any human interaction. You need to listen to each other, respect each other's point of view, and not expect the other to be perfect. After all, you're not."[3]

However, some could argue that this fundamental of human interaction does not always come easily, especially because moments of intense creativity can drive people to submerge in their own experiences and emotions. Other times, the source of disconnect may come from the very nature of the training of each department, which may bring to the surface mismatched creative repertoires when brainstorming narratives and visuals together. One approach to overcome these challenges is to turn the team's attention to the client's interests and the success of the brand. In this sense, although challenging each other may feel uncomfortable at times, emerging from these brainstorming sessions for a few moments to realign on client interests serves as a reminder to keep the conversation respectful and avoid deviations from the strategic imperatives of the brand.

Another key approach for a successful partnership between these departments is alignment on the creative brief, which is the document used to outline the strategy of a project. The brief contains the purpose of the project, audience, messaging, scope of work, timeline, and other key information that helps all members of the team to understand details about the piece that they will develop (Box 1),[4] and it is a document that can be altered in case objectives or the scope change. The problem proposed in the brief needs to be clear for both medical and creative teams prior to their initial conversations and brainstorming sessions.[3] This is a critical step for medical communication agencies, given that most art directors do not have scientific training, as opposed to traditional teams in consumer agencies, in which both the copywriter and the art director tend to have similar backgrounds. Having that in mind, a good approach to level set the team when discussing a brief is to present the problem or the unmet need of the project in layman's terms.

Along these lines, it is reasonable for medical, creative, and client services teams to write the creative brief for each project together. Joining brand strategy, which is also a reflection of a company strategy, with solid scientific evidence and translating the problem that the brief proposes to solve into approachable language can enhance innovation and lead to a much more productive relationship between medical and creative teams.

Box 1. Key Information Covered by a Creative Brief

1. Company requestor
2. Project description
3. Objective
4. Audience
5. Unmet need
6. Desired response
7. Project overview
8. Creative approach
9. Project scope
10. Constraints and assumptions
11. Timeline
12. Success criteria
13. Budget

THE IMPORTANCE OF AVOIDING MISBRANDING

Creative teams from consumer agencies are known for nurturing powerful storytelling in pieces that face fewer guardrails than medical communication agencies do. Although cultivating robust storytelling skills is critical for the success of promotional medical pieces, ensuring scientific accuracy and avoiding misbranding are also key for complying with the ethical paradigms of medical communication. Principle 2 of the American Medical Writers Association Code of Ethics states the following: "Medical communicators should apply objectivity, scientific accuracy and rigor, and fair balance while conveying pertinent information in all media."[5]

In addition, avoiding misbranding is critical for compliance with the US Food and Drug Administration (FDA) regulations. The Office of Prescription Drug Promotion (OPDP) is a section of the FDA, and it protects the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. All pharmaceutical advertising and promotional labeling undergoes review by the OPDP to ensure that the information in these promotional materials is not false or misleading.[6]

Among the tasks performed by the OPDP are providing written comments to pharmaceutical sponsors on proposed promotional materials to ensure clear and unambiguous communication of the laws and regulations relating to prescription drug promotion, reviewing complaints about alleged promotional violations, initiating compliance actions on promotional materials that are false or misleading, comparing the product labeling and promotional materials of various closely related products to ensure that the regulatory requirements are consis-

tently and equitably applied, traveling to major medical meetings and pharmaceutical conventions to monitor promotional exhibits and activities, and acting as a liaison between OPDP and other divisions within the FDA on promotional issues.[6]

Prescription drug promotion should not be false or misleading. Specifically, every promotional piece must have a balance between efficacy and risk information and reveal material facts about the product being promoted, including consequences that may result from the use of the drug. In this respect, when medical writers and creative teams work together to develop a promotional medical piece, they must make sure all claims are appropriately supported and all comparisons are derived from head-to-head studies. In addition, when crafting narratives, it is indispensable to account for fair balance throughout the piece. For example, if alluding to the overall response rate after the use of a medication, one needs to account for the depiction of safety data in the same section.[6]

Given the importance of certifying that all promotional pieces comply with the FDA guidelines, a promotional review committee comprising representatives from the pharmaceutical company's medical, legal, and regulatory (MLR) departments is charged with ensuring materials are fair balanced and meet function-specific standards while achieving marketing's goals. Each representative in an MLR committee has specific responsibilities and characteristics (Box 2).[7]

Box 2. Key The MLR Promotional Review Committee

Medical representative: Individual with an MD, PharmD, PhD or other advanced degree. Responsible for critically evaluating material for scientific and medical validity and consistency with the FDA-approved labeling.

Legal representative: Attorney with a JD degree. Responsible for advising on legal risk by broadly reviewing materials for compliance with federal and state laws and industry codes/guidances. Areas of expertise include copyright and trademarks, fraud and abuse, and anti-kickback issues.

Regulatory representative: Individual who generally has an advanced degree in the sciences or healthcare and acts as the representative during interactions with the FDA or OPDP. Responsible for ensuring that the material complies with all applicable FDA laws and regulations on drug promotion.

TECHNIQUES FOR BUILDING OPTIMAL PARTNERSHIP

Once medical, creative, and account services (ie, the department responsible for ensuring that the client's needs are met accurately and on time) are aligned on the creative brief and all key aspects of the project to be developed, such as unmet needs and the chosen tactic, timeline, and supporting scientific data, have been identified, it is time to let the creativity flow. Although creative teams are more familiar with the techniques that boost the production of ideas for narratives and visuals than are medical writers, medical teams have a critical role in shepherding brainstorming sessions to ensure both scientific accuracy and compliance with the FDA guidance. This fine balance translates into a partnership that combines the freedom of creation with regulatory and scientific guardrails, and it requires a strong sense of respect for each other's views and expertise.

As a rule of thumb, medical and creative teams should follow the classic recommendation for brainstorming sessions in their everyday interactions: never use the word *no*.

As a rule of thumb, medical and creative teams should follow the classic recommendation for brainstorming sessions in their everyday interactions: never use the word *no*. In brainstorming sessions, this recommendation is important to avoid ruling out any of the ideas—because this is an early stage in the development process, all ideas should be received positively. In addition, from a human point of view, the word no tends to cause unwillingness to participate and negative emotions overall. Instead of using the word *no*, one can modulate their tone of voice to make it clear they are unconvinced.[3]

On this note, it is crucial to avoid long debates. Instead of spending extensive minutes or hours trying to kill each other's suggestions, it is preferable to use the time available to put forward new ideas. In addition, it is essential that medical and creative teams inspire each other on a daily basis. According to Paul Monnes, Medical Director at BGB Group, a medical communication agency, "The best approach is partnership. Medical brings deep knowledge of the data, creative crafts evocative expressions of that data. When medical and creative colleagues can inspire each other, you develop strong work" (instant message, September, 2021).

Another key recommendation is to never show any disagreement in meetings with the broader team (ie, account, project management, editorial, and strategy). Both the medical and creative teams need to establish internal alignment prior to sharing their proposals with other departments to avoid flattening their credibility with the team. When creating an inno-

vative piece, medical and creative teams should weave into each other and become a fort with a grounded understanding of the brand. There are several approaches to optimizing a partnership between medical and creative teams during brainstorming sessions (Box 3).[3]

Box 3. Discussion Techniques to Optimize Partnership Between Medical and Creative Teams

What You Want to Say	How to Say It
Acceptable, but we can do better.	Good.
Following strategic imperatives, but not very interesting.	Yes, that works (neutral tone of voice).
I see something interesting, but it does not work.	Good—let's develop this idea a bit more.
Off-brief and not interesting at all.	I see (neutral tone of voice).
Terribly off-brief.	Can you say that one more time?
Very boring idea.	OK.
Terribly off-brief, boring, and uninspiring.	How about a coffee break?

Adapted from Veksner S. How to Make it as an Advertising Creative. *Laurence King Publishing Ltd; 2010.*

THE IMPORTANCE OF EMOTION IN MEDICAL COMMUNICATION

HCPs, the audience for HCP-focused branded and unbranded promotional pieces, have been overwhelmed with content and messages from an increasing number of stakeholders through numerous channels, an unparalleled reality that demands unprecedented outputs. According to Chris Bartley, Deputy Managing Director at the medical communication agency Havas Life Medicom, "Cutting through the noise starts with developing a 'big idea' and requires clarity, originality, consistency and stand-out design in its execution. The fundamentals of creativity have never been so important. A great creative delivers an instant understanding of the problem and the solution on both an emotional and rational level. It's difficult to describe, but when you see it, you know—it's got that wow factor."[8]

When touching upon medical content, it seems natural to distance ourselves from emotions, just like most physicians do. Physicians, on one hand, are taught to remain detached from participating in any depth of emotions to maintain the objectivity considered crucial to accurate clinical decision-making. On the other hand, emotions are already highly present in the patient–physician relationship. According to the author of the book *From Detached Concern to Empathy: Humanizing Medical Practice*, Jodi Halpern, emotions should be recognized and used constructively in the service of empathy. In fact, in Halpern's view, critical clinical decision-making and diagnosis depend not on emotional distance but on emotional engagement that allows the physician to gain a deeper understanding of, and insight into, the patient's experience of illness.[9]

Along these lines, emotional connection can be used as an approach to innovate in promotional medical education pieces. Creating room for emotions that we all yearn to express provides a sense of identity and genuineness. In addition, emotions create a bridge for HCPs to connect with their patients on a human level.

Although creating an emotional connection between a promotional medical piece and its audience can be perceived with skepticism by some, it is a powerful storytelling resource that should be explored whenever applicable and executed according to the FDA regulations. Tapping into emotions not only creates a memorable learning experience but also provides a chance to relate to the patients treated by the audience of these promotional pieces.

Numerous approaches can be deployed when aiming for innovation, and it is true that technology can help create a highly engaging piece that will catch the eye of the audience. However, that does not necessarily equate to a memorable experience. For example, a conference booth employing an interactive game to engage visitors can create an enjoyable experience, a pause from long and tedious presentations. However, if it does not also create an emotional connection, the audience will likely turn its back once the activity is over and soon forget the core messages, if not the product altogether.

These observations highlight the importance of creating a strong partnership between medical and creative teams—after all, exploring genuine and relatable emotions within every medical piece requires complete alignment and enthusiasm for working together as a team. Anything less than a solid alliance will likely not tap into real emotions and therefore will not result in a memorable and innovative piece.

CONCLUSION

The evolving landscape of medical communication with the incoming creative teams from consumer agencies has created a new opportunity for medical writers to explore new approaches to storytelling and visual engagement. Thus, building a synergistic relationship between medical and creative departments is imperative to bring differentiation and excellence to our industry.

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CALENDAR OF MEETINGS

Please confirm with individual meeting hosts

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NOVEMBER 2-5, 2022
DENVER, CO

Trends and Opportunities for Medical Communicators

Alliance for Continuing Education in the Health Professions
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Aurora, Colorado
https://www.acehp.org/Annual-Conference

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January 25–26, 2022
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https://www.ismpp.org/european-meeting

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February 17–20, 2022
Philadelphia, Pennsylvania, and Virtual
https://meetings.aaas.org/

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San Antonio, TX
https://aphameeting.pharmacist.com

DIA Europe 2022
March 29–31, 2022
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https://www.diaglobal.org/en/flagship/dia-europe-2022

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https://www.diaglobal.org/Flagship/DIA-2022

Walter Clement Alvarez: Physician • Researcher • Columnist

Thomas A. Lang, MA / Principal, Tom Lang Communications and Training, Kirkland, WA

Abstract

The American Medical Writers Association (AMWA) currently bestows 3 awards in honor of 3 of its members: Harold Swanberg, MD, the founder of the Association; Walter Alvarez, MD, in retirement, a nationally syndicated health columnist;; and John McGovern, MD, a philanthropist who supported initiatives in biomedical communications. However, the details of the lives of these men are unknown to most AMWA members. Accordingly, this biography describes the life and accomplishments of Walter Alvarez to recognize his achievements and to contribute to the history of the profession and of the Association.

