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INSIDE

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

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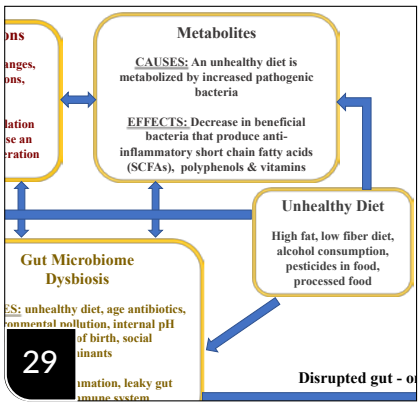

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL
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***AMWA JOURNAL* MISSION STATEMENT**

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

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FROM THE EDITOR

Michael G. Baker, PhD
Editor-in-Chief

The Spring 2024 issue of *AMWA Journal* is dedicated to exploring trends and opportunities in medical communication, as presented and discussed at the AMWA Medical Writing & Communication Conference in November of 2023 in Baltimore, Maryland.

In the current issue, among other topics, we also address the making of international standards for writing in plain language, generative artificial intelligence in clinical research, use of innovative tools and lean writing processes for regulatory document writing, the role of the gut microbiome n health, and the roles and risks of specialized medical writing.

In subsequent issues this year, the themes will be Digital Revolution (Summer 2024), Educating the Next Generation of Medical Writers (Fall 2024), and Health Economics and Outcomes Research (HEOR; Winter 2024). We are seeking a Guest Editor for the Educating the Next Generation of Medical Writers theme issue and if you are interested in the role, please contact me at journaleditor@amwa.org.

AMWA Journal will continue to bring you great content every quarter and on an ongoing basis we invite your contributions via our website: https://amwajournal.org/index.php/amwa/about/submissions.

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2023 Harold Swanberg Distinguished Service Award

Joan Affleck / Associate Vice President, Medical Writing, Merck & Co, Inc, Rahway, NJ

Joan Affleck received the 2023 Harold Swanberg Distinguished Service Award, named in honor of one of the founders of AMWA. This award is presented to an active AMWA member who has made distinguished contributions to medical communication or rendered unusual and distinguished services to the medical profession. At the 2023 AMWA Medical Writing & Communication Conference, Joan Affleck accepted the award at a plenary session and presented a MedWrite Talk entitled "Living Your Legacy."

SWANBERG ACCEPTANCE SPEECH

Thank you so much. This is a wonderfully humbling recognition for me. You know, in my heart of hearts, I'm a writer. And I can personally now attest to how great it feels when a writer gets good reviews.

The Harold Swanberg Distinguished Service Award feels like a starred review or maybe a lifetime achievement review. But as some of you know, I'm still living my legacy. Receiving this award from AMWA, from all of you, is one of the greatest highlights of my 25-year career. It's deeply touching to be honored here because the Swanberg Award recognizes distinguished contributions to medical communication. That means, to me, distinguished contributions to healing, to saving people's lives, to relieving people's suffering. What greater purpose could we have in this world?

This writer, Joan Affleck, stands a little in awe of the research, medicines, and treatments that have come to be in the time that I've been a medical writer. In the sweep of medical progress, I have also witnessed AMWA's progress. I have seen AMWA grow into an organization with astonishing openness to raise our game with innovations, training, credentialing, and a ceaseless quest for improvement.

We've become a vibrant and healthy neural system for our profession, moving medical information and messages between a myriad of stakeholders. Today, for me, AMWA is a professional organization like no other that I have ever experienced. We enjoy overwhelming support and endorsement from many companies; you've seen our wonderful sponsors. Our people know that their work is worthwhile, important, and life-changing.

We have won relevance. We have won a seat at the table. I sincerely thank AMWA and its leadership team. In particular, I thank you, Susan Krug, for your leadership and your friendship. I thank Dr Swanberg and the other founders of AMWA. I thank my spectacular team at Merck—super smart people who amaze me constantly with their devotion, innovation, and creativity. I thank all of you here for giving your hearts and souls to the work we do as writers and as communicators. You're really the ones who have put the shine on this shining hour. Thank you so much.

LIVING YOUR LEGACY: AN AMWA MEDWRITE TALK BY JOAN AFFLECK

Mark Twain is said to have written that the 2 most important days in your life are the day you're born and the day you find out why. My talk today is about that second day. The day we find out why. The day we understand our purpose. The day we know what we stand for. And the way we show it to others.

We're all writers here. We tend to think the way writers think. Like storytellers. Stories have a beginning. They have a middle. They have an end.

