AMERICAN MEDICAL WRITERS ASSOCIATION
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AMWA JOURNAL

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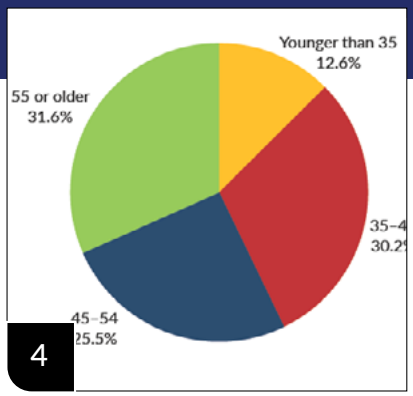

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In support of the mission of the American Medical Writers Association (AMWA) and to advance the broader profession, the *AMWA Journal* publishes content that reflects the interests, concerns, and expertise of medical communicators. Its purpose is to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

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FROM THE EDITOR

Michael G. Baker, PhD
Editor-in-Chief

AMWA, like numerous organizations sensitive to the needs of its members, has embarked on an initiative to explore internal diversity, equity, and inclusion (DEI). In this issue, we describe AMWA's commitment to DEI through an initiative including the formation of a Diversity & Inclusion Assessment Task Force. We also examine the makeup of our members via a summary of our most recent prior member survey in a piece titled "AMWA: Who We Are." A new survey of AMWA members, the 2022 DEI Survey, has been distributed, and we encourage you to complete it soon if you haven't already. Results from this survey will be analyzed by the Diversity & Inclusion Task Force and thus will inform upcoming DEI efforts. Additionally, in this issue we have DEI-related pieces on embracing accessibility and avoiding bias in accredited continuing education.

In a future issue, we will return to the topic of DEI to evaluate what we have learned and the enhancements to the organization that have come from AMWA's important initiative.

Yours in medical communication excellence,
Michael

An Update from the AMWA Diversity and Inclusion Assessment Task Force

Gail V. Flores, PhD / AMWA Diversity and Inclusion Assessment Task Force Chair

In November 2021, the AMWA Board of Directors approved the creation of a Diversity and Inclusion (D&I) Assessment Task Force. The charge of the task force is to analyze membership data and receive member input to help determine the current status of the organization's D&I; identify deficiencies, needs, opportunities, and challenges related to D&I; and recommend initial strategies to enhance D&I efforts within the organization.

The response to a call for volunteers in January and February of 2022 was positive, and several AMWA members expressed their interest in serving on the task force. Task force members were selected with consideration of their diverse perspectives, backgrounds, and experience with D&I initiatives. The task force first met virtually in March, and developed a Diversity, Equity, and Inclusion (DEI) survey that launched in August. The goal of the survey is for AMWA to gain an understanding of who our members are and what our members need with respect to DEI within the organization and in their professional lives.

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FEATURE

AMWA: Who We Are

Elizabeth Kukielka, PharmD, MS, MWC / Senior Medical Writer, CiTRUS Health Group, Philadelphia, PA

ABSTRACT

Medical communicators are professionals with a knowledge of both medicine and writing who are able to deliver complex scientific information to a variety of audiences. As the leading professional organization for medical communicators with a membership of nearly 5,000, the American Medical Writers Association (AMWA) is well-situated to tap into their member network to better understand the diverse backgrounds and experience of medical communicators. In this article, AMWA presents the demographic data (eg, age, gender, education, and work experience) received from the Medical Communication Compensation Survey to create a snapshot of the medical writing community. AMWA emailed the most recent Web-based survey to medical writers and editors during the first quarter of 2019. Overall, 7,456 individuals received the survey, and 1,418 respondents completed the survey. About two-thirds (66.1%) of the respondents were employed by a company, similar to the 2015 survey (65.1%), whereas the remaining one-third were freelancers. Most respondents were female (83.4%), and the average age of all respondents was about 48 years. The average time spent working for pay as a medical communicator for all respondents was 12 years. Most respondents held a doctoral-level degree (46%) or a master's degree (32%) as their highest level of education. Nearly half of all respondents had their highest degree in the field of science (47.2%), whereas 9% had their highest degree in English. A key takeaway from the survey is that medical communicators are a highly educated group of professionals, indicating a commitment to continuous learning. AMWA members are encouraged to keep their member profiles up to date to provide additional demographic information to support AMWA's mission of promoting excellence in medical communication and providing educational resources in support of that goal.

Medical communicators are professionals with a knowledge of both medicine and writing who are able to deliver complex scientific information to a variety of audiences, such as health care providers, patients and their caregivers, industry professionals, and public policy officials. Individuals working in the field of medical communication may have such titles as medical editor, medical writer, scientific writer, technical writer, regulatory writer, promotional writer, and health care journalist, among many others. Medical communicators are responsible for the development of materials in formats ranging from print publications to digital media, and some examples of their work include abstracts and posters for scientific conferences, grant proposals, health education materials, science textbooks, continuing education materials for health care professionals, sales training materials for pharmaceutical or medical device representatives, and regulatory documents for submission to health agencies.

As the leading professional organization for medical communicators in the United States and worldwide with a membership of nearly 5,000, the American Medical Writers Association (AMWA) is well-situated to tap into their member network to better understand the diverse backgrounds and experience of medical communicators. One valuable information source is the Medical Communication Compensation Survey conducted periodically by AMWA. This survey provides dependable salary information upon which employers and employees in the field of medical communication can base their salary negotiations. In addition to details about compensation, the survey also collects a wealth of demographic data from respondents, including age, gender, education, and work experience. In the following pages, AMWA presents the demographic data received from the survey to create a snapshot of the medical writing community.

METHODS

AMWA has been conducting periodic compensation surveys since 1989, and the most recent survey was deployed

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to medical writers and editors during the first quarter of 2019. The purpose of the survey was to determine prevailing annual income and fee levels and to study different factors affecting pay (eg, years of experience, education, certification, employer type, type of work, and position level), based on the results of previous surveys. A Web-based survey was emailed to 7,456 individuals (3,835 AMWA members and 3,621 nonmembers). Nonmembers included lapsed AMWA members as well as individuals who were never AMWA members. Among those, 271 people requested to be removed from the survey panel and 55 emails were returned, bringing the revised total number of respondents to 7,130. The survey included a question about whether people had worked for pay as a medical communicator during 2018 so that individuals who did not work in the field within the time window of interest could be excluded.

RESULTS

Overall, 1,418 individuals completed the survey, yielding a response rate of 20% and showing an increase in participation from the 2 previous surveys deployed in 2011 and 2015 (Table 1). More than four-fifths of respondents (81.3%)

Table 1. Demographics at a Glance for All Respondents, 2007–2019

	All Respondents' Demographics: 2007-2019			
	2007	2011	2015	2019
Number of Respondents				
All Respondents	1704	1193	1292	1418
Employee	1183	819	841	938
Freelance	521	374	451	480
Employee/Freelance	--	--	104	109
Gender				
Female	83%	84%	85%	83%
Male	17%	16%	15%	16%
Prefer not to answer	--	--	--	1%
Age (mean)				
All Employee	44	45	45	46
Freelance Only	48	50	50	52
% Years of Medical Writing Experience				
<2	14%	11%	8%	7%
2-5	20%	20%	25%	26%
6-10	28%	25%	25%	19%
>10	38%	43%	42%	49%
Years of Medical Writing Experience (mean)				
All Employee	9	11	11	11
Freelance Only	13	15	17	15
% Highest Level of Education				
Bachelor's	36%	28%	21%	21%
Master's	34%	34%	32%	32%
Advanced Degree	30%	38%	40%	46%
% Field of Highest Degree				
Science includes biology, medical technology, health sciences, and nutrition	40%	44%	50%	47%
English	--	--	9%	9%
Medicine	4%	4%	5%	5%
Pharmacy	5%	5%	4%	5%
Journalism	5%	5%	4%	4%
Communications	4%	4%	4%	3%
Liberal Arts	11%	11%	4%	3%
Medical Writing	--	--	4%	2%

reported that they were AMWA members. About two-thirds (66.1%) of the respondents were employed by a company, similar to the 2015 survey (65.1%), whereas the remaining one-third were freelancers (Table 2). When asked to describe their employer, 19.4% of all employee respondents indicated they had worked for a pharmaceutical company, 14.4% had worked for a medical communication company, and 13.8% had worked for a clinical or contract research organization. Most employee respondents indicated that the main area in which they had worked was regulatory writing (40.8%) or scientific publication (24.8%).

Table 2. Type of Employment, 2015 and 2019

	Survey Participants: 2015 & 2019			
	2019		2015	
Employees	938	*66.1%*	841	*65.1%*
Freelance	480	*33.9%*	451	*34.9%*
Freelance Employees	109	*11.6%*	104	*13.8%*

Most respondents were female (83.4%) (Table 1). The average age of all respondents was about 48 years. The average age for employees was 46 years, whereas for freelancers it was 52 years. More than half of respondents were 45 years or older, and only 12.6% were younger than 35 years (Figure 1).

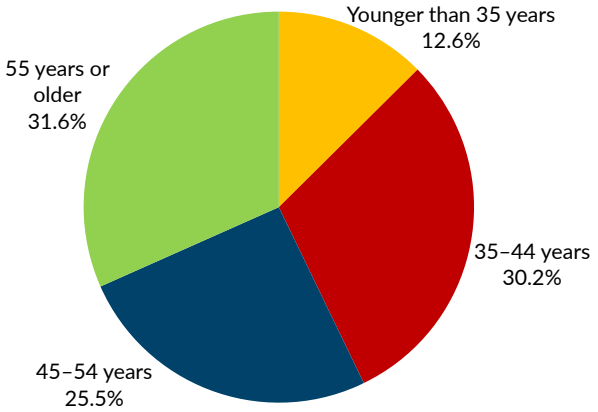

Figure 1. Age of all respondents, 2019. n= 1,394. *Source: AMWA 2019 Compensation Survey.*

The average time spent working for pay as a medical communicator for all respondents was 12 years. Nearly half (48.9%) of all respondents had greater than 10 years of experience as a paid medical communicator (Figure 2), with an average of 12.4 years. Employees averaged 10.9 years of experience, whereas freelancers averaged 15.4 years.

Most respondents held a doctoral-level degree (46%), such as a PhD, MD, or PharmD, or a master's degree (32%)

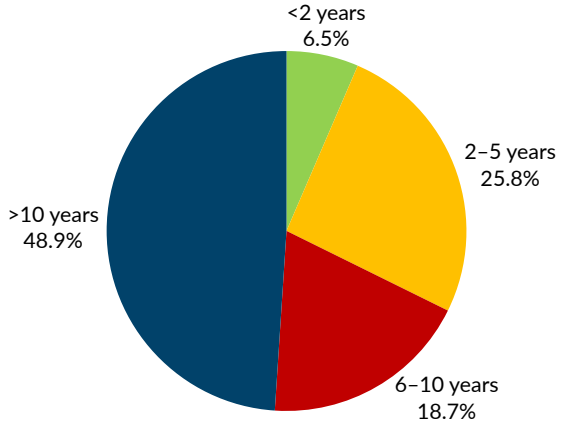

Figure 2. Years of experience as a medical communicator for all respondents, 2019. n= 1,414. *Source: AMWA 2019 Compensation Survey.*

as their highest level of education (Figure 3). These percentages were similar between employees and freelancers. Nearly half of all respondents had their highest degree in the field of science (47.2%), which included biology, chemistry, medical technology, health sciences, and nutrition, whereas 9% had their highest degree in in English; these proportions were similar to those observed in the 2015 survey. Employees (50.4%) more often had their highest degree in science than freelancers (41 %) (Table 3 on next page).

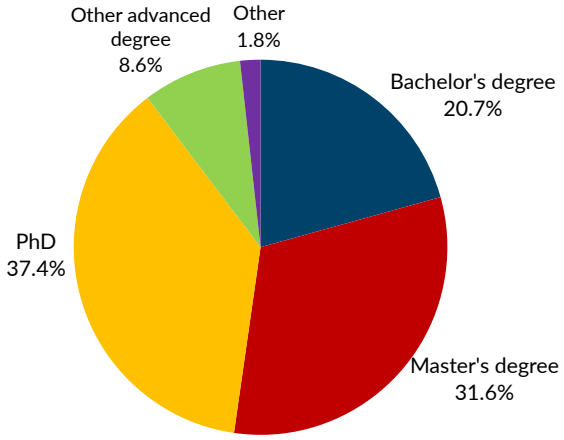

Figure 3. Highest level of education for all respondents, 2019. n= 1,415. *Source: AMWA 2019 Compensation Survey.*

Overall, about one-fifth of respondents (22.6%) held the AMWA Essential Skills certificate. Among all respondents, the certificate was held for an average of 8.6 years. Freelance respondents (10.4 years) held the certificate longer on average than employees (7.6 years). When asked about certifications, 41.1% of respondents reported they held the Editor in the Life Sciences (ELS) certification, 17.2% held the Certified Medical Publication Professional certification, 11.7% held the Medical Writer Certified

certification, and one-third of respondents held other certifications (Figure 4). The ELS was held most often by those having a bachelor's degree as their highest degree (51.5%).

More than two-fifths of respondents (44.1%) had worked in regulatory writing in the pharmaceutical, biotechnology, or device industry during their career. Of those who worked in regulatory writing, 77.7% had written clinical study reports (CSRs), 74.4% had written study protocols, 64.7% had written investigator brochures, 63.5% had written regulatory responses or briefing documents, and 60.0% had written summary documents for supplemental drug submissions during their career (Figure 5). On average, a medical communicator who had worked in regulatory writing had written 32.8 nonclinical/discovery and chemistry, manufacturing, and controls (CMC) documents, 28.3 CSRs, and 28.3 study protocols during their career. On average, freelance respondents had written more CSRs, study protocols, investigator brochures, and summary documents for drug submissions in their careers than their employee counterparts, whereas employees had written more nonclinical/discovery and CMC documents and aggregate reports than freelance respondents.

Table 3. Field of Highest Degree, 2019

	All Respondents Fields of Highest Degree: 2019		
	All Respondents (1,418)	Employee (938)	Freelance (480)
Business	2.2%	2.0%	2.5%
Communication	3.0%	3.2%	2.5%
Education	1.2%	1.2%	1.3%
English	9.0%	9.6%	7.9%
Health care administration	0.5%	0.6%	0.2%
Journalism	3.5%	3.4%	3.8%
Liberal arts	2.9%	3.0%	2.7%
Medical writing	2.1%	1.9%	2.5%
Medicine	5.3%	3.8%	8.1%
Nursing	1.6%	1.0%	2.7%
Pharmacy	5.3%	4.4%	7.1%
Public health	3.5%	3.6%	3.1%
Science Includes biology, chemistry, health science, medical technology, and nutrition	47.2%	50.4%	41.0%
Technical writing	1.8%	1.5%	2.3%
Other	11.0%	10.3%	12.3%

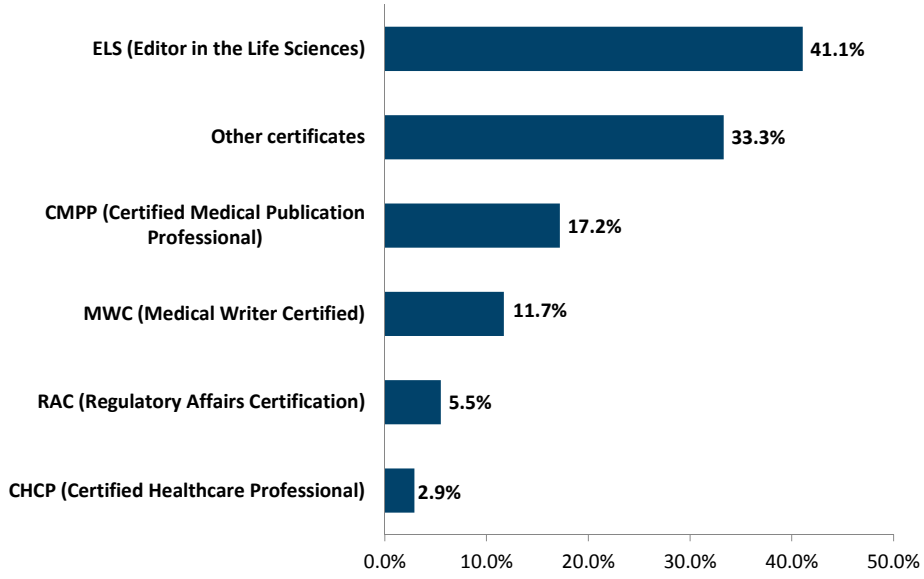

Figure 4. Certifications for all respondents, 2019. n= 384. *Source: AMWA 2019 Compensation Survey.*

CONCLUSIONS

One key takeaway from AMWA's Medical Communication Compensation Survey is that medical communicators are a highly educated group of professionals, with nearly half of respondents reporting that they have an advanced degree. The high level of education among AMWA members and other medical communicators indicates a commitment to continuous learning. A new content strategy plan was developed following the 2019 survey with goals that included aligning AMWA's educational offerings with the needs of the membership and fulfilling AMWA's mission. In developing the content strategy, AMWA relied on data from the compensation survey, other surveys of the membership, and other data sources. One critical data source is the demographic information collected through AMWA member profiles, such as gender, race, highest level of education, primary workplace, and areas of professional focus. These online profiles may be accessed by members

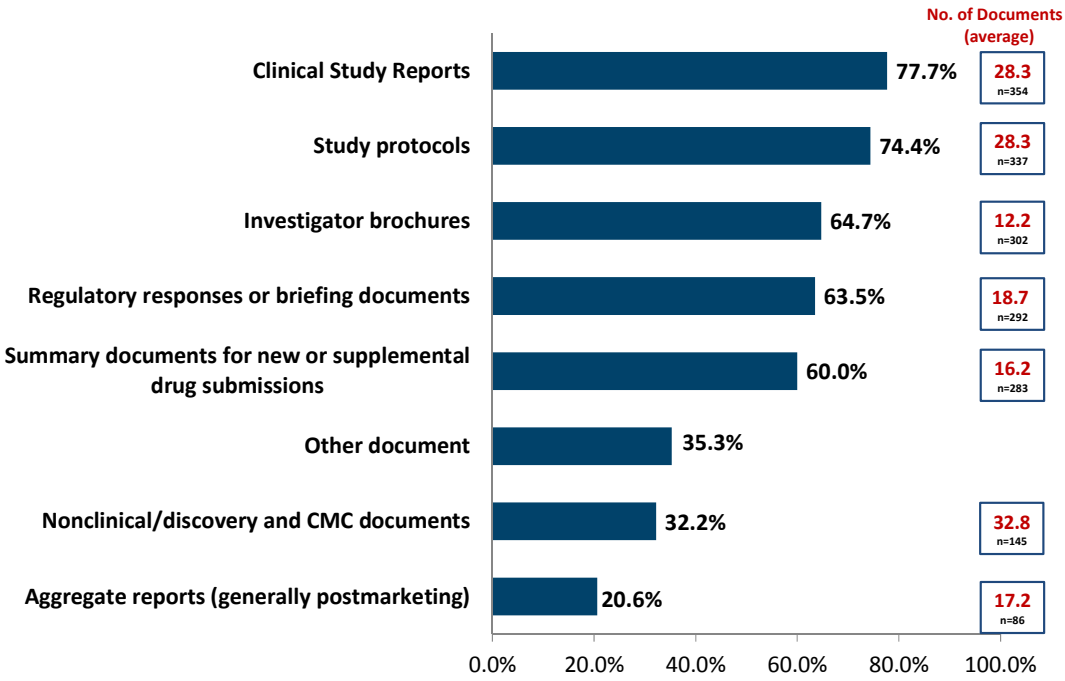

Figure 5. Documents authored during career for all respondents who had worked in regulatory writing, 2019 (check all that apply). n= 583. CMC=chemistry, manufacturing, and controls. *Source: AMWA 2019 Compensation Survey.*

at any time by logging into the AMWA website. By keeping member profiles up to date, members can support AMWA's mission of promoting excellence in medical communication and providing educational resources in support of that goal.