Introduction

Walter Alvarez was an accomplished researcher and physician. As a gastroenterologist, he was the first to identify what is now called Alvarez syndrome, a medical disorder of unexplained neurotic abdominal bloating, and Alvarez-waves, or painless uterine contractions that occur throughout pregnancy.[1] He was among the first to call attention to food allergies,[2] brought worldwide attention to what would be called psychosomatic medicine,[2,3] and was an early supporter of LGBTQ+ rights.[2] Despite these achievements, however, what he did in retirement is what caught AMWA's attention.

The Alvarez Family

Walter Alvarez was a remarkable man with a remarkable lineage. His father, Luis F. Alvarez, was born in Spain, orphaned early, and taken by a relative to Cuba at age 13, where he completed high school. He next went to San Francisco where he learned English, graduated from medical school, and started a family.[4] He eventually became a government physician in rural Hawaii and was later appointed to run a new hospital for patients with Hansen disease (leprosy),[5] where he developed an early diagnostic test for the disease. He also became the personal physician to Queen Lili'uokalani of Hawaii.[6]

Walter's sister, Mable, was a renowned artist whose paintings were exhibited nationwide and are held in private collections around the world.[7] His brother, Milton, became a businessman in the southern Philippines, in a Sultanate of the Islamic Moro people. He was so well liked that when the Sultan died, he was offered the position of Sultan (he declined).[3] His brother, Harold, became a Professor of Dental Surgery at the University of California Medical Center in San Francisco and had a successful private practice.[3]

Walter's son, Luis, was one of the most notable nuclear physicists of the 20th century. He made the first precise measurements of neutrons; invented the cyclotron, ground-controlled radar (which allows planes to land in poor visibility), the transponders that identify airplanes in flight, and a stabilizing optical system for cameras; analyzed the Zapruder film of the Kennedy assassination; received the Nobel Prize in physics; and—probably most importantly—invented the stroboscopic golf-trainer that helped President Eisenhower improve his golf swing.[8]

Walter's grandson (Luis's son, also a Walter) was a geologist and professor in the Earth and Planetary Science Department at the University of California, Berkeley. He studied the phenomenon of "geomagnetic reversals," which occur when magnetic poles trade places, and was able to estimate the dates of these reversals—over the past 100 million years.[9] In 1980, he and his father proposed the "Alvarez hypothesis," which postulated that an asteroid hitting the earth ended the age of dinosaurs 66 million years ago.[10] Their hypothesis was confirmed in 2010.[11]

Growing Up in Hawaii

Walter Clement Alvarez was born in San Francisco in 1884,

the son of Luis F. Alvarez, MD, and Clementina Alvarez. An older brother had died of diphtheria at the age of 4, making Walter the oldest of his 4 siblings: Milton, Florence, Mabel, and Harold.[3] When he was 3, the family moved to Hawaii, where his father was a government physician in rural Oahu caring for migrant workers in the sugar cane plantations.[3,4]

Walter and his siblings grew up in relative isolation. His mother taught him to read, and he remained a voracious reader throughout life. He often accompanied his father on medical rounds in the countryside. On these trips, he encountered the *kahunas*, the shamans who could put spells on people that actually resulted in death.[3] He would remember this phenomenon when he began to investigate why his patients had symptoms for which he could find no medical cause.

One day, his father had to operate on a field worker who had lost his hand. The operating theater was the front lawn of the Alvarez house, and the operating table came from the kitchen.[3] Walter assisted in the surgery—at age 7. He credits those experiences with his decision to become a doctor.[2]

After 8 years in Oahu, the family moved to Honolulu, where Walter's father ran a new experimental hospital for treating leprosy.[2,12] In Honolulu, Walter had access to better schools. Still, much of his education came from extensive reading on a wide variety of topics in the local library.[3]

After graduating from high school in Hawaii in 1901, Walter returned to San Francisco, where he enrolled in Cooper Medical College (later to become the Stanford University School of Medicine).[2,13] He was only 17, but at that time, medical schools required only a high school education to matriculate.[3]

Private Practice

Walter began his internship and his research career in a San Francisco hospital in 1906 (he was there for the great earthquake). In his first published article, he confirmed the recent discovery of *Treponema pallidum* as the cause of syphilis.[14] Some 25 causes of syphilis had been proposed, so his diagnostic confirmation of *T. pallidum* was important. The article was published in the *Journal of the American Medical Association* when he was just 22 years old.

In the early 1900s, patients were routinely "purged" with laxatives before surgery to clear their bowels, even though the process weakened and dehydrated them. When no one could tell him why purging was done, he spent weeks in the library researching the practice. He concluded that its origins were the cleansing rituals that many preliterate cultures used to prepare someone for an ordeal, such as an initiation rite. He also found no evidence that it was effective. In one of his earliest publications, he made the case that purging was harmful and should be stopped.[15] The article is credited with reducing the practice worldwide.[2]

Walter married Harriet Skidmore Smythe in 1907.[16] Later that year, their first daughter, Gladys, was born,[17] and Walter took over his father's medical practice, which was now in a remote mining camp in Cananea, Mexico (Figure).[18] As in Hawaii, he was again living among indigenous people who held different beliefs about health, sickness, and healing. When he noticed that many of his patients expressed strong emotional reactions and exaggerated symptoms that seemed unrelated to organic causes, he made a point to spend time with the local *curanderos*, or traditional healers, learning how they understood and treated their patients. With this understanding, he could provide better medical care by helping patients suspend prescribed cultural reactions: "I can't listen to your heartbeat if you continue to wail." His patients could now stop the expected wailing because "the doctor said so."[3]

Figure. Walter Clement Alvarez, age 23. Used with permission of Mayo Foundation for Medical Education and Research

After 2 years, however, he was ready to return to San Francisco and so accepted an offer to open a practice with his former teacher and mentor, a gastroenterologist named Dr Schmoll.[2] Their practice soon became the most prestigious in the region (according to Walter, perhaps with understatement, because they were so successful in treating millionaires for gout and in diagnosing syphilis with the new Wassermann test).[2]

During this period, he began taking notes on his patients who reported abdominal pain or discomfort but in whom he could find nothing physically wrong. Other physicians had given these patients an undefined diagnosis of "autointoxication" and often put them through one or more exploratory surgeries. Walter remembered the *kahunas* and the *curanderos*. He was also aware that "confession of a sin made to a physician can be just as effective…as a confession made to a priest," and noticed that abdominal symptoms often disappeared when patients resolved some issues in their lives. In 1912, he gave his first lecture on what later would be called psychosomatic medicine, and he continued to investigate this mind-body relationship throughout his career.[2]

Walter was a gifted diagnostician. Without modern testing, physicians actually had to look at and listen to their patients, and the best physicians were masters of careful observation. To show interns how important this skill was, Walter interpreted a chest radiograph picked at random. His observations: the

radiograph was of a woman about 50 years old, who was tall, slender, and frail. She was Catholic and had had several children. She had had tuberculosis and possibly a mild case of polio as a child and, at some point, pneumonia. She probably had high blood pressure, arteriosclerosis, and arthritis. Finally, she quite likely hunted pheasants with her husband or brother and had been thrown from a horse. (His explanations for each observation are in his autobiography.[2] Sherlock Holmes, move over.)

During this time, he learned one of his little "diagnostic tricks": "When you can't identify the cause of a patient's discomfort, ask the spouse." (!)

After 3 years, Dr Schmoll's mental health began to decline (he was eventually institutionalized), and Walter left the practice. In 1912, he accepted a position at Harvard University, working with Dr Cannon, a renowned gastroenterologist, researching the anatomy and physiology of the bowel (OK, he studied flatulence in rabbits. But the research was far more important than the subject implies).[12] During this period, Walter also introduced the term "irritable bowel syndrome."[19]

While in Boston, Walter decided he needed access to a broader range of the scientific literature. Already fluent in English, Spanish, and French, he could also understand Italian from his study of Latin, but he could not read German. So, for the next 4 years, he studied until he could easily read technical articles in German.[2] (This period coincided with WWI, but his studies were unrelated to the War. Walter does not mention either WWI or WWII in his biographies.) Walter explained his enthusiasm for learning by citing the Greek origins of the word: en-theos, the "God within."[3] This drive to expand his knowledge was lifelong. When insulin was discovered, he visited the Canadian scientists, Drs Banting and Best, who had discovered it. He made a point to meet Sir Alexander Fleming, the discoverer of penicillin, and when he became frustrated at how to care for his gay and trans patients, he sought out Dr Alfred Kinsey, the pioneer in research on sexuality and gender issues.[3]

When the family returned to San Francisco in 1915, in addition to Gladys, they had 3 more children: Luis (1911), Robert (1913), and Bernice (1915).[20]

Back in San Francisco, Walter ran a highly successful medical practice from 1915 to 1925, spending a half day at his office and the other half conducting research at the University of California, Berkeley.[2,18] Although he was primarily a clinician, by 1919, his reputation as a basic researcher led to his election to membership in the American Physiological Society, the Society for Experimental Biology and Medicine, the American Society for Pharmacology and Experimental Therapeutics, the American Society for Clinical Investigation, and the American Roentgen Ray Society.[13]

Also, in 1919, he turned his full attention to statistics,[21] which he regarded as essential for doing research. Later, he was instrumental in establishing the statistics department at Mayo Clinic.[2]

Walter eventually parted ways with other physicians in the San Francisco County Medical Association over their opposition to "much-needed workman's compensation laws" and was looking for a new opportunity. As luck would have it, at a conference, he sat next to a member of the board of directors of Mayo Clinic, who immediately offered him a position at the Clinic, which he took in 1926.[2]

His Career at Mayo Clinic

At Mayo Clinic, Walter got his wish: he could continue his research, see patients, and support his family. Eventually, his worldwide reputation as both a researcher and a clinician in gastroenterology led to his presidency of the American Gastroenterological Association in 1928.[2] From 1937 until he retired from Mayo Clinic in 1951, he was also editor-in-chief of the *American Journal of Digestive Diseases*, which later became *Gastroenterology*.[22]

Walter was an early advocate of health education.[21] In 1932, he proposed that the Clinic create a museum of medicine to help patients and the public understand the human body and its ailments and treatments. The museum continues today as Mayo Clinic Heritage Hall.

In his second autobiography, he recalls that "Two of my most grateful patients were notorious gangsters, who, strange to say, I came to like." One, "a well-known citizen of Chicago" from whom Walter removed a painful gallstone, begged Walter to "commit some crime so that through his friends he could 'get me off.'" The other kept asking if there wasn't someone Walter wanted "bumped off," which would be done without charge!

In his 25 years at Mayo Clinic, Walter published nearly 350 scientific articles.[21] Several times, he ran afoul of the young editors in the Division of Publications run by the legendary Maud Mellish. He tells about how they tried to make his writing more scientific by using more technical terms, such as replacing "hiccup" with "singultus," and adhering to arcane rules of grammar when he wanted to write less formally. They also wanted to soften some of his more challenging conclusions. "Fortunately for me…the Editors-in-Chief Maud Mellish and later Richard Hewitt always came to my rescue; they chased away the young ladies with the blue pencils…"[2] (Dr Hewitt was President of AMWA in 1955.)

Retirement, Sort Of

In 1950, Walter turned 65, retired from Mayo Clinic, and moved to Chicago. Within 6 months, however, he agreed to be the editor-in-chief of *Geriatrics* and *Modern Medicine* and would remain so until he retired again, 25 years later, at age 90.

Walter continued to write after he retired. As a journal editor, he had written hundreds of editorials. In Chicago, he continued this practice as a newspaper columnist, gaining fame as "America's Family Doctor" for his practical and understandable columns on personal health.[23] His columns were soon syndicated in hundreds of daily and weekly newspapers throughout North America and in several countries.[17,24] These columns, the 17 books he published during this period, and his "reassuring clinical wisdom and compassion" made him a beloved and world-famous physician.[25]

In his editorial office in Chicago, Walter hired a young woman just out of college to become his editorial assistant. Kelley Williams would spend the next 14 years editing his writings, producing weekly syndicated television and radio programs, and helping to coordinate his many professional activities and lectures at scientific conferences. She even suggested the wonderful title for his first autobiography, *The Incurable Physician*. Walter, in turn, mentored her in medical writing and broadened her understanding of medicine and of life. In 1987, Kelley became President of AMWA, where she helped develop the core curriculum that was the backbone of the Association for many years (Kelley Williams, personal communication, June 28, 2020).