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When we think of a career, for example, we think of a beginning, and a middle, and an end. Whatever we have achieved at the end—the thing we leave behind for others to (hopefully) admire—that's our legacy. Right?

We leave behind a legacy. Now, what if I challenge that notion?

What if there's another way of looking at a legacy? A whole different way of thinking about the purpose of a purpose? What if legacy isn't something left over after years of work? What if, instead, legacy is ever-present? Real-time? This exact moment? What if all of us are, here and now, actually living our legacies?

I want to suggest today that we stop thinking of a legacy as an epilogue, something we leave for others to stand around and admire. Instead, may I show you a legacy?

Right here. It's the living, breathing form of Joan Affleck. It's standing in front of you. Living. In the moment. Vital. Engaged.

This legacy is alive and well. This legacy is a woman, a mother, a medical communicator, a cancer survivor, a public health servant. This legacy is a mad enthusiast of Paris and New Mexico and yoga and running, and great books and raindrops on roses and whiskers on kittens and, well, you get the picture.

I believe something today with all my heart. Legacy is not what you leave. Legacy is what you live.

For some, a legacy means things they achieve, palpable things. The buildings they design. The software they create. The records they set. For others, a legacy is much simpler. It can be described in terms of who we are. The qualities of a person.

So, what would happen if we all committed, here and now, to living a legacy? Of being aware that who and how we are influencing other people every single day?

Well, you ask, how? I don't think it's that hard. I see 3 simple steps.

First, define what you stand for.

It may be big. It may be small. It certainly may evolve over time. I know that my own purpose has evolved, as my life deepened and matured, and I found new passions and causes.

The point is this: Whoever you are *now*, however you are now, take a stand.

Live who you are. Live how you are. Think of your legacy as the next action you take, the next sentence you speak.

Second, make a commitment to mastering whatever you stand for now.

Do it through devotion. Do it through study and learning. Do it through practice, repeated mindful actions in pursuit of purpose. But do it.

Third (and in my mind most important), *live into your purpose*. Every single day.

Life can change in an instant. There's nobody in this room that doesn't understand this way deep down. Live fully committed to what you stand for. Even if it's really hard. In time it will bring satisfaction. It will also open unexpected paths to explore.

So here's today's call to action.

Live your legacy. Don't aim simply to be remembered by a legacy.

And this is actually far more than a call to action. It's a *cri du coeur*, a cry of the heart. A cry from my heart. What I'm saying, even imploring, is *to use every moment of your precious life*. You have just one.

There's a poem I love. It's by the late Mary Oliver, who left us in 2019. Her legacy?

An extraordinary, vibrant, beautiful life, crystallized in poetry that brought joy and inspiration book after book, verse after verse … a *living* legacy every day of her 84 years on this earth.

I'll share the last lines of her famous poem, "The Summer Day."

I don't know exactly what a prayer is.
I do know how to pay attention, how to fall down
into the grass, how to kneel down in the grass,
how to be idle and blessed, how to stroll through
the fields,
which is what I have been doing all day.
Tell me, what else should I have done?
Doesn't everything die at last, and too soon?
Tell me, what is it you plan to do
with your one wild and precious life?

So, dear colleagues, wonderful professional associates, friends, and loved ones, tell me, what is it you plan to do with your one wild and precious life?

Whatever you choose, let all of us see it, share it, learn from it, hour by hour. Let us see it now—not later.

If you remember nothing else of my talk, please remember this that I wholeheartedly believe:

A legacy is not what you *leave*. A legacy is what you *live*.

Acknowledgment: *I thank Kathy Adamson, DVM, for their help in bringing the acceptance speech transcript to the page.*

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CONFERENCE

2023 John P. McGovern Award Address

Jessica Steier, DrPH, PMP, and Andrea C. Love, PhD / Hosts, Unbiased Science Podcast

The John P. McGovern Award is named in honor of John P. McGovern and is presented to a member or nonmember of AMWA to recognize a preeminent contribution to any of the various modes of medical communication. The McGovern Award is presented during AMWA's Medical Writing & Communication Conference.

The McGovern Award address was a back-and-forth conversation between the recipients.

Jessica Steier: We want to start by thanking AMWA from the bottom of our hearts. This award is the highest honor. It still feels like a fever dream, especially since Dr Peter Hotez received it last year. We share this recognition with all of you who truly do lifesaving work that impacts people's everyday lives. Thank you. Thank you all so much.

Andrea C. Love: Yes, it's truly an honor to be here. We've been so warmly welcomed. We're very much looking forward to connecting with everyone for the remainder of the conference.