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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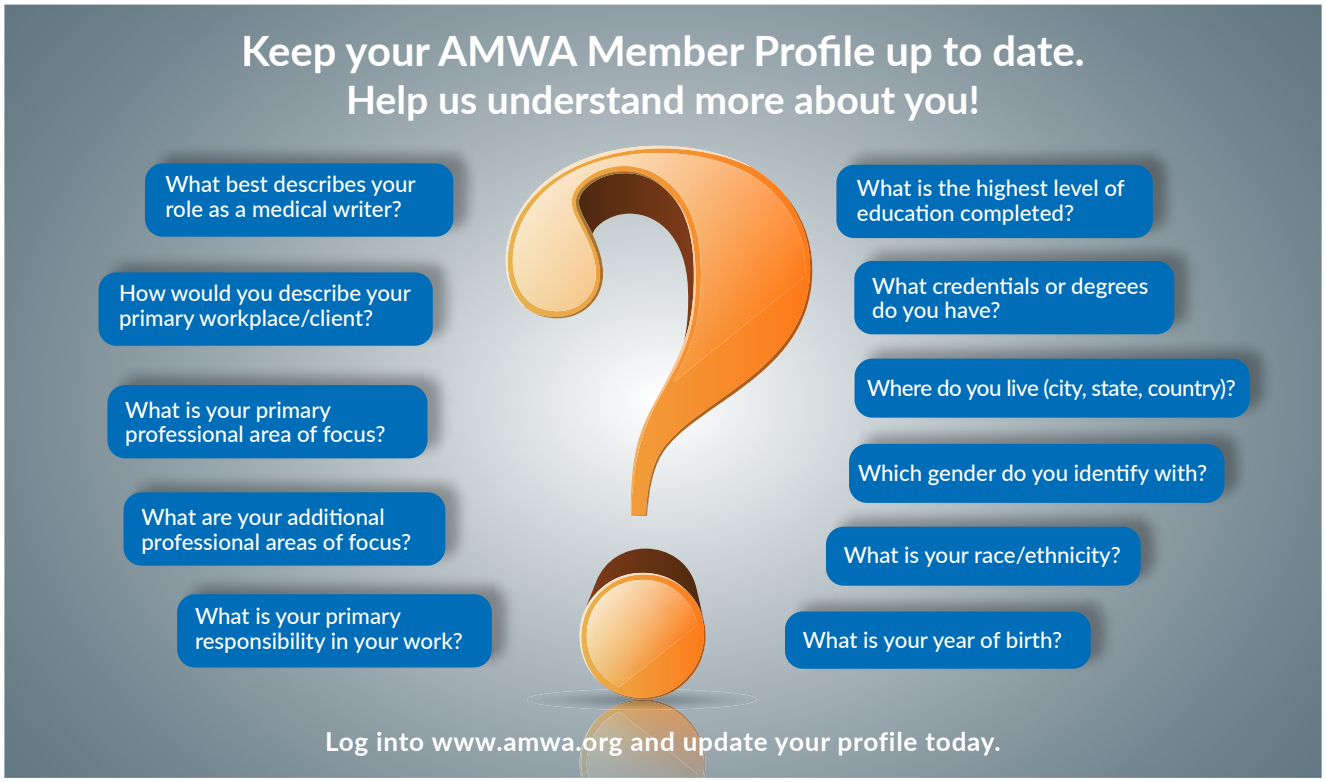

FREELANCE FOCUS


Sherri Bowen


Phyllis Minick

Jam Session for Seasoned Freelancers—Part 2

Brian Bass, with commentary from Cathryn D. Evans, Phyllis Minick, and Sherri Bowen

Last month in the *AMWA Journal*, you may have read the first installment of the review of the popular annual conference session, the Jam Session for Seasoned Freelancers. Here we summarize and discuss the experiences, ideas, concerns, and challenges faced by seasoned freelancers that there wasn't space for in last month's issue. If you missed last month's article, we reviewed managing stress; email, travel, and security issues; and sculpting your business. Here, we discuss doing business with friends, referring clients, legal battles, and one of the costs of doing business.

* * *

THE FRIEND ZONE

When a seasoned freelancer finds themselves working with a friend and an issue or a concern arises, the best thing to do is leverage the friendship to be honest and transparent—something you might not be able to do if the person were not a friend. Explain what isn't working and why and ask for help to make it work better. Be proactive and act quickly so the issue doesn't fester. Problems are much easier to resolve when they're small.

Tips From Seasoned Freelancers

It is my view that, when working with one of your personal friends, the reporting structure should be *quite clear.* [In fact, whether working with a friend or colleague—freelance or as an employee—the reporting structure always should be crystal clear. There is no such thing as a "lateral hierarchy."] When I hire a friend, I expect them to follow my direction; if they have opinions that differ, I definitely wish to hear them and often have changed something based on input from others who work with/for me. But my vote is the final vote if the person has been hired by me. If a person is truly a close personal friend (outside of any business relationship), then I expect that we would be able to speak together honestly and try to compromise. However, if actual *friction* occurs and it seems impossible to resolve, then decide whether you want to keep the friend or the project/client—and eliminate one of them.

—Cathryn D. Evans

At an AMWA national conference in San Diego several years ago, I encountered a young woman who had been in a workshop with me, and we chatted about issues raised by the speakers. Of course, the matter of "getting started" as a medical writer arose. Numerous workshop attendees had complained about related difficulties and obstacles. Engaging with the 50 or so eager faces surrounding me, I felt obliged to say, "In this room, I see and hear individuals who are educated, energetic, and eager. I can't help but say, have faith in yourself! Never stop trying. Back away from any failed attempts. Focus on your eagerness for new opportunities. Seek new options."

Subsequently, that young woman took a new job. The pay was terrible, and the working conditions were worse. But she has kept in touch with me and has recalibrated to a different job. She is still a "work in progress, " but she continues to correspond with me and actually has improved her working life. Each of us has gained a new friend!

—Phyllis Minick

* * *

MATCHMAKING

Some seasoned freelancers manage their workloads by referring clients when they're either not the right person for the job or already committed to another assignment. When you're ready to make an introduction, first contact each person involved to make sure they're aware and on board. Then, send an email to both the client and the person you're referring to them. Introduce them to each other and say something relevant and complimentary about each of them. End the introduction by wishing them both well and

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reminding the client that you look forward to working with them when the next opportunity arises. Some seasoned freelancers make so many referrals that they keep a spreadsheet of who they refer and to whom.

Tips From a Seasoned Freelancer

If I am unable to take on a particular project for a prospective new client because of my schedule, I will give the person the name and contact information (email and telephone number) of a qualified colleague who might be able to fit the project into their schedule. I will recommend the person based on my personal experience working with them. If this exchange is by telephone, I will follow up with an email to the person I recommended with the name and email of the new client. If a long-term good client needs something and it is nearly impossible to fit it into my schedule, I will try to *make it possible* to fit it in, even if it means working nights, etc. I have referred a number of such new clients to other writers but have not followed up to see if the connection worked out; some writers do email and thank me.

—Cathryn D. Evans

* * *

LINGERING LEGAL BATTLES

It has been a few years since California enacted AB5 and threatened the livelihoods of freelancers everywhere. Since then, the COVID-19 pandemic has taken center stage, but seasoned freelancers know they need to remain vigilant and vocal and do everything possible to show that their freelance business is a real business. This includes establishing your freelance business as a recognized business entity, such as an LLC or S-Corp, and describing your freelance business as a vendor rather than as a contractor.

Tips From a Seasoned Freelancer

Years ago, a member of this Freelance Contributors Group advised all of us to insert in each of our work contracts a "hold harmless" clause. She cited a coworker who had written medication instructions for a pharmaceutical company's package insert. A patient sued that company, and the writer was also sued. I later included a similar hold harmless clause in my contract as a freelance writer with a major pharm company. The company agreed to my contract without question. Anyone accepting this suggestion should have an attorney write that clause for their personal situation.

—Phyllis Minick

* * *

THE COST OF DOING BUSINESS

Seasoned freelancers have noticed an increasing number of clients requiring their vendors to participate in standard operating procedure (SOP) training, sensitivity training, and other similar programs. Should you charge for your time? You bet! Employees of the company are required to go through the same training and their salaries are not docked for the time, so freelancers should not be financially penalized either. When a client asks you to participate in an internal training program, simply ask them how they want you to invoice for it. If they balk about compensating you for your time, consider it a red flag.

Tips From Seasoned Freelancers

Of course the freelance writer/editor should charge for any time required to study a new client's SOPs and other training material! It should not even be a question. But if you are not sure, just tell the client, "Okay, I will charge this time at my normal hourly rate of $XXX and invoice you once I complete the training." Especially if the project you are about to undertake is based on a *fixed-fee bid*, you should communicate that all extra activities not associated with the specific project, as outlined in your contract, will be charged hourly—just to be certain that the client does not think your training is part of the project bid.

—Cathryn D. Evans

Absolutely, you should charge for this kind of training time! In fact, all your time spent on behalf of a client's business—whether it be training or even time with the IT staff to fix issues with your client-issued laptop computer—should be billed at your regular hourly rate. I have never had a client balk about compensating me for training time, especially since it's their requirement that I complete such training. I have also never asked ahead of time how they want training time to appear on an invoice. I just include a line item for training (and a separate one for "IT issues," when necessary) on my invoices. I do recommend printing or saving a copy of any type of confirmation of your completed trainings. Some companies record your training module compliance automatically in their internal system, but it's a good idea to keep a copy for yourself, just in case of any future disputes.

—Sherri Bowen

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CE CRAFT CORNER

Avoiding Bias and Ensuring Content Validity in Accredited Continuing Education: What Do the Latest ACCME Standards Mean for Medical Writers?

Andrew D. Bowser, ELS, CHCP / IconCME, Philadelphia, PA

ABSTRACT

Some continuing medical education (CME) activities are developed using financial support from entities such as pharmaceutical companies that may have a commercial interest in the therapeutic area being discussed. Accordingly, standards intended to shield CME from industry bias have been in place for decades. The latest iteration of these standards from the Accreditation Council for Continuing Medical Education (ACCME) has a special significance to medical writers due to their emphasis on clinical content validity. Once a separate entity, the content validity requirement is now incorporated into the ACCME standards. In fact, it is positioned as the number 1 standard, emphasizing its importance. It should be relatively straightforward for writers to support the goals of the guidance—that is, to provide relevant and scientifically accurate content that is free from industry manipulation or influence. However, the standards as published are not prescriptive in how to achieve these goals, leaving writers to ponder exactly what it means to be "fair and balanced." This article provides background on the ACCME standards with a special emphasis on their relevance to CME writers, describes helpful downloadable resources for writers, discusses some scenarios that medical writers may encounter, and provides practical advice in interpreting and applying the current standards when developing content for CME activities.

Medical writers are instrumental in the development of continuing medical education (CME) content. The key opinion leaders and expert faculty members may get premier placement on the marquee, but it is often the medical writer (staff or freelancer) generating the manuscript text, PowerPoint slides, clinical multiple-choice questions, interactive patient cases, animation storyboards, video and podcast scripts, and other scientific content that helps drive improvements in clinician knowledge, competence, and performance.

These CME writing assignments are often rigid and flexible at the same time. Medical writers may be asked to stay within the guardrails of preexisting learning objectives and content outlines, and their work is typically subject to multiple reviews by faculty experts, peer reviewers, and CME providers. Even so, writers often find themselves in the position of making high-level decisions regarding content direction, often entirely on their own, or with a minimum of guidance.

The nature of CME content decisions that medical writers tackle independently can vary widely. One day, it's selecting citable peer-reviewed sources for a PDF monograph on best practices in diabetes management. The next day, it's describing the complexities of therapeutic selection in a PowerPoint deck on relapsed/refractory multiple myeloma—a disease state in which (at last count) there were 30 reasonable multidrug regimens to choose from, depending on the number and type of previous treatments given.[1]

This task of content decision making becomes even more challenging when writers consider the potential for bias in the materials they are developing. Many CME-related writing assignments are to provide content for activities that are supported—that is to say, developed using a financial grant from a company or companies that likely have a commercial interest in the therapeutic area. Thus, direct industry support for an activity is a potential source of bias (although not the only source, eg, faculty may have their own conflicts of interest that need to be resolved).

Although data from the Accreditation Council for Continuing Medical Education (ACCME) indicate that the vast majority of accredited educational activities (upwards of 90%) receive no commercial support at all, the total sum of grant funding is nevertheless large. Accredited providers have reported more than $700 million per year in commercial support since 2016 with a grand total of nearly $723 million in 2020, the most recent year for which this statistic is available.[2]

With those kinds of numbers in mind, medical writers have a considerable responsibility to help ensure that supported CME content is scientifically sound and devoid of industry manipulation or influence. Toward that end, standards have been promulgated by the ACCME, the nonprofit

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that accredits organizations that offer CME and recognizes state medical societies as accreditors of local CME programs.

NAVIGATING COMMERCIAL INTERESTS

The first set of ACCME standards intended to guide the CME-industry relationship was released in 1992, and in 2004, more stringent standards were put in place to ensure the independence of CME activities, particularly with regard to conflict of interest. The latest iteration, "Standards for Integrity and Independence in Accredited Continuing Education,"[3] was released in December 2020 and has been adopted by 7 additional accrediting bodies across multiple health professions. As of January 1, 2022, all providers in the ACCME system are expected to comply with the new standards.

Medical writers should take note of how content validity is central to the new ACCME standards (Table 1). In a Viewpoint published in *JAMA*, ACCME President Graham McMahon, MD, MMSc, explained that content validity requirements had been part of ACCME policy for many years, but separately from the standards. Now, McMahon said, content validity is included as the very first standard, which was intentionally done to emphasize its significance: "With the proliferation of medical misinformation and disinformation, as well as questions about the validity of science, issues related to content validity are more important than ever."[4]

In a nutshell, the expectations for content validity are as follows:

- Recommendations for patient care have to be based on current scientific evidence and clinical reasoning while providing a fair and balanced view of options for diagnosis and treatment.
- Any scientific research used to support or justify a patient care recommendation has to conform to generally accepted standards for study design, data collection methods, analysis, and interpretation.
- Although discussion and debate are appropriate, the education can't advocate or promote practices that are not firmly based on current scientific evidence and clinical reasoning.
- On a related note, the education cannot advocate for unscientific approaches or medical practices that are known to be ineffective, or have risks that outweigh the benefits.

APPLYING THE ACCME STANDARDS

Those requirements may sound straightforward on paper, but they are sometimes challenging to apply in actual day-to-day medical writing practice. The ACCME does offer some helpful general advice on best practices (Table 2) along with a helpful peer review checklist available for download. For example, multiple perspectives can be

Table 1. New ACCME Standards for Integrity and Independence in Accredited Continuing Education

Standard	Applicability	Accredited Provider Responsibility
1. Ensure Content is Valid	All accredited CE	Ensure that education is fair and balanced, and that any clinical content presented supports safe, effective patient care
2. Prevent Commercial Bias and Marketing in Accredited CE	All accredited CE	Protect learners from commercial bias and marketing in accredited CE
3. Identify, Mitigate, and Disclose Relevant Financial Relationships	All accredited CE	Identify relevant financial relationships between individuals in control of educational content and ineligible companiesa and managing these to ensure they do not introduce commercial bias
4. Manage Commercial Support Appropriately	Accredited CE that receives financial or in-kind support from ineligible companies	Ensure that the education remains independent of the ineligible company and that the support does not result in commercial bias or commercial influence
5. Manage Ancillary Activities Offered in Conjunction With Accredited CE	When there is marketing by ineligible companies or nonaccredited education associated with the accredited CE	Ensure that education is separate from marketing by ineligible companiesb and from nonaccredited education offered in conjunction with accredited continuing education

CE, continuing education.

[a]*An ineligible company is a company ineligible to be accredited in the ACCME system; their primary business is producing, marketing, selling, re-selling, or distributing health care products used by or on patients.*

[b]*Includes advertising, sales, exhibits, and promotion.*

Adapted from Standards for Integrity and Independence in Accredited Continuing Education. Copyright 2020 by the ACCME.

Table 2. New ACCME Standards for Integrity and Independence in Accredited Continuing Education

Focus Area	Recommendation
Level of Evidence	Clearly describe the level of evidence on which the presentation is based and provide enough information about data (study dates, design, etc.) to enable learners to assess research validity
Sources	Ensure that, if there is a range of evidence, that the credible sources cited present a balanced view of the evidence
Recommendations	If clinical recommendations will be made, include balanced information on all available therapeutic options
Risks and Adverse Effects	Address any potential risks or adverse effects that could be caused with any clinical recommendations
Evidence Base	If the evidence base is low (or absent) for a topic or treatment, consider alternate strategies, eg, a debate or dialogue between multiple faculty representing a range of opinions and perspectives

Adapted from the Toolkit for the Standards for Integrity and Independence in Accredited Continuing Education. Copyright 2020 by the ACCME.

provided to address a clinical question in which there is considerable debate (eg, "should routine colorectal cancer screening begin at age 45?").[5]

However, many questions remain that are not necessarily covered in detail in formal guidance. For example,

- If one treatment is discussed in detail, does that mean others need equal coverage in order to be fair and balanced?
- What if there is only 1 relevant treatment for a specific disease state covered in the education?
- Is it strictly forbidden to use brand names for drugs? And if so, what do I do when the use of generic descriptors is overly complicated or confusing?
- Can I cite a company press release? And if not, how do I properly cite research that apparently hasn't been published or presented yet?