Walter wrote on a wide range of topics, among them, the use of a psychological evaluation when diagnosing illness, the use and misuse of tranquilizers, the use of hypnosis in treating asthma, the activity of obese girls, the effects of glue-sniffing in children, office treatment of behavior disorders, depression, psychotherapy, sleep disturbances, and suicide. During this period, he became the most widely read and respected physician of the 20th century. At the peak of his activities, he had 12 million readers[24] and received more than 100,000 letters a year asking for medical advice.[2] His books and editorials in *Modern Medicine* and *Geriatrics* were enjoyed by thousands of physicians.

Throughout his professional life, Walter was interested in the genetic determinants of disease, especially psychiatric disorders (Box 1). In part, his interest stemmed from his colleagues who did not routinely take thorough family histories of their patients and so missed many diagnoses. Also, in the early 1900s, the "nature vs nurture" debate was in full swing, and "nurture" was more popular among some physicians, who were quick to blame parents for the mental health issues of their children. (One section of Walter's essay on heredity is titled "The Taboo Against Even Mentioning Heredity."[2])

Walter believed he never adequately understood his patients who had questions or concerns about their sexual lives or gender identity. Medical schools seldom addressed the topic, which was considered taboo and was accompanied by much incorrect information. Walter did what he always did in such cases: he sought the best information he could find. He became good friends with Dr Alfred Kinsey, who had just completed his landmark surveys, *Sexual Behavior in the Human Male* and *Sexual Behavior in the Human Female*. (Kinsey's research was funded in part by the Rockefeller Foundation, where the research department was headed by Dr Alan Gregg, for many years a prominent member of AMWA.) Walter accepted the variety of gender identities as natural differences, not as moral failings to be punished or "cured," and had great sympathy for his patients and the fear, guilt, anxiety, and discrimination they experienced.[26] He sought to educate his colleagues and the public on the natural biological realities and on the unjust social consequences of sex and gender identity (Kelley Williams, personal communication, June 28, 2020).

Box 1.

Early in his career, Walter became interested in genetics and the effects of heredity on health. He relates a story told to him by an elderly doctor who had attended Walter's lecture on the topic. A census taker had knocked on the door of a shack in the course of his duties, and the door was opened by a girl who appeared to have a developmental disability but was nevertheless able to communicate. When the man asked if her father was in, she replied, "Naw, he's in the penitentiary." When he asked if her mother was in, she replied, "Naw, she's in the state hospital." Asked if she had a sister, she said, "Yeah, she works in the red-light district." Did she have a brother? "Yeah, he's at Harvard Medical School." The man, stunned, said, "You mean your brother is a Harvard professor? "Naw," she said. "He's no professor. He has two heads; he's in a bottle of alcohol."

His Legacy

In 1975, Walter retired for the second time. His wife had died in 1973, and he eventually moved back to San Francisco to be with his children and grandchildren. He died there in 1978, but not before hiring yet another editorial assistant and writing until his death (Kelley Williams, personal communication, June 28, 2020).

Walter kept a diary for most of his life. Before writing the *Incurable Physician* (published in 1963),[2] he read all 62 volumes of the diary to prepare. He published 2 autobiographies, in 1963[2] and 1976.[3] The biographies include many of his editorials.[27] His second autobiography is filled with stories and anecdotes from his practice of medicine, which makes it quite engaging (Box 2 on next page). The stories make it clear that although "many physicians treat diseases, Alvarez treats people who have diseases."[23]

Box 2.

Walter tells a story about why physicians shouldn't jump to conclusions about their patients. One of his patients, a woman, was told by another doctor that her poor health was caused by not having children. "I know your type well. You doll yourself up in the morning, play cards in the afternoon, and live a stupid, indoor existence." Later, she told Walter that "I didn't bother to tell him that my husband smuggles whisky across the Canadian border. Most nights I sit in the car with him, watching out for hijackers, with a submachine gun across my lap."

For his achievements in educating the public about health and disease, AMWA created the Walter C. Alvarez Memorial Award in 1982 to "honor excellence in communicating health care developments and concepts to the public."[28]

Walter's last column, written 4 years before his death at age 94, was titled "The folly of retirement at age 65."[29] He clearly knew of what he spoke.

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SOCIAL MEDIA

How to Make LinkedIn a Career-Building Tool

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Although it may seem like an unsolvable mystery and the constant changes are maddening, LinkedIn is a great way to find clients or a job and to build a strong network. This article highlights recent changes that medical communicators should know about and the 3 steps to making LinkedIn a career-building tool: (1) develop a complete, relevant, compelling profile; (2) build a big, relevant network; and (3) be active.

With 58 million companies on LinkedIn and 774 million members (as of September 2021),[1] LinkedIn is a great way to find clients or a job and to build a strong network. Every minute of the day, 3 people are hired through LinkedIn and 4 out of 5 people on LinkedIn are decision-makers for their businesses.[2]

That's why medical communicators need to know how to use LinkedIn, even if it seems like an unsolvable mystery and the constant changes, like the recent new look, feel, and features, are maddening. To make LinkedIn a career-building tool, you need to

1. develop a complete, relevant, compelling profile,
2. build a big, relevant network, and
3. be active.

These 3 things help you rank higher when LinkedIn generates search results so more clients or employers will find you. Also, you can strengthen your network and gain knowledge, advice, and support from colleagues. This article highlights how to make LinkedIn a career-building tool and the recent changes—some good and some not so good—that medical communicators need to know about.

Develop a Complete, Relevant, Compelling Profile

Profile completeness and relevant keywords in your headline are at the top of LinkedIn's search algorithm criteria. A complete profile includes

- the industry and location,
- a profile photo,
- the current position (under Experience),
- 2 past positions,
- education,
- at least 3 skills, and
- at least 50 connections (not technically part of your profile, but this is part of LinkedIn's criteria for a complete profile).[3,4]

How Strong Is Your LinkedIn Profile?

- Click on your profile.
- Scroll down to your dashboard (only you can see this).
- Move your cursor over your profile strength meter to see what you've already done.
- Follow LinkedIn prompts to complete your profile.

Write a Clear, Compelling Headline With Relevant Keywords

Your headline is the most important part of your profile, followed by the About section. LinkedIn's recent changes increased the number of characters you can use for both.

- Headline: from 120 to 220 characters
- About: from 2,200 to 2,600 characters

Having more space for your headline and About section can be helpful, but you don't need to use all of it. You only have 3 seconds to capture attention with your LinkedIn

profile.[5] Headlines at or close to 220 characters are too crowded to create a good first impression (Figure 1).

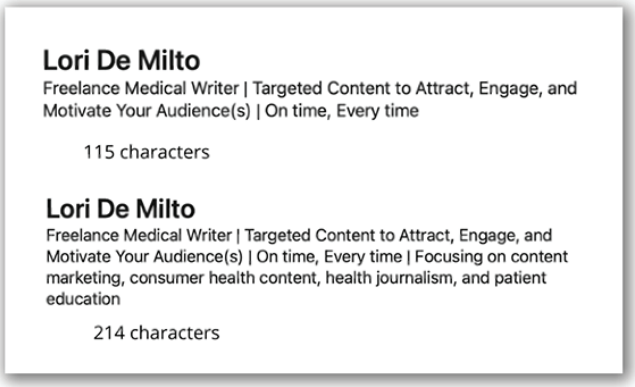

Figure 1. A clear, concise headline vs a too-long headline.

In your headline, clearly say what you do and how you help your clients or employers. Include relevant keywords, such as "freelancer," or your job title. Here is a simple headline formula:

- For freelancers:
  Freelancer medical writer [or editor, etc.] |Helping X do Y
- For employees:
  [Job title] | Helping X do Y

Use a professional, high-resolution head and shoulders shot, and if you create a custom banner, make sure it's professional and clear. The OpenToWork photo frame around a headshot is a new feature that I think makes freelancers and job seekers look desperate. If you have a complete, relevant, compelling profile, clients or employers will find you through their searches. Also, the use of the OpenToWork frame can lead to scams and spam.[6]

Make Your About Section Compelling and Relevant

Once clients or employers click on your profile, keep their attention by making your About section compelling and relevant. The first 220 to 270 characters with spaces count most. That's what shows before people must click "see more." On mobile devices, about 102 to 167 characters show.

Make sure the first 220 to 270 characters build on your headline and offer a clear, client- or employer-focused message. Attract clients viewing your profile on a smart phone or tablet by putting as much of your key message as possible in the first 102 to 167 characters.

In the rest of the About section, include just enough content to show clients and employers that you're a good choice for them. Briefly summarize your relevant experience, including services if you're a freelancer, and your background. Make sure your profile is public.

Your LinkedIn profile isn't a resume

- Be interesting and conversational.
- Write short sentences and short paragraphs.
- Use bulleted lists for anything else that works well in a list.
- Include a call to action (eg, contact me to [benefit to client or employer]) at the end, and include your contact information again.

The new Featured section is very useful for medical communicators (Figure 2). The Featured section lets you display your best work to anyone who looks at your profile. It's prime LinkedIn real estate: below the About section and above the Activity section. You can include many types of content in the Featured section, such as

- media files, such as documents, presentations, and videos;
- links to external blogs or work samples; and
- your website (for freelancers) or your resume (for employees).

If you had any media in your About section before, LinkedIn moved it to the Featured section. Check your Featured section and customize it to highlight your best work. If you didn't have media before, it's easy to add a Featured section. If you have at least 2 pieces of relevant (to clients or employers) content, you should have a Featured section. It's easy to add, delete, and move content in the Featured section.

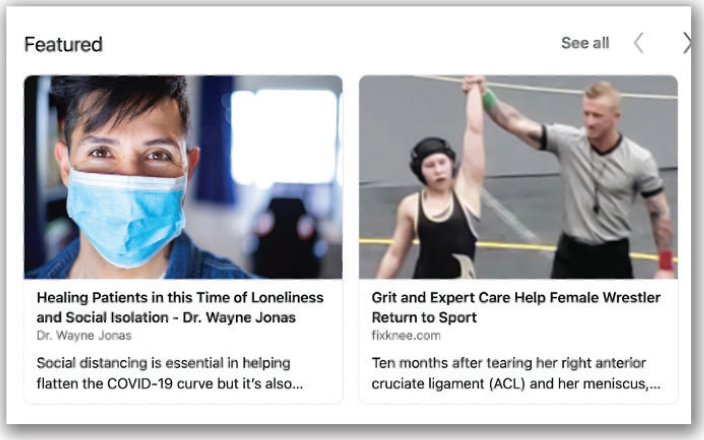

Figure 2. Sample Featured Section: Lori De Milto.

Build a Big, Relevant Network

Even if you have a complete, relevant, compelling profile, you won't show up in search results unless the searcher is connected to you. LinkedIn has 3 types of connections:

- First-degree connections: your direct connections

- Second-degree connections: people who are connected to your first-degree connections
- Third-degree connections: people who are connected to your second-degree connections

The closer the searcher is to you (first- or second-degree vs third-degree connection), the more likely you'll show up in search results.

Having at least 500 first-degree connections gives you a powerful network. Say that you're connected to 500 relevant people, other medical communicators and people doing related work. If each of your connections has 500 connections, you now have access to 250,000 people, many of whom are also medical communicators. It looks good on your profile when you have at least 500 first-degree connections because after 500, LinkedIn just notes "500+ connections."

It's easy to build a relevant network of 500+. Invite

- colleagues from professional associations,
- people you're working with now (colleagues, clients, and employers),
- people you've worked with in the past, and
- friends and colleagues from school.

