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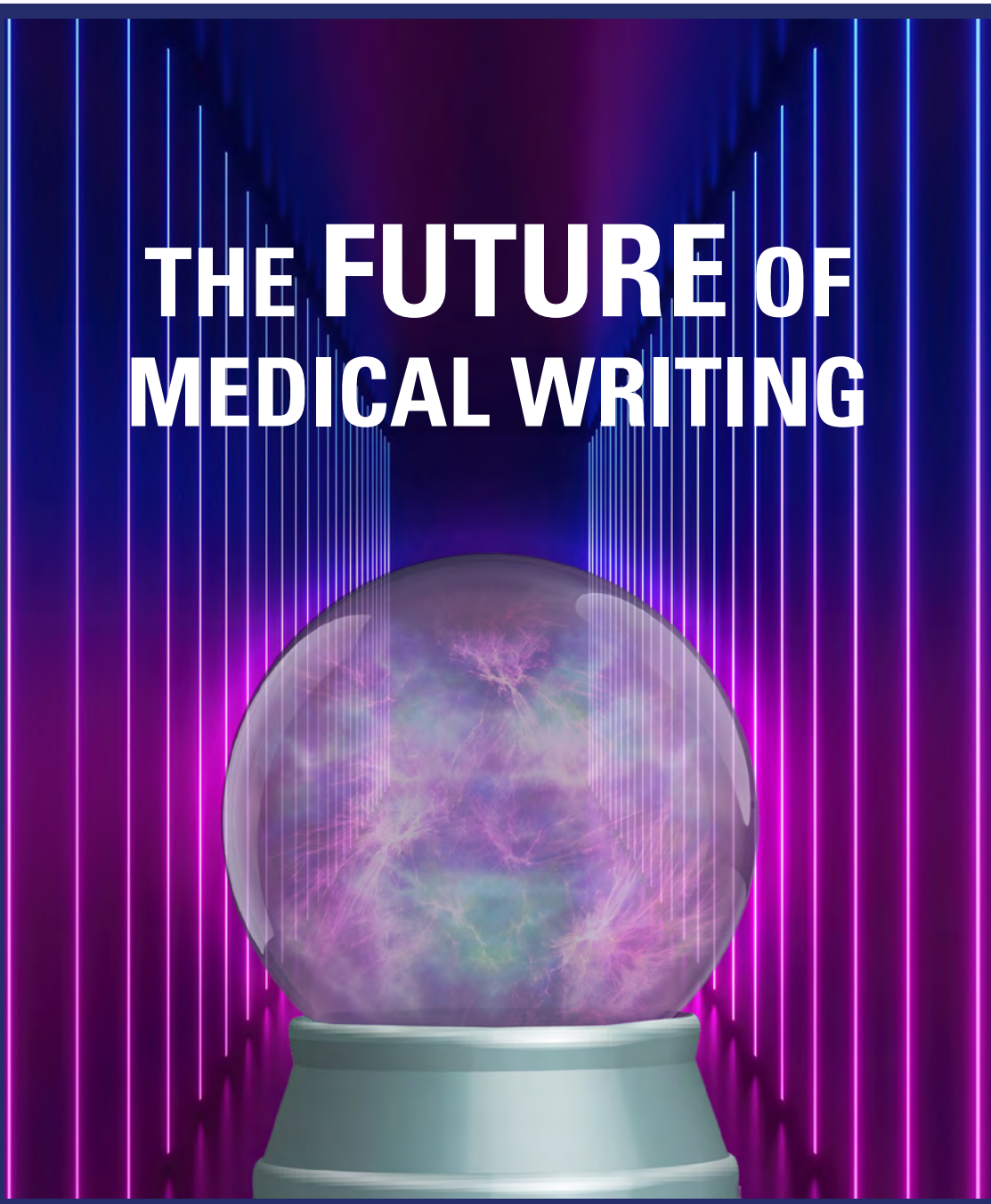


THE OFFICIAL JOURNAL OF THE AMERICAN MEDICAL WRITERS ASSOCIATION
THE RESOURCE FOR MEDICAL COMMUNICATORS

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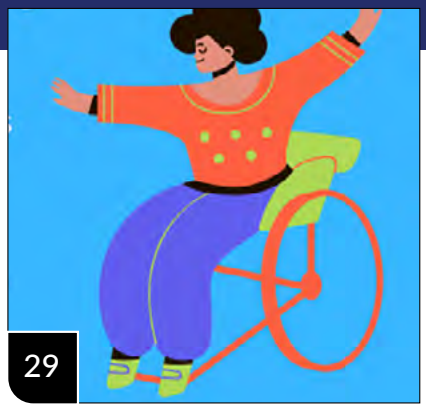
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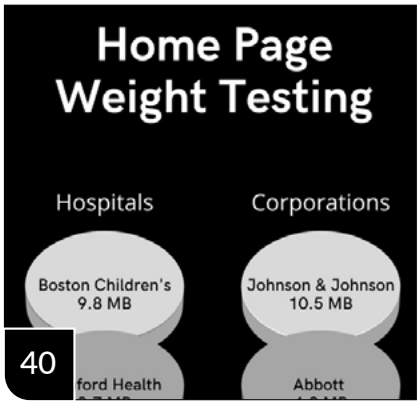

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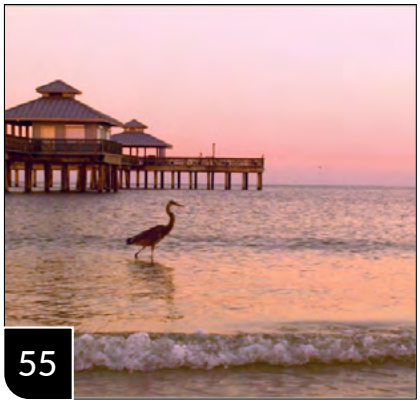
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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V37 N4 / 2022

FROM THE GUEST EDITOR

# The Future of Medical Writing: Gazing into the Crystal Ball

**Art Gertel, PhD** / MedSciCom, LLC, White House Station, NJ

Over the past eight decades, the role and perceived value of what we've come to know as the medical writer has evolved. As the process of document production became more complicated and time-consuming, a separate group of specialists evolved to serve the role of "medical writer." Although this role may not have been formally defined, and certainly not consistently so, this was the genesis of the professional we consider to be the medical writer.

When AMWA was founded, members were physicians who wrote. The documents that they generated were primarily manuscripts for publication, content for medical textbooks, and, perhaps, case studies. In 1940, there were only rudimentary documents created for submission to a fledgling Food and Drug Administration. Indeed, regulations, as we know them, had not yet been formulated.

As regulatory document requirements became more structured and went beyond case study descriptions, expertise had to be expanded from medical and scientific knowledge to an understanding of what would satisfy the requirements of regulators—requirements that were constantly evolving and becoming more stringent. At the same time, there was a move toward globalization and the need to serve at least two masters—FDA, the European Medicines Agency (EMA), the Japanese Pharmaceutical and Medical Devices Agency (PMDA), etc.

The world of publications has, likewise, undergone significant changes. At the outset, the end product was printed hard-copy articles in medical and scientific journals, the majority of which were only available by subscription to those with advanced degrees in the life sciences or to physicians. For most of the profession's history, there was no internet and, therefore, no access by the general public to this information. We now live in a technologically enabled environment where information is posted online, often unvetted, and assumes a life of its own—freely distributed, manipulated, misinterpreted, and all too often "weaponized."

Through the years, the role of the medical writer was often determined by corporate, or even team, culture. Depending upon the experiences, inherent biases, and personalities of your team members, the medical writer was viewed as a secretary, editor, wordsmith, or valued interpreter of data and expert communicator.

In preparing for this special topics edition of the *AMWA Journal*, I wanted to tap into a broad and varied spectrum of those who practice the trade of professional medical writing as well as some who collaborate with them. In eliciting thoughts, I decided to create a series of virtual panels, thus allowing for a more conversational and interactive experience among participants. What has resulted is a series of collective thoughts on where the profession is going, and which forces will shape the context within which we will ply our trade going forward. In one case, individuals formed their own "panel of one"; however, panels mostly comprised colleagues either from the same company or those who were invited because they were members of a particular professional organization (eg, the Drug Information Association (DIA)) or represented a particular viewpoint within the medical writing community.

I provided a framework for the panel discussions, based on my 2020 "crystal ball" predictions, on the occasion of AMWA's 80th year. I posited that the environment—scientifically, technologically, socially, and politically—will continue to evolve, although inexorably toward what end, it is impossible to divine.

My musings, below, apply to all segments of the medical communications community—regulatory medical writers, information specialists, publication professionals, teaching faculty…and others who represent the broad spectrum under the medical writing umbrella. Contributors were asked to choose one or more of the topics presented below and to share their perspectives, either as a consensus or as individual observations. The suggested overarching themes and subtopics follow; however, panelists tended to free-associate, and although some of the suggested topics were addressed, panelists sometimes elected to discuss topics of particular interest to them.


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## TECHNOLOGY

- There will certainly be an increased use of artificial intelligence, automated templates, and eSubmissions to regulatory authorities.
- Data will become more available in real time as clinical studies leverage personal data interfaces, including "wearables" or even "implantables." This may result in the medical writer accessing, aggregating, interpreting, and communicating trends and signals throughout the course of a study, rather than only at the point of Last Patient, Last Visit.
- The current coronavirus pandemic has accelerated the work-from-home model. Technology will continue to enhance this practice, removing many of the barriers and inconveniences we now face. It may become an opportunity to be a "work-from-home planet."

## WHAT ABOUT THE AUDIENCE?

- Information may be provided to a broader range of consumers. No longer will results of studies be limited to regulators and scientific/medical cognoscenti. With greater access to posted documents in a variety of portals, the public will seek and access information that is important for informed decision-making. The patient will have a stronger voice in determining their treatment, and this will extend to end-of-life decisions. Social media will amplify results and will spread misinterpretations and poor quality data. *Caveat emptor*!

## ROLE EXPANSION

- Medical writers will assume a stronger role as "guardians" of best practices. Not only do regulations constantly evolve, but so do publication practices. The medical writer will have to maintain a high level of awareness and familiarity with current best practices and will have to serve as a "gatekeeper" to best ensure that these are not violated. This will require that the medical writer assume the role of educator, communicating the essence of these standards and the rationale for adhering to them.

## GLOBALIZATION

- A single global regulator? Not likely, but a lot can happen in 80 years. The trend toward mutual recognition among regulators will continue, with common guidance and templates. Yes, there will still be regional differences; however, the core dossier will serve all masters.
- Our professional associations (eg, AMWA, EMWA, ISMPP, etc) have represented a "Balkanized" community, despite the significant overlap in membership profiles, educational program content, and common interests and goals. Recently, the three organizations mentioned have successfully collaborated to develop Joint Position Statements addressing systemic and institutional deficiencies. I trust that this will continue and hope that at some point, we will realize that we have a stronger voice through alliances not just within the medical writing community but with associated institutions (eg, academia, medical and scientific journals, regulators, etc). I have long been an advocate for the Intergalactic Medical Writers Association. Perhaps, one day!

## OTHER THOUGHTS

- Pressure to release data in "real time" for publication – technology allows us to do so, particularly given the increase in use of patient-reported outcome platforms that gather data in real time and adapt to prior responses. This allows the release of "raw data" that may have been only minimally vetted.
- Society will determine that resources are insufficient to provide all services to all patients. This rationing of health care may seem Draconian; however, in a world of limited resources, algorithms will be applied to human healthcare. This will result in a greater need for medical communicators to develop materials to educate the public, including lawmakers, about the rationale for allocation decisions.

The panels represented participants from across the globe, and I thank them for their insightful observations and suggestions as to how the profession might best confront unmet needs, opportunities for growth, and the challenges that have been long-standing, are only recently emerging, or that we may imagine in a cloudy future.

The future will reveal itself over time. As one of my heroes, that great sage, Yogi Berra, likely said, "It's tough to make predictions, especially about the future."

***Author declaration and disclosures:*** *The author notes no commercial associations that may pose a conflict of interest in relation to this article. The author has met all of the authorship criteria recommended by the International Committee of Medical Journal Editors (ICMJE).*

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V37 N4 / 2022

THEME ARTICLE

# The Evolution of Medical Communication

**Suzanne DeVandry, PhD, RN** / Executive Director, Medical Writing, Merck & Co., Inc, Rahway, NJ

**Speakers**
**Joan Affleck, MBA** / Associate Vice President-Medical Writing, Merck & Co., Inc, Rahway, NJ
**Dikran Toroser, PhD, CMPP** / Senior Director, Publications, Merck & Co., Inc, Rahway, NJ
**Genevieve Walker, PhD** / Freelance Medical Writer, Bridge Health Communications, Portland, OR

## ABSTRACT

Key thought leaders discuss their views of the evolution of medical communication focusing on their grand visions for medical communicators, what we learned from the pandemic, and what will be required in the future. Topics touch on the impact of developing technology, communicating with the public, managing social media, standardizing education requirements, and preparing the next generation of medical communicators.

## INTRODUCTION

In this contribution to "crystal ball" musings, diverse thought leaders chimed in on their visions of medical communication and medical writing in 10, 15, and 20 years.

Three seasoned professionals from different areas of medical communication provided commentary:

- Ms Joan Affleck, Associate Vice President-Medical Writing, Merck & Co., Inc
- Dikran Toroser, PhD, CMPP, Senior Director, Publications, Merck & Co., Inc
- Genevieve Walker, PhD, Freelance Medical Writer, Bridge Health Communications

The moderator's (Dr Suzanne DeVandry) prompt is provided for each topic, followed by the responses of panel participants. Each perspective offers insights on some of the vital questions of our day.

**What is the grand vision for medical communicators? How do we become the people who can help humans around the globe understand what they need to do to be healthy and how to meet the challenges when certain life-changing events occur?**

**Genevieve Walker:** My grand vision for medical communicators is that we continue to be facilitators in getting health and science information to the people who need it. Regulatory bodies. The FDA. Members of the public. The "worried well"—people who aren't sick but who really crave health information.

We should facilitate getting it to these audiences clearly, with as few frills as possible, and with as much need to know as possible.

**Joan Affleck:** Some factors need to be brought into consideration. We hear a lot about digitization in the press, and some people view digitization as the prioritization of data over words and messages.

That's actually a piece of misinformation. Data support the messages. And we need the messages. If we learned nothing else from the pandemic, it was that too often people don't understand the messages, and sometimes the messages aren't clear.

It should be a real reminder to us that when we start thinking about prioritizing data, it means the messages are even more important. We need to be able to explain what those data say, how to interpret them. This will become more and more important—the creation and curation of messages. I think it is vital to the work of medical communicators today.

**Dikran Toroser:** Medical communicators are going to be the gatekeepers to make sure that our stuff is stamped with dependable, peer-reviewed credibility. The speed at which communications have been produced … the speed at which things have reached the literature … the involvement of medical writers … the type of work that medical writers have been asked to do … the type of output in which medical writers are involved … all the changes are just staggering. And all of this is happening right now.

As medical communicators, we have to keep on top of this, because we hold the gate—the gate where authors


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are involved with what is done ethically, with who gets the data. We are at the center of most things. So I think these are exciting times.

**How do you see the evolution of medical communications through the next 10 to 20 years?**

**Joan Affleck:** I've been thinking about this a lot actually. It's one of my preoccupations. When I think of medical writing 15 to 20 years from now, for me, that means anybody who is 55 years [old] or younger in medical communication has a major stake in this conversation and should be participating in it. I feel we're missing those voices. One of the things I think about is how to bring them into the conversation.

I am not planning to be working as a head of medical writing at Merck in 20 years. I may be doing something else, but I'm not going to be head of medical writing at Merck. I want someone else to do that job, and I want somebody else to be shaping the profession.

**Genevieve Walker:** Patient engagement has really skyrocketed since I entered medicine in 1990. We have much more available for patients to access. We have much greater need and a drive for people to be involved in their own health and health care, be it changes in insurance, clinical care, regulations, or whatever else.

People have a lot more responsibility and a lot more options than they once did. So I think that my sector of medical care—health education, patient education—is a growing part of the field.

**Dikran Toroser:** In the last few years, work in day-to-day jobs as well as the final output has become more electronic. The job has become pretty much paperless. During the pandemic, a lot of companies got caught unaware. Forms for clinical trials used to be paper … and suddenly, you couldn't get from A to B.

Everything is searchable at a speed we had no awareness of a couple of years ago. I can find things in a database within minutes, look up congresses, find abstract requirements, touch base with medical communicators. So that's been a major development.

We'll be software dependent. It's going to be a long time before a Clinical Study Report will be written by a machine. We'll always need people, but things are going to get much faster because some of the routine aspects of our work will be handled by artificial intelligence.

**Genevieve Walker:** There was a time 10 or 15 years ago when we were concerned that medical communication would be outsourced to large content mills. But because medical communication is pretty high touch and the language is usually quite high level, it requires very careful handling. The outsourcing didn't happen the way that we thought it would.

My concern now is that we keep that hands-on high touch. Let's respect that very careful and compassionate way of working with the words around medicine and health while we are separated. In a big medical writing department, say at Merck or at the University of Texas, people may have worked together in an office for many, many years. There is a give and take, a flow, that goes on when humans are together.

That may not be very visionary. On the other hand, it might be all that we need.

**What has the pandemic taught us? What things have happened or what things have we learned from the pandemic that we will want to continue to move forward and develop?**

**Genevieve Walker:** We have a couple of things going on with science medicine and the public that became very clear in the pandemic.

We have folks who are able to do their own research, who understand a concept like risk or a concept like relative risk. Then we have a vast number of people who have no idea what that means, who have no way to calculate their own risk.

We have people talking about disease and health care who are in no way related to disease and health care and really should not speak about it. It causes a lot of frustration. The pandemic highlighted that science can be politicized to serve the ends of almost anyone.

So one lesson I see is the repeated lesson. Science is hard to understand in patient education. The lesson for us is to present information simply. Not dumbing it down. Simplifying it: Clear. Short. Usable. Do this, not that. And communicating to people that you have rights, and you have some responsibility for yourself—those are important lessons for good or for ill that came out of the pandemic.

**Joan Affleck:** You know, the veil was pulled back, and we could see that most people in this country, in the United States, do not have a high level of health literacy or numeracy, and I'd be willing to bet that the competency is not that much better around the world. Maybe in a few countries it is, but in general that literacy and numeracy are poor.

> This whole question of the competency of professionals and the quality of our work keeps me up at night. How do we continue to show the value of what we do? How do we convince others that ours is a special skill set? —Joan Affleck

So we're going to have to think about real ways to be able to test information to know whether it's comprehensible to people and to figure out new ways of delivering that information. We just can't go on the way we've been doing things in the past. What we were doing before is not going to get us to where we want to be in the future.

**Dikran Toroser:** Because of the pandemic, the format of communication really morphed into various types of media—voice, video, and others. There's a lot more output and it's going to be available whether we like it or not, in lots of venues. It's not just going to be in PubMed. It's also going to be leaked out in social media.

Some of the [other] changes from the pandemic will stick. For example, I don't think we're going to be in the office 5 days a week anymore. We're wiser about how inefficient that is. At the same time, I don't think we're going to be remote 100% of the time. We just lose so much by being remote all the time.

And we need things like our congresses, where the medical communicator interacts with stakeholders, rubs shoulders with people doing analysis … you know, being there at the inception of the concept. That stuff I think has to happen face to face.

**What is the role of education and certification in establishing a consistent quality of practice in medical communication?**

**Joan Affleck:** This whole question of the competency of professionals and the quality of our work keeps me up at night. How do we continue to show the value of what we do? How do we convince others that ours is a special skill set?

Are we going to look at academic education, apprenticeships, certification, continuing education requirements? These are some of the standard professional benchmarks. Or we could go to some totally new paradigm. The point is that we have to do something.

Again, this is where we need the voices of people who are mid-career to help steer the profession into the future. I challenge people under age 55 to step up and get involved. If you don't know how, call me. We'll talk about it.

**Dikran Toroser:** You've got to be familiar with your guidelines. I'm a CMPP-certified medical publication professional. I took the exam to be CMPP qualified, and I attend the meetings and have peer review.

Many of us are actually editors for journals. I interact with a number of clinical journals, and peer review is not just off the top of your head. Training will be required to make sure that you look at things in a nonbiased manner, that you view things appropriately. There's a lot of training to keep up with the field, and it's expected.

My recommendation is for new aspiring medical communicators to get in with the local AMWA chapter. I'm in Boston, and the Northeast chapter is brilliant. You have to make contact with people. That's the way it works.

**Genevieve Walker:** I don't feel there should be one standard for every type of medical communication.

I know that AMWA has made great strides in developing a medical writer certified designation with a test. However, what if we had a certification process that really reflected the differences among types of medical communications? I think it's really important, because folks who are generally good at regulatory writing often can't do writing for patient education and the public. Those are different skill sets, different mindsets. They're different backgrounds, and maybe even different imaginations.

I would love to see education and certification going more in a direction that mirrored what we do to certify physicians, where you pass a board exam in your specialty or related specialty. I think it would be preferable to have separate certifications.

**What do the medical communicators of the future need to be successful?**

**Dikran Toroser:** Cultural awareness. Many of our companies are global, but suddenly the medical writer is having to interact with someone in China, someone in Japan. There are cultural differences. There are certain ways to behave if you actually want to get done what you need to be done.

So cultural awareness is number one. Number two is that you can't drop basic things like grammar. Grammar is always

important. Finally, you need a simple awareness of what to do if you're contacted by a predatory journal. You need to recognize it. You need to recognize the URL address. If it's from somewhere that's suspicious, you need to warn your authors.

So, it's a diversity of skills.

**Joan Affleck:** Unfortunately, today we do a lot of templated work – agencies give us templates to fill in. Our future depends on having people who think a lot more freely outside of a template, beyond just plugging in information here and there. We want people who understand that.

Medical communication is at the intersection of data and messages, all the way from the protocol throughout the life cycle. Our work requires multiple points of view, and medical communicators really need to be thinking of the role holistically.

Medical communicators need to be at the right tables, whatever those right tables are talking about. We need to be educated about the capabilities and limitations of our profession and be forward-thinking in terms of what we're going to need to help design programs, platforms and systems, their interoperability.

A big question is how do we control information, the way reputable newspapers and journals manage it? How do we lock down what the real message is? How do we win that credibility with the public? I don't know the answer to that, but it's a problem for us.

I think in regulatory medical writing we've had a small lens. We've been thinking our work is just for this company, not anything bigger. We need to blow that attitude apart. We need to acknowledge that we are a crucial part of a global public health network, and we need to participate in that.