We begin with an introduction to both of us. I'm an immunologist and microbiologist by training. I previously worked in academic research, but I have been in the biotech industry for the past 9 years. That's my paying job. I develop new immunotherapeutics and oncology drugs, and I conduct vaccine research and development. In addition to my job and my work at Unbiased Science, I also am the executive director of the American Lyme Disease Foundation. I succeeded Phil Baker who unfortunately passed away just a couple of months ago. I step into his very big shoes in the Foundation and in the world of Lyme disease misinformation.

Steier: Love following Andrea's introduction.

I am a completely different type of scientist from Andrea. I'm a public health data scientist. I cofounded and serve as the CEO of Vital Statistics Consulting, which is a public health data science consultancy.

Prior to these roles, I did consulting work for departments of health. I also worked in clinical academia and as an Advanced Analytics team member for the Lewin Group, which is the health policy arm of Optum and United Health. So really, I design evaluations of health policies and

programs to determine whether they do the things that they are intended to do.

Andrea and I met almost 2 decades ago when we were both undergrads at Stony Brook University. Andrea was in Honors College, and I was in the Women in Science and Engineering Program. We were just a couple of nerds hanging out, and we kept in touch over the years. We cheered each other along in our respective careers as scientists.

And then I became a mom in 2016.

Are you familiar with the "mom groups" on Facebook and other forms of social media? I like to say that they are a dumpster fire of misinformation. So, I reached out to Andrea.

Love: Jessica asked, "Have you seen all this stuff about MTHFR [a folate-associated enzyme] and vaccines?" I replied, "Oh yeah, let me tell you about it."

Steier: Parents were advising against giving antibiotics to children. Instead, they were recommending to slice onions, put the pieces on the child's feet, and have the child sleep that way overnight. "Andrea," I said. "We have to do something about this."

But then life happened. Careers. Families. So, as much as we wanted to address the misinformation, we put that dream on hold.

Love: Yeah, until COVID happened.

For 5 to 7 years, we had been thinking about the need to address scientific misinformation. We finally realized

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there was never going to be a good time. We just had to start. People were being inundated with misinformation. They were drinking from the fire hose of preprints. Media outlets were mischaracterizing in vitro studies as being clinically relevant to humans. There was a simultaneous mistrust of governmental agencies and political figureheads. We thought, "Someone's got to try and help to drown out the noise." Being relatively independent scientists in our own respective careers, we determined, "We're going to tackle this."

We started out very small. We hosted Instagram Live events from our own personal pages. And we got really positive feedback. People commented, "You've got this dynamic; you've got this chemistry."

Together, we have the population health level and the biomedical level of science covered. From these 2 perspectives, we are able to explain well why one gets lymphadenopathy after a vaccine injection in the armpit, why getting a low-grade fever after a vaccine should not be a cause for concern, and why putting sliced onions on one's feet does nothing to cure an illness.

Steier: Exactly. In 2020, we found ourselves dispelling these bits of information separately but equally. We realized we should join forces. That's the birth of Unbiased Science.

We initially thought that the social media platforms were going to be ancillary to the podcasts. However, they turned into separate entities. So, we have a weekly podcast, which dives deeply into specific topics. It just hit one million downloads.

Love: The podcast allows me to get into the granularity of things. That's my wheelhouse. I can talk about data all day long.

In addition to our podcast, we have Instagram pages, Facebook pages, a Threads account, and a Substack. These social media platforms allow us to explore other types of formats, infographics, short videos, long videos, and long-form content. Different audiences are present on these different platforms. So, the variety of platforms allows us to reach more people of different ideologies and different generations who may believe in different types of science misinformation depending on their communities and their upbringings.

Steier: And just to be clear, neither one of us has received any formal training in communication. This has been a lot of learning as we go. We've made mistakes, and we've learned from them.

One of the key takeaways has been that different people consume information and learn in different ways. And so, as Andrea was just saying, different platforms are popular with different demographics. For example, the longform content that is more popular on Facebook skews to an older and politically right-leaning demographic, whereas the graphics and videos of Instagram are more popular among younger-aged parents.

Love: The millennials.

Steier: The millennials. And we're pushing ourselves now to get more involved in TikTok.

Love: For the Gen Z fans.

Steier: For Gen Z, right. The different modalities present different opportunities to connect with different audiences. That is something we keep in mind every time we develop content.

Love: We actually frame things in different ways, and we create different formats to resonate with different audiences, different education levels, and different demographics.

Unbiased Science was born out of COVID misinformation. But it's not just COVID, right? I've been harping on the misinformation about genetic engineering and GMOs [genetically modified organisms] since I was an undergrad. I do gene editing all the time in the lab. So, we also tackle misinformation on GMOs and food ingredients and chemistry. Our ultimate goal is to improve science literacy, because that's really what it all comes down to.