You can also build your network through your LinkedIn activity.

When you invite someone to connect with you, always add a personal note. Mention what you have in common or why you want to connect. For example,

"Hi Lori. I see that we're both members of AMWA. Please join my LinkedIn network."

Accept connection requests from people you don't know as long as they are also medical communicators or are relevant to you in another way. Don't accept connection requests from people you don't know who aren't relevant to your career.

Be Active

Being active means engaging with other people on their content and posting your own content. Along with ranking higher in search results, being active helps you build relationships that can lead to referrals for freelance work or jobs. You can strengthen relationships with people you know and build relationships with people you meet on LinkedIn. Once you learn what to do, being active doesn't take much time or effort.

Review your LinkedIn feed—the content that shows up when you click on your LinkedIn Home page—about twice a day. Look for relevant posts by relevant people. LinkedIn offers 4 ways to respond: like, comment, share, or send.

Liking is lazy and won't help you build relationships with people. Responding under "like" with an emoji is a new feature. The only time I think this is acceptable is if you've already made a meaningful comment, the person who posted the content has responded, and you just need to acknowledge that response. But be careful which emoji you use; the 2 emojis with a heart aren't professional, and the emoji of a face is questionable.

Commenting is the gold standard on LinkedIn. Each comment is a way to boost your career because your name and the beginning of your headline are visible along with your comment. Also, commenting allows you to actively engage with the person who wrote the post and with other people who comment on the post.

Write a meaningful comment. For example, if the post highlights an article with 10 tips for being productive, comment on which tip you want to try or what you've already learned from the article. Make sure the person who wrote the post sees your comment by tagging them. To tag someone

- type the @ symbol,
- type the beginning of the person's name, and
- choose their name from the list that LinkedIn provides.

If you comment on the post of someone you're not connected to, that person is likely to accept a connection request from you, as are other people who comment on the same post. Your invitation could be something such as,

> "Hi Lori. I really liked your post on XYZ. Please join my LinkedIn network."
>
> *or*
>
> "Hi Lori. I see we both commented on Lisa's post on XYZ. Please join my LinkedIn network."

Sharing means you can share the post with anyone, your connections, or groups. Reshares get fewer views than other content and people are less likely to comment on a shared post than on an original post. Sending, a new feature, lets you send posts to a specific person or people you choose.

Once you get comfortable commenting on other people's posts about once or twice a week, do your own post. You can post about medical communication news and updates; useful free content like blog posts, podcasts, and webinars; and much more. Include about 2 to 5 sentences about the content, with a link to the full content (news, blog post, etc). Increase the number of views and engagement by using an image. If the full content has an image, LinkedIn will automatically use this image after you add the link. Easily find content to post through AMWA and other professional associations and email newsletters (eg, Smart Briefs).

Whether you're engaging with other people on their content or posting your own content, always be professional

on LinkedIn. Ignore anything that is controversial or disrespectful.

Know LinkedIn's Limitations

When used as described in this article, LinkedIn is a career-building tool for medical communicators. Like all social media, however, it is easy to waste time on LinkedIn. It is important to be strategic about building your network and your LinkedIn activity. Also, certain features, such as Stories, can be risky. LinkedIn says that the Stories feature is like a virtual water cooler in an office. But in an office, you know the people you are talking to, and can say the right things to the right people. On LinkedIn, your connections and followers can see your stories, and they can share them with anyone. In addition, the stories are only visible for 24 hours. Writing a relevant post is a much more efficient way to use LinkedIn to build your career than posting a story.

Make LinkedIn a Career-Building Tool

With the tips in this article and a little effort, you can more easily get clients or a job and build a strong network. Just follow these 3 steps

1. develop a complete, relevant, compelling profile,
2. build a big, relevant network, and
3. be active.

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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"I Can Help You If You Would Just Let Me!": The Journey From Vendor to Trusted Partner An Interview with Demetrius Carter

Diana Henzel, PharmD / Freelance Medical Writer, ACE Medical Writing, Norfolk, VA

Successful vendor–sponsor relationships, such as those between a contract research organization (CRO) and pharmaceutical company, assure and accelerate regulatory success for new products. Often, however, this relationship fails, which delays approval and, in turn, costs the pharmaceutical company money by shortening the market time of the product.

Demetrius Carter, MBA, PMP, RAC-US, shared insight on this relationship at the AMWA Carolinas 2021 Spring Conference by providing methods of assuring and accelerating regulatory success for pharmaceutical companies, reasons that CRO–pharmaceutical company relationships fail, successful mitigation strategies, case studies illustrating failed relationships, and, finally, techniques to strengthen and transform the CRO–pharmaceutical company relationship into a strategic partnership.

Mr Carter is a clinical development executive with over 20 years of drug development experience in the pharmaceutical and medical device industries. He is the Senior Vice President for Regulatory Services at Certara Synchrogenix, where he is responsible for their Regulatory Writing, Strategy, and Operations teams. His presentation was entitled "'I Can Help You if You Would Just Let Me!': Best Practices in Overcoming a Challenging Sponsor."[1]

AMWA: ***How Can CROs Assure and Accelerate Regulatory Success for Pharmaceutical Companies?***

Carter: To assure and accelerate regulatory success for pharmaceutical companies, 5 key components of the CRO's regulatory process must be fully established and supported by the following key CRO personnel and advanced technology.

Regulatory and Medical Writing

Writers should be experienced at producing all document types for major regulatory agencies by using the Common Technical Document (CTD) format. Technologies used by writers should drive efficiency and accuracy and speed the time to document completion. This should produce high-quality documents that are properly managed across the document development life cycle.

Regulatory Consulting and Regulatory Affairs

There should be a robust drug development strategy to guide document development. This should include a clear submission strategy directed by effective leadership, a gap analysis to detect and provide solutions to inadequacies, and expedited pathways to advance urgent documents. This should be an integrated global strategy so that content from the primary submission can be reused for submission to multiple regulatory markets.

Regulatory Operations

The CRO should be an expert at submitting regulatory documents by using advanced technology that is compliant with global health authorities. This expertise should include a simplified submission review, proactive management of timelines and deliverables, and electronic CTD delivery for every therapeutic area.

Regulatory Technology

To save time and resources, the CRO should use advanced technology powered by artificial intelligence (AI) to map clinical data to templates and automate development of documents.

Transparency and Disclosure

CROs should meet and exceed compliance requirements by providing services such as data anonymization and redaction powered by AI, clinical trial postings and result disclosure, plain language summaries, and strategies to promote patient engagement.

Although the outlined approach may be ideal for large CROs, smaller organizations may not have the financial resources to establish all 5 components. For example, significant technology investments may be too costly for small CROs. In this situation, these organizations may choose to focus on achieving operational excellence and raising their profile through consistent and high-quality delivery of their medical writing and regulatory affairs services.

AMWA: ***What Are Some Primary Reasons for a Failed CRO–Pharmaceutical Company Relationship?***

Carter: Some of the primary reasons for a failed CRO–pharmaceutical company relationship include failing to deliver the document by the agreed upon timeline, delivering a document of poor quality that does not meet expectations or industry standards, missing a return on investment when the cost of services for the deliverable does not match the pharmaceutical company's perceived value, and a failure to address ongoing performance concerns within the relationship.

AMWA: ***How Can CROs Show Their Value to Pharmaceutical Companies?***

Carter: By developing a unique value proposition (UVP). This will describe the benefits the CRO can provide, and what makes these benefits valuable to the pharmaceutical company. The UVP should be focused and easy to articulate. For this to occur, the CRO must understand the pharmaceutical company's challenges and describe how the CRO's service will address those challenges. The CRO must also present key differentiators that distinguish its services from those of other CROs and describe the key benefits it brings to the table. Finally, the CRO must craft a message that demonstrates the value of their solution to the pharmaceutical company.

AMWA: ***How Can Writers Improve Their UVP?***

Carter: To improve their UVP, writers should regularly review and reflect upon their performance by using a 360-degree review process that includes a self-evaluation. In addition, writers should choose 1 to 2 areas to improve upon annually, such as technical skills, knowledge, abilities, or competencies. A writer should compare the quality of the services provided with the fee the writer charges. This fee should be commensurate with the writer's experience and the service provided. Finally, writers should find opportunities to innovate, such as the use of technology to improve the quality and efficacy of their documents.

In the book, *Good to Great*, Jim Collins describes the Hedgehog Concept.[2] This concept is based upon understanding the intersection of 3 circles (Figure 1). When using these circles, writers should consider

1. Passion. To be the best, writers should only focus on activities they can be passionate about.
2. Excellence. Being good at something is not enough. Writers must understand what they can excel at to truly be great.
3. Drive. Know what activities drive consistent and reliable capital and profitability.

All 3 circles are required to transition from being good to being great. At the intersection of these circles is the target goal.

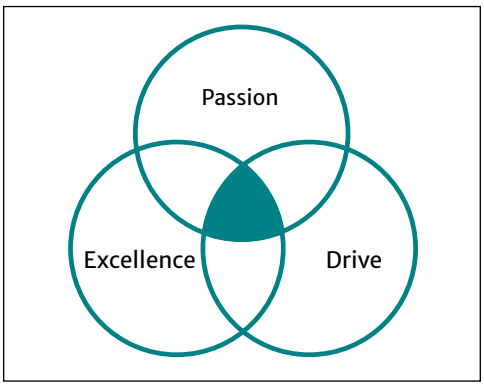

Figure 1. A depiction of the Hedgehog Concept. Adapted from The Jim Collins website.[3]

AMWA: ***How Can Writers Create Credibility When They Are New to a Team?***

Carter: To create credibility,

- be accountable,
- demonstrate technical acumen,
- give and earn respect,
- talk less and act more, and
- demonstrate commitment.

AMWA: ***How Can Writers Manage a Team Without Authority?***

Carter: Leading peers or more senior team members through document preparation requires writers to

- understand the team goals and motivators,
- set and document expectations at the project's start,
- be an empathetic listener,
- hold team members accountable through consistent follow-up,
- create positive visibility for team members, and
- master their emotional intelligence.

Remember that managers control and direct but that leaders influence and inspire.

AMWA: ***Do You Have an Example of a Pharmaceutical Company Hiring a CRO for Its Expertise but Then Not Using This Expertise? If So, How Do You Recommend Mitigating the Issue?***

Carter: Yes. In this example, a pharmaceutical company hires a CRO for its therapeutic expertise and experience with the Food and Drug Administration (FDA) Center for Drug Evaluation and Research Office of Rare Disease, Pediatrics, Urologic, and Reproductive Medicine. In their desperation to accelerate their New Drug Application (NDA) submission due to competitive pressures and their desire to be first to market, the company asks the CRO to write their summary of clinical safety and the integrated summary of safety with only 1 year of data, although FDA guidance suggests at least 2 years of pivotal safety data. This places the NDA at risk for rejection by the FDA.

To mitigate this issue, the CRO should transparently share its concerns and prior experience and ensure that communication reaches key stakeholders. Risks and mitigation strategies should be documented in meeting minutes. Finally, the CRO should stay motivated and demonstrate its technical expertise by delivering a quality document.

AMWA: ***Do You Have an Example of a Pharmaceutical Company and CRO Not Agreeing on a Timeline? If So, How Do You Recommend Mitigating the Issue?***

Carter: Yes. In this example, the pharmaceutical company and CRO agree in a contract that the Clinical Study Report (CSR) for a pivotal study will have 2 drafts and a final draft; however, the tables, listings, and figures (TLFs) will not be available until the final draft. This CSR is on the critical path for the NDA submission. Here, the issue becomes the late delivery of the TLFs, which leads to compressed timelines for delivery of the final CSR and a limited time for a full quality-control review. In this situation, the delays with the final draft are leading to a protracted review cycle with the introduction of new reviewers and new stakeholders.