**Genevieve Walker:** We are here to communicate. We are here to be great conduits and interpreters, not to promote specific findings or points of view. I actively discourage people from believing what they read on Twitter, Facebook, etc. As we've seen, those platforms aren't channels of communication per se. They have agendas behind them, no matter whose it may be. There are lots of channels, and each one is a business. Somebody's making money, and they're making money off you.

So I think we need to refresh people's memories. There's quality. And then there are junk sources of information. We need to be pretty clear about that. That would be a good stand for medical communicators to take.

Success is easier with an attitude of service, an eagerness to learn, and a spirit of willingness. We have an enterprise centered on the patient—centered on the person who needs information.

And we are all in service of something greater, which is access to health.

**Suzanne DeVandry:** Thank you to our panelists for sharing your thoughts and vision of the evolving field of medical communication. In response to our questions, we heard several common themes about the benefits and challenges of working in a virtual environment, the need to extend the vision of medical communication to include global health literacy, the urgency of building trust with patients and providers, learning from the pandemic how information may be used and misused, and preparing the next generation of medical communicators.

Other questions still remain: How do the various specialties of medical communicators best work together to optimize information dissemination? How do we manage and improve the flow of information in the public sphere to ensure accuracy? What can we, as medical communicators, do to elevate global health literacy and positively impact global health? How do we overcome negative societal perceptions and gain the trust of the patients we serve?

The answers to these questions and others will shape the evolution of medical communication.

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## BIOSUMMARIES

**Joan Affleck** is an Associate Vice President at Merck & Co., Inc, where she leads the Medical Writing Department. Throughout her 20 years in the pharmaceutical industry, her work has focused on solving information management challenges by learning from a variety of industries and developing novel approaches. Following university studies in science and literature, Joan moved to Paris to edit a peer-reviewed international medical journal. After several years in publications, she shifted to the pharmaceutical industry. She has created and developed medical writing teams in North and South America, Europe, and Asia. Joan holds an MBA from Columbia University, where she is a Lang Center Innovation Fellow and guest lecturer at Colombia Business School. She has served as an advisor to the

Healthcare Businesswomen's Association and TransCelerate BioPharma Inc and is a member of the University of Virginia Darden School of Business Leadership Communication Council. In 2020, she received the President's Award from the American Medical Writers Association. Find Ms Affleck at Merck Sharp & Dohme, LLC, at joan.affleck@merck.com.

**Dikran Toroser** is a Senior Director of Project Management in Global Scientific and Medical Publications at Merck Sharp & Dohme, LLC. He has a PhD in Biochemistry from Newcastle upon Tyne (UK). He did his post-doc at the Cambridge lab (UK) on genetics and then moved to the US to work as a senior biochemist/researcher for the USDA. Dikran has been in publications since 2004, working at large pharmaceutical companies as Publications Lead and most recently at Amgen and also Takeda as a Publications Group Lead. Dikran has an extensive background in publication planning as well as medical writing. Dikran is active in professional organizations (AMWA, ISMPP, ACSE) and is an author on guidelines for the publications profession (eg, AMWA/EMWA/ISMPP Joint Position Statement and "GPP4" ["GPP 2022"], the latest Good Publication Practice guidelines for industry that was published in September 2022). He is one of the founding faculty for the UC San Diego medical writing certificate and is a consulting director for the course. Find Dr Toroser at Merck Sharp & Dohme, LLC, at dikran.toroser@merck.com.

**Genevieve Walker** writes and edits patient education and consumer health materials in plain language. A medical communicator since 2002, she is a past president of the Northwest AMWA chapter, a new current member of the Southwest chapter, and the leader of the AMWA credit workshop Writing and Designing Materials for Patient Education. Dr Walker is also an instructor in the University of Chicago's Graham School Medical Writing & Editing Certificate program. Dr Walker holds a PhD in English from the University of Oregon. She has studied the principles of health literacy, readability, user-friendly design, and plain language since the mid-2000s. Her background includes courses in adult instruction and linguistics. Find Dr Walker at Bridge Health Communications at genevieve@bridgehealthcomm.com. To see her work, please visit www.bridgehealthcomm.com.

AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V37 N4 / 2022

THEME ARTICLE

# Globalization and the Future of Medical Writing

**Julia Cooper,**[1] **Jeannene Butler,**[2] **Kelley Hill,**[3] **Garima Pallavi,**[4] **Grishma Kanchan,**[4] **Jonathan Mackinnon,**[5] **Renee Primus,**[6] **Matthew Renda,**[3] **Linda Yih,**[7] **and Nan Wang**[8] **/** [1]Parexel International (IRL) Limited, Dublin, Ireland; [2]Otsuka Pharmaceutical Development & Commercialization, Princeton, NJ; [3]Alexion, AstraZeneca Rare Disease, Boston, MA; [4]Parexel International India Development & Commercialization Safety Services Private Limited, Bangalore, India; [5]Parexel International S.L., Madrid, Spain; [6]Bristol Myers Squibb, Princeton, NJ; [7]Parexel International LLC; [8]Bayer Healthcare Co. Ltd., Beijing, China

## ABSTRACT

Medical writers play a key role in global regulatory submissions across the pharmaceutical industry. Before the COVID pandemic, many companies were working toward development of global regulatory submissions, with their medical writers playing a key role in this process. During the pandemic, the need for greater collaboration in fully remote working conditions, inclusion and transparency, and the unprecedented demand for speed and quality of clinical development has brought global ways of working into even greater focus. A panel of medical writers, including department and regional heads and subject matter experts, were invited to consider how other influences on our industry may drive the evolution of medical writing yet further as a global profession in the coming years. This article summarizes the panel's responses to 5 questions on the future direction of the profession.

Medical writing is an increasingly global profession. During the past few years, the effects of the COVID pandemic have only served to increase the ways in which it is possible to be a medical writer on global teams regardless of one's own location. We invited a panel of medical writers to gaze into their crystal balls and consider how medical writing may yet further evolve as a global profession over the next 10, 20, or more years. Participants were invited to consider 5 questions on the future direction of the profession and to provide short responses to as many of the questions as they felt able. Our panel included department and regional heads and subject matter experts (SMEs); their biosummaries can be found at the end of this article.

**How has the impact of the pandemic and increasing demands on the speed, quality, and complexity of clinical development driven globalization? What solutions initiated from medical writing have been successful to accommodate this change? Where might this lead us next?**

**Jonathan Mackinnon:** The pandemic and increasing complexity of clinical development is driving a need for more expansive multinational or multiregional clinical trials that cover a greater geography in order to access increasingly specific participant populations. In response, medical writing associations are increasing education/training efforts in how to manage these changes as part of regulatory document preparation. Over time, this might lead us to increased specialization within the medical writer community where—once a writer has an established a base skill set via experience across regulatory documents—they start to specialize in certain areas so that they can stay up to date with the current challenges, eg, data analysis and reporting versus study design and setup.

**Linda Yih:** In terms of impact, more compounds seem to be moving ahead "at risk," so teams need to take this into account when it comes to planning and contingencies. Successful writers have been able to drive effective


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collaboration and communications, mediate differences, and validate actions to meet overall goals. Cultural awareness (whether country, company, or team-specific) has become key to encourage open discussion and ensure all parties are heard and understood. Future collaborations may require refined skills in managing conflict, negotiation, influence, and persuasion.

**Renee Primus:** During and postpandemic, we have witnessed the importance of rapid mobilization to meet new and unexpected global requirements ensuring patient safety and access to treatments. The consequences of global disruption have pointed to the need for greater collaboration, inclusion, and transparency and a call to action for a shared objective among all members of the health care system. Members of the medical writing profession have been and continue to be well-positioned as problem solvers during disruption by bringing innovative solutions and leading complex deliverables. For example, COVID-related country-level commitments and the development of processes, tracking, reporting templates, and oversight to meet compliance and quality were key leadership contributions from medical writers—and during a time of urgency and under some extreme conditions. In addition, structural, content, and harmonized updates to existing regulatory documentation (eg, Periodic Aggregate Safety Report and the Clinical Study Report) provide another example of leadership from medical writing to drive well-communicated, transparent, and consistent reporting for global digestion. The call to action includes greater data-sharing using secured technologies and harmonized ways of working including more integrated and collaborative health authority (HA) shared accountabilities.

**Nan Wang:** COVID has had a negative impact on a global basis in certain industries, but other professions that can be relatively easily adapted into remote forms will experience heightened demand, such as medical writing. The unprecedented demand for the speed and quality of clinical development has driven us to pursue even higher levels of globalization. Ever-increasing global standardization and automation should be the key drivers for a successful medical writing organization.

**Jeannene Butler:** One "silver lining" for the pandemic was that it necessitated organizations to think differently about the conduct of their clinical trials, and we saw innovative solutions designed to keep clinical development programs moving forward, despite the limitations to person-to-person contact. In medical writing, there was also no pause in our work, and globalization of our regulatory submission documents continued to be a focus for our team. We often preplan for global submissions by starting our documents much earlier, even before the completion of the final clinical trial, with region-specific background text and assumed successful outcomes. Adding in more automation and technology to this early-writing process can help to reduce the time and effort for the medical writers and may also reduce the impact for rework by the medical writers in the later stages of document development.

**Kelley Hill & Matthew Renda:** Medical writers have always been able to work remotely. During the pandemic, they exemplified efficient and effective communication, high productivity, and high quality, helping the world adjust to remote work. Increased demands leading to increased collaboration across time zones have necessitated the use of shared document platforms and highlighted the importance of careful document handoffs to "follow the sun." However, the expectation that one is always available increased propensity for "burnout," which many experienced as time went on. Multitasking was taken to an extreme in some cases, which may have led to a decreased ability to focus and affected critical thinking. It will be increasingly important to leverage technology and prospective planning wherever possible and have priority established by management to keep focus and quality from all contributors at its peak.

**Julia Cooper:** Medical writing lends itself to remote working, and this has been a common model in North America and parts of Europe for many years. During the pandemic, virtual teams were a necessity (and still are) but also brought benefits such as being able to hire diverse talent in geographical locations where office-based working was previously the norm. Employee satisfaction has increased through flexible working hours, autonomy, and the ability to work from different locations. Zoom, Microsoft Teams, and similar platforms help maintain employee engagement; however, building team cohesion can still be a challenge. In the future, we need the technology to evolve yet further (think Star Trek holodeck!) to provide an environment as close as possible to a face-to-face meeting when opportunities for in-person meetings are limited or nonexistent.

**Grishma Kanchan:** With increased demands on the speed, quality, and complexity of clinical development,

globalization via social integration has been one of the biggest outcomes of the pandemic. Medical writing has predominantly been a geographically diverse team; however, the pandemic pushed us to focus on sustainable and inclusive growth, which required changing our work culture to maximize contributions of people globally. Medical writing was quick to implement platforms for global collaborative work. With technologies continuing to improve, we must be open to new ways of working, such as collaboration in the Metaverse. The Metaverse could aid meaningful interactions between colleagues by replicating an office environment. Communication in the Metaverse may also be more authentic and build trust when compared with face-to-face conversations which may, at times, be affected by social anxiety or lack of confidence. Coming together in the Metaverse can be empowering by creating a space where people at work can feel present, connected, and productive. The Metaverse could also give medical writers the chance to observe, learn from, and work alongside the best in the industry, without physical or geographical barriers. In clinical development, medical writers could immerse themselves in real-life scenarios and gain insights into a patient's or physician's journey to devise solutions for existing challenges. The Metaverse may also allow medical writers to understand the "larger picture" by helping to visualize the clinical development process from drug discovery and development to approval and postmarketing surveillance. This could provide writers with key knowledge to understand the target audience and write better and effective clinical documents.

**How might the medical writing profession be defined in the future, eg, common certification or development programs, shared job descriptions, intergalactic medical writers association, sharing ideas across companies, different relationships between clinical research organizations (CROs)/contractors and sponsors, other?**

**Linda Yih:** We can make great strides together by sharing ideas and solutions to common challenges across companies. AMWA is already spearheading this effort with industry leads on several important topics. On a more granular level, this can be achieved by building mutually trusting relationships between CROs/contractors and sponsors. All involved need to be transparent with their needs and concerns and open to others' perspectives.

**Jeannene Butler:** Regulatory medical writing is quite different from other types of medical writing and would benefit from having its own global standards and development programs. A global regulatory medical writing organization would allow for a more focused view of our specific writing profession but expanded to include perspectives and ideas from across the world. An increased focus on education for newer medical writers at the undergraduate level is needed. This could be in the form of 1 or 2 courses for regulatory medical writing to be added to the curricula for related health science degrees or expanded to develop an overall medical writing major program at colleges and universities, where common elements of scientific writing are taught, and the regulatory medical writing courses could be a concentration for that major.

**Renee Primus:** The regulatory writing profession requires recognition as a defined role in driving speed to patient. A common pain point by writers is that they are not always used for their skills in strategic writing and leadership but instead misunderstood as formatters and scribes. The writer brings value as an expert on regulatory requirements supporting regulatory review and approval and accordingly shapes documents to strategically address these requirements. Sponsorship across pharmaceutical companies and CROs to form well-defined, harmonized, and consistent position profiles capturing core capabilities and responsibilities would promote the profession and effectively pave the way to a degree-facing curriculum integrated with regulatory affairs. A curriculum design recognizing the multiple and overlapping responsibilities between regulatory writers and regulatory strategists would meet the needs of future changes to the regulatory landscape promoting speed to patient.

**Nan Wang:** Medical writing has a long history in Europe and North America and is well defined and recognized in the pharmaceutical industry.

- In the future, the medical writer's role and responsibility will be better recognized and accepted in other developing regions, eg, Asia-Pacific. The trend has already been observed in China.
- An industry community facilitating knowledge and experience sharing across companies and the understanding between CROs, sponsors and investigators will play a more important role.

**Kelley Hill & Matthew Renda:** Assuming that "medical writing" in this instance refers to regulatory writing, building a framework for developing writers within secondary education/universities would provide a pipeline of future

writers. This would include a broad framework that begins with superb writing skills as well as expanded skill sets required for data interpretation and detailed knowledge of regulatory governance. To further career development, management training would include strategic planning, project management, resource planning, technology skills, contract negotiation, and the ability to coach for career development. The business of medical writing also requires the need to assess what skill sets are needed for specific projects. In addition, the expanding requirements for transparency and plain language writing offer separate but related paths for development. Core competencies could be identified and job levels that are aligned across companies would also help define specific job titles, making them more uniform across the industry. This would help control "title inflation," which is often the reason writers will leave one company to move to another, which erodes institutional knowledge and experience, the bedrock that medical writers contribute to drug/device development.

**Garima Pallavi:** Clinical trials are becoming increasingly complex; adoption of advanced technology is slowly becoming the norm. The pharma industry is moving toward personalized medicine/precision medicine. This shifting landscape requires medical writers to be adequately equipped to develop expertise in these areas, understand and expertly design studies, and communicate results to regulators. Complex study designs call for medical writers to develop the right amount of subject matter expertise. The rapidly changing regulatory terrain also requires medical writers to continually learn and develop their core competencies. The COVID pandemic has underscored that the magnitude of globalization in the health care industry is going to see a steep rise. Companies that already had medical writing operations spread out globally experienced minimal disruption in their business. To keep up with the rapidly evolving demand in the industry, companies must focus on building a globally diverse talent pool. Global capability centers (GCC) are swiftly becoming the new normal, and companies are giving up their traditional beliefs about having a concentrated talent pool to adapt to a GCC model. The advantages of a global talent pool are multifold: from ensuring round-the-clock business continuity to leveraging on a world-class talent pool and building resilient and agile capabilities. Building and nurturing a global talent pool will require using shared job descriptions, employing standard hiring methodologies, a common approach to training, upskilling of staff, and applying uniform performance and conduct standards. Professional medical writing associations offering certification programs such as AMWA and EMWA provide vast opportunities for writers to learn and expand their network; however, these associations have mostly had a strong regional presence. To meet the fast-paced demands of the industry, it will be imperative to shift the mindset to have a global community of medical writers, which allows the whole fellowship to develop common skills. COVID has taught us that we can successfully organize virtual conferences and training programs and make SMEs more accessible to colleagues globally. The future of medical writing will be about breaking down silos and unlocking a diverse talent pool that transcends geographical boundaries.

**Jonathan Mackinnon:** As complexity increases, it's likely that certification or training programs will become more commonplace to demonstrate a base skill set. Within regulatory medical writing, my view is that study design and transparency will be significant drivers of lasting change.

- Study design: complexity and simplicity are at opposing ends of the pendulum but are increasingly being woven together as more specific interventions (more targeted action and more complex endpoints) are being included in studies looking to simplify participation and minimize burden. Medical writers will need to be able to navigate the increased design and analysis complexity as well as participate in risk assessments, derisking (eg, applying passive data collection from digital health technologies to replace on-site clinical assessments), and subsequently simplification.
- Transparency: regulatory documents used to be considered highly prized proprietary information with restricted access, whereas now, publicly available redacted regulatory documents substantially increase medical writer access to precedent content. Consequently, how medical writers engage with precedent and standardized content and how that content facilitates downstream process will form part of a medical writer's training.

**What kind of regulatory changes might impact the way medical writers work in future? Do you anticipate recent or future regulations (what kind?), or changes at the regulators themselves, driving change for medical writers? What could that look like?**

**Jonathan Mackinnon:** Maturation of the understanding of risk and risk mitigation (International Council for Harmonisation of Technical Requirements for

Pharmaceuticals for Human Use (ICH) E6[R2]) as well as a fundamental shift toward Quality by Design (ICH E8[R1] and the likely reflection of this in ICH E6[R3]) will have a material impact on medical writer work in the future. More sophisticated risk management strategies, targeted enrollment and forecasting, and quality-focused study design will change the way studies are designed and analyzed. Designing study protocols will combine a greater understanding of risk management and mitigation verbiage with new methodology for constructing studies that focus on critical to quality factors; for clinical study reports, reporting on these strategies will become more commonplace.

**Kelley Hill & Matthew Renda:** Increased transparency requirements (ie, European Union Clinical Trials Regulation (EU CTR)) are already changing the way writers work, as personal protected data need to be identified early as part of an overall disclosure strategy and company confidential information adapted as more information becomes public during development. Specific examples: instead of "47 year old female from France," data output is changed so the text reads "a 40 to 50 year old person from Western Europe."

One huge change would be if regulators move from the current document-centric Common Technical Document (CTD) structure to a real-time study data flow. Advanced computation in the coming decades might permit regulators to automatically interpret trial data with marketing applications built on a rolling basis. In such a future, medical writers would leverage technical and data science skills because documentation would be reduced to introductory/contextual statements, leaving interpretation up to the agencies.

**Renee Primus:** The regulatory writer carries both technical and strategic expertise; current and future changes to the regulatory landscape, speeding access of new health care products to patients, will require this expertise more than ever and are already happening. Over the past 5 years, Food and Drug Administration (FDA) initiatives have been introduced with impact to the regulatory writer. For example, Real-Time Oncology Review and the Assessment Aid aim to increase the speed of information for regulatory review and require both exquisite planning and focused reporting of complex and approval-supporting data—with quality. In addition, parallel review initiatives such as FDA Project Orbis require new approaches to work concurrently with multiple participating countries—with speed. Accumulus Synergy, creating innovative solutions to reduce regulatory review times and transform global data exchange, is another good indication of reshaping the industry by removing barriers to speed of information. In all these examples, the agile regulatory writer possesses the range of technical and behavior skills to both inform needed changes as well as execute in a changing global regulatory environment.

**Nan Wang:** Harmonization of regulations across the globe can be expected to enhance the global simultaneous development and make drugs available to patients quickly.

- Medical writers in different countries/regions will work more closely and share knowledge and understanding, which will contribute to the establishment of the "global" document strategy and the process to support global simultaneous submission.
- Medical writers working in specific countries/regions with unique regulatory requirements should take the initiative to understand a global approach and promote local requirements with solutions. They should take the bridging role to implement global-level standardizations.

**Jeannene Butler:** Based on recent learnings from EU CTR, we may need to consider revising the process and/or structure of how protocols and amendments are developed. Protocols require structure to clearly define parameters for the conduct of a clinical trial; however, because many trials are now being conducted globally, we need to consider how best to accommodate region-specific changes and requests from HAs in an expedited manner. For example, EU CTR Requests For Information (RFI) can come in from various member states, and these require responses, and often protocol amendments, within a couple of weeks. Instead of creating and maintaining country-specific protocol amendments for each change, perhaps the protocol could exist in an electronic format with version control and the ability to tag country-specific elements and switch the view depending on the region where the investigator is conducting the trial.

**How might the skills profile and daily work for medical writers of the future be shaped by enhanced standardization, harmonization, automation (artificial intelligence [AI]), or other factors?**

**Jeannene Butler:** Although no AI would ever be able to completely replicate the skill and art of a human medical writer's work, technology can, and should, be enhanced and socialized to make our jobs easier. If there was an increase in standardization and enhanced technology to assist with the daily work of medical writers, we would need to adapt

by becoming more tech-savvy ourselves, for example, learning the AI systems and coding to modify those as needed for our specific documents. What would NOT change would be the ability of medical writers to analyze scientific data and craft language around those results, and the critical soft skills of leadership, communication, and collaboration with our project teams and SMEs.

**Renee Primus:** Strategy and data design to support critical messages and drive labeling claims are key writer competencies but not leveraged enough due to some siloed ways of working across teams where preplanned data templates and lack of technology restrict manipulations. Technologies that allow direct interface and strategic data design for automated data entry while maintaining integrity would enhance more direct review and interpretation by regulators. Writers working collaboratively to bring their insights will enhance team effectiveness in the production of fit-for-purpose, message-driven documentation that aids the regulatory reviewer in their decision-making roles. In general, the more we remove the unnecessary and replace with strategic information design, the greater the value that writers bring to documentation will be realized.

**Jonathan Mackinnon:** It is likely that future medical writers' skill sets will include elements of data science and content management as clinical research transitions from a document- to content-driven industry. Rather than developing a document in isolation, writers will be expected to work with interlinked content that is developed in parallel—as opposed to sequential document preparation.

**Kelley Hill & Matthew Renda:** Consideration of diversity and inclusion are missing from many types of document templates and should become part of the training for medical writers. In addition, as industry moves to adopt automation and content-reuse to aid in document development, commensurate technical proficiency will be increasingly important for future medical writers.