Steier: It helps in our communication efforts that we are different types of scientists with different personalities and from different backgrounds. I grew up in South Brooklyn at the foot of the Coney Island boardwalk. My dad did not graduate from high school. My mom is a first-generation American. Andrea grew up in the woods of rural Connecticut. She enjoyed looking at bugs, and she knew she was going to be a scientist.

Love: Yes, I collected bugs as a young child and grossed out people with whatever critter I happened to find in the woods that day. You know, Giardia was a part of my daily life when I was a kid.

Steier: We're not academics. We're just independent scientists who are looking to connect with the general public. According to feedback we have received, people appreciate our straight talk, real talk. We do not use highly technical language, which is not to say that that language is not appropriate in different settings. But we want to connect with people who have no formal scientific training and are

mistrustful of science in the medical establishment. We have to play around with different forms of communication, and we will share some examples of this.

Andrea and I have completely different backgrounds. Andrea is a biomedical scientist. She starts talking about T cells, and I have no clue what she is talking about. I, on the other hand, can go off talking about regression modeling techniques. These different scientific perspectives really help us give a comprehensive picture of a topic.

Love: That's really the goal of Unbiased Science: to take an interdisciplinary approach.

Our previous work in academic research allows us to understand the ivory tower perception that many people have with academic jargon. Jess now has her own company, and I'm in biotech. I work routinely with regulatory teams, GMP [Good Manufacturing Practice] lab facilities, and cell manufacturing. So, I have an understanding of what goes into an IND [Investigative New Drug] submission or a BLA [Biologics License Application].

We draw from these clinical and industry experiences when we ask questions like, "Why are you mistrusting of these agencies where the goal is to evaluate the safety and the efficacy of a product?" We also use our teaching skills—I taught clinical microbiology to medical students, Jess taught Physician Assistant (PA) students, and we each have worked with kids in high school and younger—as we answer, "What is the message that we are trying to convey, and who is the audience?"

Steier: Something worth noting here, and something we are going to reiterate later on, is that people must begin to talk about science communication early in a child's life. These scientific techniques must be taught to children in elementary school all the way through undergrad and graduate studies. My husband is an ER doctor, and he had no formal training in this area. Communication about science must be incorporated at every stage of education and development. Social media has changed the game completely.

Love: I want to talk about gaps in science literacy. Civic science literacy is the ability to not only find scientific information, but to understand it and use that understanding to make decisions. Decisions include those related to opting to get vaccines, voting for political policies or legislation, and not being afraid of food ingredients.

Let's begin our discussion of this topic with a poll of the audience. What proportion of Americans are considered civically, scientifically literate? You have 4 options: 13%, 59%, 43%, or 28%.

So, let us have a show of hands for 13%.

Steier: We are all pessimists.

Love: We are not very optimistic. What about 59%? A few optimists. What about 43%? Some people over there. And 28%? Okay.

The answer is 28%. We generally have people either answer 13% or 28%. Unfortunately, that is a dismally low number. We're not going to beat around the bush there. We want to improve that. This 28% is representative of people in our communities, in politics, on social media, and who have families. If these people are unable to make sense of credible science, then they might be guided to make decisions based on false information.

Steier: There is a real disparity between the 28% of people who are scientifically literate and over 50% of people who are interested in scientific matters. They crave scientific information, but they just don't have it. We are trying to bridge this gap and reach those people who fall into that doughnut hole.

Love: A variety of factors form gaps in science literacy. We will talk about 5 of them: the lack of fundamental scientific knowledge, vulnerability to logical fallacies, overconfidence in one's level of scientific knowledge, lack of understanding of research and design, and incorrect understanding of the process of scientific discovery.

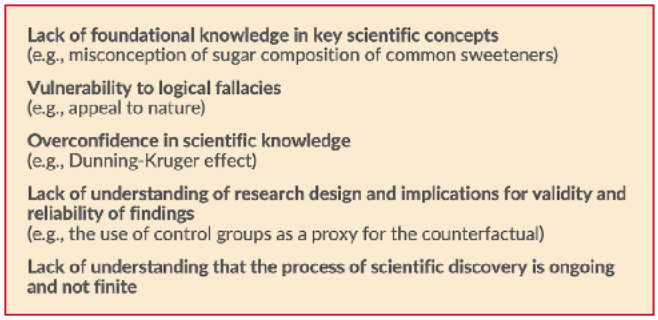

Figure 1. Common gaps in science literacy.