Missing timelines or producing poor-quality deliverables can negatively impact long-term credibility and goodwill. To mitigate this issue, the writer, and project manager, if available, should assert themselves and push back. For example, they can advise the pharmaceutical company of the consequences of this shortened review cycle, and of changing reviewers and stakeholders. They should partner with the pharmaceutical company to negotiate a realistic timeline. To speed document development while the TLFs are not available, the writer should develop a shell CSR by using draft or placeholder data and seek approval by using the agreed upon template. In addition, the writer should identify quality risks and mitigation upfront (eg, using draft data). Finally, the writer should use online review technology (eg, PleaseReview) to facilitate authoring followed by comment-resolution meetings.

AMWA: ***Do You Recommend That Medical Writers Increase Their Project Management (PM) Skills? If So, What Skills or Concepts Are Important to Project Management?***

Carter: Yes. Upskilling your PM skills is critical to increasing your effectiveness as a medical writer. Pharmaceutical companies are increasingly expecting medical writers to take a leadership role within the submission team. PM is multifaceted and includes communication, teamwork, analysis, project planning, establishing a budget, establishing goals, understanding risks, problem solving, meeting deadlines, and reaching milestones.

Medical writers should be aware of 2 project management theories. In the first theory (Figure 2),[4] a project has 3 limitations: time, cost, and scope. Time refers to the project timeline, cost refers to the budget established for the project, and scope refers to the project purpose and requested deliverables.

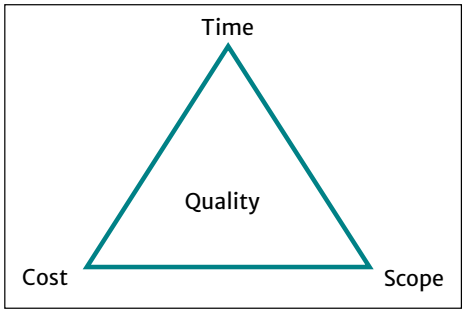

Figure 2. Project Management Theory 1. Adapted from the Skill Point website.[4]

A change in any one of these limitations will require an adjustment to the remaining limitations. For example, if the pharmaceutical company requires an expedited timeline, the cost of the project would increase as more writers are allocated to its completion. Additionally, quality is a key factor with this theory because changes to any of the limitations may affect the quality of the deliverable.

An updated version of this theory (Figure 3)[4] shows quality as a fourth limitation. Customer satisfaction becomes the key factor in this second theory, as a project's success is defined

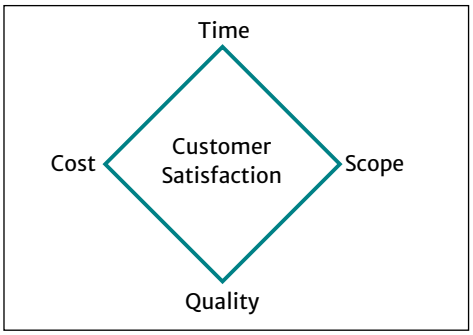

Figure 3. Project Management Theory 2. Adapted from the Skill Point website.[4]

by meeting or exceeding a customer's (pharmaceutical company's) expectations.

AMWA: ***Do You Have an Example of a Pharmaceutical Company Losing Confidence in a CRO? If So, What Advice Do You Have for the CRO to Regain the Pharmaceutical Company's Confidence?***

Carter: Yes. In this example, the pharmaceutical company and CRO have been in a long-term consulting relationship; however, the last few projects have not gone well, which has resulted in the projects being pulled back in house. Additionally, there have been changes in the internal leadership of the pharmaceutical company, which has led to a decline in outsourced projects to the CRO. Here, the issues include the negative feedback on recent projects and the relative anonymity of the CRO in terms of the new leadership at the pharmaceutical company.

Confidence can be lost overnight, and regaining confidence takes a significant amount of time. To mitigate this issue, the CRO should review the performance feedback and develop a corrective action plan, collaborate on the lessons learned, and take accountability. It can then offer some concessions to the pharmaceutical company, such as a lower rate or credit for future work. A cooling-off period may be necessary. In addition, successfully completing lower-complexity tasks may help reestablish credibility.

AMWA: ***Do You Have Any Proven Techniques for Transitioning a Business Relationship Toward a Partnership?***

Carter: Yes. To strengthen and transform the CRO–pharmaceutical company relationship into a strategic partnership, a CRO must build TRUST with the pharmaceutical company. TRUST is an outward expression of the value proposition a CRO brings to the partnership. The letters of this acronym represent the qualities the CRO must demonstrate:

- Technical competency—knowledge and skills to successfully complete the deliverable
- Reliability—trustworthiness and consistent performance
- Unity on purpose—understanding and alignment with the pharmaceutical company's goals
- Service orientation—priority being given to the pharmaceutical company's needs and excellent customer service
- Transparency—discussion of any issues and advice based on experience

AMWA: ***What Are the Key Takeaways for Transitioning From a Relationship to Partnership?***

Carter: For a CRO to transition from a transactional relationship to a strategic partnership with a pharmaceutical company, there are 3 takeaways:

- manage projects effectively,
- create and deliver on the UVP, and
- establish value through TRUST.

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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The Razor's Edge of Predatory Publishing An Interview with Jeffrey Beall

Mary Kemper, BS / Medical Writer, Mayfield Clinic, Cincinnati, OH

Predatory Publishing

At the time Beall stopped his blog *Scholarly Open Access* in 2017, he had been tracking scholarly publishing, the exponential growth of predatory publishers, and predatory stand-alone journals for nearly 10 years. He became immersed in researching this online aspect of deceptive and questionable scholarly communication while a faculty librarian at the University of Colorado Denver, where he worked as an expert in metadata for library discovery systems. Aiming to maintain the integrity of the academic record, Beall created a list of suspect scholarly publishers and shared it with the public on his blog. Beall's list was free; it exposed various types of deceptive practices, corruption of the editorial office and peer review, fraud, and hidden publishing fees. With evidence received from duped researchers themselves and gathered from the predators' websites, Beall uncovered how these publishers lured researchers into such trappings, which was exacerbated by institutional pressures such as the publish-or-perish mindset.

The path of academic publication became a razor's edge: would authors take the narrow and often hurdled path of legitimate scholarly publishing or be lured knowingly or otherwise by predatory journals?

Beall's commentaries examined flaws in open access, shortcomings of librarianship, and the effects of widespread library cancellations of subscription journals. He warned of a scholarly publishing industry that failed to regulate itself. As predatory publishers grew exponentially, so did the numbers of complicit authors who took the fast, easy route to publish and pay article processing charges (APCs) to advance their own careers. Beall's critics were not only the predatory publishers and the authors who published with them but those who dismissed the value of his work because he was a critic of open access.

During the 5-year period that Beall ran *Scholarly Open Access*, predatory publishers grew from about 20 in 2011 to >1,100 in 2017. The research community was jolted when he closed his list, which is still used today in an archived version (https://beallslist.net). As of September 2021, Cabells' Simon Linacre reported in the firm's blog *The Source* the unfortunate accretion of 15,000 predatory journals (a third of which are medical titles) and a gray zone of nearly 30,000 journals (https://blog.cabells.com/2021/09/01/mountain-to-climb).

I had the privilege to speak with Jeffrey Beall during a Zoom meeting in August of this year and later met up with him in Denver in September.

Jeffrey Beall is acclaimed for his work in alerting the global research community to the deep threats posed by predatory publishers in exploiting the gold open access publishing model. His work advocated for the protection of individual authors and the scholarly global community by maintaining the integrity of the academic record. He coined the terms predatory publisher, hijacked journals, predatory conferences, and misleading metrics and founded his blog, *Scholarly Open Access*, in which he maintained a list of predatory publishers from 2012 to 2017. AMWA readers can read his reflection on this period[1] and track his investigative work exposing predatory publishers in his nearly 40 publications on the topic since 2008, including interviews, the archived version of scholarlyoa.com (https://beallsist.net), and YouTube lectures.

Interview

AMWA: ***We appreciate your taking the time to speak with AMWA and want to acknowledge your work against predatory publishing. While you sought to safeguard research integrity, you established a foundation for thinking critically about this topic. Many of us wonder how you have been since you stopped the blog. Tell us about how you are doing now.***

Beall: I retired in 2018 from my University of Colorado faculty position. I moved to southern Colorado, specifically Walsenburg, Colorado, in Huerfano County and the nearby Sangre de Cristo Mountains.

As for tracking predatory publishing, I keep up by reading Google alerts that I receive on the topic. Recently, Paolo Crosetto's blog piece "Is MDPI a predatory publisher?" piqued my interest, as I had spent years tracking some of this publisher's troubling tactics on my blog.[2] I occasionally accept invitations to speak, as I did earlier this year virtually for a university in Spain. My invited opinion piece, "Open access, research communities, and a defense against predatory journals" was published this year in a platinum open access journal for a medical society based in Kazakhstan.[3]

I'm also digesting several articles analyzing my work. It's both interesting and hard to read a critical analysis of one's work.

AMWA: ***Readers may be interested your background. Most of your work on predatory publishing was done while you were a university librarian. What early experiences shaped your viewpoint and drew you to library science?***

Beall: I'm from California, earned a bachelor's degree in Spanish, and thereafter served in the Peace Corps in Guatemala. After completing a master's degree in English, I went to Saudi Arabia and taught English to employees of the Saudi government. Within a year, I wanted a change, so I got my master's degree in library science at the University of North Carolina at Chapel Hill.

After working in the library at Harvard University for 10 years, I moved back to the west in 2000 to the Auraria Library at the University of Colorado Denver. Throughout most of my library career, I quietly worked in the library's back room researching issues related to library metadata, full-text searching, and information retrieval. The roles of academic librarians were taking on increasing importance with the advent of scholarly open access publishing.

My interest in scholarly publishing began in 2005 as a Scholarly Initiatives Librarian. In 2008, I began tracking spam email invites to publish in what I would later call predatory journals.

AMWA: ***In your 2012 interview in the Open Access Interviews column by independent UK journalist Richard Poynder, you describe your metadata work in librarianship and research in scholarly communication (https://poynder.blogspot.com/2012/07/oa-interviews-jeffrey-beall-university.html). How were your role and interests changing at that time?***

Beall: As a faculty librarian, I studied bibliographic databases, including library catalogs, the effects of typographical errors in library databases, and the weaknesses of full text searching. In 2012, I gained tenure and was promoted to associate professor. Academic libraries play an important role in vetting publishers and maintaining online repositories of benefit to authors, but they largely failed to warn about the shortcomings of open access. Actually, the open access movement inspired many libraries to create new open access repositories; I've criticized them because they are expensive to operate (licensing fees, staff salaries) but are accessed very little. (Print repositories of journals have indeed been weeded from libraries, but the online counterpart versions offer great added value and have been backed up well.)

AMWA: ***You came up with the term predatory publisher and became an activist for your faculty and the scholarly global community. What was that early period like?***

Beall: My first article on the topic, a 2009 review of Bentham Open, highlighted how this publisher was exploiting the gold open access model with its 200 journals, each with few articles, and charging authors high publication fees.[3] It was published in the *Charleston Advisor*, a journal that typically publishes reviews of electronic databases that librarians license. My review alerted libraries to the transgressions of this particular publisher and to the larger problem of linking to publisher sites like these, which flood the scholarly literature with poor quality work.

I understood this was a new concept that needed a name. I landed on the term *predatory publisher*. I knew it wasn't perfect but liked the predatory metaphor and felt the alliteration would help make it be easy to remember. I later learned in my travels that the term doesn't always translate well. Although others have advocated for a different term, *predatory publisher* caught on. I also coined the terms *hijacked journal*, *predatory conference*, and *misleading metrics*.

The Bentham Open article went largely ignored until late 2011 when the nursing research community, specifically the International Academy of Nursing Editors, took notice. They have since conducted extensive research and felt vulnerable, realizing that their many specialty nursing fields would be targeted by the predators. Discussion of Beall's list on this tight-knit community's listserve garnered significant attention, and interest spread to other research communities.