**Nan Wang:** Medical writers will need to be able to translate the dynamic regulatory environment and diverse regional regulatory requirements into standardized and harmonized document strategy in order to foster communication efficiency. They will be able to work across boundaries and codevelop automation (AI) tools, which will add value to the medical writer's daily work. With the powerful automation/AI tools in place, medical writers will concentrate more on the generation of the content flow and process management to ensure adequate communication among cross-functional expert groups.

**Julia Cooper:** Technology applications for medical writing are evolving at a pace that would not have been anticipated a few years ago. It may be many decades before AI can fully replace a human medical writer; however, repetitive tasks may soon be accomplished by automation and/or AI, allowing the writer to focus on the science. For example, patient narratives can already be programmed to a large extent. New AI-based tools may enable writers to generate tables and listings via an interface directly linked to the study or submission database, without requiring involvement of a programming team, or to identify trends and patterns in data for consideration when writing results sections. It will be important that we collaborate globally to understand the benefits and limitations of these new tools and what this means for the medical writer skill set going forward.

**If budget and/or technology was no limit, how would you see global medical writing teams working/collaborating in the future?**

**Jeannene Butler:** In an amazing future for medical writers, there would be standard document templates and language across companies and regions, endorsed by HAs worldwide, which would only need minor customization for each organization. With standardized templates, AI would then be developed to electronically create the data-driven sections of the documents once the trial(s) have completed database lock and data cleaning. AI would also create and manage all the technical elements of the documents, including tables of contents, abbreviation lists, reference lists, and all formatting elements. Background product/regulatory text would be created once by medical writers, reviewed by teams, and stored in a common "master" location that would then be automatically pulled into appropriate sections of the documents. If that text was changed in the master location, it would be automatically changed in every related document, and there would be regional variations tagged as well. Medical writers would continue to work with the project SMEs to draft and refine summary and conclusion text for each document as their main focus.

**Renee Primus:** Modernization of ICH M4 guidance on the CTD – in particular on structure/content and leveraging cloud-based templates and tools—would be one great opportunity for the field of medical writing to work together and drive innovation.

**Kelley Hill & Matthew Renda:** Structured content use is already being adopted across the industry. Perhaps it would be possible to develop a shared platform of common text across all pharma/science for certain topics; for example, disease descriptions that are automatically updated with info from new publications.

**Nan Wang:** Medical writers will work with automation tools much more often. The human medical writer will focus on message and content, and the tool will focus on repetitive and routine tasks in the background. Medical writers from different countries/regions will work on global master documents, with knowledge and technical support, and contribute to the packages submitted in different regions. Medical writers will be involved much earlier in the process and will obtain better overview of the data flow in drug development.

**Julia Cooper:** In the future, medical writers will be able to focus on the science, for example, through intelligent access to content libraries for authoring protocols and semiautomated generation of Clinical Study Reports and submission documents. The writer will truly be recognized as an expert in their own right, responsible for guiding the team through the limitations and advantages of an automated document generation process.

**Jonathan Mackinnon:** Ideally, deeper organizational collaboration on document standards, content standards, and content management processes.

**Linda Yih:** Medical writing teams would have a budget and time to train junior staff on live project work and allow them to shadow senior writers to learn the nuances of managing a team with confidence. Collaborative authoring tools would support training as well as urgent projects. As new technologies are introduced, writers will need to be agile in their learning while managers provide a safe environment for learning. The next generation of writers may also have ideas on how to use or create technology to work in more efficient and meaningful ways. Knowledge-sharing and lessons learned sessions may be held to encourage transparency and continuous improvement.

**Grishma Kanchan:** Metaverse! The Metaverse has the potential to break down physical and geographical barriers between people. Medical writing is a global team, and with the majority of writers working remotely and virtually, using the Metaverse to explore a collaborative world and to be able to connect and interact with one another is an exciting possibility.

## LOOKING FORWARD

The future of medical writing will bring many opportunities to evolve as a global profession, learning to adopt new content-driven ways of working, expanding our skill set into data science, and capitalizing on new technologies that replace repetitive tasks. With a track record for agility, medical writing is well-placed to adapt to this rapidly changing environment. Considering some recent developments that could not have been anticipated a few years ago, we need to remain vigilant to anticipate emerging global industry trends and what these may mean for expansion of our skill set. As a global profession, we also need to take ownership and drive these opportunities in a direction that increases the future value of medical writing yet further.

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**Julia Cooper, PhD**, is Corporate Vice President, Head of Global Medical Writing Services at Parexel International. She leads a team of around 270 clinical and regulatory writing staff across the Americas, Asia, Europe, and South Africa. Julia has been a member of AMWA and EMWA since 1995. From 2013 to 2016, Julia was based in Parexel's Shanghai office, where she helped set up the China Medical Writers Community. She is an EMWA Nick Thompson Fellow and serves as chair of the AMWA Executives Advisory Council.

**Kelley Hill** is Executive Director, Medical Writing and Clinical Trial Transparency at Alexion, AstraZeneca Rare Disease. She is a scientist and professional communicator,

with experience spanning over 30 years across the pharmaceutical industry and academia. She has extensive clinical regulatory and scientific writing experience in complex therapeutic areas, with a focus on rare diseases. She has served as a contributor to and in a leadership role for global clinical regulatory submissions supporting review and approval of drugs for diseases with unmet medical needs. She is an innovator with expertise in process improvement and operational excellence, and her global teams' performance has redefined benchmarks within Alexion for collaborative achievement and efficiency.

**Grishma Kanchan** is a Senior Medical Writer at Parexel International and has been with the organization for close to 7 years. She has a master's in Biotechnology from the University of Salford, United Kingdom, and predominantly works in the rare diseases and disorders sector.

**Jonathan Mackinnon, PhD**, is an Associate Director Medical Writing Services at Parexel International and a subject matter expert on clinical study protocols. He also teaches protocol development and trial design at the London School of Hygiene and Tropical Medicine.

**Garima Pallavi** is a Senior Director at Parexel International. She leads the medical writing department in India and possesses around 18 years of regulatory writing and leadership experience.

**Renee Primus, PhD**, is Head of Global Scientific and Regulatory Documentation at Bristol Myers Squibb with 25 years of experience in nonclinical research and clinical regulatory sciences. Renee and her team drive documentation strategy and authoring of message-driven, fit-for-purpose regulatory documents in support of drug development, submissions, and approvals.

**Matthew Renda, PhD**, is Director of Medical Writing Operations at Alexion, AstraZeneca Rare Disease. He has 12 years of academic research experience focused on gene therapy and 15 years of pharmaceutical development experience providing regulatory submission management and medical writing leadership to optimize cross-functional processes, implement innovative technologies, and efficiently develop clinical documents.

**Nan Wang, PhD**, is Head of Medical Writing at Bayer Healthcare. She has more than 12 years' experience in medical writing from both pharmaceutical companies and a CRO. Nan is a founding member and chairperson of the China Medical Writers' Community.

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THEME ARTICLE

# Technology to Further Medical Writing: Status and Future Vision

**Helle Gawrylewski, MA**[1] **and Nimita Limaye, PhD**[2]**/** [1]Former Senior Director, Global Regulatory Writing, Johnson & Johnson, New Hope, PA; [2]Vice President, Research, IDC Health Insights, Needham, MA

The panel members respond to questions that have been raised during sessions on different developments in using technology in medical writing. Medical writing is a profession dedicated to transforming data and analyses into useful and digestible information, whether that information involves regulatory applications or documents for the public and, specifically, patients. Decisions about treatments or granting of approvals depend on the distillation being accurate, clear, and understandable. Using available technology well can support this goal in that it is a means for shifting a writer's focus from what can be accomplished by artificial intelligence (AI), machine learning, and functions to the creation of content.

**What are the drivers for using aspects of automation in medical writing, what gaps has it filled?**

**Helle Gawrylewski:** In the pharmaceutical industry and in health care, automation in the writing process has spotty adoption depending on the size and digital sophistication of a company. Automations have been used effectively in writing by templates in which sections are prepopulated based on text from other documents. The protocol might be populated with text from the investigator's brochure (IB) or protocol concept document. Some companies have developed or acquired systems that can be used to accomplish this type of text before population and reuse. Microsoft Word itself has some slick automated capabilities that may not be fully used, like text tagging for reuse in other parts of a document. Another gap filled is the writing of routine text in documents like the safety narratives in clinical study reports (CSRs). Narratives are required in the CSR but are onerous to write, especially in cases in which there are many variables or many study participants with adverse events as in an oncology study. US Food and Drug Administration (FDA) reviewers have not been fond of safety narratives being totally written by automation, so this is not as common as it might be. But hybrid narratives, in which the data appear in brief tables and the discussion and assessment are written by a medical writer, can be efficient and accurate and medically useful. Safety narratives written entirely by AI require a large data set to teach the algorithms to produce adequate text.

The writing process also has benefitted from automation in review tools and quality control (QC). It's useful for the applicable style manual to be digitally available and automatically applied for document checking. Routine checks can be more efficient this way and a time-saver for the writer. Tools for the review cycle have also been used because it's tedious to send out sequential versions for document review when this can be done by a tool like *Please Review* and others, in which all comments can be seen by the team, tracked, and ultimately incorporated. Technology improves the process immensely and has had a positive impact not only on efficiency but also quality.

Other parts of an eCTD (electronic common technical document) have also benefitted by making the integrated summaries of safety and effectiveness (ISS and ISE) linked to the individual reports for a population, and the literature summaries can be captured by AI technology. I'm not sure how many companies take advantage of AI in this respect, but Nimita can perhaps address this more fully.

Other options for the use of AI and deep learning can be technical summaries of results for registries, and these can be populated when a CSR is written, as can the FDA Study Snapshots for safety by demographic characteristics that are required at approval. It's possible to populate the requirements automatically as an application is being built.

Scientific writing in another language, also referred to as translation or localization, benefits from at least some aspects of machine translation. Companies that use translation memories, machine learning, or advanced deep learning methods (also known as deep structured learning, with multiple layers between the input and output layers) can produce complex documents in many languages quickly, required for Lay Summaries in the European Union (EU) portal (implemented in January 2022). This


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type of automation requires standardization of concepts and terms so that coding can be used for digital exchange. Groups like the Clinical Data Interchange Standards Consortium (CDISC) and the Medical Dictionary for Regulatory Activities (MedDRA) code research terms and adverse events so they can be easily exchanged.

All of these uses require standardization of terms and definitions. A concept that assists in reusing information: text must also be considered data. Written content is data, and a document is just a compilation of data elements. Computer systems can be designed to use natural language processing (NLP) to understand written text. Machine learning and deep learning keep advancing, making these tools a substantial efficiency gain for any organization. It's also a boon to medical writers who can use the tools to summarize large amounts of data to ensure that all applicable resources are considered.

**Nimita Limaye:** Helle has made some great points. The future of medical writing is really about automation with the human in the loop. It is about leveraging not only robotic process automation and AI, but also about the use of machine learning (ML) techniques, such as NLP (which turns text into structured data) and natural language generation (which turns structured data into text). The challenge with training ML algorithms is the availability of massive labeled data sets. Transformer-based neural network architectures operate in a two-stage process, unsupervised learning on large volumes of unlabeled datasets, and then supervised learning on smaller amounts of labeled data. These are very powerful models and can be game changers, but these are still early days. There has been a very interesting report in the June 2022 edition of *Scientific American* about how a GPT-3 transformer was trained to write an academic paper about itself.

Automation will bring in significant efficiencies and reduce not only costs, but will also reduce the monotony associated with authoring the often-repetitive sections associated with regulatory documents and will improve quality. One is seeing a flurry of innovation, with technology vendors actively innovating to drive "intelligent authoring." Technology in medical writing will be increasingly adopted by the life sciences industry, and the future is not about the why, it is about the how. It is about how do you successfully implement it at scale. The industry is still stuck in a "pilotitis" mode, that is, operating on running one pilot to see if the technology really works, which is not surprising because it is such a highly regulated industry.

**What are the areas in which use of the technologies might not be the best option and what barriers still exist in the industry?**

**Helle Gawrylewski:** Aspects that require expert scientific knowledge and assessment may be able to be produced by automation but at this time still require human evaluation and judgment. Electronically translated text still needs human review because language nuances and cultural aspects are difficult to program, especially in many languages. A native speaker should always review and verify. Writers work in a global arena and should take this responsibility very seriously. For safety narratives, the medical assessment is also better written by a qualified medical writer. Machine written text can take on a repetitive quality and be interpreted as obviously machine written and not properly evaluated.

**Nimita Limaye:** Absolutely—addressing scientific and cultural nuances is critical. And I believe that writing is not just a science, it is an art. The sentience that a human can bring in can make all the difference, especially when it comes to developing lay summaries or building out informed consent forms. In addition, interpreting findings often requires looking across multiple data points, possibly in different reports. Algorithms may not be configured to do that. This is where the scientific thinking that a medical writer brings to the table counts.

**What barriers to adoption exist in the industry?**

**Helle Gawrylewski:** Structured authoring has been difficult to adopt because the application initially did not support Word documents and the formatting was an issue. Using structured authoring requires staff training and often an authoring tool does not integrate well with other older systems. It's easier for a new operation or initial public offering (IPO) to start with structured authoring than to have a large organization scrap all the old systems and replace them. Cost is definitely an issue but also technical competency of the staff. Even Word is not actually used to its full capacity! Document experts are often not writers, and many writers are not sophisticated technology experts! In the past writers have been reluctant to embrace automation because they think it will replace them. But the fact is that not everything they write is worthy of their full attention. So, offloading what can be offloaded allows full-time focus on the critically important document sections and elements.

There are some specific phases of research or types of research documentation for which automation seems to be more useful than for others.

In early phase 1 studies, much of the results are focused on data and assessments are straightforward, like blood levels for $C_{max}$, AUC, and such. Wearable devices that record results digitally are ideal in many types of studies in which tracking is important and in which some participants can be unreliable, such as in cardiac and diabetes studies.

Automation of patient diaries has always been a good use of automation, and now it's possible to use smartphones and audio recording to get quality real-time data.

**Nimita Limaye:** I think that the biggest barriers to adoption are change management and "pilotitis." Automation creates concerns with many medical writers. Will their roles be replaced? No, not really. They will actually move up the value chain. The grunt work will be taken care of by AI/ML. The medical writer will need to ensure that the data are represented in the right way, are being interpreted appropriately, and that the messaging is correct. It is important that the value of automation of medical writing is recognized. Secondly, implementing any technology requires investment, and returns come when the solution is implemented at scale. Hence, many times, companies do not see the returns after running a pilot, and then determine that this is not a good solution. That should not happen. Skill development is also important. Not everyone is tech-savvy, and the ability to navigate various tools requires training. Ensuring transparency and regulatory compliance will be critical.

**What promising developments in automation exist in the near future as advances in AI and deep learning technologies continue to evolve?**

**Helle Gawrylewski:** Access to efficient and useful information from large databases that are untapped and useless to regular human review, like Clintrial.gov, can have considerable impact. How many people can review and get value from all of the studies registered and reported there? The information is only as useful as we can accurately search and summarize it using AI and other newer methods of deep learning. I've seen it done and can say that it's exciting and not used nearly as much as it could be. The same applies to the EU portal that will contain not only CSRs but entire applications and IBs.

Workflows can be made efficient and accurate using automation and AI by an authoring system that reuses, and is connected with, all data elements linked for easy searching, correcting, and replication. Providing drug labels globally in all native languages that are accurate (and correspond with the master label), accurately translated, localized, and kept up to date in a master system for tracking and updating. I hope this will be more common than it is now. I think an AI and deep learning system to render research into plain language to make it accessible to the public could be a remarkable way to counter misinformation and shine a light on all the great scientific research that goes on but is inaccessible to most. It's said that the vaccines were developed so quickly that they can't be safe—wrong! The platforms were used for years before for other vaccine development, especially the standard ones used for Ebola and tuberculosis, but the public finds it hard to follow or understand what goes on in research. And we need to modernize regulatory processes and health authority reviews, continue to have applications and data digitally accessible and reviewable globally. If we are transparent and share, scientific data will help us make better decisions faster and promote not only cures but the prevention and avoidance of disease.

**Nimita Limaye:** One will see the increasing use of real-world data; data will be flowing in, fast and furious. It will be extremely challenging for medical writers to handle this scale and speed. This is where technology will play a valuable role. In addition, as global regulations keep evolving, dynamic document templates that embed this intelligence real-time will reshape the future of medical writing.

***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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## BIOSUMMARIES

**Helle Gawrylewski** has a MA from University of Pennsylvania, is a Woodrow Wilson Fellow, and is a former Senior Director in global regulatory and medical writing at Johnson & Johnson (J&J) (retired). Her experience in regulatory medical writing and global regulatory affairs spans more than 49 years in the pharmaceutical industry at Hoechst Roussel Pharma, Novo Nordisk, and Janssen research and development of J&J. During that time, Gawrylewski was directly involved with 55+ regulatory applications for marketing approval and in all aspects of product life-cycle development, ranging from early to full development and post-marketing medical affairs.

She managed and mentored staff from two to 125 and is a strong proponent and advocate of regulatory medical writing. She established linguistic services like translation and related global partnerships in medical and regulatory writing, leading outsourcing relationships in India and China and worked on the first team to submit a drug application electronically to the FDA. She led document management implementation and transparency activities internally while serving as a team lead at TransCelerate in the Clinical Trial Document Transparency group, later in PHUSE as a team member, and also on teams at Janssen that produced several European Medicines Agency Policy 0070 submissions of transparent clinical reports. In regulatory, she established global labeling outsourcing. Externally, Gawrylewski was the Pharmaceutical Research and Manufacturers of America representative in the ICH E3 Q&A working group that clarified standards for study reports, was a member of the CDISC Glossary Team and was the lead for 7 years, and was DIA MW community lead for and a core team member for 8 years. Gawrylewski is dedicated to cross-industry groups designing approaches to common problems in clinical trials, including clear goals/design, auditable conduct, subsequent clear reports, and transparent results in plain language and well-defined scientific terms shared in multiple languages. She is a member of the Multi-Regional Clinical Trials Plain Language Glossary effort, the PHUSE Transparency Term Harmonization Team, and contributed 2 chapters to the Regulatory Affairs Professionals Society's Regulatory Writing: an Overview. Experience shows that such work allows medical knowledge to advance and ultimately to make a difference in patients' lives.

**Nimita Limaye**, PhD, is a Vice President of Research with IDC Health Insights and leads Life Sciences Research and Development Strategy and Technology, providing research-based advisory and consulting services as well as market analysis on key topics related to the life sciences industry with a technology lens. She is an executive business leader with over 25 years of experience working in the pharmaceutical, contact research organization, and life sciences technology consulting industries. She is the past chair of the Society for Clinical Data Management board and is the current chair of the global DIA medical writing community. She has chaired several conferences, led industry roundtables, given keynotes, and has authored close to 100 publications and white papers. Limaye has led medical writing operations, managed strategic outsourced partnerships, and has conducted workshops on the outsourcing of medical writing.

AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V37 N4 / 2022

THEME ARTICLE

# The Future of Medical Writing: A Panel of One

**Lisa Chamberlain James, PhD** / Senior Partner, Trilogy Writing & Consulting, Cambridge, England

Of all the points in the evolution of the medical writing profession, I believe we are at the pinnacle of what promises to be the most exciting and biggest paradigm shift in medical writers' roles and responsibilities. With an accompanying leap in the introduction and use of technology in ways we have only dreamt of until now, this is a huge opportunity for all of us. However, it will also require medical writers to expand and hone their already extensive skill sets, and for their managers to embrace new technology and empower their teams to really grow and flourish into their new roles. For those forward-thinking companies, the rewards—including increased job satisfaction, faster and more effective submissions and approvals, increased general public engagement, and productivity from their teams—promise to be significant.

## GLOBALIZATION OF MEDICAL WRITING

### Collaboration Among Professional Organizations

Collaboration and harmonization have to be the key aims and the buzz words for this next phase of medical writing evolution. Each region doing slightly different things in slightly different ways is not only inefficient, but ripe for increased human error. There is an increasing demand for more and better medicines and information delivered more quickly to patients and the general public, and, coupled with a lack of highly trained medical writing professionals, the only way to meet this demand is to collaborate and harmonize as much as possible. This plea extends not only for collaboration and harmonization among professional organizations, but among regulatory agencies. Let's take one document—the Clinical Study Report (CSR)—as an example: imagine a utopian situation in which all CSRs were written and data were presented in the same way. Not only would these documents be much easier and quicker to produce and review, but much of the first draft at least could be automated, freeing medical writers to focus on their higher value skills of discussing key messages and key data points with their clinical and regulatory teams, and honing and crafting the final documents to be the concise and accurate representations of data that currently can take months to prepare (see comments on the shared technology question).

Harmonization of document templates and guidelines could also positively impact the dearth of skilled medical writers. Not only could they leverage their knowledge and experience more easily between regions, but it would open up more career opportunities for them geographically, making the profession more attractive and increasing retention of talent.

### Defining the Profession Along Agreed Lines

With collaboration and harmonization across the industry come the added benefits of common training and educational aims and needs. This would allow certification systems to be put into place with meaningful outcomes and measurements and allow and encourage medical writers to expand their skill sets to meet the growing demands of the profession without relying solely on an individual company's commitment to and expertise in their training.

### Expansion to Other Professional Associations/ Professions With Venn Diagram Overlap

Of course, the benefits of harmonization extend beyond the medical writing sphere. There are many areas of overlap with organizations such as SCOPE, the International Committee of Medical Journal Editors, TransCelerate, and the Patient Information Forum. If the medical writing community can engage and collaborate more with these organizations, we can pool resources and knowledge and make a much larger impact on the guidelines and templates and information available to the general public. Such organizations could also potentially contribute to aspects of any certification schemes for medical writing, bringing their specialist knowledge of their areas and offering specialist training opportunities. This can only benefit medical writers and the profession as a whole.

### Shared Technology

There is no doubt that the industry is ripe for an explosion


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of shared and new technology, including etemplates, virtual and real time clinical trials, etc. TransCelerate has already made huge strides in producing and making freely available some excellent templates for medical writers to use, which will hopefully encourage harmonization of documents across the industry. Beyond that, software and technological advances are already taking shape, and regulatory agencies are preparing themselves (the United Kingdom has proposed a new pro-innovation framework1 for regulating artificial intelligence). Some initial offerings have been in place for several years now, and these are being expanded with new technologies to automate initial drafts, bringing the benefits and advantages already mentioned.