I consulted several medical writers and others with CME experience (see **Acknowledgement**) to review possible solutions to these and other issues. A summary is below. First, however, it's important to emphasize that it is generally *not* all on the medical writer's shoulders to parse out difficult situations regarding fair balance, potential conflicts of interest, or other issues. On the contrary, it is *the accredited provider of the educational activity* that is ultimately responsible for ensuring that the overall activity is in alignment with the ACCME standards. The staff of the accredited provider should be skilled and experienced in applying the ACCME standards and can be an excellent resource for anyone who is involved in CME content creation or execution. Accordingly, writers are strongly encouraged to reach out to the accredited provider for the activity when they are unsure how to proceed. Ideally, this would occur early on rather than later in the content development process, especially so that carefully crafted content isn't unexpectedly sidelined by content revision needs at the last minute.

Although the following tips should not be taken as gospel or unassailable expert advice, they may offer a path forward that may be acceptable for your dilemmas regarding content validity:

Provide fair balance—but not necessarily equal time. Although it's important to avoid focusing on a specific treatment and to discuss efficacy as well as safety data, there is no need to discuss each treatment option with exactly the same emphasis. Let the strength of evidence and US Food and Drug Administration (FDA)-approved indications guide the weight of discussion. For example, 2 treatments for a specific dermatologic condition may appear to have similar rates of response and tolerability, although upon closer inspection, the evidence for treatment A is from a randomized, placebo-controlled phase 3 trial, whereas treatment B is supported by a single-arm phase 2 trial. Furthermore, treatment A may have a specific FDA indication for the dermatologic condition, whereas treatment B is used off-label to treat the condition (off-label use is common and sometimes necessary, but the education should be upfront about that, and ideally refer to the evidence supporting the unapproved usage).[6] High-quality review articles and clinical practice guidelines may offer clues in terms of cataloging the evidence to date, although caution is advised in relying on stale information, particularly in fast-moving areas like immuno-oncology in which new data are always a meeting away (or less).

In some cases, a therapeutic area may be so underserved that there is only 1 relevant emerging or novel treatment option (eg, in a rare disease in which the previous standard of care was supportive care). In that case, providing fair balance may be a discussion of emerging therapeutic options in earlier stages of clinical investigation. Failing that, balance can be provided by ensuring adequate discussion of the potential risks of therapy alongside the potential benefits (as is good practice for CME writing in any case).

Cite credible and acceptable sources. Experienced CME writers generally recognize a hierarchy of evidence and sources, although caveats apply at each level:

- Peer-reviewed and PubMed-indexed medical journal articles are usually considered highly citable, but some judgment is required on the part of the writer, as not all peer-reviewed research is of high quality, and not all journals are as impactful as others (did that promising-looking study end up in the *New England Journal of Medicine* or in a little-known journal?).
- Clinical practice guidelines also rank high, particularly if provided by well-known medical societies or organizations (such as the American Heart Association), although not all guidelines are rigorously developed. Look for methodologies such as the GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) system, which can be used to evaluate evidence quality and quantify the strength of health care recommendations.[7]
- Medical meeting presentations are generally considered fair game. However, the information in a meeting abstract may not be peer reviewed. In addition, the conclusions of the research may change substantially from the submission of a meeting abstract to the actual meeting presentation, and sometimes, to the subsequent publication of those results in a peer-reviewed journal.
- Many agree that company press releases are not appropriate to cite, although as a result, it can be tricky to develop a state-of-the-art CME presentation when a potentially practice-changing clinical trial result is available only in the form of a press release. Although there are no easy solutions, one approach may be to reference publicly available details of the clinical trial design (eg, from the ClinicalTrials.gov database) and state in the activity that published/presented results are awaited.

Avoid corporate logos and (usually) brand names. When it comes to avoiding industry influence in CME activities, it's a no-brainer to omit corporate logos, and it's considered best practice to eschew brand names—although this is not always straightforward or without challenges. Medical devices, biosimilars, and proprietary formulations of common drugs are just 3 of the categories of products that are sometimes difficult to discuss without dropping brand names. The COVID-19 vaccines present a new wrinkle, as they are widely referred to by the manufacturer's name, so many learners won't immediately know whether the Pfizer mRNA vaccine is BNT162b2, mRNA-1273, or Ad26.COV2.S (it's BNT162b2). Finally, some audiences may know a specific drug only by its brand name, making education based on generic names an uphill battle. If the brand name can't be avoided, make sure to apply the standard equally, for example, don't use a brand name for one drug and a generic name for the others.

Don't forget about the other standards. Content validity is just 1 puzzle piece (although an important one) in the new ACCME Standards for Integrity and Independence in Accredited Continuing Education. There are important intersections between this guidance and the medical writer's work. Writers should make sure that disclosure information, including their own, is provided in the activity they are developing (Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships), and may need to solicit that information if it's not already available. Another example: a faculty member tries to add a PowerPoint slide that their local drug rep said would be "just perfect" for the accredited activity; the writer should decline and remind faculty that decisions regarding the education must be made without influence or involvement from pharmaceutical company employees (Standard 2: Prevent Commercial Bias and Marketing in Accredited CE).

CONCLUSION

Medical writers are often on the front lines of developing accredited continuing education. Accordingly, writers must help ensure that the fundamental principles of integrity and independence govern the development of specific educational activities. Toward that end, writers should have a thorough working knowledge of the latest ACCME Standards for Integrity and Independence in Accredited Continuing Education. Reviewing available ACCME resources (including the aforementioned guidance and checklist for clinical content validity) will help writers apply the standards to their current projects and navigate some of the nuances described in this article. With that background, medical writers will be better prepared to develop clinical CME content that is fair and balanced, unbiased, and supportive of safe and effective patient care.

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RESOURCES

- ACCME Standards for Integrity and Independence in Accredited Continuing Education (PDF)
- Toolkit for the Standards for Integrity and Independence (in particular, pages 7-8, "Guidance for Planners, Authors, and Faculty: Ensuring that Clinical Content is Valid")

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SOCIAL MEDIA

Diversity, Equity, and Inclusion Embraces Accessibility

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ABSTRACT

According to the Centers for Disease Control and Prevention, about 1 in 4 Americans have a disability.[1] As the population ages, there is an increased need for technology and accessibility (equal access), including Web accessibility. Accessibility is often defined in terms of 2 distinct measures: compliance with standards and usability for people with disabilities. The most common accessibility guidelines are the Web Content Accessibility Guidelines (WCAG) 2.0/2.1 and the Section 508 of the Rehabilitation Act. They are written to support the accessibility of HTML content. According to the W3C Web Accessibility Initiative, "Web accessibility means that websites, tools, and technologies are designed and developed so that people with disabilities can use them." [2] Business owners, medical writers, technical editors, social media managers, Web designers, and information technology administrators play a critical role in ensuring a better Web experience for all of us. In this article, we share practical ideas for you to show your commitment to diversity, equity, and inclusion with changes you can make to your website and content today. Accessibility solutions, such as using image alternative text, camel case in hashtags, white space around headings, margins, indentations, and columns, and strategically using fonts and color contrasting, are a few of many effective ways to provide accessible content to a larger audience. We also share other ways to address accessibility with creative strategies, such as podcasting. For medical communicators, strategies in communication, such as descriptive language and the use of storytelling techniques, are vital to ensuring your audience has a clear understanding of the message.

According to the Centers for Disease Control and Prevention, about 1 in 4 Americans have a disability.[1] Disabilities can be situational, temporary, or permanent. Some are hidden, such as chronic fatigue syndrome, diabetes, depression, visual and auditory disabilities, or learning difficulties. As the population ages, there is an increased need for technology and accessibility (equal access), including Web accessibility.

Most information today is shared via the Web, and the Web is the first impression someone gets of your organization. If your information isn't accessible to those who have different abilities and disabilities, your information will not have the desired effect, and your organization's reputation may be in jeopardy.

Think about it this way—what thoughts do you have about information and organizations when you cannot access their information on the Web? Maybe they choose not to have a website, or the colors give you a headache, or maybe that autoplay video has a sound you find irritating, so you turn it off. How do you feel about the organization and/or the information they are trying to share at that moment? For people with different abilities and/or disabilities, this is a routine experience for everything in the world around them.

Accessibility is often defined in terms of 2 distinct measures: compliance with standards and usability for people with disabilities. According to the W3C Web Accessibility Initiative, "Web accessibility means that websites, tools, and technologies are designed and developed so that people with disabilities can use them."[2] So, why should you care about accessibility? Here are several reasons:

- It helps ensure equal access.
- You'll broaden your audience and expand your customer base.
- It means search engines will be able to read your site more completely.
- It's done for legal reasons.
- It generates a positive media response.
- It supports corporate social responsibility.
- It's also the right thing to do. This builds trust and brand loyalty.
- It improves usability for users in general.

We all benefit from a win-win approach.

Business owners, medical writers, technical editors, social media managers, Web designers, and information

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technology administrators play a critical role in ensuring a better Web experience for all of us. Many people like graphs and other data visualizations, but these can create difficulty for users who are visually impaired and/or blind. Why? Screen readers may not always read and interpret these displays correctly. A screen reader is a software program that allows people who are blind and have low vision to read the content on a computer screen. It's done with a voice synthesizer or braille display. So, it is important to have a text description and/or plain text summary to ensure that the data can be accessed by everyone.

GUIDELINES

The most common accessibility guidelines are the Web Content Accessibility Guidelines (WCAG) 2.0/2.1 and the Section 508 of the Rehabilitation Act. They are written to support the accessibility of HTML content.

The WCAG 2.0 have long been the gold standard for accessibility on the Web. They were published in 2008. WCAG 2.1 were released in 2018, and it covers a wide range of recommendations for making Web content more accessible.

Three Levels of WCAG 2.0/2.1 Conformance

WCAG 2.0 A, AA, and AAA standards all have success criteria that must be met.

A—Minimal compliance

AA—Acceptable compliance (Aim here)

AAA—Optimal compliance

The principles underlying WCAG 2.0 and 2.1 make the acronym "P.O.U.R.":

- Perceivable
- Operable
- Understandable
- Robust

First, your content must be perceivable. Second, the interface elements in the content must be operable. Third, the content and controls must be understandable. Finally, your content must be robust enough to work with current and future technologies.

What are some easy and fast changes you can make to your website and content today to be more inclusive? We have some practical ideas for you to show your commitment to diversity, equity, and inclusion.

ACCESSIBLE SOCIAL MEDIA BEST PRACTICES

Alternative text is the first principle in Web accessibility. Web accessibility is likely to become a major ranking factor for Google in the future. Adding relevant alternative text to your images is one easy and effective way of doing it to improve your visibility.

An alternative text is a written description of an image or graphic that a screen reader can read out loud. Alternative text is often referred to as "alt text," "alt tags," or "alt attributes." It communicates the graphic's purpose and context. It's not too long, so aim for a maximum of 100–125 characters. In addition, don't feel like you need to describe everything.

One can think of it as an alternative to viewing the image for users who are blind or have low vision. It is also helpful for people with sensory processing disorders or learning disabilities. A missing alternative text is one of the most common image accessibility complaints, and it's one of the easiest things to fix.

An alt tag can help your photo be more accessible and discoverable. It can also boost your image search engine optimization. Remember, Google is pushing for the use of alt text because it can't see the images that you upload to your site. But alt text helps the search engine categorize your photos.

Image Alt Text

When using image alt text, it should not include "picture of" or "image of." A screen reader already tells the user this information. On the other hand, it is acceptable to use the words "this screenshot" or "this illustration" in your alt text. In certain situations, it may be helpful to distinguish between paintings, screenshots, or illustrations. But it's a best practice to avoid the more generic use of terms, such as image, icon, or picture.

Here's an example of a good alt text:

Two chocolate brownies stacked on top of each other with blueberries, raspberries, and mint leaves on top (Figure).

Figure. Two chocolate brownies stacked on top of each other with blueberries, raspberries, and mint leaves on top. © [nata vkusidey] / Adobe Stock.

Here's an example of a substandard alt text:

Brownies

As a general rule, there must always be an alternative description tag for every image. However, if you wish for the screen reader to just bypass or jump over the image, a null or "" is put in the text section of the tag: for example, <alt> "" </>. In this case, a decorative image doesn't need alternative text. A decorative image is used only to evoke a feeling or reinforce accompanying copy rather than to convey meaning on its own. Simply putting a null mark in every alt text would technically pass a lot of software-generated validation tools, but the image would not be accessible. Again, it's important that whoever is designing or adding content to the page makes a decision regarding the purpose of the image and what it is intended to convey. When in doubt, it is acceptable to add descriptive alternative text.

Complex Images and Long Descriptions

Complex images can be challenging for many people to understand. For example, people with low vision, learning disabilities, and limited subject-matter experience often find them confusing. A good practice is to simplify the image or graphic.

For charts, graphs, diagrams, illustrations, and other complex images, simple alt text may not be sufficient to convey the information. In this case, the image's alt text should direct the user to the long description conveyed by the image.

Here's a tip: use lists, headings, and other structural elements to organize content in a long description.

Headings

Headings are an important part of an accessible website. Sections must have headings that identify them. Make sure your content is well-formatted with headings and lists. That way, readers can use their screen reader's quick navigation keys to find their way. This adds clarity and orients users to the overall document structure.

Navigation

Your website needs to be navigable. But can it be navigable without a mouse? People who are blind or have low vision use the keyboard to navigate, not a mouse. For a website to be accessible, it must work without the use of a mouse.

Color and Contrast

Your website needs to be distinguishable for an optimal experience. What are some best practices on using color? Text (paragraph text) and interactive portions should have a contrast ratio of 4.5:1. For large text, your text ratio can be 3:1.[3]

Color alone should not convey information on a website. Why? Some people are blind, have color blindness, or have color-contrast deficiencies. The most common form of color deficiency is deuteranopia, red-green. Plus, the most common offender: links. Other best practices one should consider include:

- Avoid using the following color combinations: red/green, blue/green, and yellow/red.
- Use plenty of white space.

Two reputable contrast checkers that should be included in your toolbox:

https://userway.org/contrast/000000/ffffff
https://webaim.org/resources/contrastchecker

Use Camel Case in Hashtags

To make your hashtags more accessible, capitalize the first letter of each word. This is called "camel case." When you capitalize the first letter of each word, screen readers now have the indication they need and are much more likely to read the hashtag as intended. Note how these 2 examples are written:

#StateOfMentalHealthInAmerica2021
#notcamelcase

The first example is using camel case in hashtags; the second is not.

In the same theme, capitalize the first letter of each word in a URL. According to the American Foundation for the Blind, this will make it easier to understand for people who are blind or have low vision when they use screen readers.[4]

Here's the bottom line: it's not only friendlier for people who are blind or visually impaired who use screen readers, but it's also friendlier for people with dyslexia or cognitive disabilities. In essence, #CamelCase is easier for everyone to read.

Emojis and GIFs

Limit the use of nontext objects like Emojis and GIFs. You can write a description of an emoticon in parenthesis or brackets after sending it.

:) <smiling face>

In addition, double-check the emoji's description before using them. Plus, place emojis at the end of posts and tweets to avoid clarity issues.

GIFs and Animations

Avoid sharing GIFs that contain rapid flashing content that may trigger epileptic seizures in people with photosensitive epilepsy. Plus, ongoing animation can be distracting for people with attention deficit hyperactivity disorder (ADHD).

Multimedia Content

Audio and video content can be difficult for some users. For example, people who are deaf or blind or have low vision or hearing loss may not be able to perceive video or audio content. In addition, people with cognitive impairments may find the pace of multimedia content challenging.

One of the best alternatives for multimedia content is a text transcript. Written transcripts are recommended for all video and audio content. In that theme, videos should be described and captioned.

Closed captioning has been around for many years. It can help make a video or movie more accessible. It benefits people with learning disabilities, ADHD, autism, and hearing loss. In addition, it helps people in other ways, such as when we are in a noisy environment or if our audio is poor. Captions can also support us if the person in the video is a fast talker or has an accent. Some captioning apps include MixCaptions, Clipomatic, AutoCap, Kapwing, Clips, and Threads.

On the other hand, an audio description is a newer technology that can supplement closed captioning.[5] It is a form of narration used to provide information surrounding key visual elements in videos for consumers who are blind or have low vision. In other words, you can think of audio description as providing a verbal version of the visual image.

Live-Streaming Tips for Accessibility

For live-streaming events, consider these 3 tips:

1. Use video services that have live-captioning capabilities like Zoom or Google Meet.
2. Provide a transcript or fully captioned video soon after your event ends.
3. Hire an on-camera interpreter for an additional level of accessibility.

Images With Texts

As a general rule, images of text are not allowed. If you cannot avoid images of text, it's best to have the same text in the alt attribute. Remember, Google likes text-based content. Exceptions can be made for company logos, brand names, and other situations in which the way that the text is presented visually is crucial to its meaning.

White Space

Standardize site structure and page creation by liberal use of white space. Active white space is intentionally used to create structure and flow on a page. It can serve other purposes, such as helping readers to process the text more efficiently and directing them to important information. Be sure to use white space around headings, margins, indentations, and columns. Learning how to properly use white space can garner attention, sales, and impact.

Font Style

Font style is a critical element of accessible website design. In this case, readability is the most important factor. Choose a font that has easily recognizable characters, such as sans serif fonts: Arial, Calibri, Helvetica, or Verdana.

"The US Department of Health & Human Services unofficially recommends the following fonts for PDF files: Times New Roman, Verdana, Arial, Tahoma, Helvetica, and Calibri."[6]

The minimum font size on your website is 16 points or 16 px. It depends on the font because fonts tend to vary.

When users zoom in on the page, they have to be able to zoom to 200% without affecting the content.

Finally, avoid italics, all caps, bold type, or other formatting that could affect readability.

Acronyms, Abbreviations, and Jargon

Spell out acronyms when they're first introduced in your text to your readers. Plus, avoid abbreviations, jargon, and figurative language.

Web Content Reading Level

Create content for the appropriate reading level. The general standard for Web content is eighth grade. The goal is to keep sentence structure simple and paragraphs short. It's OK to be conversational, but keep it clear and concise. This helps many users with cognitive and visual disabilities.

Adding Hyperlinks

Avoid these words or phrases in links:

- Click here
- Read more
- More info here
- Link to (some link destination)

It is best to tag the actual message as a hyperlink. If it is a link, it automatically means click here.

Another way to address accessibility is with creative strategies such as podcasting. Podcasting can use audio to

assist the visually impaired, but it can also have text captions or a transcript to assist people with hearing loss.

DEVELOP A NEW STRATEGY—PRESENT LIKE A PODCASTER

As a medical communicator, drafting and scripting presentations can become an important part of your job, in addition to making presentations oneself. A great way to learn how to inform, educate and entertain an audience without relying solely on visual aids can be derived from the art of podcasting. So… what is a podcast?

One way to think of a podcast is a television show for the ears. Podcasts are a series of recorded audio files that, in a similar manner to a television show, tend to tell a story with a focus on a specific theme, generally within 25 to 45 minutes. Much like a presentation they can be used to inform, educate, or entertain an audience.