AMWA: ***Your 2012 article in* Nature *entitled "Predatory publishers are corrupting open access"*[5] *was published the same year that you launched your blog* Scholarly Open Access. *You exposed their lack of transparency and their dishonesty, the effects of a lack of integrity on scholarly literature, the mutable nature of their deceit, and the public's access to bad science.***

Beall: This invited opinion piece for *Nature,* published in September 2012, increased attention on this topic and led to the term *predatory publishing* going viral. After that, researchers from all over the world began forwarding me spam emails they received from newly appearing predatory journals, offering helpful tips on establishing criteria to evaluate them, and revealing their own misfortunes in dealing with these predators. These examples provided evidence for my blog posts and complemented what I uncovered on the websites of predatory publishers and stand-alone journals.

AMWA: ***You issued serious warnings at a time when numbers ranged initially from about 20 to later hundreds of predatory publishers and stand-alone journals. Tell us about launching your blog* Scholarly Open Access.**

Beall: My first list in 2010 was followed by *Scholarly Open Access* in 2012. I wrote 2 blog posts each week; I enjoy writing and had lots to write about in explaining why I listed a particular publisher. Some of the predatory publishers and journals were so clearly fraudulent or silly, and it was fun for me to write with a sardonic approach. Nonetheless, the harm was proliferating.

I noticed the medical research community was hit hardest. Predatory publishers targeted grant funds, knowing that scholarly authors could use them to cover their APCs. They took advantage of the pressure-to-publish culture of medical research and appealed to busy clinical researchers, offering a fast, easy route to publish.

AMWA: ***You were bringing a lot of attention to your university. What was the response?***

Beall: The university was of 2 minds. It favored the positive attention metrics that were garnered through the numerous mentions I and the university received on various websites and publications.

However, the dark side of that attention emerged by 2013. Predatory publishers on Beall's list began to lose income. They complained, asked to be removed, and began searching the University of Colorado's website to harvest the emails of various administrators. In their mass emails, their claims, such as that I was a criminal, were initially difficult to deal with. However, the university counsel quickly understood the motivation of their baseless accusations.

My reviews on *Scholarly Open Access* were comparable to a book review. That is, I applied the same skills used in organizing reviews of books or electronic databases for various professional library journals. I was clear that the blog's list and reviews were my opinion.

AMWA: ***Beall's list included predatory publishers and stand-alone journals that violated a number of traditional ethical norms in scholarly publishing practices. Your work critiqued a particular publisher, constructing a foundation about how they exploited the gold open access model. How did you come up with this strategy, and how did it evolve as the number of predators was increasing?***

Beall: Researchers sent evidence, often in a trail of emails, after having unknowingly submitted their papers to predatory publishers. Many became suspicious when, the day after submission, their article was accepted for publication and accompanied by an invoice for the APC. Obviously there had been no peer review. Researchers told me all kinds of stories of egregious practices by these predators and sent me the solid evidence related to transgressions of peer review integrity, editorial standards, business ethics, indexing, and archiving.

AMWA: ***You wrote twice-weekly blog posts about select publishers, such as Frontiers or OMICS. You tracked their fake addresses to actual locations, found stolen identities, and detailed deceptive practices (eg, misleading metrics, claims of being included in prestigious scholarly indexes) to lure authors. Can you describe your process of investigation and writing these commentaries?***

Beall: For each blog post, I had evidence provided by researchers or evidence that I encountered myself. I also examined the publishers' websites for the number and quality of published articles and identified their predatory practices that violated scholarly norms. From the start, rather than individual journals, I focused on publishers, many of which had a fleet of journals. Because these publishers would quickly add titles to their portfolio to generate income or remove others, tracking individual journals would have been impractical and time consuming.

Shortly after the launch of *Scholarly Open Access*, various mentors gave feedback urging me to document the criteria used to assess the publishers. As the criteria evolved over time, I eventually used 3 versions during the 5-year period of scholarlyoa.com.

AMWA: ***What was noteworthy among the predatory journals that targeted medicine?***

Beall: I first noticed the spam emails from library science journals when I was looking for places to publish. Medical specialties, like nursing and ophthalmology, began to monitor activity in their fields. Predatory publishers proliferated in medicine,

often launching one journal per specialty based on a list of every specialty taken from a hospital's department listings. Big fleets of predatory journals were exploiting researchers, but there were also researchers taking advantage of their fast, easy, and often cheap publishing route.

Medical society journals contribute significantly to keeping societies afloat through a fair subscription price. These fees make a little overage that can help cover journal costs and pay for other services to benefit residents and students, for example. Open access doesn't work like that: APCs do not generate enough income for administrative services, such as managing peer review or providing high quality editorial support.

AMWA: ***Besides providing highly detailed information, you framed the rise of predatory publishers in the context of the open access social movement and the culture of scholarly publications. How did your viewpoint about the open access movement evolve?***

Beall: I was always critical of the open access movement. Although scholarly open access publishing offers the benefits of being free to read for everyone and of allowing reuse and repurpose under the Creative Commons license, it had major flaws. From my position as a scholarly communication librarian, I argued that advocates for open access lacked foresight about its unintended consequences, such as open access threat to science or the pollution of research databases. Their promotion continued even after the problems of predatory publishing clearly emerged.

The open access movement attempted to stigmatize and shut down traditional scholarly publishers using the subscription model to publish high-quality vetted research. These publications appearing on library platforms also added value to research by increasing accessibility to resources and citations.

AMWA: ***In 2013, criticisms included your review criteria, transparency of your methods for placing a publisher on your lists, and other alleged biases found in your blog*** **Scholarly Open Access.** ***OMICS threatened to sue. In 2015, some of your professional library colleagues cited bias. How did you weigh all these criticism and threats?***

Beall: Several publishers threatened but never actually sued. In 2019, a federal judge ordered the journal publisher and conference organizer OMICS International to pay $50.1 million to resolve the Federal Trade Commission (FTC) allegations of deceptive claims and hidden APCs.[6] Although ordered to cease operations in the United States, the publisher responded by creating many smaller publishing brands, such as Sunkrist, to hide the association with OMICS International. Therefore, the action by the FTC, though significant, is not having any significant impact. For example, when a subsidiary of OMICS International acquired society journals, specifically *Pulsus* in Canada and its 2 dozen medical society journals, including *Cardiology*, the journals' quality declined.

I discussed the strains of decreased library budgets, journal subscription cancellation projects, and the shortcomings of my own profession in ignoring the true causes of journal price increases to favor the more politically correct advocacy for open access.[1]

AMWA: ***In 2014, you began a sabbatical at a time when there were more than 400 predatory publishers and more than 300 stand-alone predatory journals. What did you want to accomplish during that year?***

Beall: During that 6-month period in 2014, I wrote several articles and traveled for speaking engagements, including to northern Iraq. I enjoyed these engagements, which began in 2013, and eventually had traveled to dozens of states and 20 countries.

AMWA: ***You shut your blog down in 2017 with a listing of 1,155 publishers and 1,294 journals. You must have faced some difficult decisions during that period.***

Beall: It was a very difficult period. Within the first 6 months, I wrote "What I learned from predatory publishers," my account about what I learned about scholarly publishing, the pressure that researchers face, and the aggressive strategies that some predatory publishers used to fight me.[1] There was a lot of emotion in this article. One of the main and unique points that I made in this commentary was that researchers who publish in predatory journals often become their defenders.

AMWA: ***Since 2017, researchers have tried to update your list or create their own unique lists of predatory publishers and/or journals for developing countries (http://kscien.org/predatory.php). In 2017, Cabells Scholarly Analytics launched their subscription products that included their Whitelist and Blacklist of 4,000 predatory journals from 18 disciplines that violated their behavioral indicators.[7] Today Cabells has subscription products called Predatory Reports and Scholarly Analytics and a team of experts to evaluate an estimated 15,000 predatory journals (a third are medical titles) and 11,000 legitimate open access journals, respectively. Another 30,000 journals are considered to be in a gray zone. In his 2020 opinion piece "Why we should have listened to Jeffrey Beall from the start," Mike Downes says, "Misguided criticism of Beall himself was counterproductive in the fight against fraudulent publishers."[8] Downes advocates for policy and prosecution of these scam open access predators. What's the future of tracking predators and educating authors at a time when many may not have access to subscribe to those reports?***

Beall: I'm glad Cabells has taken on this effort. Additionally, the business of scholarly publishing hasn't adequately policed itself and needs to establish a credentialing system (eg, like the field of pharmacy) to separate bona fide journals and publishers acting in good faith from predatory journals and publishers. Before open access, libraries played an important role in not subscribing to junk journals and in preserving scholarly integrity.

AMWA: ***Through* Scholarly Open Access, *you connected with academics and publishers from all over the world in exposing the high stakes on the razor's edge of scholarly publishing. You identified numerous scams and harms caused by predatory publishers in ethics, finances, and quality, and pursued getting these open access scammers out of scholarly databases. You warned of the dangers of citation contamination, corruption of public trust in science, and risks to high-quality medical journals and research funding. Thank you, Jeffrey Beall, for creating an outstanding resource for the academic community. Your activism is a model for upholding the integrity of scholarly publishing, examining the flaws of open access, and avoiding the dangerous path of predatory publishing.***

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Resilience: One Family's History
The Skills and Tools for Organizing Large Amounts of Discordant Information Into a Cohesive Story

Judy Stone, MD / Cumberland, MD

Larry Lynam of the AMWA Florida Chapter graciously invited me to speak last year at one of the monthly First Thursday virtual networking meetings the chapter regularly organizes. Our initial focus was on how I researched and wrote my memoir, *Resilience: One Family's Story*, which was published in October 2019.[1] Following my presentation, we had a lively discussion on the tools I used to organize the large amount of information generated from my research to write the memoir. As the processes and tools I used in writing the memoir are equally valuable in my medical writing, I was prompted to write this article to share them with the wider AMWA membership.

The memoir is the story of my family, beginning with village life circa 1910 to 1920 in rural Hungary, their experiences throughout the Holocaust, and their journey toward rebuilding their lives in a new country that was not entirely welcoming. Unlike a typical biography, my book is a collection of biographies of different family members. Sources included 9 surviving family members, 8 of their children, and oral history interviews that were acquired over many years. I learned what a challenge it was to weave those overlapping stories together into a coherent and compelling whole and had to develop a new skill set, which was narrative writing.

The details I gleaned felt like an overwhelming amount of material to organize—from the interviews with many of the recounted paths and experiences during the war being quite different, to research on the Jewish culture and traditions of Eastern European villages, to historical details of the Holocaust. Additionally, I searched for source documents belonging to each member of the family in order to more fully understand their lives and put events into context, which was very time-consuming and challenging.

My initial foray into writing the biography did not go well. I thought I would write a chapter for each family member, telling their stories chronologically. I began with my maternal aunt. When I reached the time in her story when she was liberated from the concentration camps and became engaged to my father's brother, I realized that there was no way that the chronological format would work, as I hadn't introduced him earlier! It was back to the drawing board for me, with reading more memoirs and biographies. *Fragments of Isabella* by Isabella Leitner[2] resonated with me as the most powerful memoir I had read, and it provided me a fresh approach on how to write my family's story.

I also hired experienced writers to coach me. This was perhaps the smartest decision I made. I normally write medical explainers or perspectives and was inexperienced in writing this sort of vivid, descriptive narrative usually found in novels/books. Prompted by my first writing coach, I looked back at the prewar photos we were so fortunate to have and worked to describe every detail graphically. I repeatedly reinterviewed those characters in my book who were still alive to elicit memories and descriptions of their households, scents of cooking and baking, textures and colors, in order to paint a vivid picture of rural village life. My second writing coach also radically changed my perspective. I had been studiously trying to remain an objective observer narrating my family's experiences. My coach, however, was adamant that "I" was what was missing from the story and that I needed to write about my relationships: those with my aunts and uncles as well as my perspectives and reactions to family secrets I learned during the interviews and writing.