### Common Lexicons

The general public are increasingly demanding more understandable and better information about their medicines and therapies. This is essential not only to engage the public in clinical development, but to help them better use their medicines. If we are truly to ask the general public to be involved in the decision making about their treatment or involvement in trials or in any stage of clinical development, we must clearly explain the benefits and potential harms, along with the context surrounding the need for the treatment, therapy, or intervention.

However, it is an extremely difficult and highly skilled task to convert complex clinical and medical information into plain language. The first step is to find suitable vocabulary! Excellent and ground-breaking work has already been done by organizations such as the Clinical Data Interchange Standards Consortium and the Multi-Regional Clinical Trials Plain Language Glossary Group. A common lexicon is essential to be able to communicate with the general public to reduce the confusion created when different wording is used to explain the same disease or procedure. Sharing the lexicons and making them freely available is a huge service not only to the medical writing profession but to the general public as a whole, and the continuation and expansion of these initiatives will allow medical writers to connect with audiences that have been out of reach for them until now.

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## BIOSUMMARY

**Lisa Chamberlain James, PhD**, is a senior partner and CEO of Trilogy Writing & Consulting. Aside from management activities, she leads client projects with extensive experience in a variety of documents. Lisa has a special interest in writing for the public and in patient information. Following a PhD and post doctorate in Pathology at Cambridge, Lisa began her medical writing career in 2000. Since then, she has been involved in EMWA as a member of the Educational Committee, as a mentor, leader, and assessor of workshops, and teaches and reviews workshops for AMWA. Lisa holds an EMWA professional development certificate, is a member of TOPRA, DIA, and PIPA, initiated and chaired the EMWA Pharmacovigilance and Communicating with the Public Special Interest Groups, and is also chair of the Geoff Hall Scholarship Committee, section editor of the "Medical Communications and Writing for the Public" section of *Medical Writing*, and a Fellow of the Royal Society of Medicine.

AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V37 N4 / 2022

THEME ARTICLE

# What About the Audience?

**Kimbra Edwards, PhD** / Associate Director of Medical Writing, Center for Information and Study on Clinical Research Participation (CISCRP), Boston, MA

**SPEAKERS**
**Samuel Entwisle, PhD** / Medical Writer, Center for Information and Study on Clinical Research Participation (CISCRP), Boston, MA
**Zack Fey, BS** / Medical Writer, Center for Information and Study on Clinical Research Participation (CISCRP), Boston, MA

Information may be provided to a broader range of consumers. No longer will results of studies be limited to regulators and scientific/medical cognoscenti. With greater access to posted documents on a variety of portals, the public will seek and access information that is important for informed decision-making. The patient will have a stronger voice in determining their treatment, and this will extend to end-of-life decisions. Social media will amplify results and will spread misinterpretations and poor-quality data. *Caveat emptor*!

**Are you scared or excited (or both!) by the increased use of social media to communicate scientific information? What can medical writers do to help stop the spread of misinformation?**

**Samuel Entwisle:** I would say both! I'm not very comfortable with social media myself, so the idea of engaging with these platforms and communicating medical information on a regular basis is a bit anxiety-inducing. But I think this can be an important role for medical writers, especially as rabbit holes of misinformation on social media can make finding accurate information difficult. I do think there is a great opportunity for collaboration between medical writers and online content creators who are savvy with how to get good social media engagement. And we should make as many plain language materials as possible free, available, and easy to discover online so that content creators can access them. I think it's essential to build increased literacy about clinical research, and social media will have to be a big part of that.

**Zack Fey:** I'm with Sam on this one. Regarding the surge in the sheer quantity of avenues to access scientific information, I could not be more excited. But, when it comes to social media specifically, I am more apprehensive. There is a seemingly infinite number of posts, articles, photos, and videos competing for attention on social media. And I have found myself and others skip over a scientific article in favor of something that takes less effort to read or is something more immediately captivating. It will be a challenge to create interesting and accurate scientific content that is able to compete on the mainstage of the ever-expanding universe that is social media.

**Samuel Entwisle:** Absolutely. If you're trying to compete for attention on social media, the way to do that is by having big, flashy, or controversial headlines, not through nuance or data that is presented in a neutral way. This is the world we live in. But we still need ways to counteract the bad information that tends to go viral, to "develop antibodies" against it, you could say. Maybe it's rare that a piece of neutrally presented clinical trial information will explode on Twitter. But maybe that's okay! We can still make it as easy as possible for people who are actively seeking this type of information to access it, and then measure our success by making sure that people are in fact accessing it. Some clinical trial sponsors are starting to think about this more seriously now, but we can definitely do better.

**Kimbra Edwards:** Social media plays an extremely powerful role in people's lives today. For better or worse, many turn to their social media feeds for information on a variety of topics, including scientific information. Scientific information communicated through social media often uses catchy headlines and abbreviated formats, which serve as a quick and convenient way to consume information in a world where it feels mandatory to stay in-the-know and offer an opinion on a given hot topic. As my colleagues have


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stated, a primary concern with social media is the spread of misinformation. Misinformation seems to spread on social media either because important nuances aren't captured, or someone uses the platform to speak on a topic without fully understanding it.

So, what can medical writers do to help counteract misinformation? One option is to use your own social media to spread accurate scientific information, either by writing your own posts or simply sharing posts from verified sources to increase their visibility. If social media isn't your thing, another option is to utilize the appealing aspects of social media in your work. This could include using concise language, explaining the "so what?", and exploring alternative formats such as videos.

**How can medical writers enhance the quality of documents made available to the public?**

**Zack Fey:** As medical writers a (or dare I say, the) key skill we are always improving is our ability to communicate. Communication is important in every aspect of life and especially when creating something for others to read and engage with. Getting to know the audience we are writing for helps first and foremost. After that, we are tasked with putting words on paper in a way that best speaks to the target audience. It is easy to accidentally lose sight of your audience from behind your computer screen and favor your own grammar, structure, and clarity preferences. But that is the everyday challenge we happily accept.

**Samuel Entwisle:** Yes, getting to know our audience is so important, and it's easier said than done. I think Zack is right on that we must have a degree of humility about it and not get too married to our own opinions about what good writing looks like in other contexts. User testing can help a lot with that. And I think life experience helps as well, which is another reason why diversity in culture, race, class, gender identity, and so on is so important for good medical writing. I also really value close collaboration with editors and graphic designers. You could be writing the clearest, best sentences in the world, but if they are not formatted in a friendly way, or if they're not accompanied by graphics that draw you in and lead you along, then I think you'll be missing opportunities to engage with your target audience.

**Kimbra Edwards:** One way for medical writers to enhance the quality of documents written for the public (or any audience, really) is to write them in plain language. Utilizing plain language best practices allows you to communicate more effectively. Another way, as stated above by my colleagues, is to consult with others who have expertise outside of yours. These experts might include graphic designers, editors, or patients. Lastly, it is important to actually apply the learnings from these experts (for example, don't ask patients for their feedback to simply check a box).

**What are some strategies medical writers can use to ensure data and information are communicated accurately but still in a way the reader can understand? How do you best balance scientific accuracy with clarity?**

**Samuel Entwisle:** This is always the challenge, right? I write a lot of plain language summaries of clinical trial results, and one thing I try to tell myself is there's no such thing as perfection. It helps to approach these plain language materials with a sense of priorities. What are the most important take-home points that we need to convey? In my case, this would usually be the results of the primary endpoint of the trial, and maybe a secondary endpoint, plus some key safety data. Once we now have this in mind, we can work backwards and ask what the reader needs to have a great understanding of these take-home points. If a certain concept is critical for this understanding, we can spend some time and really explain it. If not, we can give it more superficial treatment or omit it entirely. But there will always be trade-offs, and people may not always agree on how to navigate them.

**Zack Fey:** I am generally a proponent of presenting something in the most concise way possible, especially in plain language documents. Recently, I have been writing a lot of 2-page plain language protocol synopses for clinical trials based on the European Union Clinical Trials Regulation. When space is at a premium, I may omit the explanation of a term entirely instead of including a superficial explanation that may confuse the reader more. In the future, we may be able to offer an optional third page of the synopsis with a glossary of terms. Clarity and accuracy can easily coexist under the right conditions.

**Kimbra Edwards:** Like Sam, I find remembering the bigger picture key. What exactly do you want readers to walk away with? Writing with this in mind, it becomes more obvious how best to position data and other information. When considering the balance between scientific accuracy and clarity, I also think about the balance between complete transparency and thoughtful data selection. Of course, it is important not to cherry pick positive data, but it is also important to not overwhelm the reader with copious amounts of data

that might be misinterpreted. For example, patients and the public tend to assume that all adverse events are caused by the study treatment, even when it is clearly explained that this is not the case. This can give the impression that the study treatment is less safe than it is. Thus, writers of plain language summaries of clinical trials should consider only including possibly related adverse events above a thoughtfully determined frequency threshold.

**What are some ethical concerns when writing for patients and the public? How can we as writers best mitigate these concerns?**

**Zack Fey:** One of the biggest ethical concerns is the source of funding and information. Medical writers must accurately, fully, and nonpromotionally convey scientific information to patients and the public while still meeting the sponsor's requests and needs for a given project. Often, the needs of the public and a sponsor can seem at complete odds with one another. With a title like "medical writer," someone may think all we do is sit at a keyboard and type about science. What I've learned is that while writing is a large part of the job, learning to successfully compromise on complex topics to provide useful documents is more the task at hand. A medical writer must take seriously the duty of being one of the checks and balances to all scientific information that reaches the public.

**Samuel Entwisle:** Compromise is an important skill for medical writers, especially those balancing the interests of trial sponsors and patients. One thing that can help a great deal is defining detailed processes and templates that the writer and the clinical trial sponsors agree to. This can prevent some difficult situations when deciding, for example, which endpoints or safety data to include in a plain language summary, or whether to refer to a drug by its trade name. Mutually agreed-upon processes and templates can help to keep plain language deliverables nonpromotional. Ultimately, increased literacy about health and clinical research is in everyone's interest.

**Kimbra Edwards:** Much of the "friendly friction" we encounter with sponsors arises from disagreements on data inclusion and the overall messaging of the results because we strive to present results in a nonpromotional, neutral way. Luckily, we work with collaborative sponsors that respect the CISCRP's independent positioning and patient-centered approach, so typically this friction is resolved after a brief explanation of why we do things the way we do them. It is important that other medical writers working with sponsors (or other stakeholders with varied interests) feel comfortable enough to uphold the high ethical standards that come with writing for patients and the public.

**What are the benefits and challenges of user-testing documents with the intended audience (public, patients, health care providers, etc.)?**

**Samuel Entwisle:** I think the benefits of user testing are clear. In general, getting feedback from your intended audience is essential for a writer. It is crucial to get input from all stakeholders, especially patients and the public, regarding how information about medicine and clinical research is communicated. We are lucky enough to work at an organization in which almost every deliverable we create is user tested by a review panel of patients, patient advocates, and members of the public. This gives us confidence that we are creating high-quality deliverables, and it has also led us to accumulate a great body of knowledge and the best practices about how to best communicate about clinical trials in a clear and humane way. One challenge, I think, is that we want to avoid over-correcting. For example, if one person makes a comment that they don't like how a certain concept is explained, but 9 people like it best the way it is but say nothing, we want to make sure we don't fix what isn't broken.

**Zack Fey:** A challenge I see with user testing is that the public, patients, and health care providers can provide feedback that is too general. A comment such as "this is good," for example, isn't very helpful. Like Sam said, user testing is great to build the "confidence that we are creating high-quality deliverables," but the best feedback takes time and active engagement from the reviewers. Finding reviewers that are willing to give up their time to provide quality feedback that will translate into an improved deliverable is no easy task.

**Kimbra Edwards:** Another challenge with user-testing documents with their intended audience is the extra time it takes. There is no doubt that the feedback obtained by user testing can be valuable, but with strict deadlines, it can be a real challenge to fit meaningful user testing into a project timeline. One strategy is to start your project as early as possible. Plain language trial results summaries can have strict posting deadlines. To meet these deadlines and still have time for user testing, we have started drafting the summaries based on the tables, figures, listings document instead of the clinical study report, which can often take much

longer for sponsors to finalize. If you can't start your project any earlier, another strategy is to start recruitment for the user testing far in advance. Having your reviewers in place and ready to go, with clear deadlines and expectations communicated, is very helpful.

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

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## BIOSUMMARIES

**Kimbra Edwards** is the Associate Director of Medical Writing at the Center for Information and Study on Clinical Research Participation (CISCRP). CISCRP is a nonprofit organization focused on increasing awareness and understanding of clinical research participation. Edwards helps oversee the creation of easy-to-understand trial resources for patients, participants, and the public. This work utilizes a patient- and community-centric approach to build accessible and engaging content. Edwards earned her BS in Neuroscience from Trinity College and her PhD in Developmental and Brain Sciences from University of Massachusetts Boston.

**Samuel Entwisle** is a Medical Writer at the CISCRP. Entwisle helps to create plain language trial results summaries and plain language summaries of publications among other lay-language resources. Entwisle earned his BS in Biochemistry from the University of Maine and his PhD in Molecular and Cellular Biology from the University of Washington.

**Zack Fey** is a Medical Writer at the CISCRP. Fey helps create easy-to-understand trial resources, including plain language protocol synopses and plain language trial results summaries. Fey earned his BS in Economics from George Washington University and did a postbaccalaureate premedical program at Tufts University.

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TOPICAL FEATURE

# Reflections on Working as a Medical Writer with a Disability and How Medical Writers Can Be Disability Allies

**Jeanette M. Towles, MA, RAC-Drugs** / Synterex, Inc, Dedham, MA

## ABSTRACT

I am a firm believer that things happen for a reason, but also that good comes from talking about how things came to be the way they are.

The first part of this article describes my personal journey navigating the complexities of having a disability concurrently with those of being a medical writer and from that standpoint can be considered subjective compared with the data-driven information we are used to seeing in our daily work. It is not meant to be a history on disability law or a comprehensive treatise on why people with disabilities are underemployed—other authors have covered those topics in great detail in other milieus, to incremental avail—but, rather, to raise awareness of potential challenges within the medical writing context and how navigating stakeholders' assumptions about health circumstances can be as arduous as managing the health condition itself. The second part of this article provides practical suggestions on things the medical writing community can do to make sure their own can keep being strong contributors no matter what their circumstances are in life. It is the author's hope that this article will represent the start of a dialogue within our community and that by sharing one story others feel comfortable sharing their own.

Growing up, both of my parents were disabled. So, from a young age, I always had many responsibilities and frequently found myself teaming up with my brother to get through chores—more chores than my friends ever had. The silver lining is that this circumstance gave me the work ethic and sense of teamwork I have today, but I was also witness to the struggles my parents faced in the health care system, including a lack of access to therapies and stigma.

I often think of how I am just about the same age now as my mother had been when she was forced to leave the workplace because of her health condition. About 7 years ago, I started to encounter my own health issues. At the time, I was an undisputed strong scientific contributor, and my managers stated as much in reviews. I had progressed on a steady path from writing to upper management. Eventually, however, I could not follow the pattern of a normal workday and simultaneously address my health concerns. Many of the challenges I faced involved someone in a decision-making capacity making assumptions about my intentions, my needs, or my work—assumptions that were fundamentally false.

Here is an example: I was 5 minutes late to a meeting because I had to run to the bathroom to take a medication I need at a certain time of day. A company leader assumed I was not being respectful of her time and confronted me upon my arrival.

Here is another example: I hurt my back overexerting myself during a regulatory submission (too many consecutive hours at my desk), and I had to go to physical therapy. Because I could not make late-day submission meetings, I was told I was failing at my job.

It seemed that overnight, despite having declared my disability and asked for accommodations from day 1, I would not be permitted to maintain a seat at the table, so to speak—one that I had worked so hard to earn. So, I had to create a new table. Now, I put into my business all the time and energy I used to dedicate to someone else's vision.

I often think back to what it would have been like for my mother had a work-from-home option been more commonplace, and had she not been forced to leave the workforce at such a young age. I was lucky that I found another avenue to be able to continue contributing, although I would be remiss if I implied this was an easy path.

As a hiring manager, I also hear all the time other examples of the type of issues I ran into, including women who either were told they would not want to come back to work after they had their babies or were told they outright had no job to come back to once they went out on maternity leave.

This is the *ladder of assumptions* rearing its ugly head; in these cases, the person on the receiving end of data has translated an observation through a series of filters (the


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rungs on the ladder) into a conclusion (Figure 1). The conclusion might seem right because it is based on what the observer comes to believe is true, but that truth has no correlation with the reality of the intentions or actual circumstances of the person being observed.

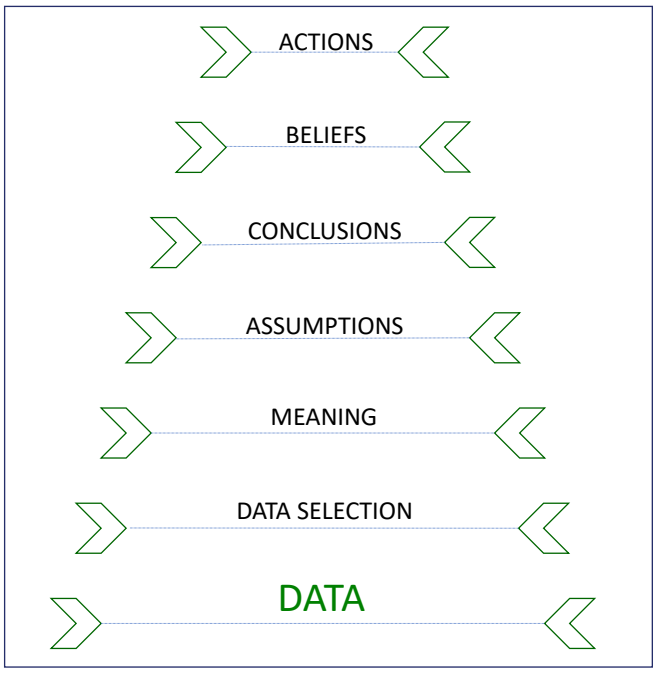


**Figure 1.** The ladder of assumptions (also known as the ladder of inference). Adapted from: Senge 1994.[1]

The stress of coping with a health concern compounded with that of managing the aspersion of others' inferences amount to a recipe for failure for anyone who cares deeply about what they do for a living. Add to that the stress of deadlines, strict regulations, and other quirks inherent in our industry—perhaps not even knowing who to trust to talk to about any conflicts that have come up or accommodations needed, or embarrassment over how these things have been actioned to date—and one could quickly end up with a work environment that contributes further to health decline and precludes continued work.

I cannot go back in time and change others' reactions or my health, or convince my younger self to have courage because it does get better, but I can advocate so that no one else in our community unwittingly finds himself or herself in the same situation without help. Toward those goals, here are some tips on how not to fall victim to the ladder of assumptions and to support those with disabilities working in our medical writing community.

**1. Avoid making assumptions about capabilities.**
When employers think about hiring those with disabilities, the desire may be there in theory, but the procedures and infrastructure to do so may seem prohibitively daunting. There is often confusion over even the etiquette of how to interact with prospective employees with disabilities and fear over saying too much or too little.[2] This hesitation is reflected by the rate of unemployment by those with disabilities historically being nearly twice that of those who do not have disabilities.[3] To overcome this barrier, avoid making assumptions that a resource or vendor is not qualified enough or will need too much help to be effective; individuals with disabilities or disability-owned business enterprises bring expertise and very often have a commitment to hiring others who have also experienced or been a victim of the ladder of assumptions. Keep in mind: these are individuals who, due to something intrinsic that they had no control over, are used to overcoming as barriers things that are quotidian to everyone else. A recent disability-related article circulating on social media about the return to the office after COVID-19-related closures details barriers such as "inaccessible commutes, painful chairs, binding clothing," and "social cues in break rooms," but also, in the experience of one worker with cerebral palsy, "even the inherent focus needed to move through a building," as she navigated the fear of falling while moving between multiple meeting rooms daily.[4] According to a leading organization that helps promote corporate inclusion efforts, Disability:IN, workers with disabilities are "regularly forced to adapt to an inaccessible world, and these experiences have sharpened their problem-solving skills and their capacity for innovation."[5] These skills would make for an ideal medical writer in any circumstance.

To address the question about what you can or should say (or cannot and should not say) to an employee who has a disability, there are some guidelines from the Equal Opportunity and Employment Commission, which are slightly different prior to hire and after hire (Figure 2 on next page).[6]

Prior to a job offer, you cannot ask questions about an applicant's disability or questions that are likely to reveal whether an applicant has a disability, even if the disability is visually apparent. Employers can ask an applicant to voluntarily report a disability for affirmative action purposes.[6] Following hire but before start of work, an employer may ask disability-related questions and conduct medical examinations as long as it does so for all employees in the same job category. After employment begins, an employer may make disability-related inquiries and require medical examinations only if they are "job-related and consistent with business necessity."