Leaning on lessons learned from professional podcasters and storytellers, the following are some key strategies to make presentations audio friendly.

Scripting the introduction

- Focus on the subject and clarify it to listeners by telling the audience what to expect from the presentation. (eg, "You will learn or discover X as a result of the findings that will be shared today.").
- Insert a question to engage the audience and start the thought process.
- Establishing the concept with the necessary background (eg, "In order to understand X, let me first explain Y.").[7]

Scripting the narrative to ensure the speaker is not reliant on visual aids to explain key findings.

- Using clear, descriptive language that emphasizes the main points.
  - Recommended: the research found that feature X is expressed in 30% of the population and feature Y in 60% of the population, with other features representing 10%, indicating that feature Y is more prevalent in Z population (speaker uses a pointer to highlight information on the chart).
  - Not recommended: if you look at the above pie chart, in which the blue represents feature X and the green represents feature Y, you will see that feature Y is more widely expressed in our population (listener has no concept of how wide the gap in expression is or the expression level of other features).
- Use delivery notes within the script to introduce pauses, emphasis, pace, and other strategies to prevent the audience from losing focus due to a monotone presentation.[8]

Script the conclusion to emphasize the main point of the presentation.

SUMMARY

With approximately 25% of the US population having a disability, a focus on the use of accessibility features in technology and comprehensive communication is critical for the clear and accurate dissemination of knowledge. For an organization, the benefits of presenting accessible content can range from ensuring that a broad customer base understands the value the organization provides to legally meeting compliance standards. Accessibility solutions, such as using image alternative text and strategically using fonts and color contrasting, are a few of many effective ways to provide accessible content to a larger audience. For medical communicators, strategies in communication, such as descriptive language and the use of storytelling techniques, are vital to ensuring your audience has a clear understanding of the message.

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IN THE SERVICE OF GOOD WRITING

If I Were King of the Forest…! — The Grammar, Meaning, and Logic of Conditional Statements

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ABSTRACT

This article provides a basic overview of the grammar of conditionals, the role of conditionality in predicate logic, and the difference between conditionality and causality. Medical writers must achieve mastery of these concepts, which are important not just for clear writing but for rational thinking. English speakers use conditionals for many different purposes, such as describing facts, habits, and rules (zero-order conditionals); describing the future consequences of realistic, possible, or likely events (first-order conditionals); expressing the likely consequence of some uncertain or impossible event (second-order conditionals); or talking about how things could have turned out differently if some condition had been met in the past (third-order conditionals). Conditionals also allow one to ask questions about the consequences of an event or to express the conditions under which a command should be followed. Conditional constructions are also sometimes used in expressions that don't really express conditions (relevance conditionals). The grammatical differences between these expressions are subtle, involving the tense and mood of the verbs. Conditionals allow you to talk about how the truth-values of different propositions are interrelated. Thus, once you master the grammar of conditionals, you can begin to learn the rules and pitfalls of deductive and inductive reasoning. In science, such reasoning is often the first step toward proving causality. The existence of a tight correlation between two phenomena does not prove that one causes the other, but the lack of a correlation suggests that a causal relationship is unlikely.

A conditional statement is a way to say that the truth of one statement depends on the truth of some other statement. A conditional statement contains 2 clauses: an *if*-clause (also known as the *antecedent* or *protasis*) and a main clause (also known as the *consequent* or *apodosis*). In the movie *The Wizard of Oz*, the Cowardly Lion sings, "If I were king of the forest…" He then describes what he and others would do. Of course, because he is cowardly, he does not rule the forest, and nobody does any of those things.

Conditional statements can do something that seems like alchemy: they can combine 2 false statements and turn them into a truth. That's because the truth of the conditional statement depends not on the truth value (truth or falsity) of either of its clauses but on the relationship between the truth values of the 2 clauses. In each conditional statement that the Cowardly Lion makes, both the *if*-clause and the main clause contain a statement that is false. Yet, the conditional statement that he makes by putting those false statements together is true because if the antecedent were true, the consequent would also be true: if he did rule the forest, others would respect him.

The grammatical rules for making conditional statements in English are simple, yet conditionality is a complicated subject that has been an active area of research in linguistics, philosophy, and cognitive science. As medical writers, we need to pay attention to 3 basic issues related to conditionality:

- Intelligibility—Is the conditional statement grammatical and meaningful?
- Linguistic modality—Does the antecedent contain a statement that is definitely true, possibly true, or utterly impossible? Is the consequent a statement of fact, a suggestion of what might be possible, a command, a threat, or something else entirely?
- The relationships between the statements—How tight is the relationship of the truth values of statements in the antecedent and consequent? Does this relationship reflect some underlying cause-and-effect (causal) relationship? Are these 2 statements not telling the whole story?

As medical writers, we often need to express what is always true, what is generally or occasionally true, and what is true only under certain conditions. We must also grapple with questions of cause and effect and warn people about possible consequences. In English, we can use conditional

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statements to describe statistical and causal relationships, establish rules, make promises and threats, issue warnings, or even just express our feelings. Yet all these different kinds of expressions have similar grammatical forms. Unlike some languages, such as Spanish, English does not use word endings to mark the conditional mood of verbs. Nevertheless, there are grammatical rules that you need to follow when making conditional statements. This article explains the rules, as well as how conditional statements can be used to express all these relationships.

STRUCTURE OF CONDITIONAL STATEMENTS

All conditional statements include at least 2 clauses, one independent and the other dependent. A *clause* is a word string that contains a subject and a predicate. The consequent of a conditional sentence is an independent clause because it can stand on its own as a sentence. In contrast, the antecedent is a dependent clause (ie, it cannot stand on its own as a sentence) because it is introduced by a subordinating conjunction—usually "if" but sometimes other words, such as "when" or "unless":

> If I were king of the forest…!

This *if*-clause (antecedent) acts as an adverb that modifies the rest of the sentence. The antecedent expresses limiting conditions for the main clause of the sentence, whether that main clause is a statement or a command.

The word *antecedent* comes from the Latin for "to go before." However, the antecedent of a conditional statement does not have to be at the beginning of the sentence. If the antecedent is at the beginning of a sentence, set it off with a comma; but don't use a comma to set off an antecedent that follows the main clause.

- If I were you, I would not do that.
- I would not do that if I were you.

Sometimes, the subordinating conjunction "then" is used to mark the consequent of the conditional statement, but it is optional:

> If the light is green, [then] you can go.

Note that the clauses within a conditional statement can be compound (ie, they contain more than one independent clause):

> When it is warm outside and the sun is shining, I ride my bicycle and she goes swimming.

TYPES OF CONDITIONAL STATEMENTS

There are 5 basic kinds of conditional statements. Each serves a different purpose (or set of purposes) and follows a different set of grammatical rules in English.

Zero-Order Conditionals

A *zero-order conditional* is used to describe facts, habits, and rules. The verbs in the antecedent and consequent are often in the simple present tense. Because the zero-order conditional expresses something that is always true, as long as the conditions are met, the timing does not matter and may go unspecified. In fact, the consequent may describe an event that happens before the event described in the antecedent, even though the word *antecedent* means "that which goes before" and *consequent* means "that which follows."

- If the solution is alkaline, the litmus paper turns blue.
- Whenever she leaves the house, she takes her cellphone.
- If the patient is allergic to penicillin, a macrolide antibiotic is used.

Zero-order conditionals have been described as indicative conditionals (the indicative mood is used for expressing facts and truth). However, the clauses contained within the antecedent and consequent are not statements of fact. For example, the *if*-clause is not saying that there *is* a patient who is allergic to penicillin. Also, if nobody has a penicillin allergy, then it's possible that nobody will get the macrolide. Thus, the verbs in the antecedent and consequent of an indicative conditional are not expressing a realis modality. As I explained in an earlier installment of this column,"[1] *realis modalities*, such as the indicative mood in English, are used for expressing facts and truth. *Irrealis modalities* are used for expressing other things, such as questions, commands, the antecedents and consequents of conditional statements, and statements that are contrary to fact. Nevertheless, the conditional statement, taken as a whole, can be a statement of fact. A fact is not the same thing as a statement of fact; a fact is something that makes a statement of fact true or false. For example, if I state that there is a piano in my living room, the existence of the piano in my living room is the fact that makes my statement true. A conditional statement can be true if the facts support it.

Even though zero-order conditionals are called indicative conditionals, the consequent might not express something that is always true every single time the antecedent is true. It might instead express what is typically or often true. To clarify how tight the relationship between antecedent and consequent are, you can use adverbs such as "always,"

"usually," "generally," "sometimes," or "occasionally" in the consequent.

> If you call her during business hours, she usually answers.

For zero-order conditionals, the words "when" and "whenever" can be substituted for "if."

> She takes her cellphone whenever she leaves the house.

The clauses in a conditional statement can also take a negative form:

> If the sun is not shining, the solar oven does not work.

If the consequent is always true whenever the antecedent is true, the antecedent is considered a sufficient condition for the consequent:

> If patients with scurvy get vitamin C, they recover.

Of course, in medicine, the outcome of any case is going to depend on many factors, some of which go unstated and possibly unnoticed. As Shakespeare's *Hamlet* put it, "There are more things in heaven and earth, Horatio, than are dreamt of in your philosophy."[2] Thus, it goes without saying that a patient who has had major bleeding from scurvy might need a blood transfusion, in addition to vitamin C. If, on the other hand, the antecedent must be true for the consequent to be true, then the antecedent is a necessary condition for the consequent. A necessary condition can be expressed by the inverse of the conditional, which negates both the antecedent and the consequent of the original conditional statement:

> If patients with scurvy don't get vitamin C, they don't recover.

The inverse of a conditional statement can be phrased with "unless they do" instead of "if they do not":

> Unless they get vitamin C, patients with scurvy don't recover.

You can also use "only if" to express a necessary condition:

> Patients with scurvy recover only if they get vitamin C.

Although a necessary condition must be present for the consequent to occur, the consequent might not occur even if the necessary condition is present. So, although it is generally true that people recover from scurvy if they get vitamin C, they might not recover if the vitamin C is given too late.

If an antecedent is both necessary and sufficient for the consequent to be true, the statement is biconditional. A *biconditional statement* is true when its antecedent and consequent always have the same truth value (ie, both true or both false). Biconditional statements can be phrased with "if and only if":

> Patients with scurvy recover if and only if they get vitamin C.

First-Order Conditionals

First-order conditional statements are used to describe the consequences of realistic, likely, or possible events. Even though the *if*-clause generally refers to something that has not yet happened, its verb is in the present tense, whereas the consequent uses the future tense.

First-order conditionals are often used in negotiations.

> If you finish the work early, I will give you a bonus.

First-order conditionals can also be used to issue threats and warnings and to express superstitions. Note that in those cases, the event described in the main clause might not happen, even if the condition in the *if*-clause is met:

- If you hit me, I will hit you back.
- If you don't control your blood sugar, you will have serious complications.
- If you break a mirror, you will have 7 years of bad luck.

Second-Order Conditionals

Second-order conditionals can be used to express hypothetical conditionals. Hypothetical means founded on an idea that has not been verified as true. To emphasize the uncertainty or impossibility of the hypothetical antecedent, its verb is in the subjunctive mood, which follows the same conjugation as the indicative past tense in English. That's why the verb sounds as if it is in the past tense, even when it is describing something that could happen in the future.

A second-order conditional can be used to express a future event that would happen if some unlikely hypothetical event were to occur:

- If I won the lottery, I would buy a fancy new car.
- If I were to start training today, I would be ready to run a marathon by next summer.

You can also phrase the second-order conditional without an "if," but then you would have to switch the order of the subject and verb:

> Were we to give up this fight, it would mean the end of democracy.

A second-order conditional can also be used to express what would be happening now if things were different. These statements are *counterfactual conditionals* because the condition described in the antecedent is contrary to fact:

> If wishes were horses, then beggars would ride.

Third-Order Conditionals

A *third-order conditional* is also counterfactual because it deals with conditions that were not met. It explains what would have happened in the past had the condition been met. The verb in the *if*-clause is in the past-perfect tense, and the verb in the main clause uses "would have" and the past participle.

> If I had known that you were coming, I would have baked you a cake.

Mixed Conditionals

There are 3 basic kinds of mixed conditionals. They all deal with counterfactual statements in the *if*-clause and the main clause. One deals with the consequences in the present if something different had happened in the past. The verb in the *if*-clause is in the past perfect, and the modal auxiliary "would" is used in the main clause:

> If Julie had scored higher on her MCAT, she would be in medical school today.

Another mixed conditional deals with what would happen in the future if something in the past had been different. The past perfect is used in the *if*-clause, and the auxiliary "would" is used along with some expression of the future. Sometimes, "would be" and the present participle are used, or "would" and the bare infinitive, plus some adverb or adverbial phrase to indicate a future timeframe.

- If she had booked the flight earlier, she would be going with us on Wednesday.
- If she hadn't forgotten to book the flight, she would go with us on Wednesday.

Another mixed conditional deals with a counterfactual *if*-clause in which the present tense is used to express a general fact or truth, and a main clause that talks about the past:

> If I were rich, I would have given you the money.

Other Conditionals

In a conditional question, the antecedent acts as a modifier to the question asked in the consequent:

> What do we do if the patient is allergic to penicillin?

In a conditional imperative, the antecedent modifies a command that is given in the consequent:

> If you think that someone is having a stroke, call an ambulance immediately.

There are also many statements that are phrased as conditionals, even though the truth value of the consequent has nothing to do with the truth value of the antecedent. These are sometimes called *relevance conditionals* or "biscuit conditionals":

- There are biscuits in the pantry, if you want some. (The biscuits are there, whether you want them or not.)
- If you ask me, she's out of her mind.

The phrase "if only" can also be used idiomatically to express a wish:

> If only it would stop raining!

THE LOGIC OF CONDITIONALS

When we study conditionals, we set foot on the bridge that connects grammar to logic. We have to think about how the truth values of the clauses within a conditional sentence relate to the truth value of the conditional sentence as a whole. We can then incorporate that conditional sentence into a logical argument, which may reveal other truths.

Conditional Statement

Logicians often use capital letters, such as P and Q, to stand for propositions. A proposition is a statement that can be true or false. The word *proposition* comes from the Latin for "something put forth." A proposition can be a supposition: something that you accept as true for the purposes of an argument. Grammatically, a proposition has a subject and a predicate whose verb is in the indicative mood. Logicians often use T and F to stand for "true" and "false" and a right-

ward-pointing arrow to indicate an if-then relationship. So, P→Q means "if proposition P is true, then proposition Q is true." (Note that the conditional statement P→Q is also a proposition because it can be true or false.) The table shows the possible truth values of P and Q, and the effect that these truth values would have on the truth of the various conditional statements involving P and Q. Note that P→Q is false *only* when Q is false while P is true. (This relationship holds when P→Q is a hard rule that allows for no exceptions.)

Inverse Statement

Logicians often use a tilde (~) to indicate negation. To form the inverse of a conditional statement, you negate both the antecedent and the consequent.

- Conditional: If I am king of the forest, I get respect. (P→Q)
- Inverse: If I am not king of the forest, I don't get respect. (~P→~Q)

Note also that the negation of a negative statement is a positive statement:

- Negative statement: There are no cookies in the jar.
- Negation of negative statement: There are cookies in the jar.

A conditional statement can be true while its inverse is false, and vice versa (ie, even a person who is not king of the forest can be respected) (Table).

Contrapositive Statement

To form the contrapositive of a conditional statement, you negate both propositions and switch the positions of the antecedent and consequent.

- Conditional: If I am king of the forest, I get respect. (P→Q)
- Contrapositive: If I do not get respect, then I am not king of the forest. (~Q→~P)

A conditional statement and its contrapositive are logically equivalent to each other (ie, they always have the same truth value) (Table). Thus, you can prove that a conditional statement is true by proving that its contrapositive is true, and vice versa.

Converse Statements

The converse of a conditional statement is made by switching the clauses.

- Conditional: If I am king of the forest, I get respect (P→Q)
- Converse: If I get respect, I am king of the forest (Q→P)

A conditional and its converse do *not* always have the same truth value (Table). Lots of people who get respect are not king of the forest. The converse and the inverse of a conditional statement are logically equivalent to each other (ie, they always have the same truth value) (Table).

Biconditional Statements

As described above, a biconditional statement is a way of saying that both a conditional (P→Q) and its converse (Q→P) have the same truth value (Table). Either they are both true, or they are both false. A biconditional statement can be expressed with a double arrow: P↔Q. Writers can express biconditionality by saying the conditional statement and adding "and conversely." Writers can also express biconditionality by saying "if and only if." Logicians sometimes abbreviate that to *iff*.

Valid and Strong Arguments

Logic is the study of how statements can be combined into arguments. For example, you could assert that both "If P, then Q" and "P" are true. You can then use those propositions as premises to support the conclusion that Q must therefore be true. The premises of an argument are *if*-statements, and the conclusion is a *then*-statement. The ∴ symbol is used as a conclusion marker. It can be translated as "therefore."

P→Q
P
∴Q

Table. Truth Table

Antecedent	Consequent	Conditional	Inverse	Contrapositive	Converse	Biconditional
P	Q	P→Q	~P→~Q	~Q→~P	Q→P	Q↔P
T	T	T	T	T	T	T
T	F	F	T	F	T	F
F	T	T	F	T	F	F
F	F	T	T	T	T	T

→, if-then; ~, not, ↔, if and only if.

In logic, an argument is valid if its conclusion must be true whenever all of its premises are true. If an argument is valid and its premises are all true, then it is sound. Its conclusion will therefore be true. There are 2 important valid arguments that relate to conditionals:

- Modus ponens—If P→Q is true, and P is true, then Q is also true. "Modus ponendo ponens" is Latin for "the method of placing by placing."
- Modus tollens—If P→Q is true, but Q is false, then P is also false. "Modus tollendo tollens" is Latin for "the method of removing by removing."

Formal Fallacies

A logical fallacy is an error in reasoning that may lead you to draw a false conclusion, even if your premises are true. Formal fallacies are logical fallacies that result from the improper form of the argument. Informal fallacies can result from other problems, such as a misunderstanding of the meaning of the words involved. The following formal fallacies arise from a misunderstanding of how conditional statements work:

- Affirming the consequent—If you know that P→Q is true, and Q is true, but then conclude that P must therefore also be true, you have made an error called affirming the consequent (Q being the consequent). This error is also called the converse error (Q→P is the converse of P→Q), or the confusion of necessity and sufficiency. You can see that P can be false even when P→Q is true and Q is true (Table).
- Denying the antecedent—If you know that P→Q, but that P is false, and you assume that Q must therefore also be false, you are making an error called denying the antecedent (P being the antecedent). It is sometimes called the inverse error (~P→~Q is the inverse of P→Q). You can see that Q can be true even when P→Q is true, and P is false (Table).