Through this work, I was able to break through my writer's block. I proceeded to write my recollections and my family's experiences as a series of vignettes and not worry about connecting them all until later. In addition, I also used 2 important tools. The first tool was a detailed timeline noting not only what happened (births, marriages, deaths, concentration camps, immigration, etc.) but also how old each individual was at the time. A separate line for each person made identifying relationships easier. This proved invaluable in helping me understand some of the family dynamics, which were essential in fleshing out the characters and story development. I had looked at superimposing our events on historic timelines from the US Holocaust Memorial Museum but decided that was needlessly cumbersome and added little.

The second tool was using software programs to help me organize my family's story (Table). I initially just transcribed audio tapes; however, I quickly changed to using the software Transana when transcribing my oral history interviews. Transana is a program to help users manage and analyze large collections of media data. I preferred using Transana to using a simple tape recording because it allowed me to make a searchable database of video clips based on the individuals and key words. I particularly liked that I could annotate emotions and nonverbal clues seen in the videos in the transcriptions and better visualize clips I might want to highlight in my book. I also inserted time stamps for both reference points because my initial aspiration was to make a short video for Holocaust education. I did not find iMovie to be as readily searchable for clips of specific topics as Transana was. If writing about heated exchanges at medical conferences or debates for instance, Transana might be a useful software platform because one can better analyze gestures and nonverbals.

Zotero was also a useful adjunct to my research. For *Resilience*, I used it to organize genealogic details and track source documents for each person. I had tried Evernote but found it harder to organize, as it felt like a large junk pile. I also found Zotero easier to use than Endnote and liked that it was free and open-source. I also use Zotero extensively in my medical writing (Figure 1). I find it helpful for annotating references, searching by keywords, and collecting small facts that I can

Table. Useful Organizational Software Tools for Medical Writers

Software Tool	Zotero	Scrivener	Transana
Best Use	• Can import articles and bibliography information while browsing. • Searchable for facts and random bites of information that an author may want to use repeatedly in articles. • Can sort bibliographies into collections and tag with keywords.	• For writing and rewriting. • For writing that requires many citations or referring to source documents. • Can import articles without bibliography data.	• For analysis: can add codes and make a database of video clips for analysis. • Can insert timestamps into transcript.
Cost	Free	30-day free trial; $49	$150
Ease of Use	Easy	Moderate	Difficult
Available Aids	Tutorial	Tutorial and videos	Tutorial and demonstrations
Website	https://www.zotero.org/	https://www.literatureandlatte.com/scrivener/overview	https://www.transana.com/products/transana-basic/

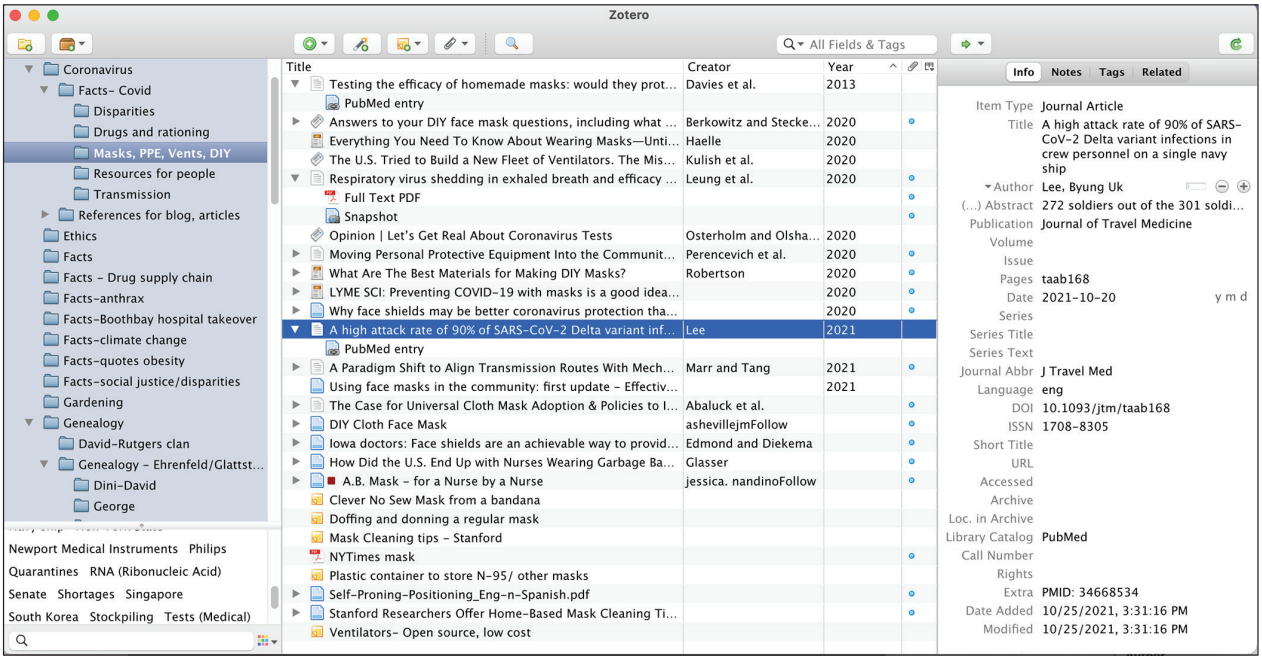

Figure 1. Screenshot of a Zotero file. On the left is the master folder, with nested folders and subfolders within it. Here, parts of my coronavirus and genealogy folders are shown, with keywords below. In the center are the individual articles and notes in a folder, downloaded via a Chrome extension. On the right is bibliographic data for the selected article. This can be exported into one's writing project.

readily use in a variety of medical articles (eg, details about specific infections that won't change a great deal over time).

Scrivener was a third software program that proved invaluable in organizing my information and drafts. First, I made a folder for each of the major family members ("characters"). Within each, I had subfolders for the following categories: childhood, prelude to war, the war years, liberation, coming to America, and later years. As I transcribed each interview tape (including timestamps), I dropped passages into the appropriate subfolder (Figure 2). Scrivener also made it so easy to annotate each bit of information as to its source. This was sometimes handy when people's memories diverged, but I felt it critical to have my sources verifiable in case I was ever challenged by any Holocaust deniers. My book was received with excellent editorial reviews and was adopted as a "First Year Read" by one college for its incoming students. I'm satisfied that I met my initial goal—my promise to my family that their stories would not be forgotten. I would still like to continue educating individuals about "othering," teaching tolerance, and about the Holocaust—messages that remain necessary now. The task of writing such a complex biography was more difficult than I had anticipated. It was a larger-than-expected undertaking because of the vast amount of details and information that had to be organized and annotated, gleaned from many hours of interviews.

In my medical writing, I have to gather and review scientific publications and news reports, dissect out and analyze the details, and then reframe the story for a specific type of audience. Two of the tools that I used in writing this biography—Zotero and Scrivener—have also served me well for years in my medical writing. They are very adaptable for an individual writer's needs as to the level of detail one wishes to organize, and Scrivener includes several formats to accommodate different writing styles. They have both helped me organize my writing and ensure the accuracy of its content. Scrivener has also helped me be more efficient in my writing. I hope you will find the same to be true for you.

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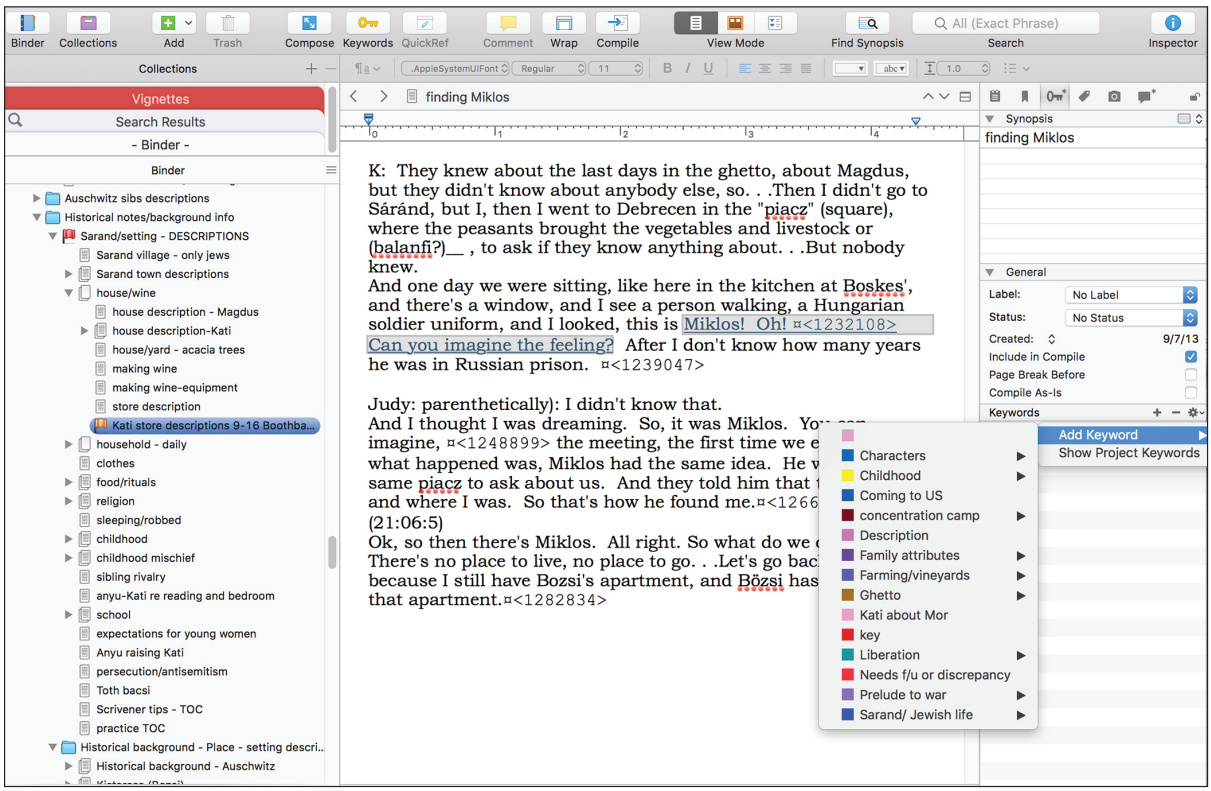

Figure 2. Screenshot of a Scrivener note. On the left, the Binder is the equivalent of a table of contents with nested folders. This shows some of the files for the historical background portion of the book. There were similar folders for each person and other major topics. In the center is a sample transcript relating to my aunt learning that her brother, Miklos, was still alive. The numbers in brackets refer to the Transana timestamps. The pop-out box in the center shows the subfolders I created within each family member's main folder, demonstrating the depth of organization that Scrivener provides. On the right the possibility of adding keywords is illustrated, among other options.

AMWA, EMWA, and ISMPP Promote Ethical, Professional Medical Writing in *JAMA Oncology* Letter to the Editor

Thomas M. Schindler, PhD[1] **and Gail V. Flores, PhD**[2]/ [1]Head Innovation Medical Writing, Boehringer Ingelheim Pharma GmbH & Co KG, Biberach, Germany; and [2]2020–2021 President, AMWA; Encore Biomedical Communications LLC, Encinitas, California.

In March 2021, Del Paggio et al. published an article in *JAMA Oncology* that included disparaging comments about medical writers. American Medical Writers Association (AMWA) leaders, in partnership with representatives from the European Medical Writers Association (EMWA) and the International Society for Medical Publication Professionals (ISMPP), immediately and swiftly drafted and submitted a letter of response to this article, which was published on August 26, 2021, along with 2 other letters and the authors' response to all 3 letters. Del Paggio et al.'s article reported on multiple aspects of randomized clinical trials in oncology, including the use of professional medical writers. Specifically, the authors stated, "There is reason to be concerned that medical writers may unduly influence the interpretation of trials, … as it is unlikely that medical writers have a neutral effect on the clinical trial reporting."[1]

Although we all share an understanding of the value of medical writers, it is imperative that we respond publicly to these attacks to safeguard the reputation of our profession. As highlighted in our letter, the use of our profession's expertise improves accuracy, timeliness, and adherence to ethical conduct. Evidence from independent research on the benefits of working with medical writers was included in the response. The commitment of medical writers to adhere to Good Publication Practice (GPP3) guidelines and to ethical principles in scientific publishing as well as to the professional codes of conduct of their professional organizations was also identified as a significant benefit of working with professional medical writers. Although the letter is behind a paywall, *JAMA Oncology* has granted the authors free access to the full text to share with our members; note that this link should not be shared outside of the AMWA membership.