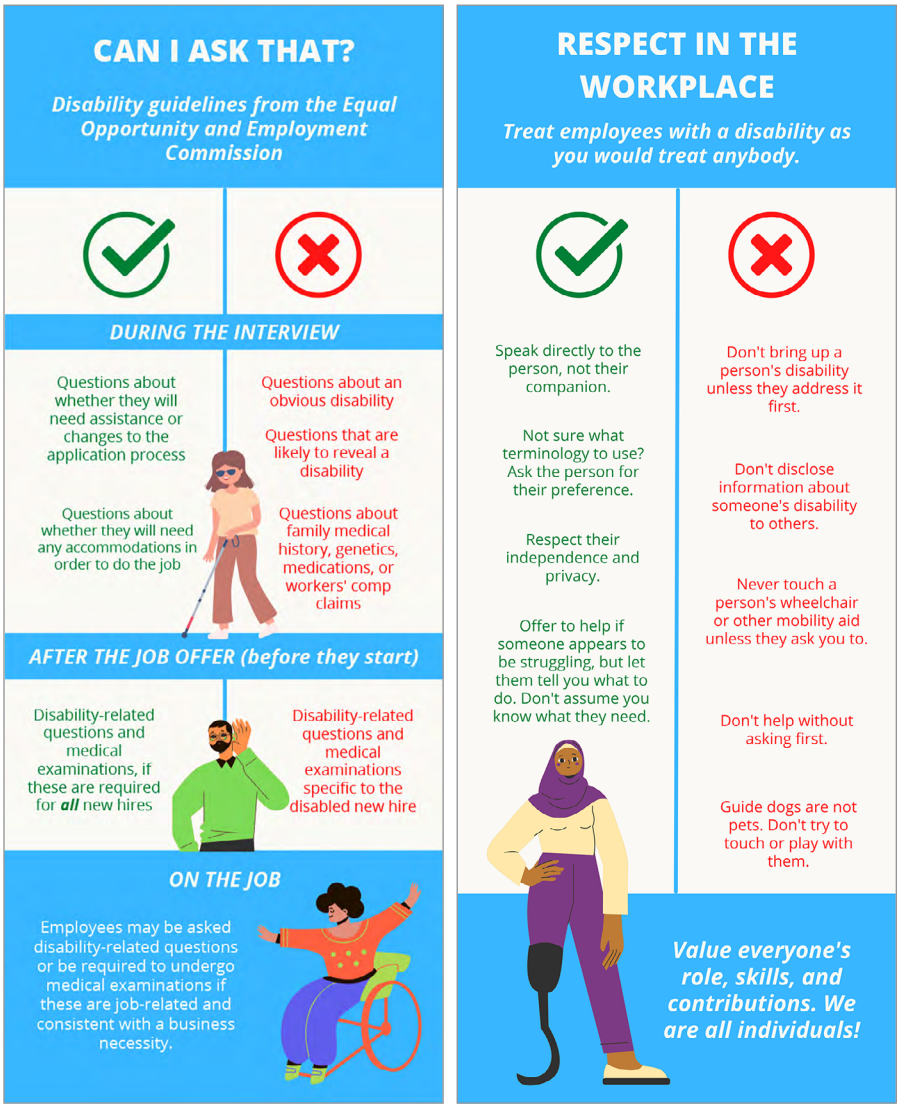


**Figure 2.** Communication guidelines for interacting with an employee or prospective employee who has a disability.[2,6]

Beyond the regulations, however, the key thing is to remember that what an employee who has a disability generally wants in the workplace is not to feel like his or her role or talents are diminished, even if he or she gets to the same goals a little differently (Figure 2). Avoid terminology like "handicapped" that causes the individual behind the disability to be minimized and words that pity the person with the disability.[2] Essentially, operate just as you would with anyone else.

Lastly, to quote my mentor and disability advocate Joyce Bender (2021), "sign the contract!"

To truly have an inclusive workplace is to not only interview those with disabilities—either those who self-identify or by intentionally seeking out any number of available databases of prescreened individuals or vendors with disabilities who are seeking work—but also to follow through to onboarding that disabled employee or vendor. That person cannot maintain their economic freedom[7] or contribute just by a company providing them lip service. The people who work on medicines in the life sciences, and thus the people who manage documents to help those medicines get to the clinic and market, should be reflective of the people in the community who will receive those medicines, which includes the over 1 billion people living with disabilities worldwide.[3,8]

**2. Have a support system in place.**

It is fundamental to point out: Not every disability is the same. Do your homework. These are potential corporate resources for integrating employees with disabilities into your team:

1) Formal training programs for those without disabilities to learn about the tools and accommodations available for better integration across teams;
2) Formal tailored onboarding programs, including disability-specific information such as reasonable accommodation procedures and orientation materials that are in accessible formats;
3) Mentoring and career development programs; and
4) Employee resource groups.[3,9]

Even if no formal employee resource groups have been formed, make sure that any support resources are created and posted in an accessible way. According to a web accessibility company's assessment, up to 98% of US-based websites are not fully accessible, and other research by the Pew Research Center showed that people with disabilities are approximately 3 times as likely to never go online and are around 20% less likely to subscribe to home broadband and own a computer, smartphone, or tablet. So, change can happen from the level of content creation.[10]

It is equally important to leverage your influence to promote a culture that does not cause your employees to defend themselves or their needs repeatedly. As an example, I once had to fill out a form justifying equipment accommodations that had to be approved by 3 different

managers, which seemed like an unnecessary process causing me to have to disclose my needs repeatedly across the company, which may make some people uncomfortable. Once an employee states their requested accommodations to Human Resources, they should not have to repeat them or remind anyone; it is the company's job (and in the company's best interest) to know what that person needs to do their job successfully. Also, if someone in the disabled community is brave enough to come to you with suggestions on how to make a policy more inclusive or a resource more accessible, any instinct toward defensiveness should be resisted—or, worse, gaslighting and telling the person it does not impact them; they are not pointing out an issue to you because they think whoever put the policy or resource in place is a bad person but, rather, because their unique viewpoint may not have been known when it was put in place.

**3. After you listen, be vocal about your support.**

The Americans with Disabilities Act of 1990 (ADA) makes it unlawful to discriminate in employment against a qualified individual with a disability.[11] Under the ADA, employers are required to offer reasonable accommodation, which is defined as "any change or adjustment to a job or work environment that permits a qualified applicant or employee with a disability to participate in the job application process, to perform the essential functions of a job, or to enjoy benefits and privileges of employment equal to those enjoyed by employees without disabilities."

Let your colleagues know, both within and outside of medical writing, that including those with disabilities in your resourcing pool, as well as offering economically feasible accommodations per the ADA, is not just a requirement to be dealt with—it is a winning strategy. In fact, the majority of requested accommodations cost nothing to implement, with the rest costing only $500 per employee on average.[3] Common accommodations in the medical writing field may include more obvious ones like equipment requests (adjustable height desks, headsets), software (speech recognition, closed captioning), or flexible schedule, but there may be other less obvious ones such as need for accompanying service animals, a quiet or lighted workspace, a space with certain temperature parameters, or need for a color-coded filing system.[12] Given that disability inclusion is also gaining ground as an important topic for corporate responsibility and investors, with more CEOs every day signing onto pledges like "Investors are 'IN'" and "CEOs are 'IN'" and using tools like the Disability Equality Index, a benchmarking tool that helps companies build a roadmap of measurable actions that they can take to achieve disability inclusion and equality it is likely that most Boards of Directors would be supportive of and tout any successes you have had making your medical writing team more inclusive.[5,13,14] This index is scored on a scale of 0 to 100 points, with 80 and above achieving a title of "Best Places to Work for Disability Inclusion," and measures based on answers and supporting documentation for the current year (or, for some questions, a recall of 1 year) the weighted domains of culture and leadership, enterprise-wide access, employment practices, accommodations, and supplier diversity, as well as the nonweighted domain of non-US operations. In fact, the Board of Directors will be so supportive because data have shown that those who championed or improved upon their corporate disability inclusion practices were more likely to have shareholder returns outperforming those who did not champion or improve their practices.[3]

**4. Celebrate disability.**

During the COVID-19 pandemic, the author heard from many medical writing managers that they were trying to cut their employees slack for extenuating circumstances (including caring for children or sick family members), in particular when it came to performance evaluations, and to ensure the protection of their time off and work-life balance (2021).

This was a breath of fresh air and should absolutely continue. As we envision what a return to the office or living with the pandemic looks like, it will be critical to bear in mind that there will be a large segment of the population who will still face the same day-to-day struggles of trying to fit in with a typical pattern of the workplace or workday, and that their intrinsic features create hurdles for them every day in the workplace, in addition to any extrinsic hurdles (like COVID-19). Now that we have proven that people can innovate (including producing life-saving vaccines for a novel virus) without being in the office face-to-face, and that it is not prohibitive to have a budget for technologies to enable accessible work, will we maintain that position so that those with mobility issues, for example, can innovate with us? I, for one, am hopeful that we can do this within medical writing and serve as a paragon of how to do it right. It should also be pointed out that medical writers with disabilities make for fierce leaders, as they already are used to advocating and negotiating to get what is needed. As Disability:IN points out, "The very experiences that have resulted in exclusion from all levels of corporate America are what make them such important assets to corporations…they are a large untapped labor force market due to inaccurate assumptions about their abilities; they

represent a significant consumer population; and they bring different perspectives."[13] It has further been acknowledged by Disability:IN that "Companies that are disability-inclusive are thus better positioned to execute responsible governance, effective risk management, and optimal decision-making, as well as enhanced customer alignment, employee engagement, and transparency, as compared with those without."[13] Thus, it is important not only to include people with disabilities on your medical writing team but also to give them the support and resources they need to get where they want to go in their careers, including positions of leadership. Your department will shine within the organization as a result of these efforts, and good leaders will create other leaders.

## CONCLUSIONS

As hard as it is to tell a story that may evoke feelings of exclusion or pain, the more we tell our stories in the medical writing community about how it is to work with a disability in the health care field, or about any other times we may have been affected by the ladder of assumptions, the better chance we have of colleagues understanding our needs and how to help us in the workplace.

By following the tips in this article, and by engaging with your employees to find out what else they need to feel supported for their specific situation, you can start your journey to making your medical writing team successful in disability inclusion and not accidentally rule out your best employees with preconceived notions.

Coming together in our community around this topic through more regular and open dialogue hopefully will lead us to a universal position: we are not going to allow our colleagues with disabilities to lose the opportunity to contribute, and we are not going to lose strong leaders from the workplace due to lack of accessibility. Not on our watch.

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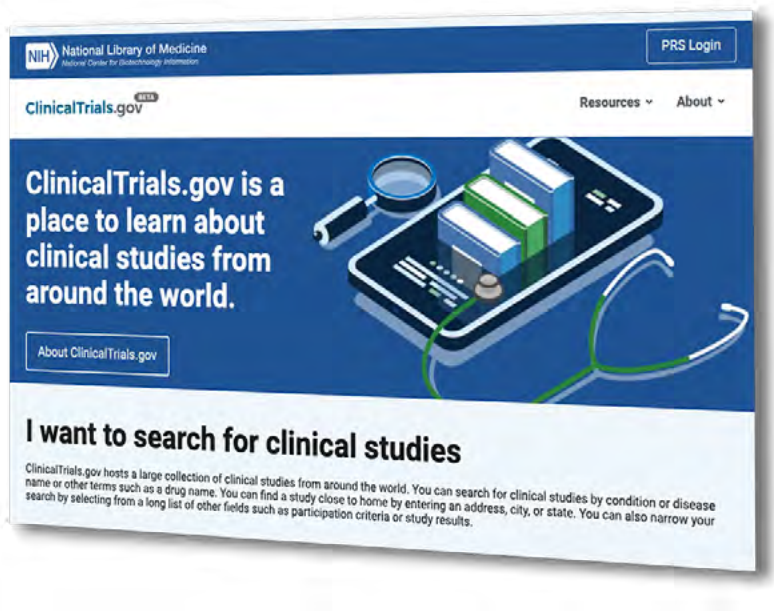
TOPICAL FEATURE

# On to the Next Level: ClinicalTrials.gov Goes (More Fully) Plain!

**Thomas M. Schindler, PhD** / BioNTech SE and *Lay & Regulatory Writing*, Mainz and Biberach a. d. Riss, Germany

It's a rather tacit revolution that happened on September 26, 2022, in the "What's new" section of the https://clinicaltrials.gov website. A short announcement states that "*A Plain Language Checklist for Lay Brief Summaries (PDF) is added to the Support Materials under Data Element Definitions, Templates, and Checklists. The checklist identifies plain language best practices to help investigators write brief summaries that can be easily understood by the general public.*"




This unemotional announcement is a tremendous move toward more understandable entries in ClinicalTrials.gov (CT.gov)—that is, a move returning to CT.gov's original intentions. The purpose of CT.gov was to make information on clinical trials available to the public, initially to "individuals with serious or life-threatening diseases or conditions, to other members of the public, to health care providers, and to researchers."[1] Hosted by the National Library of Medicine, CT.gov was to be a "consumer-friendly" database that provides easy access to information about clinical trials for patients and their families and members of the public.[2] In 2007, by the US Food and Drug Administration Amendment Act (FDAAA), the mandatory registration of clinical trials was complemented with the requirement to make full trial results available.[3]

However, over the years, CT.gov moved further and further away from its initial intentions and became a website for pharma companies' transparency experts, competitive intelligence analysts, investors, and clinical trial aficionados. This development was a consequence of the technical operationalization of the transparency regulations without having the end user in mind. Responding to the growing disconnect between intention and status, CT.gov has in 2019 initiated a modernization effort with the objective to "deliver an improved user experience."

To foster the overarching objective of transparency of clinical trial research activities, more and more information is to be provided by sponsors and investigators about their clinical trials. The information itself is—however—not presented in a way that "normal people" can readily understand. The disconnect between intention and current practice is particularly obvious for 2 data fields that are of great importance to patients: the Brief Title, a short title describing the trial, and the Brief Summary, a short summary that is meant to provide a general, high-level overview of the trial.

As per CT.gov guidance,[4,5] the text that sponsors are to enter in these data fields needs to be in lay language; that is, it needs to be understandable for the public. Despite CT.gov's intentions, sponsors have not lived up to this.[6,7] To the contrary, Brief Titles are often full of abbreviations and specialist language that renders them incomprehensible for most members of the public. This also applies to the Brief Summaries, which should provide a short, high-level summary of the clinical trial detailing its goal and the intended indication. From a patient view, this is particularly unhelpful as the CT.gov website returns a list of study titles as a response to a search request (eg, trials in a disease area). Thus, the interested user is provided with a list of study titles that mean little to them because they often lack the special-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ist knowledge to fully understand them. Furthermore, if the user then clicks on a title, they are shown the Brief Summary, which should ideally provide key information about a trial in understandable language. However, the user is often provided with a paragraph of clinical trial gobbledegook and insider technical slang written for the fellow specialist.

Prior to the September announcement, CT.gov had supplied very little guidance on the content of Brief Summaries; therefore, the new guidance amounts to a major improvement. By explicitly providing a plain language checklist, CT.gov reemphasizes the requirement that these key data fields need to be understandable to patients and the public. Should all go well and sponsors do implement the new guidance, key entries of CT.gov will become a lot more accessible for the public—a true revolutionary development, as the database gains a lot more usability for everybody.

For people familiar with plain language writing, the checklist provided is unspectacular and summarizes the most important points of writing in plain language. Although CT.gov addresses the checklist to study managers and investigators, the task of developing useful study titles and understandable study descriptions is better handled by professional writers even better by professional writers with expertise in plain language writing.[8] As anybody who wants to have a go will quickly find out, it is a challenge to provide good study titles and even more so to provide a good, useful study description. It is an even greater challenge doing this in a systematic way across different disease areas in the context of a larger company or research institution. Few study managers would identify patient-focussed writing as one of their core competencies. Hence, the new focus of CT.gov on plain language writing opens a new realm of activity for professional medical writers, particularly those with plain language writing expertise.

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FREELANCE FOCUS


Brian Bass


Lori De Milto


Gail V. Flores

### Q1: *How can I prepare my freelance business for the recession?*

Although recessions are a natural part of the business cycle, it's still scary to be freelancing during one. This recession may have more impact on freelancers than past recessions because more people began freelancing during the COVID-19 pandemic, and we're living with staggering inflation. We're facing increased competition for freelance work, and most of us can't afford to make less money if our clients stop or reduce their use of freelancers.

Fortunately, health care is more stable than most industries in a recession, so freelance medical writers and editors will see less impact than freelancers in other industries. But even freelance medical writers and editors need to develop the right mindset and take the right actions to thrive in the recession.

What you think—your mindset—is just as important in what happens to your freelance business during a recession as what you do. Thriving takes a growth mindset, grit, and resilience. If you have a growth mindset, you believe that you can change your freelance future by learning new things, being persistent, and taking the right actions. You'll be willing to work hard to reach your goals.

Grit is having the perseverance and passion to stick with your long-term goals until you reach them. Resilience is the ability to meet adversity head-on, adapt, bounce back, and keep trying. Research shows that we can all develop a growth mindset and build grit and resilience.

Next, you need a LinkedIn profile and website that focus on the needs of your target clients and how you meet their needs. Your LinkedIn profile headline and About section must clearly say what you do, how you help your clients, and use the keywords your clients use when they search for freelancers. Also, your profile needs to be complete. Your website needs content that's compelling, clear, and focused on client needs and a design that's visually engaging, clear, fast loading, and easy to navigate.

Because there's more competition for freelance work, you need to do more active marketing, especially networking through AMWA and other professional associations. On LinkedIn, you need to be active enough to rank high when clients search for freelancers.

**— Lori De Milto**

I'm implementing 3 strategies to protect my business for this recession. All 3 strategies are actually general rules for my business. However, like most freelancers, during busy periods or times when I need to focus more energy on other areas of my life, I sometimes let my rules for successfully running my business slide. A recession is a great time to step back, assess, and reestablish practices to strengthen my business. The strategies are

1. **Increase cash flow.** Cash flow can be increased by earning more money and spending less money. Earning more may be challenging in the current environment, aside from rate increases dictated by inflation (see my answer to question 2). I plan to spend less money by comparison shopping for business travel and office supplies (and using coupons and sales where possible), and by being smarter about meal expenses to my business. However, I feel it's critical to maintain my membership in professional organizations, attend conferences, and invest in professional development opportunities to keep my business strong, so I will not be cutting back in those areas.
2. **Keep my current clients.** To keep my favorite clients, I plan to ensure I continue to deliver my best work, return emails promptly, and let them know how much I appreciate them.
3. **Find new clients.** At the same time, every good freelancer knows that relying on just a few clients can be risky. My client list shrank during the past 2 pandemic years; now, I plan to diversify and consider new clients.

**— Gail V. Flores**

* * *


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**Q2:** ***Did you freeze or increase your pricing/rates at the beginning of the pandemic? If you did, are you making any further changes to those rates now?***

Yes, I froze my rates during the COVID-19 pandemic and recession. I'm doing the same now during this recession. This shows my clients that I understand how the recession impacts them, and that I am a team player.

**— Lori De Milto**

I did not change my rates when the pandemic came upon us because I have always offered a kind of "sliding scale," so to speak, depending on the types of clients and their resources. For instance, I charge a certain hourly rate when I work directly with pharmaceutical/biotech companies, and a slightly decreased rate for contract research organizations and other agencies representing such companies—this, so that the agency will be able to mark up my rate and realize a profit. Because I feel profit is essential for agencies like these, it seems fair to modify my hourly rate for them, that is, I will reduce my rate by 20%–25% for medical writing, editorial review/critique, editing, or quality assurance/quality control. However, if a client does not have a competent project manager and requires me to fill that role, I increase my rate by 25%–50% for that function.

Likewise, for nonprofit companies, I offer a reduced rate for writing grant proposals, patient education materials, website copy, standard operating procedures, and other documents—but if they ask me to develop and write their operational plan, (essentially, to think out and write their entire business plan) then my rate is increased by a minimum of 150%.

As of 2022, I have increased my base hourly rate by 10% for all types of clients. So far, no push-back.

**— Cathryn D. Evans**

I charge by the project and don't ever consciously increase or decrease my rates. I strive to always make the most money I can while delivering a product and a partnership experience for my clients that makes them say, "Wow, let's do this again!"

At the start of the COVID-19 pandemic, I enjoyed about 2 weeks of quiet because clients were fumbling to figure out how to work from home. It was wonderful. I was able to work without constant interruption and caught up on paperwork and organizing my office. But things didn't stay peaceful for long. By the end of the first month, it seemed everyone had gotten to work at home. Unfortunately, it quickly became clear they didn't know how to get home from work. My workload exploded like never before, and it hasn't really calmed down since. I'm not complaining!

From a pricing standpoint, I'm still taking the same approach—charging as much as I can and doing everything possible to make sure my clients are happy because they've gotten a great value. But I have had to adjust my estimating to include a lot more phone and videoconference time, and that does affect my pricing. These days I find myself roped into everyone's weekly status calls "just in case" someone mentions content, plus all the project-specific calls. I compensate for that time, of course, but I'd much rather have my fingers on the keyboard being productive. I think clients so miss interacting with their colleagues every day at the office that they're compensating by inviting everyone to these calls and having as many calls as they can.

**— Brian Bass**

I did not freeze my rates when the pandemic started. During the 2007–2008 financial crisis, I froze my rates because I wanted to be "nice" to my clients. Looking back, I wish I hadn't because by doing so, I decreased my value. I saw something online recently that spelled it out really well: if you don't increase your rates to at least match inflation, you are actually reducing your rates. Therefore, I'll continue to raise my rates in alignment with inflation and my increased value because of experience. However, I can still help my clients during these volatile financial times by noting inefficiencies and suggesting ways for them to streamline processes and to assign less specialized tasks to junior writers.

**— Gail V. Flores**

* * *

**Q3:** ***How do you handle payments from international clients? Is there an optimal payment method that has worked for you?***

Generally, I am very cautious about accepting work from a client outside the United States unless the company has been referred to me by another client or colleague I trust completely. Essentially, the referring person must have worked for the international client and can assure me that this client pays every invoice within 30 days of billing. Otherwise, I ask for $5,000 up-front, deposited into my account before I will begin working; thereafter, when I have used up the first $5,000, I ask for an additional advance and then work against that. Because we have little recourse to collect from an international client, it is prudent to receive an advance before putting in time. If it is a small project, one can adjust the amount of the advance requested.

Recently it was brought to my attention that the US government has embargoed certain countries—that is, that US citizens should not work for companies/clients within these countries—and that US banks are not allowed to accept money/deposits from such countries. So far, I have been unable to verify this properly, but AMWA's Managing Editor, Rachel Mosher, provided two links to websites that may be useful in researching this topic further (Rachel Mosher, MA, e-mail communication, 5 August 2022). From Rachel: "The following information is provided by the Office of Foreign Assets Control within the US Department of the Treasury. This link details the countries that are currently sanctioned by the United States: https://home.treasury.gov/policy-issues/financial-sanctions/sanctions-programs-and-country-information. The complete list of sanctioned individuals and businesses that US nationals should avoid doing business with can be found here: https://home.treasury.gov/policy-issues/financial-sanctions/specially-designated-nationals-and-blocked-persons-list-sdn-human-readable-lists."

Additionally, I contacted my banker in person to inquire about this. She said that the tellers may not accept in-person deposits of checks from Iraq. She was not certain about direct deposits from that country. I strongly suggest that anyone, before accepting assignments being paid by a company in Iraq (or other countries on the sanctions list provided above), telephone or meet with your own banker, who should be able to identify any countries from which the bank declines to accept deposits, whether they be electronic or in person.

**— Cathryn D. Evans**

I've had the pleasure of working with a number of clients over the years that are outside the United States, and I've found that the financial arrangement varies with each one. Some have offices in the United States or US headquarters and issue checks or electronic payments in US dollars from those locations. That's the easiest way to work. Clients with only locations outside the United States have always sent payments electronically as automated clearing house transactions. I love it when my United States-based clients pay electronically, too. Nothing says, "you've got mail," quite like an email from the bank that says, "you've got money!"

In my opinion, the most important financial consideration when working with clients based outside the country happens when I submit my estimate. This is where I stipulate that the estimate is in US dollars and that payment, if issued in another currency, must be equivalent to the invoiced amount in US dollars at the time payment is made. This way, I don't have to worry about the exchange rate at the time of payment or about being paid less than the agreed and expected amount because of the exchange rate.