INDUCTIVE REASONING

When we are dealing with the realm of pure thought, we often have premises that are unquestionably true. These typically involve mathematical truths and truths made necessary by the definitions of the words we use (eg, a bachelor is an unmarried male). As medical writers, however, we typically deal with premises that describe something in the physical world. Thus, we use propositions whose truth-values are less certain (eg, they contain adjectives such as "some" or adverbs such as "usually"). The arguments that we can base on those premises are less convincing. When we are using that kind of premise, the best we can do is to formulate arguments whose conclusion is unlikely to be false.

The inductive probability of an argument is the likelihood that its conclusion will be true if all of its premises are true.

- A deductive argument is one that is intended to provide a guarantee that its conclusion is true, provided that its premises are true.
  - A deductive argument whose conclusion is always true when all of its premises are true is valid (inductive probability, 100%).
  - An argument whose inductive probability is 100% and whose premises are all true is sound.
  - If there is even the slightest possibility that the conclusion can be false when all of the premises are true, the argument is invalid.
  - The conclusion of an argument can be true even if the argument is invalid and/or contains false premises.
- An inductive argument is an argument intended to convince someone that the conclusion is unlikely to be false. Thus, its inductive probability is <100%.
- Because their inductive probability is <100%, all inductive arguments are invalid. (The conclusion can be false even if all the premises are true.)
- If the inductive probability is high, the argument is considered strong.
- If the premises of a strong argument are all true, the argument is described as cogent. Its conclusion is unlikely to be false.

Many people have seen lists of logical fallacies on the Internet but don't understand how to use that information. A fallacy is an error in reasoning. A deductive argument that contains a logical fallacy is invalid, which means that the conclusion can be false even if all the premises are true. However, the presence of fallacies or false premises in an argument does not mean that the conclusion is false. (If you reject a conclusion because you spotted a fallacy in the argument, you make an error called the fallacy fallacy.) Similarly, the presence of a logical fallacy in an inductive argument does not mean that the conclusion is false. It simply means that the argument is invalid (but all inductive arguments are invalid). The real question is whether the fallacy seriously weakens the argument.

Consider the argument from authority. When you make an argument from authority, you cite expert opinion to support your argument. This argument is invalid because it is possible for the expert's opinion to be wrong. But if the expert is reliable, then it is unlikely that the expert will be

wrong. So, the expert's opinion can add to the strength of an inductive argument.

The conclusion of an inductive argument can be false even if the argument is strong and the premises are all true. That's simply the nature of induction. However, an inductive argument can be so cogent (its argument so strong and its premises so undeniable) that doubt would be unreasonable. How cogent must an inductive argument be to be convincing? The answer to that question depends on the situation. What kind of decision are you going to make on the basis of that conclusion? Is the decision reversible? What are the possible consequences of making the wrong choice? Are those consequences minor or serious? Are they reversible or irreversible? If the consequences are serious and/or irreversible, you might insist on hearing an argument with a high inductive probability.

LOGICAL AND CAUSAL RELATIONSHIPS

Writers must think carefully about what a conditional statement implies, and what it does not imply. For example, consider the following statement:

If you pick up a guinea pig by the tail, its eyes fall out.

This statement is true, but not because of anything to do with the guinea pig's eyes. The conditional statement is true only because guinea pigs never have tails. Thus, the condition described in the *if*-clause can never be met. Because P is always false, then P→Q is always true.

If a causal relationship exists, then you expect to find a high correlation between the cause and its effect. But even if you find that P and Q are perfectly correlated (P is always true when Q is true, and vice versa), it does not mean that P causes Q. Correlation does not equal causality. Q might turn out to be the cause of P. Or they could both be results of some other unknown cause. Perhaps the correlation was simply a coincidence, a fluke—something that would disappear if you took a larger sample. Nevertheless, a correlation is a reason to be suspicious. (The word *suspect* comes from the Latin for "to look at secretly.") So, if you see that something important is correlated to something else, you may want to look for an explanation. A correlation could be evidence that some cause is having an effect. On the other hand, if P and Q do not seem to be correlated with each other, then a causal relationship seems less likely.

IMPLICATIONS FOR MEDICAL WRITERS

This article has provided a basic overview of the grammar of conditionals, the role of conditionality in predicate logic, and the difference between conditionality and causality. These are vital concepts for anyone who must think critically about any topic, including medicine. An understanding of the grammar of conditionals can help medical writers achieve better clarity in their writing. An understanding of the logic of conditional statements and the difference between conditionality and causality is essential for anyone who is writing about medical research. For example, you now know why expert opinion should be taken seriously (because experts are often right) but not too seriously (because experts are sometimes wrong). You also know why the materials and methods section of a study report is so important. It describes the conditions under which the study was conducted. If those conditions had been different, the results of the study might have been different.

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BIOGRAPHY

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ABSTRACT

For much of its history, the American Medical Writers Association (AMWA) has bestowed awards in honor of certain members: Harold Swanberg, MD, the founder of the Association; Walter Alvarez, MD, in retirement, a nationally syndicated health columnist; Eric Martin, PhD, a pharmacist instrumental in professionalizing regulatory writing; and John McGovern, MD, a philanthropist who supported initiatives in biomedical communication. However, the details of the lives of these men are unknown to most AMWA members. Accordingly, this biography describes the life and accomplishments of Eric Martin, to recognize his achievements and to contribute to the history of the profession and of the Association.

The Eric W. Martin Award for Excellence in Medical Writing was awarded by AMWA from 2007 to 2015. However, we know more about those receiving the award than we do about the man in whose honor the award is given. In part, this lack of information may be attributed to Eric himself. He has been described as a quiet but pleasant man who seldom talked about himself; the sort of person who would learn more about you than you would about him in casual conversation. (Lilian Sablack telephone call, June 27, 2020.) We know little about his personal life and not much more about his professional life, but there is something to tell.

Figure 1. Eric Wentworth Martin, PhC, BsC, Ms, PhD (1912-?)

PERSONAL LIFE

Eric Wentworth Martin, PhC (pharmaceutical chemist), BsC (bachelor's degree in pharmaceutical chemistry), MS, PhD, was born on December 6, 1912, in Kamloops, British Columbia, Canada, to Wentworth Banger Martin (1888-1945) and Ida Magdalen (1886-1984).[1] He graduated from high school in 1928, eventually entered an apprenticeship in pharmacy, and became a qualified pharmacy assistant in 1934. At some point, he became a registered pharmacist in both the United States and Canada.[1]

We know even less about his wife, Ruth D. Martin, DSc, who collaborated with him on several publications. According to Lilian Sablack, AMWA's Executive Director from 1973 to 2001, who knew Eric for some time, he rarely talked about himself. Her recollection of him was that he had no children and that Ruth may have been his second wife.

PROFESSIONAL LIFE

Much of the information on Eric's professional life comes from the "about-the-author" sections of his many publications. At some point in his career, he was Director of Communications for Lederle Laboratories in New Pearl, New York, and for several years, he was also associate professor of medical communication at Columbia University College of Pharmacy.[2] Between 1949 and 1952, he was an Associate Director of LaWall and Harrison Research Laboratories (now SGS Harrison Research Laboratories), a company that still provides consumer product testing services.[3] During this same period, he was assistant professor of biochemistry at Philadelphia College of Pharmacy. (The college eventually changed its name to the University of the Sciences. It offered the only master's degree program in medical writing in the country[4] until it was absorbed by St. John's University earlier this year.)

From 1956 to 1959, he was Editor-in-Chief of the *Journal of the American Pharmacists Association, Practical Pharmacy Edition*,[5,6] Executive Director of Spectrum at Pfizer, may have been professor of physical pharmacy at Purdue University, and later became Director of Professional Communications at the Food and Drug Administration. He was a Fellow of the American Association for the Advancement of Science and of the International Academy of Law and Science. He was also a Fellow of AMWA, the first president of the Association who was not a medical doctor, and the author of AMWA's first Code of Ethics, in 1978.[2]

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But there's more…

From 1942 until 1953, Eric served in the US Army Medical Corps and Chemical Warfare Service, which was part of the Office of Strategic Services (the OSS; forerunner of the Central Intelligence Agency). At the end of this period, he became a senior research biochemist at the Institute for Cooperative Research at the University of Pennsylvania.[7] The Institute conducted secret research into chemical and biological warfare until its activities came to light during the Vietnam War in 1965.[8] The Institute was closed in 1968.[9] (A note for balance: during World War 2, George W. Merck, President of Merck & Company pharmaceuticals from 1925 to 1950, led the War Research Service that was in charge of the US biological weapons program. Merck was awarded the Medal for Merit for his contribution to the war effort.[10])

PROFESSIONAL ACTIVITIES

Almost all references to Eric are from books he wrote or edited. They all appear to be major texts that went through several editions.

- *Husa's Pharmaceutical Dispensing*. Martin EW, ed. Mack; 1959. He edited the first 7 editions of this book.
- *Remington's Pharmaceutical Science*. Martin EW, ed. 13th ed. Mack; 1965. In 100 chapters (1,616 pages) by separate authors, the book covers the scientific, professional, and economic aspects of pharmacy.
- Martin, EW. *Techniques of Medication: A Manual on the Administration of Drug Products*. Alexander SF, Hassan, WE Jr, Sherman BS, eds. 1st ed. J. B. Lippincott; 1969. Eric's wife, Ruth D. Martin, was an associated editor of this book.
- Martin, EW. *Hazards of Medication: A Manual on Drug Interactions, Incompatibilities, Contraindications, Interactions, and Adverse Events*. J. B. Lippincott; 1978. The book cites 3,000 references and contains a 400-page table of drug interactions for more than 600 of the most widely used drugs. (The number of drugs increased to 1,000 in later editions.) Another 50-page table details how many drugs interfere with the results of laboratory tests.
- Martin EW. *Drug Interactions Index* 1978/79. Lippincott; 1978.

THE DRUG THAT CHANGED EVERYTHING

Thalidomide was an over-the-counter sedative widely used in Europe to treat anxiety, sleeplessness, and morning sickness during pregnancy. In the late 1950s, it was linked to fetal deaths and serious birth defects (the phrase does not capture the horrific effects of the drug) in thousands of newborns. At the time, drugs were tested only on rodents and did not have to be tested for teratogenic effects. The drug was never marketed in the United States because its approval was blocked by a young US Food and Drug Administration (FDA) inspector. Frances Kelsey, MD, PhD—on her first assignment during her first month at the FDA— based her decision on the fact that the data in the application for thalidomide did not establish its safety and effectiveness and that there were no data indicating whether the drug could cross the placenta.[11] Despite pressure from the manufacturer and from others inside the FDA, she prevailed in preventing the drug from being approved.[12]

Dr Kelsey also noted that there were no data from clinical trials of the drug in the United States and that there was no way of knowing whether such data would be reliable. Clinical trials were not yet required for FDA approval, and any trials that were conducted were not subject to oversight. "[T]he 'clinical trials' of thalidomide in Europe involved distributing more than 2.5 million tablets of the drug to about 20,000 patients, including 3,760 women of childbearing age, of whom at least 200 were pregnant. More than 1,000 physicians participated in these trials, but few tracked their patients after dispensing the drug."[13] (Unknown to the FDA, thalidomide had already been distributed to 1,200 physicians in the United States, many of whom were treating pregnant women. The agency eventually launched a nationwide campaign to recover as much of the drug as possible.[14])

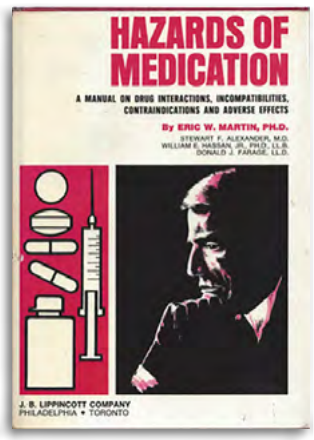

Figure 2. *The Hazards of Medication*, by Eric W. Martin, PhD. This 900-page volume contains a 400-page table of drug interactions and includes information on more than 600 of the most widely used drugs. Another 50-page table details the ways in which many drugs can affect the results of laboratory tests. The first edition sold 30,000 copies.

The thalidomide tragedy led to the 1962 Kefauver-Harris Drug Amendments to the Federal Food, Drug, and Cosmetic Act that required manufacturers to prove both safety and efficacy and greatly increased surveillance and monitoring of the drug approval process.[14] The new regulations also required manufacturers to disclose all side effects encountered in testing and to provide the public with accurate

information about the side effects and efficacy of a drug. The FDA also launched the Drug Efficacy Study Implementation, an initiative that retrospectively evaluated drugs already on the market by 1962. This tightening of regulations was global; the European Union adopted Directive 65/65/EEC1 in 1965 to coordinate the approval process in the European Economic Community, and the United Kingdom passed the 1968 Medicines Act to control the testing and manufacture of drugs for human and veterinary use.[14]

For her part in saving the United States from the same disaster Europe had experienced, President Kennedy awarded Dr Kelsey the President's Award for Distinguished Federal Civilian Service, the highest honor given to a civilian in the United States. She was the second woman to receive the award.[11]

These changes in the drug approval process and the need to meet new and extensive domestic and international licensing requirements created great uncertainty among manufacturers. To address this uncertainty, 30 pharmaceutical professionals, medical writers, and academics founded the Drug Information Association (DIA) in 1964.[15] The idea behind the Association was that "a climate of cooperation expedites the transfer of drug information from the minds of those who have it to the minds of those who need it, with a minimum of duplication of effort," according to one of the founders and its first president, Dr Eric W. Martin (Box).[2,15]

Today, the DIA has more than 22,000 members from 80 countries. Based in Washington, DC, the Association has regional offices in Pennsylvania, China, Japan, Switzerland, and India. It publishes the quarterly, peer-reviewed *Drug Information Journal*, and sponsors more than 125 meetings, trainings, and continuing education courses each year.[15]

CLOSING

The Eric W. Martin Award for Excellence in Medical Writing was bestowed on AMWA members who in the previous year published print or electronic monographs or articles on topics either for the public or for a professional medical audience.[16] The award may have been established by Eric's wife, Ruth, in honor of his life (Telephone call with Lilian Sablack June 27, 2020).

Much of Eric's life is unknown. He is not mentioned on the DIA website, and his name does not appear on Internet searches, other than as an author or on the award named for him. So, it is not surprising—and perhaps even fitting—that I still could not determine the date of his death at the time of this writing.

Author declaration and disclosures: *The author reports no competing interests with this article.*

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THE REBIRTH OF AMWA

As horrible as thalidomide was, it also saved AMWA. From its founding in 1948 and throughout the 1960s, the Association was an organization of physician journal editors. As the physician members retired and were not replaced, membership became dangerously low. Eric became President in 1970, when the need for more complete and standardized regulatory documents increased the demand for regulatory writers, which of course was Eric's area of expertise. He and four others created much of the Association as we know it today:

Arnold Melnick, DO, Executive Vice Chancellor and Provost of the Health Professions Division, Nova Southeastern University, who, in retirement with a friend, decided to start an osteopathic school in 1980 and enrolled the first class in 1981.

Red Schifrin, PhD, a clinical researcher at Hoffman-LaRoche who became Vice President and head of Drug Regulatory Affairs and was widely regarded as an expert in drug approval. His prestige was instrumental in attracting new members and sponsors.

Bill Nelligan, the executive director of the American College of Cardiology, who (surreptitiously) donated space, clerical support, and the salary for an executive director for 2 years. He remained a loyal supporter of AMWA throughout his career.

Lillian Sablack, AMWA's first executive director, was hired in 1973. She helped establish the annual meetings and brought order to the administrative functions. (Lil was my sister-in-law for many years, and we are still close. She loved to repeat a joke I once told her "What's the difference between Lil and a terrorist? You can negotiate with a terrorist." It's funny because it's true . . .)

These 4 people reorganized AMWA, began what was called the core curriculum, established a conference built around workshops of the core curriculum, and began to appeal to new constituencies. Regulatory writers began to join, as did writers and editors in scientific publications. Later, employees of medical communication companies and contract research organizations, both of which serve the pharmaceutical industry, also began to join.

The rest, as they say, is history. (Telephone conversation with Lilian Sablack, July 2020.)

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AMWA NEWS

The American Medical Writers Association (AMWA) Announces New Diversity, Equity, and Inclusion Statement

Susan Krug, MS, CAE / AMWA Executive Director

Diversity, equity, and inclusion (DEI) is a phrase that refers to organizational principles and policies that promote inclusion and representation of diverse people, including individuals of different ages, genders, races and ethnicities, religions, cultures, sexual orientations, and abilities. The AMWA leadership is committed to maintaining a welcoming environment in which all members are treated fairly, have access to programs and resources, and are empowered to contribute toward advancing the association's mission.

To further that commitment, the AMWA Board of Directors (BOD) began an important initiative in 2021 to discover, understand, and set a direction for enhancing DEI efforts within the organization. The first outcome of that initiative was AMWA's new organizational DEI statement adopted by the BOD in July 2022. The AMWA Statement on Diversity, Equity, and Inclusion reads as follows:

> AMWA is committed to creating and maintaining a culture that embraces a diverse community of individuals who value excellence in medical writing, editing, and communication. We believe that AMWA functions more effectively with diversity of thought and inclusion of varied perspectives in the shared pursuit of our mission. We strive to
>
> - Demonstrate the values of diversity, equity, and inclusion.
> - Encourage the interest, participation, and leadership of underrepresented groups within our organization.
> - Cultivate an inclusive, diverse, and accessible community of medical communicators.

A second outcome of AMWA's DEI initiative was the creation and engagement of a Diversity & Inclusion Assessment Task Force that developed the 2022 AMWA DEI Survey. The survey launched in August, and results will help AMWA gain a clearer understanding of the existing diversity of our membership, learn about current challenges or shortcomings, and recognize what AMWA is doing well so that we can continue to build upon that foundation.

By leveraging the welcoming culture of AMWA, we hope to create an even more inclusive, diverse, and collaborative environment for all. It is important that we demonstrate our commitment to diversity, equality, and inclusion to our members and staff as well as the medical communication community at large. As medical communicators, our members play a crucial part in ensuring that information about health, medicine, and science is communicated accurately and clearly to help a variety of audiences make important health-related decisions.

AMWA previously issued a statement in June 2020 (https://www.amwa.org/news/511877/A-Message-from-the-AMWA-President-and-Executive-Director.htm) on the effects of systemic racism and inherent bias that have led to health disparities that adversely and disproportionately affect minority groups. The statement acknowledged that health and well-being for all cannot exist alongside endemic racial health inequities. The message also emphasized that diversity is a strength that enriches the AMWA membership.