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FROM THE PRESIDENT / INAUGURAL ADDRESS

The Evolving Face of Medical Communication

Katrina R. Burton, BS / 2021–2022 AMWA President

When I was first approached by Kathy Spiegel to serve on the American Medical Writers Association (AMWA) Board of Directors (BOD) and chair the inaugural Chapter Advisory Council, I had no idea that my path would one day lead me to serving as AMWA President. I am deeply humbled to accept the gavel that once graced the hands of such an esteemed succession of AMWA leaders.

Through the years, I've had an opportunity to witness my predecessors successfully lead AMWA through bylaws and governance changes; timely joint statements and responses to critical issues; legislation impacting medical communicators; organizational priorities; social justice awareness; and of course—a pandemic that changed the way we live, work, learn, and connect.

One thing I know for sure is that AMWA leaders are open-minded, resilient, and constantly evolving. It is with this knowledge that I confidently step into this role. With that said, I know that I am not alone. I have the support of the Executive Committee, BOD, committee chairs, work groups, councils, a plethora of volunteers, and an amazing and dedicated AMWA staff focused on AMWA priorities.

As I look back on where it started, I realize I've had to keep evolving to appreciate where it's going. The "it" is my career in medical communication that started at Texas A&M University many years ago. It was in College Station, Texas, where I realized my passion for writing was just as deep as my interest in medicine, science, and health. It came as no surprise to those who knew me when I switched my major from Pre-Medicine to Journalism.

Fast forward 14 years later, and I strategically aligned my career to have the best of both worlds. Once I settled on what I loved to do most—sharing impactful patient stories, writing about research, clinical trials, and patient support programs—I knew I needed to enhance my skill set. I searched online for the top medical communication organization to heighten my medical writing and editing skills. Lucky for me, I found AMWA! The AMWA Southwest Chapter welcomed me with open arms and wasted no time putting me to work. I've heard from other leaders that serving at the chapter level enhanced their experience with AMWA. I, like many others, credit AMWA for helping me evolve as a medical communicator and for providing me with the necessary tools and resources.

Merriam-Webster dictionary defines "evolve" as "changing or developing slowly often into a better, more complex, or more advanced state." What does that have to do with medical communication? Let me explain. History has shown us that everything changes; and I believe how we've evolved as a society through science, technology, and research has also had an impact on how we've evolved as medical communicators. Today, medical communicators are needed more than ever to communicate the science: clinical trial results, drug discoveries, and medical anomalies that can help everyone have a better quality of life.

The Upward Path of AMWA

Over the past couple of years, we've had an opportunity to experience AMWA's revamping of its educational content, development of new targeted resources and tools, and the launch of a variety of online learning programs. As we move into the new year, there is still more to come. The Education Committee and AMWA staff are working hard to enhance and grow the AMWA Certificate program, deliver relevant online programming, and develop education activities to support AMWA members.

When we think about the relevance of our role in the medical communication space, we must also keep the value of what we do top of mind as we educate others. That's why I am so proud of the work that is being done by AMWA's Value of Medical Writing Working Group. Established out of the important and ongoing work of AMWA's Medical Writing Executives Advisory Council, this work group is working toward defining and quantifying the value of medical writing. I am looking forward to seeing this group bear fruit for the organization.

As we buckle up for where we are going, we must also appreciate where we've been and celebrate the many successes that have led us here. One of the many benefits I've enjoyed as a member is the *AMWA Journal*. It's an excellent peer-reviewed publication that we've seen transform over the years. In January

2021, we welcomed our new Editor-in-Chief, Michael G. Baker, who has been working diligently with the AMWA staff and the *AMWA Journal* Editorial Board to transition the *Journal* to a digital publishing platform. With this new technology, we will have the capability to manage the *Journal*'s editorial workflow and deliver content online. I'm excited to see two new sections added to the *Journal*, one of which is entitled "Technology Talk." I also look forward to the implementation of a strategy to put fourth themed *Journal* issues that resonate with our members. "Digital Revolution" is the first of 4 themed *Journal* issues scheduled to publish on our new digital platform in Spring 2022.

As we evolve and transition to new platforms that will give us a better reach, we must also be inclusive. An organization is strengthened by its diversity, and we must bring to the table different perspectives, ideas, and values to build upon our organizational growth. As you know, medical communicators come from a variety of different backgrounds, work settings, and specialties within the medical field. For example, I am a medical communicator in the public relations field focused on pediatric oncology. No matter what our differences are, as medical communicators we have one common goal—to communicate the science to all. That means being inclusive and seizing on opportunities to diversify our skills, audience, content, and membership. With that in mind, I am pleased to share that a new task force—the AMWA Diversity & Inclusion Assessment Task Force—was formed to identify how AMWA can foster a more diverse and inclusive environment within the association. The search for task force members, and more information on how you can support this initiative, is underway.

As we continue on this incredible journey as medical communicators, I will continue to keep our priorities at the forefront of everything we do. AMWA's most important asset is our members. We value our members, and the priorities we set are established to ensure continued growth and to give our members the best experience. As we embrace technology, inclusivity, and expand upon new ways to grow the organization, I hope you will engage, connect, volunteer, share, mentor, educate, and invite others to experience and evolve with AMWA!

Reference

1. Evolve. Merriam-Webster. Updated 2021. Accessed December 10, 2021. https://www.merriam-webster.com/dictionary/evolve

Introducing the 2021–2022 Board of Directors

Katrina R. Burton, BS / 2021–2022 AMWA President

The American Medical Writers Association (AMWA) Board of Directors (BOD) is an integral part of the organization, and as stated by Article III in the AMWA Bylaws, manages and controls the affairs, property, and business of AMWA. The BOD meets consistently throughout the year as an organized body to discuss and take action on items as they pertain to the organization. The BOD is responsible for approving the budget, committees, work groups, task forces, and the slate of nominees for elected office.

The BOD has the right to empower the Executive Committee consisting of the President, President-Elect, Immediate Past President, Secretary, and Treasurer to act in between full BOD Meetings.

In alignment with AMWA Bylaws, the BOD shall include elected Officers, an Executive Director, a Chair of the Chapter Advisory Council, and at least 5 appointed At-Large Directors. The number of members on the BOD during the board year shall be no less than 12 and no more than 17.

The full scope of the BOD's responsibilities can be found in Article III of the *Bylaws of the American Medical Writers Association*.

It is with great pleasure that I announce the AMWA 2021-2022 At-Large Directors, approved by the BOD at the September 2021 meeting.

- Joan Affleck, MBA, ELS
- Brian Bass, MWC
- Loretta Bohn, BA, ELS
- Sarah Dobney, MPH
- Kimberly Korwek, PhD
- Lynne Munno, MA, MS
- JoAnna Pendergrass, DVM
- Laura Sheppard, MBA, MA
- Shawn Watson, PharmD, PhD, BCPS
- Ann Winter-Vann, PhD

The BOD also approved the Chair of the Chapter Advisory Council (a voting member of the BOD):

- Jennifer Minarcik, MS

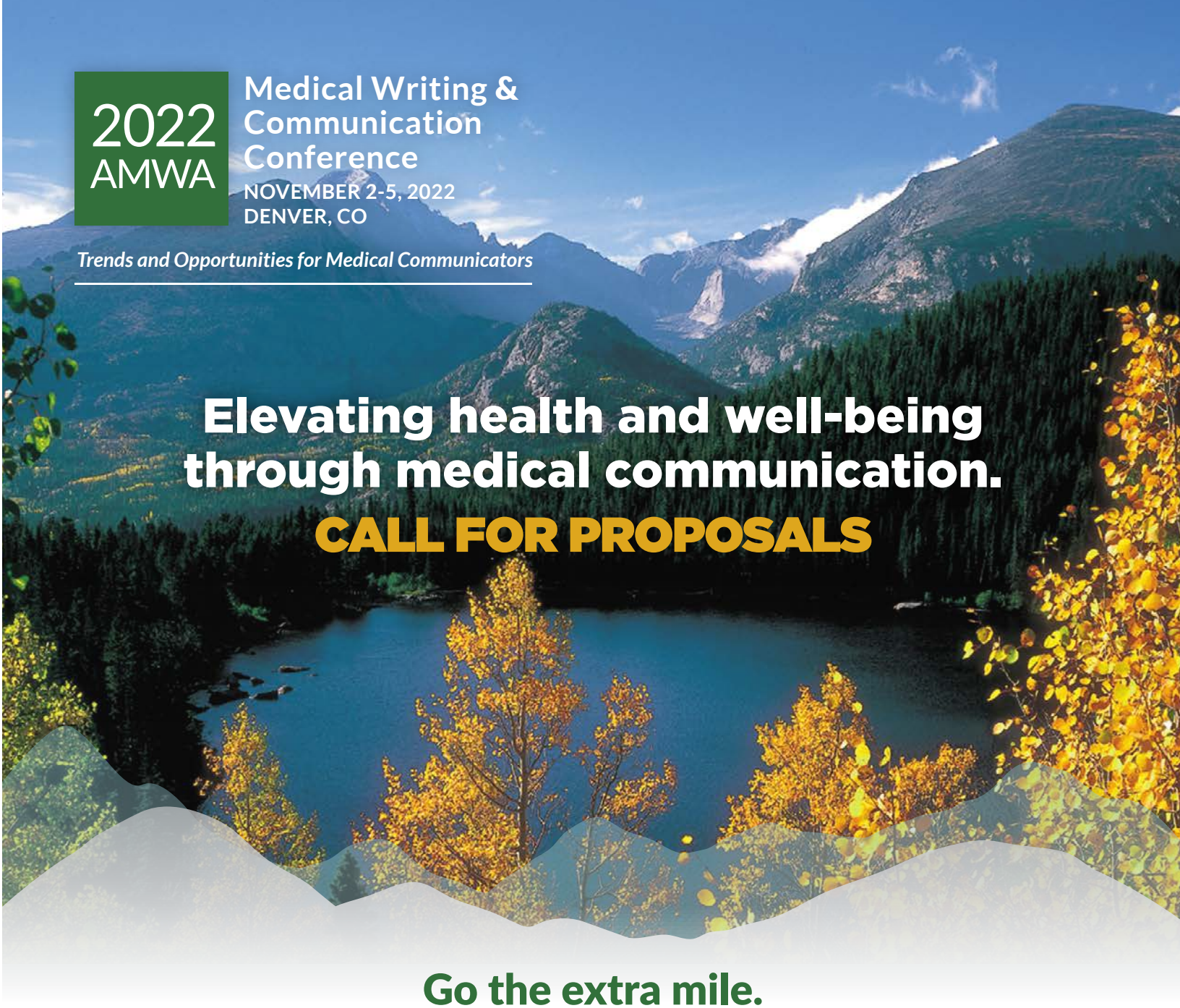
AMWA 2021-2022 Officers:

- President: Katrina R. Burton, BS
- President-Elect: Elise Eller, PhD
- Secretary: R. Michelle Sauer Gehring, PhD, ELS
- Treasurer: Julie Phelan, MD, MBA
- Immediate Past President: Gail V. Flores, PhD

AMWA Executive Director:
Susan Krug, MS, CAE serves as an ex officio member of the BOD (nonvoting member).

The 2021-2022 BOD began its service on November 12, 2021, at the conclusion of the 2021 Annual Business Meeting.

The above images were captured during the virtual Board of Directors meeting on November 5, 2021.



2022 AMWA

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- Preparing the next generation of medical writers and leaders
- Progress and developments in scientific publications
- Technology and innovation in medical communication
- The medical communicator's role in diversity, equity, and inclusion

Find submission resources at:
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