There is the matter of currency exchange fees if the exchange happens at my bank (the receiving bank) rather than at the client's bank (the sending bank). I don't concern myself with this cost for 2 reasons: first, it happens so infrequently; and second, I charge by the project rather than by the hour so I'm charging for value instead of time, and there's almost always enough money in the job to cover the relatively nominal cost for currency exchange.

I'm careful about the companies with whom I work, especially when they're based outside the United States, and particularly if they have no presence in the United States. It makes good sense to always choose your clients wisely, and even more so when you have to worry about straddling oceans, governments, languages, and currencies.

**— Brian Bass**

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EVERYDAY ETHICS

# First, Do No Harm: Ethical Considerations Surrounding the Environmental Impact of Our Digital Content

**Alisa Bonsignore** / Clarifying Complex Ideas, LLC, Phoenix, AZ

## ABSTRACT

There is a direct correlation between digital content and greenhouse gas emissions. We have an ethical obligation to mitigate our climate impacts when we can to prevent harm.

Anthropogenic climate change is expected to have significant impacts on the health and wellbeing of all humans,[1] resulting in more intense heatwaves, higher risks of flooding and damaging storms, and a changing pattern of emerging infectious diseases.[2] According to the International Panel on Climate Change (IPCC), human-induced warming of the climate system is widespread.[3] However, the impacts will be unevenly felt with more dramatic consequences experienced by women, those experiencing poverty, and Black, Indigenous, and people of color.[4-8]

Although vulnerable or marginalized populations are the first to experience the most severe consequences of climate change, none of us are immune to the long-term impacts. The 2022 IPCC Summary for Policymakers notes that "near-term actions that limit global warming to close to 1.5°C would substantially reduce projected losses and damages related to climate change in human systems and ecosystems."[9] With that in mind, we all have an ethical obligation to mitigate our climate impacts when we can.

What does this have to do with medical writing? There is a direct correlation between the content that we create and the generation of greenhouse gas emissions. "Digital is physical," says Gerry McGovern in his book, *World Wide Waste*.[10] Digital communication—which are the majority of our communication efforts—is/has a huge climate impact. Every bit and byte that we create is nothing more than energy. Energy is quantifiable. And for the foreseeable future, the use of energy emits greenhouse gases, with direct impacts on the health of vulnerable populations. Therefore, we have an ethical responsibility to consider those impacts as we consider our content strategy, content design, and content governance.

## UNDERSTANDING CLIMATE FOOTPRINT

In recent decades, we have been taught to focus on our personal climate footprint; we must make changes to our personal lives to influence the course of climate change. Although there are certainly many options for change on a personal level—household solar arrays, electric vehicles, vegan lifestyles, and abandoning air travel, to name a few—no individual lifestyles changes have as much impact as those we make at work.

A 2017 report published by CDP, the not-for-profit organization that runs the global disclosure system, states 100 companies are responsible for more than half of all greenhouse gas emissions since the start of the industrial revolution 250 years ago. These organizations are responsible for 71% of all emissions since 1998.[11] If most emissions are driven by corporations, then it makes sense that we have the most opportunity for leveraging our impact at work.

## THE CARBON COST OF DATA

There is a direct correlation between energy and data. According to a report published by the nonprofit research organization the American Council for an Energy-Efficient Economy, each gigabyte (GB) of data requires 5.12 kWh of energy.[12] This is a very abstract number; plugging this information into the Greenhouse Gas Equivalencies calculator from the US Environmental Protection Agency (EPA) shows that every GB of data generates approximately 5 pounds of greenhouse gas emissions.[13]

Note that the EPA calculator is regularly updated to reflect the current emissions per kWh in the United States. Although the world is moving away from reliance on fossil fuels, progress is slow. According to the latest data from the US Energy Information Administration, in 2021, the United States generated approximately 20% of its energy from renewable sources.[14] Even if we increase our domestic renewable energy production by 10% annually, we'll still be relying on fossil fuels for about half of our energy in the United States in 2030.


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### Emissions Example 1: Websites

Inbound marketing company Hubspot reports that the average home page weight was close to 2 MB in 2020.[15] The ninetieth percentile of webpages weigh more than 7 MB per page.[16] In the process of research for this paper, I took a random sampling of hospitals, corporations, insurance companies, and health-focused nonprofits—literally the first 8 that came to mind—and ran them through the Pingdom calculator that measures page weight, load times, and performance.[17] All of the home page weights were significantly greater than the 2.0 MB average reported by Hubspot.

Anyone who uses the internet knows that the standard for modern webpages involves large hero images, videos, or carousels that largely fill the screen. As Tom Greenwood notes in his book, *Sustainable Web Design*, roughly half of the weight of a modern webpage is imagery.[18] Worse, that imagery tends to be stock art that slows download times and adds carbon emissions, without adding value to the user's experience.

This practice goes against the concept of plain language, as advocated by Balmford.[19,20] He asserts that "plain language" is not wholly accurate. It's not simply about the choice of words and sentences, but rather the whole document, including language, structure, and design. As communicators, it is our responsibility to consider the best methods for the effective and clear presentation of information. Informative images, charts, graphs, and even videos can have a role in effective communication and should be considered on a case-by-case basis.

We can achieve our content goals with smaller page weights.

At Company A, they had an image-intensive home page. At 4.9 MB, it was heavier than the average weight reported by Hubspot, within the upper half of the sampled page weights (Figure 1). The page was loaded with stock art of health care providers in scrubs and masks; none of these images showed products or services in action, leaving the reader with no visual clues beyond the knowledge that the product was something medically focused.

Eliminating unnecessary stock images and replacing others with more informative product-oriented photos cut the page weight by half. The result was a page that still met the visual criteria expected from a professional website, but was more informative, downloaded faster, and reduced the carbon emissions by half.

The net result was a savings of nearly 17 tons of avoided emissions, or the equivalent of removing more than 3 passenger cars from the road for a year (Figure 2).

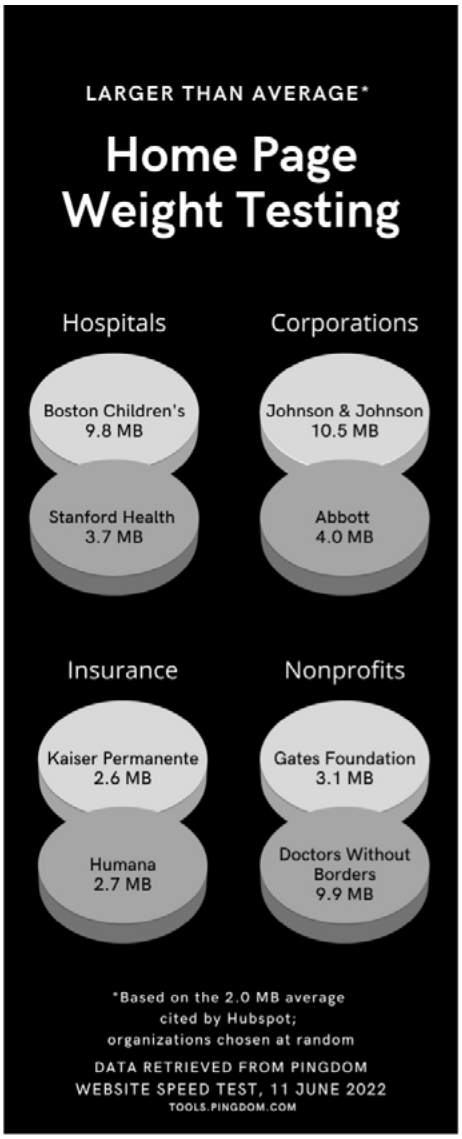


**Figure 1.** Sample page weights for health care organizations and health-focused nonprofits.

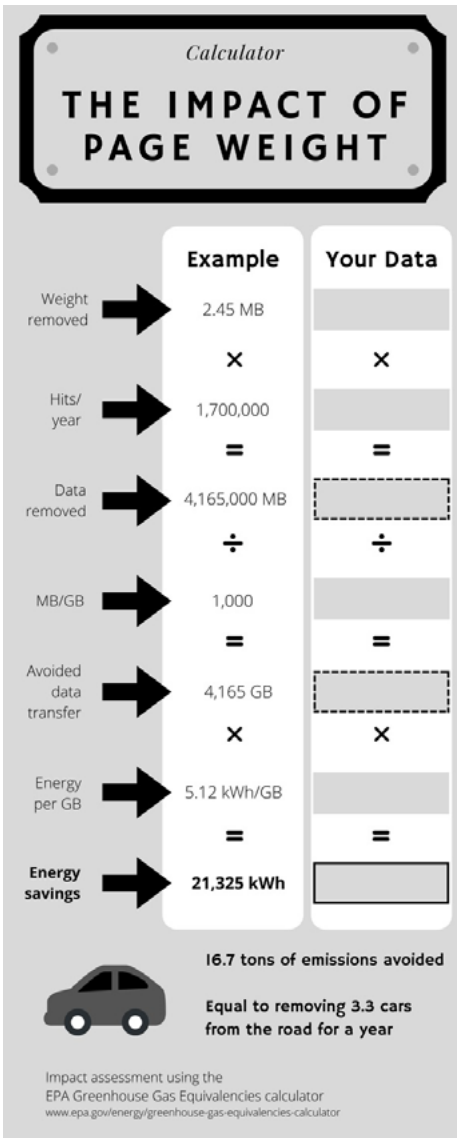


**Figure 2.** Reducing page weight also reduces greenhouse gas emissions.

### Emissions Example 2: Comparing the Impacts of Video and Audio

Just like text, there are times video and audio are indispensable tools for walking customers through setup or use of a product, or for presenting educational information. There are also times in which video is an unnecessary, heavy-weight, flashy video for video's sake—something that could have been explained just as clearly in text or imagery.

The ways in which video can be used are diverse, which makes comparative weighting difficult. Instead, let's compare audio-only podcasting with video podcasting, YouTube videos, or recorded presentations.

A half-hour video recording, complete with slides and talking head recorded at the YouTube quality of 24 frames per second will end up being about 1.73 GB.[21]

Podcast hosting company Blubrry estimates that the same information presented as a half-hour long, mono-channel, talk-only audio podcast-style recording averages about 23 MB.[22]

When working with audio and video, it's important to decide whether a video is worth 75 times the energy and correlated emissions (Figure 3). Always consider video projects on a case-by-case basis.

### Emissions Example 3: Our Meetings

Particularly since the start of the pandemic era, we've all spent a significant portion of our day on video conferences. But our use of Zoom, Teams, Skype, or related services uses bandwidth and energy, which we now know has a carbon cost.

When everyone joins the meeting with video on, the meeting requires roughly 800-900 MB of bandwidth per person.[23] For one month, I kept track of all of my daily video meetings. On average, every Zoom meeting had 5 participants (some were one-on-one, whereas others were large group calls). When everyone has their video on, that works out to an average of 4 GB of data per call.

That same call—the usual screen sharing, the speaker visible in thumbnail, but other participants in video-off mode—works out to be about 190 MB total on a five-participant call. Leaving everyone's video on for the duration is 20 times more energy and emissions intensive as a video-off meeting (Figure 4).

Many employers believe that video-on is crucial for building relationships while working remotely. A good compromise can be to have video on for the 5 minutes of meet-and-greet at the start of the meeting but turning video off during screen sharing.

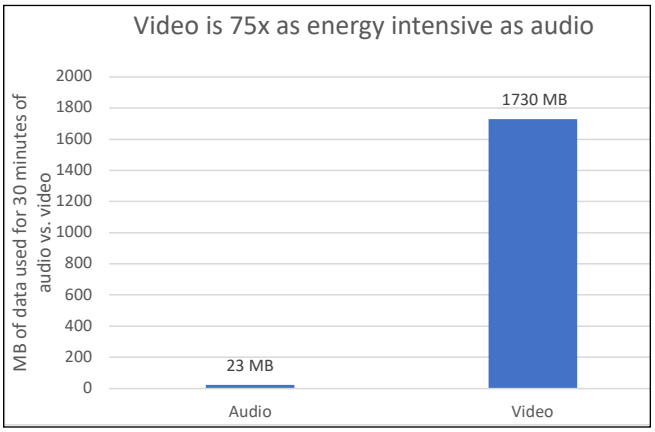


**Figure 3.** The relative data and energy impact of audio versus video.

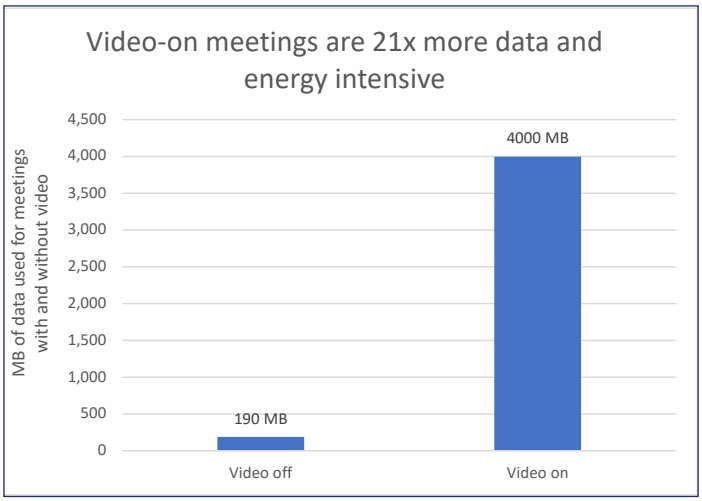


**Figure 4.** Video-off meetings use less data, less energy, and generate fewer emissions.

## CONCLUSION

We all have an ethical responsibility to reduce carbon emissions to mitigate the impacts of climate change, particularly for those who are the most vulnerable. The content that we create generates measurable greenhouse gas emissions. Knowing that the majority of emissions come from corporations and not individuals, it makes sense that we leverage our influence on our organizations to have the greatest impact on the health and wellbeing of others.

***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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## RESOURCES

**Pingdom website speed test**
https://tools.pingdom.com/

**Video filesize calculator**
https://toolstud.io/video/filesize.php

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V37 N4 / 2022

CONSCIOUS WRITING

# The 5 Most Commonly Misused Words in Medical Writing (According to an Editor)

**Crystal R. Herron, PhD, ELS** / Redwood Ink, LLC, San Rafael, CA

**"A word after a word after a word is power."**
**– Margaret Atwood**

Words are powerful. They may deceptively look like simple little strings of letters, but they hold the tremendous power of influence. The words we choose—and where we place them—influence thoughts, emotions, and behaviors.

Clear words support clear thinking. And clear writing and clear thinking go hand in hand.

Yet, some writers will throw words on the page, hoping that readers will "get the idea." But when you use words that are ambiguous, inaccurate, or imprecise, you encourage ambiguous, inaccurate, and imprecise thinking. This carelessness can cause death by a thousand cuts—each word misuse can chip away at the clarity and credibility of the work.

This chipping away can involve any one of the hundreds of thousands of words in the English language. But as a professional editor, I have noticed 5 words that are most commonly misused in medical writing: *utilize*, *increase*, *level*, *while*, and *comprise*.

## UTILIZE

Many writers write *utilize* as a synonym for *use*. But these words have different meanings. *Use* generally means to put something into action or service, whereas *utilize* means to make use of. Although these definitions may seem similar, the definition of *utilize* can suggest the discovery of a new, profitable, or practical use for something.

As a general example, imagine—or maybe you can simply recall a recent memory—that you need to remove ice from your windshield, but you don't have an ice scraper. You might utilize a kitchen spatula for the task. The spatula was not designed to remove the ice, but it does the trick.

In science and medicine, you might utilize something for a purpose that it was not designed to fulfill, such as a Petri dish for storing office supplies or a belt for a medical emergency.

To ensure your writing is clear, default to writing the word *use*, and only write *utilize* when the term is the more accurate choice. Better yet, skip the word *utilize* altogether, and stick with the more readable word *use*, which can always replace *utilize*.

### Examples

The researcher *used* a Petri dish to grow bacteria.
The researcher *utilized* a Petri dish to store paperclips on their desk.
The researcher *used* a Petri dish to store paperclips on their desk.

The emergency responder *used* a band of rubber as a tourniquet.
The emergency responder *utilized* a belt as a tourniquet.
The emergency responder *used* a belt as a tourniquet.

## INCREASE

Many writers use the term *increase* (or, conversely, *decrease*) to describe differences in data. However, they do not always consider nuances in the meaning of this term.

*Increase* means to make or become progressively greater in size, amount, number, or intensity. Based on this definition, *increase* infers a change over time or a cause-effect relationship.

But what many writers do is misuse *increase* to describe differences between groups of data. Most often, this misuse looks like *increase* paired with *versus, than, compared to*, or *compared with*. In these cases, the more accurate phrasing would be to use *higher* or *greater*.

To ensure accuracy in your writing, only use *increase* when referring to changes over time or a cause-effect relationship. And use *higher* or *greater* to refer to differences between groups of data.

### Examples

The prevalence of diabetes *increased* from 0.93% in 1958 to 7.4% in 2015.
Epinephrine *increases* heart rate and cardiac output.
Urine albumin was *higher* in patients with kidney disease than in healthy patients.
The concentration of red blood cells was *greater* in patients treated with the drug versus those who took a placebo.
High sugar consumption for 4 weeks *increased* body weight by 1 pound each week.


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The drug *increased* liver function in patients with hepatitis C.

## LEVEL

Some writers use *level* as a synonym for the words *amount*, *concentration*, or *content*. These latter 3 words have fairly simple definitions. *Amount* means the total number or quantity. *Concentration* means the amount of a component in a given area or volume. And *content* means the amount of a specified material.

But the definition of *level* is not as simple. In fact, *level* has several meanings, including a concentration of something, a position in a scale, a measurement or index of altitude, or the magnitude of a quantity related to another value. *Level* can also be used to refer to even or unvarying height, or to a device that helps to establish a horizontal line or plane. All these different meanings can create confusion for readers.

To ensure that the writing is clear and easy to understand, default to using *amount, concentration*, and *content*. Only use *level* when no other word will do.

### Examples

The treatment increased the *concentration* of antibodies in the blood stream.

The drug reduced the *amount* of tumor necrosis factor.

The bone was *leveled* during the osteotomy.

## WHILE

*While* is another word that can trip up writers. Many writers use *while, although*, and *whereas* interchangeably. But *while* is not an accurate synonym for *although* or *whereas*.

*Although* means in spite of something or even though, and *whereas* means on the contrary or in view of. These definitions are fairly straightforward.

The definition of *while* is not as straightforward because the word has multiple meanings. *While* can mean during a certain time, as long as, on the other hand, and at the same time as something. These definitions mean that *while* can sometimes be used instead of *although* or *whereas*, but not always. Even still, why risk confusing readers by making them figure out which meaning of *while* you intend?

To ensure clarity, use *while* only when referring to time. Otherwise, use a term with a more precise meaning, such as *although* or *whereas*—or even a more readable word such as *and* or *but*.

### Examples

The pharmacist prepared the prescription *while* the patient waited in the lobby.

*Although* the patient adhered to the treatment plan, their insomnia persisted.

Drug A reduced blood pressure by 10%, *whereas* Drug B reduced blood pressure by 15%.

The resident performed the surgery, *and* the attending oversaw the procedure.

The drug slowed heart rate, *but* it did not lower blood pressure.

## COMPRISE

Many writers misuse the word *comprise* in their writing. How? They erroneously follow *comprise* with the word *of*.

In these cases, writers are likely confusing *comprise* with the term *compose*. But these terms have opposite meanings. *Comprise* means to include or be made up of (ie, A *comprises* X, Y, and Z), whereas *compose* means to form by putting together or to constitute (ie, X, Y, and Z *compose* A). To give *compose* a similar meaning to *comprise*, the word must be sandwiched between a weak "to be" verb (eg, *is, are, was, were*) and the word *of* (eg, *was composed of*).

Alternatively, writers may use *comprise* as a synonym for *consists*. Unlike with *compose*, *comprise* and *consists* have similar meanings. *Comprise* means to include or be made up of, and *consists* means to be composed or made up of. But, grammatically, only the word *consists* should be followed by the word *of*.

To ensure clarity and accuracy, use *comprise* without *of*, or use *consists* instead. And if you are tempted to use the sandwiched form of *compose*, stick with either *comprise* or *consists* to reduce the word count and give your sentence a little readability boost.

### Examples

The complex is *composed* of 3 proteins.

The solution *consists* of 4 chemicals.

The team *comprises* a physician, nurse practitioner, and resident.

## KEEPING UP WITH CHANGE

Language constantly evolves, so the meanings of these words and how they are used may change in the future. The key is to stay updated on these changes so that you can use the most explicit, accurate, and precise words in your writing. In this way, you can harness the full power of words to craft clear writing that supports clear thinking and credible work.

***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 JOURNAL V37 N4 / 2022

BIOGRAPHY

# William Harold Swanberg: Radiologist, Organizer, and Philanthropist

**Tom Lang** / Principal, Tom Lang Communications and Training International, Kirkland, WA

## ABSTRACT

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

Most AMWA members have heard of Harold Swanberg, the Association's founder, but the details of his life are not commonly known. As are those of so many early AMWA members, Harold's life is notable for several reasons.[1] He contributed to the fields of radiology, scientific publications, medical writing—and chiropractic. He started several organizations in addition to AMWA, some of which were charitable foundations supporting college-bound high school students, and founded 3 journals, each of which lasted 50 years. In fact, he was an innovator throughout his life (Figure 1).

**Figure 1.** William Harold Swanberg BSc, MD, FACP (1891-1970), founder of the American Medical Writers Association.

## PERSONAL LIFE

William Harold Swanberg, BSc, MD, FACP, was born in Philadelphia in 1891.[2] Details on his early life are scant, but we do know that he was married twice. In 1919, he married Zoe Johnson (1885? -?), his office assistant at the time,[2] with whom he had a son, William H. Swanberg, Jr (1921-1987). William was likely present when AMWA was formed and may have been a member the rest of his life,[1] although probably in name only (Lillian Sablack, former executive director of AMWA, telephone conversation, July 24, 2020).