These are just the first steps that AMWA will take as it continues to address DEI needs. We are proud of our warm and welcoming community and the diversity among our regional and national leaders; however, there is always room for improvement. As we move forward, we plan to ensure that our programs, policies, and practices are fair and equitable for all among our diverse membership. We look forward to implementing enhancements throughout the organization that will align our commitment to DEI with our overall mission as we aspire to maintain a welcoming environment that celebrates differences and where people of different backgrounds feel comfortable sharing diverse, mission-advancing perspectives.

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AMWA NEWS

FROM THE PRESIDENT

A Season of Wins

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

I can hardly believe that the fall season is here. This past year has flown by and much was accomplished. As the year heads to its close, I think it is important to reflect on the milestones achieved and lessons learned.

When I took on the presidency in the fall of 2021, AMWA had just completed the second successful virtual conference. As we look forward to November, I am so excited that we will gathering in Denver this year to elevate health and well-being through medical communication. This year's Annual Conference Committee, led by Kimberly Korwek, has built a conference program that will meet the diverse needs of the AMWA membership. The committee has planned relevant and timely workshops and open sessions to ensure we all continue to grow in our field. If you haven't registered for the 2022 Medical Writing & Communication Conference, I encourage you to review the program and consider joining us in Denver.

As part of the conference program, I have the honor of presenting the AMWA President's Award to J. Kelly Byram, a member of the Southwest Chapter. Byram has been a devoted AMWA volunteer for several years, and AMWA has generously benefited from her time and generosity. Be sure to read my article about her achievements in the next issue of the *AMWA Journal*.

I also look to forward to recognizing this year's John P. McGovern Award winner, and I am excited to join our members in saluting other winners of prestigious AMWA awards at this year's conference.

Speaking of members, AMWA membership continues to grow. Our membership is now over 4,600 and growing, and I believe our growth is due to the incredible congeniality of our membership base. We are excited to see such an amazing number of members with diverse experiences and individual talents; and additionally, we appreciate those members who devote their time and expertise to the organization.

An important initiative from the past year was the development and establishment of the Diversity and Inclusion (D&I) Assessment Task Force. The task force, led by Dr Gail V. Flores, is working on identifying how AMWA can foster a more diverse and inclusive environment within the organization. I am proud to share that the D&I Assessment Task Force crafted a survey to help gather member perspective on this important topic. The AMWA 2022 Diversity, Equity, and Inclusion (DEI) Survey was recently shared with the entire membership. We hope you are able to participate in this very important survey, as your feedback is important.

In addition to the work of the D&I Assessment Task Force, the AMWA Board of Directors (BOD) recently approved the organization's first comprehensive statement on DEI. The crafted statement was shared with the D&I Assessment Task Force, the Chapter Advisory Council, and the BOD for feedback before the final statement went to the BOD for a vote. Be sure to read the new statement that is now posted online and in this issue of the Journal. Special thanks to the staff and members that worked together to make this statement a reality.

As I think about AMWA's mission and priorities, I am immensely proud of the work that is happening on the many committees that supports the core values and priorities of the organization. I am looking forward to the new educational programming in the pipeline and other amazing work underway. Further, AMWA is dedicated to providing top-tier education and networking opportunities for members. Even before she became the Director of Education for AMWA, Lori L. Alexander was a true leader at AMWA and was strongly dedicated to the improvement and advancement of education initiatives. I hope as she looks down, she sees what an impact she made on so many lives, and I look forward to the upcoming announcement regarding a legacy tribute to her work.

As I close this article, I am reminded of how our journal continues to feed and enrich our membership. Interesting and informative articles are published in the *AMWA Journal*, and I am looking forward to the preservation of that information in the new online journal system. The hard work and dedication of our new editor-in-chief, Michael G. Baker, and the AMWA staff liaison, Shari Rager, has resulted in a smooth platform transition that now allows for more modernization. The *Journal* and our organization continue to improve and grow. It is a season in which AMWA continues to win, and I appreciate being a part of the journey.

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AMWA NEWS

AMWA's Third Annual Meeting of Medical Writing Executives Tackles Value, Leadership, Change, Recruitment, and Retention

Brian Bass, MWC / Bass Global, Inc, Fort Myers, FL

ABSTRACT

The American Medical Writers Association (AMWA) Third Annual Medical Writing Executives Forum brought together executives of medical writing departments at some of the world's top biopharmaceutical companies to discuss topics of urgent relevance to the companies that employ regulatory medical writers, those who manage regulatory medical writing teams, and regulatory medical writers themselves. Participants identified and discussed many of the challenges and opportunities facing the industry today.

In 2018, the American Medical Writers Association (AMWA) launched the AMWA Medical Writing Executives Advisory Council for the purpose of maintaining a connection between pharmaceutical and biotechnology department heads and the AMWA Board of Directors. The council comprises senior-level professionals whose responsibility it is to recruit, train, and manage medical communicators. Members of the council represent some of the world's top health-science, pharmaceutical, and biotechnology companies as well as several companies that provide regulatory medical writing and consulting services. The council acts as a sounding board on issues such as workforce trends, training programs, and technologies that have an impact on the medical writing field. Council members also provide guidance on and participate in the annual AMWA Medical Writing Executives Forum.

The third annual invitational Medical Writing Executives Forum was held virtually on October 25, 2021. Joan Affleck, MBA, ELS, Associate Vice President and Head of Medical Writing at Merck & Co., chaired the forum. A list of forum attendee companies is provided in the table. The theme of the forum was *Igniting Leadership, Innovation, and Resilience in Medical Writing*. Participants divided into 5 breakout groups, each addressing a specific topic pertaining to the value of medical writing, next-generation leadership, the changing medical writing environment, recruiting and retaining medical writers, or leading in times of change. This article reports the key opportunities, challenges, insights, observations, and recommendations of the forum participants.

Table. 2021 Medical Writing Executives Forum Attendee Company List

- Alnylam Pharmaceuticals
- American Medical Writers Association
- Astellas Pharma Global Development, Inc.
- Bass Global, Inc.
- Bioforum Group
- Boehringer Ingelheim Pharma GmbH & Co. KG
- Bristol Myers Squibb
- Certara Synchrogenix
- Eli Lilly and Company
- Encore Biomedical Communications LLC
- Endo Pharmaceuticals
- Genmab
- Gilead Sciences, Inc.
- Greenwich Biosciences, Inc.
- Harpoon Therapeutics
- ICON plc
- Janssen R&D, Johnson & Johnson
- Karen L. Fink Medical and Regulatory Writing
- Merck & Co., Inc.
- Moderna, Inc.
- Novartis Pharmaceuticals
- PAREXEL
- Pfizer Inc.
- Praxis Precision Medicines
- Regeneron Pharmaceuticals, Inc.
- Roche Diagnostics
- RRD International, LLC
- Sarepta Therapeutics, Inc.
- Seqirus
- Syneos Health
- Synterex, Inc.
- Takeda Pharmaceutical Company Limited
- Trilogy Writing & Consulting
- Ultragenyx Pharmaceutical Inc.
- Whitsell Innovations, Inc.

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REVIEWING DATA/INSIGHTS FROM THE VALUE OF MEDICAL WRITING SURVEYS

AMWA formed a working group in 2021 to work toward defining and quantifying the value of regulatory medical writers. The Value of Medical Writing Working Group includes 3 subgroups: Engagement with Regulatory Health Authorities, Survey Development, and Literature Search and Assessment of the AMWA Training Outline and the DIA Competency Model. The efforts of the working group are ongoing, and initial findings have been reported.[1-3]

During the 2021 AMWA Medical Writing Executives Forum, the participants in this breakout group discussed several topics based on the working group's efforts to date.

Using The Data

A key finding of the working group's efforts that participants in this breakout group discussed is the need to educate others about the value of medical writers in the regulatory field. Their recommendations included

- Leveraging the working group's findings to start conversations with company managers and encourage investment in the medical writing team.
- Emphasizing to all stakeholders involved in the medical writing process that regulators prefer brevity; larger documents are not necessarily better.
- Educating subject matter experts, who are stakeholders and contributors to the medical communication process (eg, biostatisticians, clinicians, pharmacovigilance physicians), that medical writers are an important part of the regulatory communication process.

Data That Were Unexpected/Surprising

The survey of regulatory medical writers conducted by the working group found that many regulatory medical writers feel undervalued. The working group provided insight into how companies that employ regulatory medical writers can promote professional growth and job satisfaction. Participants in this breakout group recommended increasing opportunities for medical writers to gain soft skills training, providing more opportunities for medical writers to grow into leadership roles, and exploring mentorship programs to promote collaboration and leadership.

The breakout group participants noted that today's medical writers seem to be more willing to take the lead, which is an asset to help improve collaboration with other stakeholders in the communication process. Participants noted the ability to collaborate is as important as the ability to lead.

Although not surprising, participants in this breakout group acknowledged that in the United States and some (but not all) other countries, women form the majority in the field of medical writing. The group proposed an effort to explore what may be holding men back from pursuing a career in medical writing and how they might be encouraged to do so.

Communicating The Data

Initial findings of the working group have been published in the *AMWA Journal*[1-3] and presented at the AMWA 2021 Medical Writing & Communication Conference. Efforts are underway to also present findings of the working group at upcoming meetings of the European Medical Writers Association and the DIA, as well as at the AMWA 2022 Medical Writing & Communication Conference

Acknowledging the growing need for qualified, professional medical writers, participants in this breakout group proposed reaching out to high schools, colleges, and universities to increase awareness about the medical writing profession and encourage students to consider a career in medical writing.

Currently Missing From The Value Story

Participants in the breakout group expressed that a granular definition of quality is needed to provide a uniform and consistent target for all stakeholders to expect, measure against, and achieve. The breakout group thought it would be especially helpful for managers to know how quality affects the return on investment in medical writing in terms of the time, money, and resources invested. Understanding the dynamics of employing staff compared with contract or freelance medical writers would also be helpful for decision makers.

DEVELOPING THE NEXT GENERATION OF LEADERS FOR MEDICAL WRITING TEAMS

The dynamics of leadership and the characteristics of an effective leader are continually evolving. This breakout group considered the skills, tools, and opportunities that will likely be needed by tomorrow's leaders of medical writing teams.

Key Skills for Tomorrow's Aspiring Leaders

The breakout participants acknowledged that not all medical writers want to become leaders in the traditional sense of managing others, yet they agreed that all medical writers, regardless of their aspirations, will benefit from mastering the soft skills required to lead as an individual expert contributor. These soft skills include

- Flexibility
- Problem solving
- Collaboration

- Diplomacy
- Curiosity
- Agility
- Resilience
- Project management

An ideal way for someone to learn effective leadership skills is by observing an effective leader. Seeing firsthand what an effective leader does to inspire and guide their team and how they respond to challenges, provides aspiring leaders with the opportunity to see the key skills they need in action. The next step is to give aspiring leaders the opportunity to practice and internalize these newly learned skills in a safe environment in which they can challenge themselves, make mistakes, and build confidence.

Tools for Tomorrow's Aspiring Leaders

For medical writers who aspire to someday lead others, participants in this breakout identified several tools they will need to lead their regulatory medical writing teams. At the top of the list, leaders must have the trust of their team members, the ability to communicate with them clearly and directly, and leadership consistency. Leaders of medical writing teams must be able to provide positive feedback and reinforcement, ideally in the moment when such feedback is appropriate, and constructive feedback discretely when warranted.

Making sure everyone on the team has a voice and uses their voice to express their ideas, needs, and opinions is another important tool for team leaders. Being flexible with how people work can empower medical writers on the team to optimize their productivity while reducing work- and/or life-related stressors.

Autonomy is another important tool identified by the breakout participants. Team members should be given control of their own work when possible. Ownership—even of just a small piece of a larger project—fosters engagement.

Opportunities for Tomorrow's Aspiring Leaders

Today's leaders must make clear where opportunities for leadership training can be found within the organization, and reward those who are curious and aspire to become leaders by facilitating such training. Those who are training aspiring leaders should get to know the individuals they are training and their desired career paths so they can be guided appropriately. Mentorship is a powerful teaching tool, enabling aspiring leaders to learn by example.

Leadership desires may vary, and it is important for today's leaders to keep this in mind. Whereas, some medical writers aspire to a management track, others may aspire to leadership in a technical track. Likewise, a career path is different from a development path, and it is important for today's leaders to know the difference when providing guidance to tomorrow's aspiring leaders.

CHANGES IN THE MEDICAL WRITING ENVIRONMENT

In this breakout group, participants identified changes that are currently taking place in the medical writing environment and discussed what medical writers can do address them. They grouped the changes taking place into 3 categories:

- Financial demands
- Technological innovations
- Team challenges

Financial Demands

Breakout group participants noted the current demand for cost savings in their medical writing departments, which affects internal and external resource utilization. There is an added burden of internal resource management and oversight.

Increasing demands on the costs associated with managing outsourced medical writers includes demanding that outsourced medical writers self-manage their associated costs. On the staff side, there is currently a salary competition taking place in which managers are challenged to keep costs down while paying appropriately for qualified staff resources.

Technological Innovations

Technology enables medical writing teams to eliminate some of the more mundane tasks and increase efficiency, especially in regulatory writing with the use of standardized templates. Technology has changed the way teams interact with medical writers and not all of it is positive or useful. Overly customized software can be well intentioned but overly burdensome for medical writers to use. It is incumbent upon managers to determine the level of technology that best meets the needs of the team and the work environment without overcomplicating processes.

Although it may seem that standardized technologies cannot be applied to the unique requirements of rare disease indications, a similarly unique or specialized use of technology may not be required.

The breakout group participants also discussed the differences between logic-based and artificial intelligence-based technologies and agreed that more information is needed to choose the appropriately technology for a particular application or team.

Team Challenges

Challenges experienced by medical writing teams add expense and time to a project. Templates can help streamline these processes, provided they are not too individualized. Regulatory medical writers must keep in mind that they are writing for a health authority audience, not for subject matter experts.

Two major challenges faced by regulatory medical writers concern document brevity and timelines. Regulatory reviewers have said they want documents to be clearer and more concise, but medical writers typically lack the authority to impress this upon other stakeholders in the document development process. Verbose documents also take more time to produce, which contributes somewhat, but not solely, to the second challenge of timelines. Medical writers rarely have influence over the timelines that drive their work, and when pushed to meet timelines that may be unrealistic to the task, can experience burnout and possibly even stress-related injuries.

What Medical Writers Can Do

The breakout group participants identified ways in which medical writers can address these changes taking place in the regulatory environment. These include

- Clarifying the role of medical writers to stakeholders, some of whom who simply want scribes.
- Elevating the visibility of the medical writer as a vital member of the team.
- Engaging medical writers in setting timelines and giving them confidence and authority to push back against unrealistic deadlines.
- Conducting after-action reviews with the team to identify what went right and discuss opportunities for improvement.
- Highlighting transparency initiatives to help with standardization, use of templates, and leaner authoring.

RECRUITING AND RETAINING MEDICAL WRITERS

Participants in this breakout group discussed turnover rates, the key attributes to look for when recruiting medical writers beyond writing skill, interacting with recruiters, training programs, and methods for recognizing, remunerating, and retaining top talent.

Turnover

Some companies have experienced attrition exceeding the rate of onboarding new employees, with turnover rates among medical writers reportedly as high as 30%. Burnout is a large contributor to turnover, with some medical writers moving to freelance work to achieve a better work-life balance while others fear moving out of the company environment due to stability. Another contributor to turnover is the disparity in position leveling across companies, which may make it enticing for staff medical writers to move from a larger pharmaceutical company to a smaller biotechnology company that may be recruiting at higher positions and offering higher salaries.

Key Attributes to Look for When Hiring Medical Writers

Beyond writing skill, the breakout group participants identified a range of key attributes for hiring managers to look for when recruiting medical writers:

- Ability to work remotely
- Well-rounded document experience
- Contribution to a diverse team
- Innovative thinking, particularly concerning adoption of automation
- Emotional intelligence

During the hiring process, some companies engage panels to interview candidates, which can be intimidating and time consuming. Other companies have considerably more expedited interviewing processes. The interview is especially important because it provides candidates an opportunity to talk the talk and show what they truly know.

Many companies are focused on ensuring diverse slates of candidates for open positions as well as diverse interview panels. Building diversity strengthens the quality of a good medical writing team and can take the team to new levels of innovation including being able to manage challenges from different perspectives.

Companies that require writing tests vary between in-person and automated platforms. It was noted that writing tests can be perceived as demeaning by more-experienced medical writers who may subsequently decline and be lost as potential candidates. Developing an experience grid may make it easier for hiring managers to determine and compare candidates' true experience rather than reviewing CVs.

Interacting With Recruiters

Participants agreed that personal recommendations and referrals are best for identifying qualified candidates. Companies have had varying degrees of success using internal and external recruiters and have found that recruiters themselves need training on the skillsets required to be a successful medical writer.

Training

Several breakout group participants reported that their company provides training programs in the form of apprenticeships, writing academies, and summer internships. University training programs are needed, as well as efforts to educate students about careers in medical writing.

Retaining Top Talent

Bonuses, career ladders, and work-life balance are among the tools companies can use to retain top medical writing talent. This may include monetary and gift award programs, retention bonuses, and offering clear development and leadership opportunities. It can be challenging when an employee's drive for advancement exceeds the company's established processes and timelines for promotion.

Work-life balance is an important consideration for staff medical writers and may include opportunities for part-time work and personal time off. In the European Union, it was suggested that most regulatory medical writers are part-time. As a result, companies and staff must adapt to maintain workflow and timelines, such as document sharing among team members. Having a reliable group of backup writers can also help.

LEADING TEAMS DURING A TIME OF CONSTANT STATE OF FLUX AND AMBIGUITY

Participants in this breakout group discussed the role of team leaders in managing change within their medical writing departments, and how managers can help affect change within their teams and with outside vendors.

Managing Change

Change is constant. Critical factors in managing change are transparency, community, and trust. Managers of medical writing teams can best manage change by being upfront and honest, present and calm, transparent, and realistic (ie, not superficially or unrealistically positive). Teams tend to absorb and then radiate the mood of their environment, whether that mood is calm or negative. Managers should lead by example at all times and especially when times are tough.

Team managers should be honest about what they know and do not know to avoid team members thinking that information is being kept from them. It is easier to get a team to embrace, or at least accept, change when they understand why it is needed or happening. It can be helpful to discuss the opportunities that change may bring. However, change should not necessarily be normalized, such as when a key support structure is no longer in place. The COVID-19 pandemic provides an example of this, when schools were no longer meeting in person and employees began working from home with their children learning from home.

Affecting Change

Affecting change within a medical writing team is challenging and time consuming for the team manager. Managers must address the concerns, expectations, and needs of the team members and implement the necessary changes while also maintaining the team's focus on the project tasks, goals, and timelines at hand. Providing the information medical writing teams need to understand and be a part of the change will help suppress the speculation and rumor that might otherwise persist. Engaging the assistance and support of Human Resources when relevant can also be helpful.

Managers must be cognizant of the impact changes can have on team members. For example, working from home during the COVID-19 pandemic fostered greater productivity, but it also led to higher rates of burnout as staff found themselves working longer hours. Some breakout group participants said they provide opportunities for their team members to recharge, including offering mental health days that can be branded as "Days of Reflection" or "Curiosity Days." Change is not forever, and the medical writing team may be reassured to know that a company's or a department's response to change can evolve if something does not work as well as planned.

Change can also be difficult for vendors, whom some perceive as threats rather than members of the team. It is important to match the expectations of the team and the vendor at the start of the relationship and ensure goals are aligned.

Some participants in the breakout group noted that they invite their contract medical writers to team meetings to foster a collegial atmosphere built on familiarity, trust, and cooperation. Connecting vendor members of the team with sponsor members can help build and strengthen these relationships. In dealing with vendors during times of change, once again, communication is the key to success.

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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AMWA NEWS

AMWA Fellowships

Sarah Dobney / 2021–2022 Director-At-Large and Chair, Member Awards Committee

AMWA Fellowships are awarded to members who have made significant contributions to the goals and activities of AMWA. The 2022 Fellows are leaders with distinguished records of service at the chapter and national levels.

LORETTA BOHN

Loretta Bohn, ELS, is a senior editor/writer at RTI International, an independent, nonprofit research institute, where her current assignments concentrate in behavioral health and criminal justice. A communication specialist with 30 years of experience in editing, writing, and proofreading, she focuses on developing relationships with authors and on mentoring newer editors. Trained as a schoolteacher, she has taught writing and editing workshops for both AMWA and RTI. In her nonwork hours, Loretta runs a household for the comfort and convenience of her 2 cats, volunteers in various capacities at church, and is learning to garden.

ERICA GOODOFF

Erica Goodoff is a Senior Scientific Editor in the Research Medical Library at The University of Texas MD Anderson Cancer Center, where she has worked for the past 11 years. She began her career at a publishing house, where she started as a proofreader and then became a managing editor of several life science journals. Erica attained the Editor in the Life Sciences certification in 2010 and earned diplomate status in 2020. In her current role, she spends most of her time substantively editing research papers and grant proposals, as well as periodically presenting workshops and training sessions for her clients on how to write these documents. She is also the leader of her group's editing internship program, in which she recruits, supervises, and mentors future editors.

Erica has been an active member of AMWA for 11 years. She has volunteered for the Southwest Chapter board of directors since 2013 and has served as Treasurer of the Southwest Chapter since 2016. She has presented various open sessions, roundtables, and webinars on editing and professional development topics at both the chapter and national levels. Erica is currently a member of the Annual Conference Committee and teaches the Essentials of Copyediting workshop.

GAIL V. FLORES

Gail V. Flores is a freelance medical writer who specializes in the development of educational materials for pharmaceutical and biotechnology sales representatives in oncology. Gail's favorite parts of doing her PhD thesis research in a *Drosophila* lab at UCLA was learning how to develop publications and presentation materials that effectively and clearly communicated the results or her experiments and reading and hearing about novel research being conducted in other labs around the world. She started working as a science writer in 2000, joined AMWA in 2001, and shortly thereafter launched her medical writing business, Encore Biomedical Communications LLC. After participating in the leadership of the Pacific Southwest Chapter for 11 years, Gail joined AMWA's national leadership in 2016, had the honor of leading AMWA as President in 2020–2021, and currently serves as AMWA Immediate Past President. Over the years, Gail has been a member or chair of several AMWA committees and task forces, presented at chapter events and annual conferences, co-authored position statements and press releases for AMWA, and contributed to the *AMWA Journal*. Gail is passionate about the craft of medical writing and values the important role medical communicators play in today's world; she also treasures the friends, professional connections, and welcoming community that AWMA has provided.

Please join AMWA in congratulating Loretta, Erica, and Gail. They will be acknowledged at the 2022 Medical Writing & Communication Conference, to be held in Denver, CO from November 2–5, 2022.

The Member Awards Committee members were Melissa L. Bogen, Elizabeth Brown, Sarah Dobney (chair), Mary Knatterud, Susan Krug (ex officio), Abbie Roth, and Michael Schneir. Diane Noland from AMWA HQ provided excellent support.

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AMWA NEWS

Harold Swanberg Distinguished Service Award

Sarah Dobney / 2021–2022 Director-At-Large and Chair, Member Awards Committee

The Harold Swanberg Distinguished Service Award, named in honor of one of the founders of AMWA, is presented to an active AMWA member who has made distinguished contributions to medical communication or rendered unusual and distinguished services to the medical profession.

This year's Swanberg recipient is **Julia Forjanic Klapproth, PhD**. Julia has made distinguished contributions to the medical communication profession.

After receiving her PhD in Developmental Neurobiology, Julia Forjanic Klapproth started her career as a medical writer in the pharmaceutical industry at Hoechst Marion Roussel (later Sanofi) in 1997. In 2002, Julia co-founded Trilogy Writing & Consulting, a company specializing in providing medical writing of regulatory documentation. In addition to company management activities, she continues to contribute to client projects, writing a wide array of clinical documents.

She has also been President of the European Medical Writers Association (EMWA) twice (2001–2002, 2007–2009) and is an experienced speaker and trainer of medical writers, regularly running workshops for EMWA, giving training for AMWA, and pharmaceutical companies around the world. This training covers medical writing topics, interpersonal relationships, and effective communication skills. Julia has also been an *AMWA Journal* contributor, member of the Medical Writing Executives Advisory Council and Value of Medical Writing Working Group committees, conference presenter, volunteer since 2018, and current professional member (since 2017; Carolinas Chapter).

As part of the senior management team at Trilogy, Julia supports both EMWA and AMWA not only by giving her time to teach, but by encouraging and supporting Trilogy writers to attend the conferences and become active within the organizations themselves. Julia is a staunch supporter of medical writers and has worked tirelessly to promote their standing by regularly presenting and writing about the value that strategic medical writing brings to clinical development and campaigning for better and more focused training and development specifically aimed at medical writers.

For 25 years, she has contributed her expertise in writing and coordinating all manner of regulatory documents. She has authored articles on a broad range of medical writing topics.

In her efforts to promote the value of medical writing and train both medical writers and clinical authoring teams on good writing concepts, she has presented at international conferences and training events on a wide array of topics.

Julia's long-standing service demonstrates her passion for promoting excellence in medical communication. AMWA is proud to recognize Julia as the recipient of the 2021 Harold Swanberg Distinguished Service Award.

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AMWA NEWS

The Golden Apple Award

Sarah Dobney / 2021–2022 Director-At-Large and Chair, Member Awards Committee

The Golden Apple Award is presented to a member of AMWA to honor consistent, outstanding workshop leadership.

This year's Golden Apple recipient is **Brian Bass, MWC**. The Member Awards Committee was impressed with Brian's long-term commitment to leading workshops for AMWA and ability to keep his workshops engaging and his material timely and relevant.

Brian has a long history of supporting AMWA's educational mission. He founded the AMWA-Delaware Valley Chapter Princeton Conference in 1997, bringing a combination of educational workshops and sessions to AMWA members throughout and beyond the Delaware Valley region. He continued to chair The Princeton Conference for 16 years.

In 1997, Brian also taught his first workshop, The Creative Process in Pharmaceutical Advertising & Promotion. Since then, Brian has developed 3 new workshops to help participants develop, launch, and build successful freelance careers. Over the years he has presented these 4 workshops a total of 21 times, with an overall evaluation score of 4.63 out of 5. Brian has also developed and presented 36 open sessions and panel discussions, 16 roundtable presentations, and 10 webinars.

Please join AMWA in congratulating Brian. He will be acknowledged at the 2022 Medical Writing & Communication Conference to be held in Denver, CO from November 2–5, 2022.

The Member Awards Committee members were Melissa L. Bogen, Elizabeth Brown, Sarah Dobney (chair), Mary Knatterud, Susan Krug (ex officio), Abbie Roth, and Michael Schneir. Diane Noland from AMWA HQ provided excellent support.

The AMWA Board of Directors met July 21-22, 2022 at the AMWA headquarters office in Rockville, MD. The hybrid meeting allowed all BOD to attend, either in person or online.

Back row (L to R): Susan Krug, Kim Korwek, Loretta Bohn, Brian Bass, Sarah Dobney, Gail Flores. **Middle row (L to R):** Jennifer Minarcik, Laura Sheppard, Elise Eller, Ann Winter-Vann, Shawn Watson. **Front:** Katrina Burton. **Not pictured (attended virtually):** Joan Affleck, Michelle Sauer Gehring, Lynne Munno, JoAnna Pendergrass, Julie Phelan.

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AMWA NEWS

Slate of Officer Candidates for the 2022–2023 Election

Elise Eller, PhD / 2021–2022 AMWA President-Elect

One of the privileges of serving as President-Elect is chairing the Nominating Committee, which is charged with selecting a slate of officers for the upcoming governance year. It was my pleasure to serve with Cyndy Kryder, MS, MWS; Tenille L. Lawson, PharmD; Erik MacLaren, PhD; Julie Munden, BA; Jill Roberts, MS; Theresa E. Singleton, PhD; and AMWA Executive Director Susan Krug, MS, CAE (ex officio, non-voting member). I thank my fellow committee members for their insights and critical evaluation of officer candidates for the 2022–2023 governance year.

Each year interested members are invited to submit a board interest form for consideration of 1 of 3 elected offices: President-Elect, Secretary, and Treasurer. The Nominating Committee reviews the forms and qualifications of candidates who meet the criteria and collectively agrees on a candidate for each officer position to submit to the AMWA Board of Directors (BOD) for consideration.

I'm pleased to present the following candidates who were presented to and approved by the AMWA BOD at the June BOD meeting:

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

PRESIDENT-ELECT

R. Michelle Sauer Gehring, PhD, ELS, an AMWA member since 2009, is in her fourth year on the AMWA BOD (since the 2018–2019 term) and currently serves as secretary and liaison to the *AMWA Journal*. Previously, she served on the Annual Conference Planning Committee (2013–2020), chaired the committee for the 2019 Conference in San Diego, and was a member of Editor-in-Chief Search Task Force. At the chapter level, Michelle served as Treasurer (2012–2016), Program Chair/President-Elect (2016–2017), and President (2017–2018) of the Southwest Chapter as well as chapter conference committee chair from 2015 to 2018. She was awarded an AMWA fellowship in 2021. Michelle has taught the Ethics for Science and Medicine workshop for AMWA. She teaches Citations and References for Medical Writing and Ethics for Medical Writers at the University of California San Diego Extension. Michelle has authored or contributed to multiple *Journal* articles and serves as a peer reviewer. Michelle is the Senior Research Scientist for the University of Texas Health Science Center at Houston's Center for Advanced Heart Failure and co-owner of RnAEditing, LLC. She is the copyeditor of PURSUE and the Managing Editor of the *VAD Journal*.

SECRETARY

Kimberly Korwek, PhD, an AMWA member since 2010, has been on the AMWA BOD for 3 years. She is currently the Chair of the 2022 Annual Conference Program Committee. During the 2019–2020 term, she served as the Chapter Advisory Council Chair on the BOD, and prior to that she was a member of the Chapter Advisory Council (2017–2019). From 2016 to 2019, she was a section editor, serving on the editorial board for the *Journal*. Kim was President of the AMWA Southeast Chapter (2016–2017), serving previously as President-Elect (2015–2016). She also served as a Chapter Delegate to the AMWA BOD (2016–2017) and the Website Coordinator for the Southeast Chapter (2018–2019). Kim is the Manager of Scientific Communications within the Clinical Operations Group of HCA Healthcare. In this role, she is responsible for the management of the portfolio of comparative effectiveness research projects that seek to use data collected within the course of clinical care to improve health care delivery and patient outcomes. Kim also manages the development of scientific publications, including manuscripts, abstracts, presentations, and white papers to facilitate the distribution of research findings to internal and external audiences.

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TREASURER

Julie Phelan, MBA, MD, an AMWA member since 2009, is in her sixth year as Treasurer on the AMWA BOD and Chair of the Budget & Finance Committee (2016–2022). She was previously a member of the Budget & Finance Committee (2015–2016), the Communications Committee (2014–2015), the 2015 Salary Survey Task Force, and the Online Community and Social Media Committees (2012–2014). At the chapter level, she was President of the Greater Chicago Area Chapter (2013–2016), serving previously as President-Elect (2012–2013). She also served as Membership Chair for the chapter (2011–2015) and as a Chapter Delegate to the AMWA BOD (2013–2016). She has authored articles for the *AMWA Journal* and currently serves as AMWA's Registered Agent. She was awarded an AMWA fellowship in 2017. Julie is the founder and President of Biomedisys, Inc, a medical communication and strategy consulting boutique in Chicago, IL. She has more than 20 years of medical communication and business strategy experience including working as a biotechnology equity research associate analyst at Robert W. Baird & Co, medical and strategic advisor for an insurance corporation, and medical communication consultant.

PROCEDURE FOR ADDITIONAL NOMINATIONS

As required by AMWA's Bylaws (Article IV.2e-f), these nominations were announced to the AMWA community by email more than 60 days before the annual business meeting. A nominee who is unopposed for any office is declared automatically elected at the annual business meeting. As stated in the bylaws, additional nominations for President-Elect, Secretary, or Treasurer may be made by any member provided the member meet the criteria set forth by the BOD. The criteria and process are listed below:

- Member dues must be current, and the member must be in good standing.
- The nomination is submitted in writing to the Secretary of AMWA at least 30 days in advance of the annual business meeting. This year's annual business meeting is scheduled on November 5, 2022.
- The nomination must clearly state the qualifications of the candidate and be signed by 50 members in good standing as of the date of the receipt of the nomination.
- The nomination must be accompanied by a letter from the candidate stating that she or he is willing to serve if elected.

AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V37 N3 / 2022

CONFERENCE

2021 Walter C. Alvarez Award Address

The Journalistic Structure of Medical Revolutions

Harriet A. Washington, MA / Writer and Medical Ethicist, Fellow of the New York Academy of Medicine, New York City, NY

The Walter C. Alvarez Award is named in honor of Walter C. Alvarez, MD, a pioneer in the field of medical communication. The award is presented to either a member or nonmember of the American Medical Writers Association (AMWA) to honor excellence in communicating health care developments and concepts to the public. The Alvarez Award is presented during AMWA's Medical Writing and Communication Conference.

Image 1. *Carte Blanche*, as well as other books written by Harriet A. Washington, and an article written by Washington on the removal of the statue of Dr James Marion Sims in New York City's Central Park.

Hello. I want to begin by thanking the American Medical Writers Association (AMWA) for the Walter C. Alvarez Award. I'm deeply honored and very happy to join this august company of award winners. I'd like to share with you a bit of my odyssey as a medical writer, including some of the very important influences on my work and on my perspective.

My odyssey as a journalist and medical writer has been one of expanding my perceptions of what that means. Like many people, I became interested in both science and then writing early on. Although I wasn't quite sure how to integrate these 2, I perceived becoming a medical writer as a mission of translating science for everyday people and helping them to make the best decisions for their health and welfare and for that of their family and of society. That certainly is an important part of our mission, but with science comes human values.

I also have embarked on a discovery of things beyond pure science—human endeavors, human concerns, human biases and limitations, as well as human ethics and goals and motivations that also affect our role as medical communicators. Now it seems rather clear to me that science is not limited to data—a compendium of information and a bloodless analysis—but rather, it appropriates every human endeavor. Moreover, it's not only the values of humanity that affect science but also its limitations. The same limitations that cause people to express bias, prejudice, a narrowing of one's perceptions, a narrowing of one's horizons…these things affect science, too.

As Thomas Kuhn, author of *The Structure of Scientific Revolutions* tells us, aside from the strictly logical theories and hypotheses that enchant us all and that we rigorously adopt, there's also the effect of politics and of racial concerns and concerns around gender. Anything that affects human societies also weighs in and has some effect on the science that emanates from them. Winston Churchill probably said it most succinctly when he pointed out that "history is written by the victors." We have a view of scientific endeavor and achievement and even science's purpose, that is shaped by the values of people who are triumphant, who are dominant, who are telling their story through the history of science and through science as an endeavor.

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Dr Felix Okoye, a professor of African history, said basically same thing: "Don't let the lion tell the giraffe's story." As we look at the history of science, a history whose first draft is written by medical journalists, we come to understand that much more than bloodless numbers affect science. I didn't know this at the beginning. At the beginning, I was given a very different idea of my mission as a medical writer.

WHO CAN BE A SCIENTIST? WHO CAN INTERPRET SCIENCE?

My first job as reporter was at my college newspaper, like a lot of people. I was quickly confronted—in a polite but very powerful way—by the editors who gathered together to talk to me. The only thing they had to say was, "How can *you* be an objective journalist?" This was the 1960s, a time of racial tension on campus, and they pointed out that as an African American, I would almost certainly be promulgating the experiences and the aims of African Americans, and I could not be objective. And if I could not be objective, how could I be a good journalist?

I was a bit shocked by that and quickly pointed out that one could say that of any ethnic group; I mean, why are you singling me out? I didn't understand why they were singling me out at the time. Later, I came to understand that it had to do with who is perceived as someone who can be a scientist, and for that matter, who can be a journalist. We've long had the attitude in society that only certain people can be scientists, that objectivity is out of reach for certain people. Notably, for a time, we thought women could not be objective for various reasons, and it was also felt that African Americans couldn't be objective.

But one's definition of "objectivity" actually shrouds the uglier bias: That certain people are simply not equipped to craft an analysis that is devoid of unwanted emotional or social perspective that would "pollute" pure science. Donna Haraway articulated this point very powerfully when she pointed out that the word *objectivity* has come to stand for, in many cases, the requisite tone of the White male scientist, who was assumed to be without these kinds of encumbrances, to be objective by nature. That's actually a flaw in our society—we assume certain people can be objective by nature. Of course, objectivity itself, as we know, is a bit of an elusive goal.

This idea of who can be a scientist spills into who can be a medical journalist. For a while, I tried to hew to this ideal of someone who was demonstrating that yes, I can be objective. Yes, I can discuss things without invoking the messy business of race or of social frictions or, for that matter, of women's concerns. Discussing the science, writing about science, analyzing science, without polluting it with these concerns, became something that I set as a goal for myself. It was a goal shared by many of the people that I wrote for and worked with.

I remember, around the same time, in the 1970s, being told that medicine was an unrealistic career goal for me. I originally wanted to be a doctor, but I was told that no, there were no Black women doctors, and Black women were simply not suited for medicine, without more explanation than that. So having sterling grades and all the experiences that one would normally associate with being a good candidate didn't seem to matter. I simply was constitutionally not an appropriate candidate. At 16 years old, I didn't know any better. I've never since let someone tell me what I can and can't do in that manner.