His second wife was Mildred W. Chapman (1901-1987). Mildred had 2 daughters, JoAnn Spiva Kimball (1923-2021) and Mary Louise Spiva Burnham (1926-1999), and she and Harold had a daughter, Nancy G. Bradshaw (1935-2016). Nancy attended Francis Shimer junior college—at age 15—and, after studying at the Sorbonne, received a degree in English from the University of Missouri in 1955.[3] In the 1960s, she taught medical writing at Baylor College of Medicine. She became an AMWA Fellow in 1963.[3]

## EARLY YEARS

At age 19, Harold was working his way through medical school as an assistant in a histological laboratory when he became interested in "the claims of some of the cults of that period."[4] The laboratory appears to have been that of Oakley G. Smith, the founder of naprapathy and the Chicago Naprapathy College.[5] (Other sources describe Harold as being a student of Smith,[6,7] which may be more self-serving than accurate.) Smith himself was a protégé of Daniel David Palmer, the founder of chiropractic. For whatever chiropractic has become, it originated from Palmer's pseudoscientific beliefs about healing. Smith eventually split from Palmer in 1907 and founded naprapathy, which focuses on diet and on manipulating connective tissue rather than the spine.[7]

In 1914, after 4 years of work and at age 23, Harold published *The Intervertebral Foramen: An Atlas and Histological Description of an Intervertebral Foramen and its Adjacent Parts* (Chicago Scientific Publishing; 1914). This book presented the first photomicrographs and scientific descriptions of the intervertebral foramen (in cats).[7] A year later, he published *The Intervertebral Foramina in Man* (Chicago Scientific Publishing; 1915). These books definitively disproved the "stepping-on-the-hose" theory of chiropractic, which was the metaphor for vertebral pressure impinging on nerve cells as the cause of disease.[7,8] Several legitimate medical journals gave the books good reviews and, despite the books' conclusions, they were standard works in chiropractic for decades[8] and are still sold on alternative medicine websites.[9]


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Oakley Smith had been dissecting spines since 1905, in the interest of chiropractic theory, and Harold's work was related to Smith's investigations.[7]

A year later, at age 25, Harold graduated from the Chicago College of Medicine and Surgery, which is now part of Loyola University.[2,10]

## PROFESSIONAL YEARS

William Roentgen discovered X-rays in 1895, 4 years after Harold was born.[2] Thus, this new field of Roentgenology was only 20 years old when Harold became a physician. He might have been attracted to the field earlier, but in 1917, he enlisted in the Army Medical Corps, received a commission as First Lieutenant, and studied at the School of Military Roentgenology in Chicago before being sent to Fort Riley, Kansas. He remained in the Army reserves until 1924.[2,4]

After leaving the military, he moved to Quincy, Illinois, a small city on the Mississippi River. In 1919, he opened the Quincy X-Ray and Radium Laboratories.[2] Soon thereafter, he married his assistant, Zoe Johnson, and their son William was born.[2]

As a new radiologist, Harold was instrumental in founding the Physicians and Surgeons Radium Association of Quincy in 1921. The purpose of the Association was "to disseminate a knowledge of the use of radium and to maintain hospitals."[2]

A short 2 years later, he organized and was elected secretary of the Adams County Medical Society and was the Society's librarian for 30 years. He also suggested that the Society publish a monthly bulletin.[2] The first issue of the *Adams County Medical Society Bulletin* was published in 1923. Eventually, the name was changed to *The Quincy Medical Bulletin* to "help build Quincy into a larger and better medical center." The Bulletin was published until 1970, and at its peak, was sent to hundreds of physicians.[2]

A year later, in 1924, Harold started another journal, *The Radiologic Review*, which became the *Mississippi Valley Medical Journal* in 1939. It became *Clinical Medicine* in 1960 and was published until 1978.[2]

Harold was also a charter member of the Quincy Physicians Club, a medical study club whose members met twice a month to present and discuss cases.[2] The Club held an all-day conference every year until the Great Depression. Out of the Club would come the Mississippi Valley Medical Society.[2]

Over the next several years, Harold invented and marketed an applicator for treating gynecological cancers with radiotherapy,[11] maintained a private practice, worked as a radiologist at both Quincy hospitals and at some of the smaller area hospitals, took a graduate course at Harvard, and spent 6 months in graduate studies in Vienna (Box 1).[2]

### Box 1. Odds and Ends of Harold Swanberg's Life

In 1939, as president of the Kiwanis Club, he suggested Quincy High School develop a rifle range and coordinated its development. It was used by both the girls' and the boys' rifle teams, the Young Men's Christian Association, the National Guard, the Catholic Youth Association, and the Quincy Kiwanis Rifle Team.[14] (Gun clubs were common in high schools at the time, as well as for many years after World War II.)

He created what might have been the first registry of freelance medical writers and editors, eventually expanded so that it could also include "salaried people."[4]

He was instrumental in establishing the first vocational guidance program and a guidance counselor position at his local high school in Quincy, Illinois.[1]

In the McCarthy era of the 1950s, Harold was successful in amending the AMWA Constitution to exclude anyone in the Communist or Fascist parties from becoming members. The rationale was "Having witnessed the infiltration of other vehicles of communication by subversive forces, it is our duty to safeguard the association against such influences." The announcement was titled "Communists and Fascists Beware!"[4]

He served on the board of directors of the Unitarian Church for many years (a photograph of one of his adopted or to be adopted daughters appears in the same booklet).

His last official act appears to have been casting the only vote opposing nonphysicians from becoming president of AMWA, an initiative the board felt necessary if the Association were to continue. Thus, his death also marked the passing of the era that he began 2 decades earlier.[25] (The first nonphysician to be elected president was Eric Martin, PhC [pharmaceutical chemist], BsC [bachelor's degree in pharmaceutical chemistry], MS, PhD, who had founded the Drug Information Agency a few years before. Hardly a step down from physician presidents.)

In 1932, he published his third book, *Radiologic Maxims*, a collection of sayings and platitudes about radiology

(Figure 2).[13] The book was not well received.[13,14] In the 1950s, he also published several articles in the *Mississippi Valley Medical Journal* on medical topics and several editorials on social policy (eg, fluoridation of drinking water, Social Security) as well as with issues in medical writing.[4]

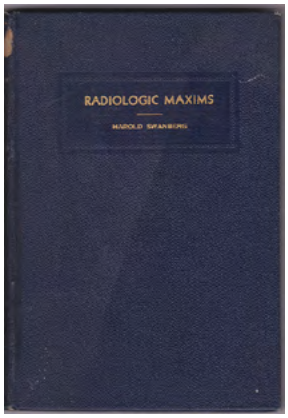


**Figure 2.** *Radiologic Maxims* by William Harold Swanberg.

In 1935, he helped found the Mississippi Valley Medical Society. The 250 charter members elected him secretary-treasurer. By 1945, it had 800 members.[2]

In 1940, he started yet another organization, the Mississippi Valley Medical Editors Association (MVEA), whose purpose was to support the editors of state and local medical society bulletins and the physicians who were writing for these publications.The MVMEA was not the first editors' association, however. To put the MVMEA and AMWA in context, we have to look at the growth of scientific publishing just after the Civil War.

## THE AMERICAN MEDICAL EDITORS ASSOCIATION

With some notable exceptions (eg, *The New England Journal of Medicine*, 1812; *The Journal of the American Medical Association* [*JAMA*], 1883), for most of the 1800s, "medical journalism" consisted of a handful of serious, society-sponsored journals (including those from state and local medical societies that would eventually be recruited by the MVMEA); many non-society proprietary journals publishing more-or-less legitimate medical articles; and advertising-driven tabloids (today's "throw-aways"). Out of this environment, shortly after the Civil War, a group of journal editors formed the American Medical Editors Association (AMEA) to promote journal editing as a "distinct medical speciality."[15]

By the turn of the century, AMEA had hundreds of members nationwide, many with international reputations,[16-19] and was important enough that several leading medical journals published reports on its annual meetings, key papers, and presidential addresses.[15] During this period, for the first time, some journal editors became part- or full-time, paid professionals.[15]

The AMEA was formed at the 1869 meeting of the American Medical Association (AMA). One of the founders—and its first president—was Dr Nathan S. Davis, the founder of the AMA.[20] Over the years, however, the values of the AMEA and the AMA diverged (Box 2). The AMEA would eventually criticize the business practices of AMA presidents George Simmons and his hand-picked successor, Morris Fishbein, who between them directed (read: ruled) the Association from 1889 to 1950.[21] (Both were eventually forced from office for ethics violations, including deceptive business practices.) Also, the AMA "opposed all health insurance on the grounds that 'no third party must be permitted to come between the patient and his physician in any medical relation.'"[22] In contrast, the AMEA had long advocated creating a national health department lead by a cabinet-level secretary "to protect the health of the public."[23,24] (The forerunner to the Department of Health and Human Services would be established in 1953.)

Harold was good friends with Fishbein, who became an important AMWA member. But it is no accident that Fishbein disparages the AMEA as a predecessor to AMWA in the very first sentence of his foreword to Harold's *History of the American Medical Writers Association*.[4] That said, Fishbein was an ardent supporter of AMWA from the beginning and used his influence as "the voice of American physicians" to advance the Association. He started the Chicago chapter, served as president of the Association in 1958, and received the Distinguished Service Award in 1962.[25]

The AMEA survived World War I but not the Great Depression. A similar fate would befall the MVMEA, which, to survive, had to evolve into a new organization: AMWA.

### Box 2. The American Medical Editors or Writers or Authors Association

In 1928, an organization similar to, or a continuation of (accounts conflict[15,20]), the AMEA was formed—the American Medical Editors *and Authors* Association—which appears to have favored the for-profit and throw-away journals who competed with society journals for advertising income. The AMA was critical of the new association because its members were publishing "proprietary preparations as have not been approved by the Council on Pharmacy and Chemistry."[20] Not said was the fact that the Council on Pharmacy and Chemistry was created and controlled by the AMA's president, George Simmons, who awarded its approval to drugs not for their safety and efficacy but for how much the manufacturer advertised in the journal. In 1889, when Simmons came to power, the journal's advertising income was $34,000; by 1909, it was $150,000.[21]

## THE AMERICAN MEDICAL WRITERS ASSOCIATION

The MVMEA did not survive World War II. The War prevented meetings between 1942 and 1948, at which time interest was waning among the 42 remaining members. Harold decided to create a national organization that would be open to everyone in medical publishing, not just to journal editors. To prime the pump, he persuaded his friend, Morris Fishbein, then editor-in-chief of the *Journal of the American Medical Association*, to offer a 2-hour course on medical writing at the 1948 meeting. On September 29, 1948, the Mississippi Valley Medical Editors Association was renamed the American Medical Writers Association, "America's only Association Devoted to Improvement of the Written Word of Medicine."[4]

In founding AMWA, Harold had several goals, all but one of which were met admirably during his time and some of which continue to drive the Association's activities today. All the successes described below were achieved by volunteers; AMWA had no paid staff until Lillian Sablack became the first Executive Director of AMWA in 1973 (Lillian Sablack, telephone communication, July 24, 2020).

**Goal 1: Publish a bulletin.** When the Mississippi Valley Medical Editors Association was renamed AMWA in 1948, it adopted the *Mississippi Valley Medical Journal* as its publication.[4] In 1951, AMWA also began to publish the *Quarterly Bulletin of the American Medical Writers Association*, which was published until 1985, at which time its name was changed to the *AMWA Journal*. The *Mississippi Valley Medical Journal* was absorbed by *Clinical Medicine* in 1960. The *AMWA Newsletter* was published beginning in 1970 and *Medical Communications* in 1972.[4] In 1978, the newsletter was incorporated into *Medical Communications*, and in 1986, *Medical Communications* was incorporated into the *AMWA Journal*.[25]

**Goal 2: Start regional chapters.** AMWA began with 42 members. By 1958, the number was 1,254, and by 1965, more than 1,800.[4] By 1965, the Association had 9 chapters in the United States and 1 in Mexico City. Today, more than 4,000 members are included in 16 North American chapters.[26]

**Goal 3: Bestow awards.** Early in its existence, AMWA established 3 awards. The Distinguished Service Award consisted of a gold medal and a certificate given for "distinguished contributions to the medical literature or rendered unusual and distinguished service to the medical profession." The first recipient of the Distinguished Service Award was Harold himself, in 1952. (The gold medal was discontinued in 1963.)[4]

The Honor Award was also a gold medal and a certificate given irregularly for "distinguished contributions to the medical literature." (That gold medal was discontinued in 1963, too.)[4]

Finally, the Honor Award for Distinguished Service in Medical Journalism was given to medical journals in 6 categories: general medical journals, specialist and research journals, state medical society journals, county or city medical journals, controlled circulation journals, and "other."[4]

**Goal 4: Establish fellowships.** The Association has awarded hundreds of fellowships over the years. Notable fellows include Morris Fishbein and George Simmons, editors of the *Journal of the American Medical Association*; Karl Menninger, founder of the Menninger Psychiatric Clinic; Alton Ochsner, founder of the Ochsner Clinic in New Orleans; Frances Kelsey, the Food and Drug Administration employee who prevented thalidomide from being marketed in the United States; Michael E. DeBakey, the heart surgeon, and his sisters, Lois and Selma DeBakey; and Joseph Garland, editor of the *New England Journal of Medicine*.[4]

**Goal 5: Begin a manuscript editing service.** Between 1952 until at least 1965, AMWA ran a contract editing service for its members to "help maintain and advance high standards of medical literature." Harold proposed the service (of course), which provided line-by-line critiques but did not do library research, compile bibliographies, or provide ghostwriting. The first editor was Theodore Peterson, a doctoral student at the University of Illinois, who, after almost 6 years, had edited 600 manuscripts. The rate was $5 per 1,000 words, and articles were limited to 5,000 words.

**Goal 6: Establish college degree programs in "medical journalism."** One of Harold's most important projects was to establish degree programs in "medical journalism."[4] (Today, however, "medical journalism" refers to "science writing.") In 1954, the University of Illinois and the University of Missouri (in conjunction with their respective medical schools) and later, the University of Oklahoma, began offering a Bachelor of Science degree in Medical Journalism and Writing. The University of Illinois program consisted of about an equal number of units in the humanities, social sciences, natural sciences, and journalism. To support these programs, AMWA established several "Harold Swanberg Medical Journalism Scholarships," funded by

donations (all from Harold, of course).[4] Although Harold approached 7 grant-making foundations and sent promotional materials to 250 pharmaceutical, medical publishing, and medical advertising companies, he obtained no outside funding.

The programs did not do well. In his history of AMWA, Harold mentions only 11 students who enrolled in the programs, and only 2 who graduated.[4] Today, however, several AMWA members are or have been closely involved with the medical writing and editing programs at the University of Chicago,[27] the University of the Sciences in Philadelphia (although the program ended this year when the University merged with St John's University), and the University of San Diego Extension.[28]

**Goal 7: Offer a traveling lectureship program.** From 1955 to 1961, AMWA member Jacques Gray, MD, MPH, delivered 37 lectures on behalf of AMWA at medical centers and pharmaceutical companies on the East Coast. Gray, a former Dean of the Medical College of Virginia and the Medical School at the University of Oklahoma, was Director at the time of Special Medical Services for Park, Davis & Company, which funded the program. He continued to lecture on AMWA's behalf until his death in 1961.[4]

**Goal 8: Exhibit at professional meetings.** In Harold's *History of the American Medical Writers Association* is a 1956 photo of him and a colleague recruiting at a booth at the World Medical Association conference in Havana, Cuba.[4] The exhibit, created by Harold (of course) was also shown at several conferences in the United States. In a related project, after one of its own meetings, AMWA published a small book titled *A Group of Papers on Medical Writing*.[29] The 11 chapters were written by distinguished AMWA members. An astounding 20,000 copies were published in 2 editions. The book is still relevant and is available for less than $20.

**Goal 9: Nurture sustaining memberships.** In 1965, AMWA had 26 sustaining members paying an annual fee to support the Association. Almost all were major pharmaceutical companies, in which AMWA members tended to be division heads or vice presidents.[4]

## PHILANTHROPIC ACTIVITIES

In 1942, Harold had founded the Swanberg Medical Foundation, a not-for-profit trust fund administered by the Adams County Medical Society, to "sponsor … things of a charitable, scientific, literary or educational nature… which would bring public and professional honor and respect to the medical profession…"[2] Eventually, the foundation supported the Society for Academic Achievement (SAA), which was "dedicated to motivate youth to achieve academic excellence … (and) to lead the academically talented to pursue the proper subjects so they can procure a college education and become future intellectual leaders."[2] The foundation and the SAA continue to make awards, most recently to seniors at Quincy High School. In 1956, Harold also developed and launched the Quincy Major Learning Program, to help high school students enter and graduate from college.[1]

## HIS LEGACY

A heart attack ended Harold's medical career in 1959. He died in 1970, at age 79, but not before publishing volume I of a planned 2-volume history of the AMWA in 1965.[2,4] (Volume II was never written.) In 1962, the Association renamed the Distinguished Service Award **The Harold Swanberg Distinguished Service Award**. This award is presented "to any active member of AMWA who has made distinguished contributions to medical communication or rendered unusual and distinguished services to the medical profession."

In his professional life, Harold formed 5 organizations, started 3 journals, and established 3 educational foundations. By founding AMWA, he created a structure that would advance the field of medical writing for decades to come. It is fitting that the Harold Swanberg Award is AMWA's highest honor.

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AMWA NEWS

## FROM THE PRESIDENT

# Inaugural Address: Say Yes

**Elise Eller, PhD** / 2022–2023 AMWA President

When I learned about the field of medical writing and attended my first AMWA conference, I knew I had found my people. However, I had no idea at the time that I'd someday be president of AMWA. I am humbled to follow in the footsteps of so many other AMWA presidents, people I have worked with and admire. And I am grateful for the people who will work with me and offer their expertise this year: my fellow officers and the rest of the AMWA Board of Directors; committee chairs and members; Susan Krug, our Executive Director; and the amazing AMWA staff.

I first heard about AMWA when I talked to a freelancer in my area, Julie Gelderloos, about medical writing. Julie convinced me to join AMWA and attend my first conference in 2009 in Dallas. I've attended the AMWA annual conference ever since. When the then-president of the Rocky Mountain Chapter, Barb Zimmerman, asked me to organize the next chapter conference, I said yes. And that's how I got sucked in. I later served as chapter president and got involved at the national level, including chairing a chapter handbook committee. After serving at the chapter level, I joined the AMWA Board of Directors and served in various roles.

I say this not to establish my credentials but to point out a common theme: each time, someone asked me to do something, and I said yes.

With the guidance of our Executive Director, Susan Krug, and the hard work of AMWA staff and volunteers, we have weathered the pandemic surprisingly well. As we come out of the pandemic, we are revitalizing our volunteer opportunities. AMWA's call for volunteers opened in late September.

Without our volunteers, our organization would not accomplish as much as we do. You, our members, are AMWA. We need our members to help us accomplish our goals and build upon what we've already achieved.

We need our members to help us accomplish our goals and build upon what we've already achieved.

Volunteer opportunities include but are not limited to selecting content for the annual conference, developing and evaluating educational content for our workshops and online learning, working for the *AMWA Journal*, participating in committees and task forces, and volunteering at the chapter or local level. Opportunities range from microvolunteering to year-long commitments.

We also want every member to feel welcome in AMWA. Recently, we launched a diversity, equity, and inclusion initiative to determine how we can make sure a diversity of voices is heard within our organization. Everyone has their own experiences, both personal and professional. Everyone has their own story. We value our welcoming and collaborative environment in AMWA, but there is always room for improvement. Our mission remains promoting excellence in medical communication. To pursue this mission, we need volunteers with a variety of backgrounds and areas of expertise.

I am excited about the upcoming year and am looking forward to seeing what we accomplish. We have a conference in Baltimore to plan and new and refreshed educational content to put out. We are constantly reviewing our educational offerings to determine what is of value to our members. The *AMWA Journal* is now using a new digital publishing platform and is updating its processes to improve efficiency and enhance the reader experience. We have important initiatives in the works, including the value of medical writing initiative and our diversity, equity, and inclusion initiative. In short, there's lots to do.

To all of those people along the way who asked me to volunteer for various roles, thank you. I said yes, and I have never regretted it. And to my readers I say: say yes. You have a place in AMWA.


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AMWA NEWS

# Introducing the 2022–2023 Board of Directors

**Elise Eller, PhD** / 2022–2023 AMWA President

The AMWA Board of Directors (BOD) is our organization's governing body. As stated in Article III in the AMWA bylaws, the BOD manages and controls the affairs, property, and business of AMWA. The BOD meets consistently throughout the year to discuss and take action on items as they pertain to the organization. The BOD is responsible for approving the budget, the slate of nominees for elected office, and any proposed amendments to the Constitution or Bylaws. It also approves committees, work groups, and task forces and fulfills such other duties as are specifically mentioned in the Constitution and Bylaws and as required by law.

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

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

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

I am pleased to introduce the 2022-2023 BOD, which consists of At-Large Directors, the Chair of the Chapter Advisory Council, and Officers. AWMA strives to have a BOD that is representative of our organization's membership, reflecting characteristics of the member population.

At its September 2022 meeting, the BOD approved the following individuals to serve as At-Large Directors for the 2022-2023 term:

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

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

- Jennifer Minarcik, MS

AMWA 2022-2023 Officers:

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

The 2022-2023 BOD began its service on November 5, 2022 at the conclusion of the 2022 Annual Business Meeting at the 2022 Medical Writing & Communication Conference in Denver, Colorado.


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AMWA NEWS

# 2022 President's Award Recipient: Kelly Byram, MS, MBA, ELS

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

*The recipient of the President's Award is selected by the AMWA President, and each year this award is bestowed upon a member of AMWA who has made distinctive contributions to the association at the chapter or national level.*

I am delighted to recognize Kelly Byram, MS, MBA, ELS, as the 2022 AMWA President's Award recipient. Kelly, a writer, editor, and founder of Duke City Consulting, LLC, received the award in November at this year's Medical Writing & Communication Conference in Denver, Colorado. Since Kelly joined AMWA, she has served at both the chapter and national levels. She is the immediate past President of the Southwest Chapter that spans Texas, Louisiana, Arkansas, Oklahoma, and New Mexico. In 2017, she volunteered to serve as an At-Large-Director for New Mexico, hosting networking events in Albuquerque and Santa Fe and has served in that role many years. In this role, she recognized the work taking place at the chapter leadership level, so when she was asked to take on a chapter officer role, she didn't hesitate.