Up to that point, I was used to being encouraged by my academic guides and leaders and teachers, so I believed them. I don't believe them anymore. And as I matured and learned more about who can and cannot be a chronicler of science and what is and isn't an appropriate addition to science, I began to understand that my mission had changed. My mission was no longer to be a translator, simply translating science without any presumptions or bias, but to analyze and also criticize science when it was appropriate.

ACADEME AS CATALYST

Criticizing science was very difficult because doing so seemed to evoke hubris. And yet I saw racial bias in the hospital that I worked in during the 1980s. I also saw racial bias in reporting about medicine and science. This troubled me. How do you counter that and still adhere to promulgating scientific rigor? I felt it must be possible, but I didn't see examples of this until I was fortunate enough to land a journalism fellowship at Harvard School of Public Health (HSPH) in 1992. They selected 3 medical journalists a year.

> **"The key role of writers in the evolution of medical thought and practice has been both exaggerated and, at key junctures, effaced. Writers are blamed for failings that they share with an inherit from scientists. Medical news has been a catalyst for change when it revealed momentous events such as 'Mississippi appendectomies,' the abuses at Willowbrook, and the USPHS study at Tuskegee."**
>
> **– Harriet A. Washington**

The years at HSPH inspired me to venture beyond translation and focus on divining the medical truth by navigating conflict of interest, financial bias, sexist, and later, racist assumptions. I was exposed to thought leaders,

public health leaders, ethics leaders, very powerful, brilliant people who were advancing public health and medical ethics. The director, Bob Meyers at the time, was deeply invested in us and in our holistic education as medical writers. He put me in touch with people like Jonathan Mann, Larry Gostin, Allan Brandt. This opened an entire world for me. I began to see my mission as something that encompassed both my desire to address troubling facets of medical problems in this country and also being true to my desire to be a rigorous chronicler of science.

None were so transformative as Marcia Angell and Patricia Thomas. We were lucky enough to meet Marcia Angell while she was editor of *The New England Journal of Medicine*. By challenging the conventional wisdom that medical practice and research were purely motivated by scientific rigor, she pointed out the immense corporate influence on any number of conflicts of interest, which had nothing to do with scientific accuracy and everything to do with promulgating power and money in the hands of people who held it. In meeting her and hearing her talk about her work so fearlessly, I felt I'd been given permission to look into things that troubled me, to see whether they were as accurate and rigorous as I'd been told or, perhaps, whether they were also being affected by conflicts of interest. And that was revelatory.

Patricia Thomas, who was then editor of *Harvard Health Letter*, commissioned me to write some pieces, but I learned more from her than simply as a medical editor. She was also challenging conventional wisdom, in part by looking at the reporting around women's issues. And one of the very basic tenets was that very often journalists were writing reports that did not include the perspective of women's health experiences. Thomas, who took me to my first AMWA meeting in 1993, helped me to see beyond the role of translation and generating accurate useful messages from medical journals, to then seeing the unsupported assumptions, subtle and missing data, unasked questions.

An example was the "inappropriateness" of including women in research because of their hormonal fluctuations, pregnancies, and monthly cycles—messy things that would disturb the pristine data, conclusions, and health portrait that could be gleaned only by investigating that 150–pound White male. And just like Marcia Angell, Thomas was fearless and pointed out that this is wrong—you're excluding more than half the population and emerging with a very inaccurate picture.

These fearless women, these fearless scientists, made me see that my mission was something deeper. I wanted to certainly promulgate medical truth, but I also wanted to look at deeper truths. How were women being mischaracterized and affected by medical missteps? How were people of color being affected?

That became my mission which I have devoted myself to for 20 years. I could not have done it without the examples set by these other scientists early on. I followed this up with a few years at Harvard Medical School where I was a medical ethics research fellow and emerged with my first important work, which was *Medical Apartheid*, essentially a correction of the history of medicine, which has systematically excluded the experience of people of color.

I went on to teach ethics at Columbia University. I teach a course on journalism and bioethics in which I talk about parallels between medicine and journalism. Very often we find scientists and physicians accusing journalists of sensationalism. Quite frankly, I can't say that we were innocent, but they also share these limitations. I remember, very frequently, having articles disparaged by scientists who'll say, "ah, that's not accurate," and more to the point, "it's written to sell more papers and attract more attention."

And yet, at the School of Public Health, I remember during the very first year being mystified by how many professors who, after having the students introduce ourselves, would flock to me. They didn't flock to the people who were brilliant, had done research, worked in the developing world, done all kinds of fascinating science. They flocked to me because they wanted media attention. A lot of these scientists had biotech companies, and they understood that media attention could help them to attract investors, and they wanted to know if I could help them do that.

There's nothing wrong with seeking attention if it doesn't interfere with the accuracy and ethics of your work. But to accuse journalists of that when the field itself engaged in it is really not fair. When I worked at *USA Today*, I interviewed a doctor who astonished me by asking, "Can you get me on *Oprah*?" He also was seeking attention for his work.

I had been told that when I worked at *USA Today*, any scientist I called would call me back immediately. That had not been my experience, but they would call back because it was *USA Today*, which at that time had a large circulation. Therefore, accusations of sensationalism or sloppy reporting can frankly go in both directions, as can less than rigorous standards. It's important to remember that and perhaps not become defensive about it.

AN APOLOGY AND A BANISHMENT

During the 20 years that I have done the work I felt greatly blessed and enabled to do by meeting these fearless scientists, there have been a few things that stand out as

especially significant. One was a 2008 apology from the American Medical Association (AMA) to the nation's Black doctors based on a paper that my coauthors and I wrote and published in the *Journal of the American Medical Association* (*JAMA*) in July 2008.[1] I then popularized the report findings in a piece I wrote for *The New York Times*.

The apology was a good sign, but what's really important about apologies is what happens afterward. In this case, what happened afterward was very promising. There were a few projects that AMA and the National Medical Association worked on together, a committee to end health care disparities and such things, that were the lasting significant events emanating from that apology.

The other event that I'm especially satisfied with was in 2018, the banishment of the statue of Dr James Marion Sims from Central Park. This was after I had detailed the unethical nature of his research with enslaved Black women who, of course, could not give consent. The statue sat right across from the Academy of Medicine in New York. Women living in the area—mostly Black and Hispanic women—ceaselessly besieged City Hall and the Parks Department to have the statue removed. They did so with assistance from mostly White medical students who also lived in the area. This happened 10 years after I had given a talk at the Academy of Medicine in which a medical student jumped up and said we ought to tear his statue down.

These are 2 really important things I have had a role in bringing attention to.

AN EROSION OF INFORMED CONSENT, A CALL TO ACTION

I'm still working on the third thing, and it is something that I hope other medical writers will find worthy of looking into. In fact, we might need a groundswell of attention. It's my contention that informed consent is waning in US research. Two laws have passed that formally allow research to be legally conducted without people's permission or without, even, their knowledge. And many, many enterprises are burgeoning.

EROSION OF CONSENT[2,3]

- Department of Defense obtained a waiver to force 8.9 million ground troops headed to the Persian Gulf to be inoculated with experimental anthrax vaccines. (1990-2005)
- Poor Black women in North Carolina were forced into racialized nonconsensual drug studies. (1994)
- New York City law enforcement officials helped researchers to coerce Black parents to enroll their boys in a study that south to establish a genetic propensity for violence without their consent. (1994-1995)
- Modifications to the Code of Federal Regulations (21 CFR 50.24) permits investigators to conduct research with trauma victims without their knowledge or consent. (1996)
- Northfield Laboratories ran a national trial in which ambulance crews randomly administered blood substitute PolyHeme to unconscious victims of car accidents, shootings, and cardiac arrests. (2003)
- Resuscitation Outcomes Consortium is recruiting 21,000 subjects in the United States and Canada to test experimental drugs and devices for severe injury and cardiac arrest without consent.

Image 2. Screenshots of articles Washington has written on lack of consent in medical research.

My concern is that there is little attention to this—people simply don't know. Unless we take a stance and examine this ethically and determine whether it's the way we want to conduct medicine and science in this country, I'm afraid people won't realize it until it's too late, until we've lost informed consent. I don't know if you'll agree with me, but I hope that people will at least think about this and whether they think it's worth their time.

Here's a copy of the article that we wrote for *JAMA* detailing the treatment of African American doctors by White doctors and *The New York Times* article accompanying that. And here are some pieces I wrote about how informed consent is being slowly and insidiously taken off the table in American medical research. And here's the book I published just this year, *Carte Blanche*, in which I talk about the erosion of informed consent, how the law is allowing informed consent to be dispensed with, and how the pandemic is, not surprisingly, escalating this tendency.

I want to share an image with you. Dr Sims' statue was carted away from Central Park and banished to Brooklyn, out of sight, and I was there.

Image 3. Sims statue being removed from Central Park.

RESEARCH IN THE DEVELOPING WORLD

The final thing I wanted to touch on is something that medical journalists should be writing about more frequently and, perhaps, should take a departure from much of the ethical literature. We are using the developing world more and more frequently to conduct research on which our medications are predicated. And yet, informed consent in the developing world, is—if anything—less frequently observed than it is in the United States. That's been a concern for a very long time. Some researchers, for a very long time, have cast a rather jaundiced eye toward informed consent in the developing world, offering various reasons why it's not appropriate, or efficient, or convenient. But the question is, is it right? Is it ethical to dispense with it? I say no.

I think that sometimes we have failed to understand the ethical breaches because they're cloaked in language that hides them. If you look at the 2014 West African Ebola epidemic, the outbreak was deeply concerning, not because of the loss of life, the many illnesses, but because there was a potential remedy, Zmapp, that was being promulgated. Only a few doses were available and discussions about who would get the medication troubled me greatly. There was a consensus that it should be given to White and Western caregivers and not be given to West Africans.

The excuses covered the gamut. Some people said the caregivers have to survive in order to treat people, so they should get it first. I can see prioritizing them, certainly. But withholding it from Africans was excused by saying that, well, Africans don't really trust Western medicine, it would be a waste, they wouldn't take it anyway, they wouldn't take it properly. And some people, including Dr Kent Brantly, who treated West Africans and contracted Ebola, said they can't really understand the informed consent as I can.

At the end, Brantly received it, but Sierra Leone's chief virologist, Dr Sheik Umar Khan, was never told it was available. He died without ever receiving Zmapp. The discussion around that was rather uninformed sometimes. One CNN doctor–journalist said, you can't give it to Africans because the medication has been only tested in monkeys, and now if you give it to Africans, people will say that that sounds racist. And I thought, surely, he must know that by law, every medication must be tested in animals first. I don't know if he did or not. But his opinion seemed to carry the day.

I had a discussion with CNN about it.[4]

Interviewer: You know, you bring up a point that I have certainly heard among some friends of mine just asking this question, you know, who is it to decide, at the end of the day, who lives, who dies. Who gets this drug if, in fact it, you know, manages to help these Americans or not?

Washington: Right. Well, that is the obvious question. And certainly, no one intends to withhold the drug from Africans. But for economic and historical reasons, that is precisely what tends to happen. It's not an accident that they, so far, have not had access to it, which I hope will change as more becomes available. There are economic reasons, a network, to which Westerners tend to have access but not people from developing countries that influences who gets scarce drugs.

Interviewer: Let me flip the script because we could be having, Harriet, a very different discussion if the headline instead were "experimental drug only used in monkeys and now being tested on West Africans." I mean, I think that there would be outrage that people would be saying they're being used as guinea pigs.

Washington: Well, those people would be wrong because it happens all the time. We have to remember that the way our system of testing drugs is designed, some people are always the first to get a drug. And increasingly, those people are people in the developing world where now 2 out of every 5 clinical trials are being held… So, it's frequently the case that these people are the first to get a drug that's been tested in animals. And that's perfectly acceptable—we've decided those are acceptable risks. What is important and what is not acceptable, sometimes, is the way in which the trials are administered and conducted.

Interviewer: What about the drug maker itself and the fact that, you know, this had only been tested, according to Sanjay Gupta, you know, in monkeys and now this is the first time it's being used in humans. Your point just being that this happens—we just don't talk about it as often?

Washington: No, my point is that this is actually more akin to the normal course of things than it looks. Our clinical trials are set up so that every drug that is tested in humans has to first be tested in animals. But if you think about it, some group of humans is always the first group to get the drug tested in them before any other humans. So, there's always a case that there are…are people who are initially tested. The questions arise when who these people are seems to be a product of some kind of bias, whether it's intentional or economic or some other kind of bias.

And when the testing violates ethical principles that are very well entrenched like informed consent, what we are frequently hearing about, in the Third World, are trials in which there's not informed consent. As we would expect to have in Connecticut, someone explain to us, according to our laws, what the drug is, what the known side effects are, what the possible results of taking a drug are, all the possible options of taking a drug, these are very carefully spelled out in our law in the Code of Federal Regulations. But once researchers begin testing drugs abroad, all too often, these rules fall by the wayside, and there's not as much oversight, so it's easy to cut corners abroad. That is actually the problem—not the fact that some people become the first group to get the medication.

Interviewer: I've got it.

Today we remain in the throes of difficult ethical decisions about the people in the developing world who are testing medications, making them possible for us to use, and then ending up without access to those medications themselves. What we're going to do will be the result of how well we're able to analyze what's happening and what the various people's rights and needs are. Medical journalists will play a key role in that. If we thoroughly look at all the issues and promulgate them, whether or not these are the issues being discussed by doctors and ethicists, then we will have fulfilled our mission to help us make the best decisions. If we fail to do that, then we will not.

I want to express, in closing, my deep, deep gratitude at not only having had the chance to pursue things that I think are really important but also to widen my horizons to be able to address what I think is important. Whether or not I look objective enough to suit other people, the example of the seminal scholars that I've learned from and the seminal writers who have fearlessly explored what they thought was key—without regard to what others thought about their objectivity—has meant everything to me.

Again, I thank you very much. And thank you for listening to me.

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Reach New Heights at the 2022 Medical Writing & Communication Conference

Kimberly Korwek, PhD / 2022 AMWA Conference Committee Chair

The 2022 Medical Writing & Communication Conference is almost here! This year's submissions continued the tradition of excellence, and the conference committee had a challenging job choosing sessions that would support the growth and development of AMWA members both professionally and personally across all aspects of medical writing and communication.

The conference theme of *Elevating Health and Well-Being through Medical Communication* will be on display throughout the educational sessions, roundtables, and poster presentations. Programming will cover the spectrum of medical writing and communication, from regulatory writing to continuing education to scientific publications, as well as core skills and development training for every career stage. The breadth of offerings is too vast to cover here (see the registration brochure for more details), but here are a few highlights of what is to come.

Inclusive language, cultural competency, and effective communication to the public will be on display through a variety of sessions. Leila Emery and Joyce Hicks from RTI Health Solutions will present on best practices in inclusive language for writers and editors. Strategies to develop low literacy patient tools will be discussed by Kristie Hold and Kate Perry from Atlantis Health. The importance of storytelling in health communication will be highlighted in several sessions, including *Using Storytelling to Capture Exceptional Care and Build Audience Trust* by Ben Riggs from Kettering Health.

Regulatory writers will have a plethora of sessions to attend, with topics ranging from document writing and time tracking to team leadership and managing complex projects. New and familiar tools will be highlighted with tips and tricks for increasing productivity and managing timelines, from PerfectIt to Power BI.

Learn about *A Journalistic Approach to Writing Better Abstracts* from Susan Aiello of WordsWorld Consulting or find answers to all your copyright questions in a session with Jill Shuman of Science Communication Network. Hear how COVID-19 has altered the publication landscape in *The New Normal in the Medical Publications Sector* or get advice on how to create the most effective posters from Michelle E. Sofa of Nemours/Alfred I. duPont Hospital for Children.

Freelancers can "jam" with each other in the popular sessions led by Medical Communication Consultant Cyndy Kryder to share tips, best practices, and stories of clients gone wrong (or right!). Sessions on career development at every stage will be available, including discussions of how to transition into medical writing, building confidence to launch a freelance career, and training leaders within a team.

Along with all the great educational content will be sessions highlighting the importance of personal development and self-care. Learn how being a volunteer chapter leader can help build skills and relationships, hear how emotional intelligence can be an effective tool in self-advocacy, and get techniques to take care of stress and tension. Don't forget to catch the Medwrite Talks sessions that feature some of the most innovative and novel ideas in the field of medical communication from compelling speakers.

Attendees will have the opportunity to experience these sessions and more with workshops, roundtable discussions, award presentations, posters, and an exhibit hall. The return to an in-person conference for the first time in 2 years will bring back the networking and comradery that is the AMWA specialty. Register for #AMWA2022 today for the best rates. See you in Denver!

Session Highlight from AMWA Conference Committee Member

The description of *Fighting Burnout at Home: The Hidden Value of Health Habits* begins with the phrase "You can't work well if you are burned out". This session has caught my attention because the boundaries between my work and home life often blur together. I know I need a reminder on how to take care of my needs and maintain a healthy balance with work.

I am also looking forward to hearing about DIY Graphics for Medical Writers. I am incorporating graphics more often into data presentations these days. Access to a graphic artist is a luxury that is not always available. Learning how to easily create some eye-catching elements is just the thing I need to produce a high-quality deliverable.

—**Stephanie S. Wenick, MPhil,** Wenick Communications, LLC

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CALENDAR OF MEETINGS

Australasian Medical Writers Association
"Honoring the Past, Embracing the Future"
September 22-24, 2022
Sydney, Australia
https://www.medicalwriters.org/events/amwa-conference-2022-sydney/

National Association of Science Writers
"Science Writers 2022"
October 21-25, 2022
Memphis, Tennessee
https://www.nasw.org/events/sciencewriters-2022-memphis

International Society of Managing and Technical Editors
"Scholarly Publishing in a Connected World: Turning Disruptions into Opportunities"
November 1-3, 2022
Virtual
https://www.ismte.org/events/EventDetails.aspx?id=1630533&group=

American Medical Writers Association
"AMWA 2022 Medical Writing & Communication Conference"
November 2-5, 2022
Denver, Colorado
https://www.amwa.org/page/Conference

European Medical Writers Association
"The 54th EMWA Conference"
November 3-5, 2022
Riga, Latvia
https://www.emwa.org/conferences/future-conferences/

American Public Health Association
"APHA 2022 Annual Meeting & Expo"
November 6-9, 2022
Boston, Massachusetts
https://www.apha.org/events-and-meetings/annual

Alliance for Continuing Education in the Health Professions
"2023 Alliance Annual Conference"
February 6-9, 2023
National Harbor, Maryland
https://www.acehp.org/Your-Learning/Events

American Association for the Advancement of Science
"Science for Humanity"
March 2-5 2023
Virtual or Washington, DC
https://meetings.aaas.org/

DIA Europe
"DIA Europe 2023"
March 22-24, 2023
Basel, Switzerland
https://www.diaglobal.org/Flagship/DIA-Europe-2023

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