Kelly took the chapter to new heights as Assistant Program Chair, introducing the chapter to new and regular programming events with a variety of talented guest presenters. She then served as Program Chair, President-Elect, and President. At the same time, Kelly was sharing her expertise at the national level leading several roundtables and open sessions at the annual conference and writing articles for the *AMWA Journal*. Kelly also served as co-chair of the Southwest Chapter's John P. McGovern Award committee, and as a member of the chapter's nominating committee. She regularly serves on panels and presents on various topics of interest including writing, editing, technology, and career spaces. Ongoing volunteer work for the chapter includes technical assistance projects, such as migrating the chapter website and designing and implementing surveys. She also manages the integration of technologies to support the chapter's operations and programming efforts. She was a key part of helping the chapter migrate to the virtual environment during the pandemic and has helped chapter leadership continue to deliver important educational content. Her most recent role was serving on this year's Annual Conference Committee helping to pull together an amazing program for the 2022 Medical Writing & Communication Conference.


*Photo credit*

It's been a wonderful experience seeing Kelly lead the chapter, share her expertise with AMWA members, and venture into the national realm of volunteerism for the organization. When I asked Kelly about why she volunteers, here is what she had to say (email communication, 27 July 2022).

"Volunteering helps members build their networks and refine their skills, and it provides opportunities to build new skills. From another perspective, as we move through our careers it's important to give back to the community by contributing our time, experience, and expertise, and volunteering provides opportunities to do that. On its own, membership in AMWA provides ample benefits and, if you take advantage of all AMWA has to offer, you will grow in your practice of the profession. Volunteering amplifies those benefits."

It is an honor to present Kelly with this well-deserved honor. Please join me in congratulating Kelly on her contributions to AMWA and for being this year's President's Award recipient.


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CONFERENCE

# 2022 AMWA Southeast Regional Conference

**Susan Krug, MS, CAE** / Executive Director, AMWA

In partnership with the Southeast, Florida, and Carolinas chapters, AMWA's 2022 Southeast Regional Conference took place June 13 and 14 at the Luminary Hotel in Fort Myers, Florida.

The conference featured the highly rated, small group, interactive workshops that are a staple of AMWA annual conferences. The popular moderated AMWA Freelancer Jam Session was also a part of the program, providing a supportive space for freelancers to share their experiences and concerns with other freelancers. Attendees gathered to hear 4 MedWrite Talks (short presentations reminiscent of the popular TEDx Talk) and had the opportunity to network with other members during breakfast, lunch, and an evening reception.


## AMWA Workshops

- *Strategies for Persuasive Writing Workshop*, Susan Aiello, PhD, DVM, ELS
- *Regulations: What does a Medical Writer Need to Know?*, Karen Bannick McQuoid, MA, RAC, FRAPS
- *Advanced Writing*, Susan Aiello, PhD, DVM, ELS

## Educational Sessions

- *Communicating Science to the Public*, Susan Aiello, PhD, DVM, ELS
- *Jam Session for Early to Midcareer Freelancers*, Jennifer Minarcik, MS
- *Public Relations in Medical Communications*, Katrina R. Burton, BS
- *Resources for Researching Medical Devices Using Publicly Available Databases*, Sara VanWyk, MPH, CCRP, RAC, MWC*
- *Think Like an Editor: Improving Document Quality for Regulatory Submissions*, Callie Compton, MA
- *Regulations: Developing a Clinical Evaluation Strategy with an Eye to Regulatory and Quality Requirements*, Karen Bannick McQuoid, MA, FRAPS, RAC

## MedWrite Talks

- *Best Practices for Client Interaction*, Sara VanWyk, MPH, CCRP, RAC, MWC
- *Small Business Survival Skills: Your Way to Success*, Queen Buyalos, PharmD
- *It's All in How You Pivot*, Brian Bass, MWC
- *Reminders of Life Lessons from the Barnyard*, Susan Aiello, PhD, DVM, ELS


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## Communicating Science to the Public

**Speaker**
**Susan E. Aiello, PhD, DVM, ELS** / WordsWorld Consulting, Townsend, TN

**By Katherine Feemster, MPH**

As medical writers, we have a responsibility to our audiences to provide scientifically sound and readily understandable information. That role is often a difficult one to navigate—not only is it fraught with potential pitfalls, but it is also one of enormous responsibility. Dr Susan Aiello gave a presentation focused on this responsibility at the AMWA regional conference in Fort Meyers, Florida, this past June. "Communicating Science to the Public" shed light on those intricacies and the importance of the role medical communicators play.

To begin with, medical writers should ask themselves a series of questions:

- On a philosophical level: why can this be so hard? Well, we all have diverse backgrounds, with varying educations, interests, and needs. This goes not just for us as writers, but also (and perhaps specifically) for our audiences. What may be obvious to one is not necessarily obvious to another.
- On a societal level: why is this type of communication important? Medical communicators help protect the public's health. When done well, our work contributes to societal advancement and scientific education.
- On a personal level: why is it important for you? What are your goals? Do you work to educate others, to influence policy, and/or to advocate for change?

The underlying theme for all these levels is trust—trust in our own abilities to provide accurate and valid information in a clear, understandable way, trust in us by our audiences and clients, and trust in the science by the general public. As the often-faceless go-betweens of the scientific and medical communities and the general public, our ability to parse and describe is the foundation of the trust between these groups.

To facilitate that trust, just like with the questions we must ask ourselves as we develop our projects, our audiences ask themselves their own questions.

- The general public asks, "How does this affect me?"
- Policy makers and/or scientists ask, "Does this affect my work?" or "Should we fund this?"
- The media asks, "Is this newsworthy?"

As we address these concerns, we should always remember that building trust between different groups and communities is essential.

The first piece of advice is to know your audience. How are they, in general, most likely to approach the topic? Is there skepticism or open-mindedness? Are they perhaps predisposed to be hostile or accepting of the information? The tone, the language, and the anticipated audience engagement are all 3 highly relevant aspects we can use to help guide our writing. We need to tailor our messages as much as possible toward the specific audiences.

Second, a helpful hint (particularly when addressing the general public) is to "think in threes." Consider the general parts of good storytelling, or even of something as simple and familiar as a knock-knock joke: an event or incident intrigues people, a conflict arises from that event, and then a resolution is achieved. Using a familiar and generally accepted pattern goes just that little bit further in helping audiences remember the information that is presented.

To expand our audience reach, interacting with the media is sometimes a necessity, and one that involves its own skill set. You should make the assumption that if there is a way for the media to misinterpret the information you are providing, it is likely to happen. Reasons for that are that the media world moves very quickly, journalists have a variety of sources at their disposal, and news organizations in general are not good at covering long-term issues. To overcome these hurdles, be sure to provide accurate, clear, and concise information. In short, get to the point as soon as you can. Try not to provide extraneous information that could either muddle the topic or be misconstrued in edited sound or video clips. The "thinking in threes" rule of thumb for general audiences is also helpful when speaking with members of the media. Your points can be preplanned and even rehearsed (depending on your level of experience or comfort with public speaking). In any case, make sure to point out the big picture of the topic or research. And remember, if you don't want to hear it, see it, or read it, don't say it. There really is no such thing as off-the-record.

Remember that science changes over time; it evolves. Scientists accept this environment, but the general public often tends to view science and health news more often with nervousness and mistrust. Explain results clearly and concisely, and then present the possibilities of what comes next in order to build that necessary trust. That in turn makes medical writers more effective liaisons between the scientific world and the general public.

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## Jam Session for Early- to Mid-Career Freelancers

**Session Moderator**

**Jennifer Minarcik, MS** / Principal, Jennifer Minarcik Biomedical Communications, LLC, Moorestown, NJ

**By Suzanne Morris, DVM, MWC**

About 15 freelancers and freelancers-to-be gathered at the AMWA 2022 Southeast Regional Conference in June to share their early freelance career experiences. Some of the participants had just decided to take the freelance plunge and were eager for tips on setting up a new business whereas others with more experience were wanting to share lessons learned. Session facilitator Jennifer Minarcik, MS, started the discussion by divulging some of the assumptions she had when she first started her freelancing career. She spoke to the misperception that freelance medical writers are all in competition with each other by pointing out the diversity of medical writing genres represented by the session's participants.

Acknowledging that the varied nature of freelance medical writing lends to camaraderie rather than competitiveness among freelance medical writers led to a discussion of networking. Although making connections with other freelancers may not translate to immediate work, networking can develop leads, elevate a freelancer's marketplace presence, and unearth other benefits. One of the more valuable of these benefits may be finding a good mentor. The more experienced session participants extolled the benefits of mentorship in guiding their early freelancing careers. But how does a new freelancer go about finding a mentor? Those who had who have benefitted from mentorship described a relationship which naturally developed from a networking connection.

Another early career misstep Minarcik discussed was the compulsion to take on every project, and the consequent erosion of the work-personal life border. Minarcik and the other more seasoned freelancers agreed that project selectivity fosters a reasonable work schedule and, potentially, better clients. Because part of cultivating a work-life balance entails supporting work hour productivity, the discussion then turned to productivity strategies. For example, creating a schedule with built-in time to respond to distractions like emails supports productivity during work hours. Protecting work time also may require establishing boundaries with clients by responding to clients only during set work hours or at set times during the week.

The conversation turned to some of the other nuts-and-bolts of running a freelance business. As with most freelance medical writing discussions, the topic of contracts arose, albeit briefly. The take-home message for new freelancers was to carefully review contracts, particularly with respect to payment parameters. Some of the freelancer participants who were just forming their businesses asked for advice on insurance and accounting. The responses from the more seasoned participants were mixed—few had insurance, and several used accounting services and software. But the consensus was that some form of accounting assistance was very helpful.

Inevitably, the discussion turned to what may be the most daunting aspect of freelance medical writing or freelancing in general: marketing. The importance of presence online, particularly on platforms like LinkedIn, was discussed at length by several seasoned freelancers. For introverts averse to overt self-promotion, a less intimidating approach may be simply posting about topics of interest, which creates an online presence and can garner attention. Another strategy was to investigate companies associated with relevant forms of medical writing on LinkedIn and make connections with their employees. Whether to solicit potential clients through email was a point of debate, with the more experienced freelancers advising that if done, it should be targeted and could backfire by annoying the targeted client. The discussion of marketing repeatedly circled back to value of networking, which can be done online and in person through, for example, AMWA events. And in keeping with its overriding theme, this AMWA session ended with participants exchanging their business cards.

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## Public Relations in Medical Communication

**Speaker**

**Katrina R. Burton, BS** / Public Relations Program Director

**By Lisa Kuhns, PhD**

According to the Public Relations Society of America, organizations and their publics use public relations as a communication strategy to build relationships that are mutually beneficial. Medical communicators help educate the public by sharing relevant health information through their own writing, and those with a marketing and public relations

(PR) background offer a unique skill set to health care institutions. Those trained in health care PR can expand their reach through a variety of platforms, including earned media, owned media, and bought media, using public relations as a tool to educate the public on medical and public health information.

PR plays a critical role in health care because it allows institutions and organizations to raise awareness about health, share groundbreaking research, and help people take control of their own health. A new treatment is less impactful if the public is not aware of its launch. PR also helps to highlight important health initiatives, reach underserved populations, and amplify the effectiveness of community and hospital-based programs and treatments. A story of patients sharing their health care journey because of the latest treatment may offer hope to others on the same journey. Accurate and factual information on health initiatives, research developments, and patient programming helps build trust in the medical community. Thus, health care PR helps spread information that can help people live healthier and more fulfilling lives.

In her presentation at the 2022 AMWA Southeast Regional Conference, Katrina R. Burton, Program Director of PR at The University of Texas MD Anderson Cancer Center, explained why it is important for medical communicators to understand the dynamics of how PR can leverage relationships between medical institutions and the public. Her presentation described best practices for developing a strategic PR plan, discussed how to identify and engage with stakeholders, and provided tips on how to build media relationships.

## Best Practices for Developing a Public Relations Plan

PR experts within a department typically develop a PR or media plan. Burton discussed the components of developing a winning plan. In her words, the plan begins by determining the "it" or the "what" that is being promoted. The "it" can be a/an

- Clinical or patient program
- Award or recognition
- Research study
- Sponsorship or partnership
- Important milestone
- Patient and clinical services
- Facility opening or launch
- Patient testimony

Once the "it" has been determined, the stakeholders are engaged, and the supporters or collaborators are identified.

The PR plan also should include the costs and budget. Costs can depend on what is being promoted and may be known or discoverable. Stakeholders and collaborators may be involved, and the budget may involve different departments, divisions, and institutions. The funds may come from grants or donors.

To complete the PR plan, the target audience must be identified, key messages developed, a timeline and deliverables determined, and the desired communication channels established. The communication channels selected may depend on the target audience, content, and timelines.

## Building Relationships to Execute the Public Relations Strategy

Every good plan involves more than the PR expert. In fact, it involves a multitude of people who are experts in social media, the web, video, photography, and more. Burton emphasized relationships are the fundamental component of any PR role and important for a successful plan. Building relationships with the internal team, media, and influencers helps to facilitate the plan's implementation. Relationships also help to build rapport and trust, open communication channels, and strengthen an organization's personal brand. "Operating in the public relations space as a medical communicator is an opportunity to enhance outreach opportunities, engage with stakeholders, and build collaborative relationships," said Burton. "It also provides an opportunity to share impactful stories of hope and important health information to help people live healthier lives."

Building relationships also defines roles and helps manage expectations. Importantly, establishing good relationships creates loyalty. "For me, building relationships with media is understanding their beat or area of focus, learning their reporting style, being familiar with the type of stories they cover, knowing their audience, and understanding how they engage on social media and with others," said Burton. "The stories I pitch to media are important to me, and I want them to be just as important to media, who in turn cares about their audience."

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## Resources for Researching Medical Devices Using Publicly Available Databases

**Speaker**

**Sara VanWyk, MPH, CCRP, RAC, MWC** / Clinical Evaluation Reporting, LLC, St. Petersburg, FL

**By Thi Nguyen, BS**

The clinical evaluation of medical devices marketed in the European Union (EU) is influenced by guidance from the Medical Device Coordination Group (MDCG) and still-relevant sections of MEDDEV 2.7/1 Rev 4 (Medical Devices Document 2.7/1 Revision 4; June 2016). In her presentation at the 2022 AMWA Southeast Regional Conference, Sara VanWyk provided an overview of relevant guidance on the clinical evaluation report, publicly available databases for literature searches, and content and release information for summaries of safety and clinical performance (SSCPs).

### Background

Historically, requirements for medical device regulation in Europe were established by the Medical Devices Directive (MDD) and the Active Implantable Medical Device Directive (AIMDD). As of late, the requirements have been transitioning to follow the Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).

To show evidence of having met the EU MDR general safety and performance requirements, manufacturers plan and report on the clinical evaluation of medical devices marketed in the EU; such evaluations align with the MEDDEV and MDCG guidance documents, including MEDDEV 2.7/1 Rev 4, MDCG 2020-6, and MDCG 2020-13 (among others). The first relevant guidance is MEDDEV 2.7/1 Rev. 4 (June 2016), which offers manufacturers and notified bodies guidance on clinical evaluation under directives 93/42/EEC and 90/385/EEC. The second guidance is MDCG 2020-6, which explains sufficient clinical evidence for legacy devices.

The third guidance is MDCG 2020-13, which offers a template for the clinical evaluation assessment report (CEAR). Each section of guidance contains pearls of wisdom regarding the device characteristics and evidence described in a clinical evaluation report, including the device description, published literature, clinical investigations, and clinical experience. This information may additionally be described in an SSCP, depending on the type of device.

### Device Description

Methods for describing the device under evaluation are outlined in MDCG 2020-13 Section C. To locate a device description, one can use the manufacturer's website, the United States (US) Food and Drug Administration (FDA) 510(k) Premarket Notification Database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm), the FDA Premarket Approval (PMA) database, or the Therapeutic Goods Administration (TGA) Australian Registry of Therapeutic Goods (ARTG) database.

### Published Literature

What literature qualifies for evaluation depends on the associated data, which can be categorized as either pivotal data or other data according to Section 9.3.2 of MEDDEV 2.7/1 Rev 4. Pivotal data must directly demonstrate adequate safety and performance (of sufficient quality and generated with the device under evaluation or the equivalent), whereas other data only play a supportive role. The same guidance also offers examples of data that lack scientific validity in Appendix A6. In terms of where to find published literature, many options exist, and Ms Vanwyk highly recommends PubMed, Embase, and the Cochrane Database for Systematic Reviews. However, other databases such as Europe PMC and Google Scholar can also be viable options.

### Clinical Investigations

In addition to searching published literature, writers are also encouraged to search data from clinical investigations. This search can help writers identify data that are not found by other means. To find clinical investigation data, writers can use clinicaltrials.gov, the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP), and Cochrane Central, although the EU Clinical Trials Register can also be a good resource.

### Clinical Experience

Clinical experience includes data on suspected device-associated deaths, serious injuries, and malfunctions that can feed into medical device reports (used in the US) and medical device vigilance (used in the EU). In the US, the FDA can use clinical experience to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments. Data can be compiled from mandatory reporters (eg, manufacturers, importers, and user facilities) and voluntary reporters (eg, health care professionals, patients, and consumers).

It is important to note that clinical experience can have limited utility because of passive surveillance. Many clinical experience databases exist throughout the world, with the US having the most databases. Available databases per country are as follows:

- **US** – FDA Manufacturer and User Device Experience (MAUDE), FDA Recalls, and FDA Total Product Life Cycle (TPLC) databases

- **Canada** – Health Canada Medical Device Incidents and Health Canada Recalls and Safety Alerts databases
- **United Kingdom** – Medicines and Healthcare products Regulatory Agency (MHRA) database
- **Germany** – Federal Institute for Drugs and Medical Devices (BfArM) Field Corrective Actions and BfArM Recommendations databases
- **Switzerland** – SwissMedic Field Safety and Corrective Actions (FSCA) and SwissMedic Recalls databases
- **Australia** – TGA Device Adverse Even Notification (DAEN) and TGA System for Australian Recall Actions (SARA) databases

### Other Resources

Other helpful resources include SSCPs, which provide publicly accessible, up-to-date summaries of clinical data and other information about the safety and clinical performance of a medical device. SSCP information can be accessed through https://ec.europa.eu/tools/eudamed/#/screen/home.

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## Think Like an Editor: Improving Document Quality for Regulatory Submissions

**Speaker**

**Callie Compton, MA** / Senior Technical Editor, Certara Synchrogenix, Nashville, TN

**By Paris Karr, PharmD**

Quality control (QC) is an integral part of ensuring accurate and consistent regulatory writing submissions. QC can be essentially defined as a process of checking consistency against a standard. However, in a writing context, QC is more specific than just "review."

Considering different types of reviews (data, subject matter expert [SME], and editorial), the omission of each kind can have different implications. Data and SME reviews can be critical for regulatory submissions, whereas an editorial review is often necessary for document appearance.

In her presentation at AMWA's 2022 Southeast Regional Conference, Callie Compton, Senior Technical Editor at Certara Synchrogenix, identified common issues in the QC process and discussed strategies for regulatory medical writers to ensure a successful QC process.

### Common Issues

Compton began by outlining several examples of document inconsistency. Such instances can include (but are not limited to) a document not aligning with sources, inconsistent terminology and style conventions, and errors in grammar, punctuation, and/or spelling. Furthermore, she also identified issues that may arise downstream in the QC process, such as inadequate time allotted for QC, vague, unclear expectations and/or instructions, and misplaced expectations for role/review type.

### Document Consistency

Compton suggested that identifying specific standards that govern the document is a crucial step for QC. However, before the actual process of QC, regulatory medical writers should consider asking the following questions to ensure document consistency:

- Does my writing align with its source(s)?
- Is my writing easy to navigate?
- Do I write about the same content in the same way?
- Do the same components in my writing look the same?

Regulatory writing may often require checking external sources such as a tables, listings, and figures document or a clinical study report. To ensure that the writing is aligned with external content, it is important to clearly identify sources in the document and to keep them organized. Compton illustrated that source references should specify document identifiers, such as the study identification, version number, or date, if applicable.

Consistent terminology and style conventions are also critical for regulatory documents. Compton pointed out that a style guide can be an important tool to help maintain uniformity when there can be many acceptable writing conventions. A style guide may specify, for instance,

- use of company/drug name
- preferred template/toolbar
- abbreviations/terminology, and/or
- usage (eg, patient vs subject).

Compton elaborated that "style" may refer to 2 different things: writing composition or formatting. In discussing the latter, a QC checklist can help guide the medical writer to consistently perform specific assessments, line edits, and spelling checks as a process.

### QC Process

Given its deadline-oriented and collaborative aspects, regulatory writing requires effective time management. Compton pointed out that inadequate time allotments for QC during development stages or at the end of a project can lead to considerable quality risk. For that reason, the start of

the project is a crucial time to accurately estimate or prioritize time for QC.

A writer should consider variables such as the types of checks needed (internal vs external), the deliverable's page count, and document type. For instance, a 200-page original protocol developed with multiple reviews involving an external SME may require considerably more adjudication time than a protocol amendment that only clarifies the study's exclusion criterion. Compton also recommended that writers think about overall timeline, analyze the complexity of content, and quantify available resources.

Vague expectations and/or unclear instructions can also be a common pitfall in the QC process. From her editing experience, Compton suggested that writers be proactive in communicating basic QC info. Ideally, the type of review, specific sections (if only parts of the document need QC), file name/location, and deliverable due date/time should be clearly specified.

Writers help delineate various roles and expectations in the QC process. To illustrate, a SME should provide review as a content expert, not editorial aspects. Compton emphasized the benefit of clearly establishing defined tasks between a writer (document author) and other collaborators.

## Think Like an Editor

Regulatory medical writers can efficiently produce high-quality documents by applying consistency with tools and employing a clear starting plan with concrete communication. Moreover, continuing to ask for QC feedback and learning from best practices will only empower writers to gain crucial perspective on the QC process.

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## CALENDAR OF MEETINGS


**International Society for Medical Publication Professionals**
"2023 European Meeting of ISMPP: Fueling Creativity"
January 24-25, 2023
London, UK
https://www.ismpp.org/european-meeting

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

**American Association for the Advancement of Science**
"2023 AAAS Annual Meeting"
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

**ACES: The Society for Editing**
"ACES Evolve: The Power of Editing"
March 23-25, 2023
Columbus, OH
https://aceseditors.org/conference/aces-2023-columbus

**American Pharmacists Association**
"APhA 2023"
March 24-27, 2023
Phoenix, AZ
https://aphameeting.pharmacist.com/

**International Society for Medical Publication Professionals**
"19th Annual Meeting of ISMPP"
April 24-26, 2023
Washington, DC
https://connect.ismpp.org/events/calendar

**Society for Technical Communication**
"STC Technical Communication Summit Conference & Expo"
May 14-17, 2023
Atlanta, GA
https://summit.stc.org/

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


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