First, the lack of fundamental knowledge. You do know that everything is chemistry, right? However, people think, "I want a chemical-free something" or "I do not want chemicals on my food." But, by eating foods of any kind, these people are ingesting chemicals. Other people worry that mRNA vaccines integrate into our DNA. However, the central dogma of molecular biology explains the reason this cannot happen.

Steier: Or consider something as basic as sugar. We wrote a blog post that ended up being super popular about misconceptions of sugar composition and the idea that honey and maple syrup are so much healthier for us than table sugar.

Love: Honey, cane sugar, high-fructose corn syrup, and sucrose table sugar each have an approximate 50/50 ratio of glucose to fructose. However, 2 of them are perceived as being healthy, and 2 of them are perceived as being evil or toxic or whatever social media is going to tell you. It's the gap in fundamental scientific knowledge and the low literacy that makes one vulnerable to being misled by people who speak very confidently on social media.

Steier: Another contributing factor to the scientific literacy gap is a vulnerability to logical fallacies. There are many fallacies, but the one that we think is especially pervasive right now is the appeal to nature fallacy: the idea that anything natural is inherently better than anything manufactured in a lab or that's synthetic. This fallacy relates to pesticides, supplements, and beauty products. It embeds itself in every industry. We can thank Gwyneth Paltrow for contributing to this fallacy and Kourtney Kardashian for introducing it to the younger generations.

Consider the idea of clean beauty and all-natural products without preservatives. So your lotion is going to become moldy in a week. Congratulations. There is a reason that we have these preservative ingredients in our products. So, we're letting folks know the purposes for these ingredients in our cosmetics and foods and that synthetic products are not necessarily more harmful to people or the environment than some natural products are.

Love: Yes. Arsenic, asbestos, and botulinum toxin are all natural. And every virus that infects you and causes illness is all natural. So, we try to reframe people's approach to these sorts of things.

Gaps in scientific literacy are also caused by overconfidence in one's level of scientific knowledge. For example, individuals' perception of the healthfulness and/or safety of foods typically relates to their perspective on biotechnologies such as GMOs. Those people most opposed to GMOs often know the least about the topic but have a high self-perception of knowledge. This inverse relationship between the level of opposition to a scientific issue and the level of actual understanding about the topic may lead to policy decisions that are not aligned with science. The inaccurately high level of self-perceived knowledge may also cause one to resist learning new information.

Steier: The fourth factor of science literacy gaps is near and dear to my heart as a data scientist: it is a lack of understanding of research, design, and implications for the validity and reliability of studies. People send us a link to one PubMed article that has an n of 10 and improper controls for a million confounding variables that undoubtedly cloud the relationship between the 2 variables of interest. Other people incorrectly assume that an in vitro study or a preclinical study that was conducted in rats automatically translates to humans.

The example we give is aspartame, which has been splashed all over the news lately. People are terrified to take a sip of Diet Coke. However, the supposed risk associated with aspartame is based on preclinical and *in vitro* studies. People do not realize that unless they drink approximately 70 cans of Diet Coke, their risk is incredibly low. In this situation, a lack of knowledge about the research design is definitely a limitation.

Love: The final gap in scientific literacy is caused by a lack of understanding of the scientific process. People tend to think of things in black and white, especially on social media platforms like Instagram and TikTok. Sites like FlavCity and Food Babe are notorious for spreading misinformation about ingredients and things. These sites claim that certain ingredients cause cancer, are toxic, or disrupt endocrine function. However, the sites fail to mention the doses and exposures that were used in the research studies. Were the studies conducted in animals? If so, what animal? Were they conducted in humans? There is a lack of nuance.

People do not realize that science is an accrual of information over time. Scientists' statements are well based on data, based on the information available right now. We as scientists may be timid to make a particular statement because we recognize that we constantly learn new information. From such a perspective, it's hard to compete with someone who makes very bold, matter of fact, confident statements that elicit emotions.

Jessica and I want people to understand that just because things change over time does not mean it was wrong and now it is right. It means that we learned more things. That is how science happens.

Steier: Science needs a new PR person. Andrea and I consider ourselves part of that PR team.

Love: I want to revisit the topic of logical fallacies as a source of misinformation in Science and Health Communication. Anecdotes are used instead of evidence. People appeal to false authorities. The appeal to nature fallacy causes responses such as chemophobia. Everybody is scared of only certain chemicals and not of other chemicals, not realizing that everything is chemicals. So, we try to explain to them that just because one cannot pronounce the chemical's name does not mean the chemical is harmful. Chemicals are named according to a systematic method related to their structure.

False balances also exist. Construction of a false balance portrays 2 inequivalent entities as equivalent. One example is the proposition for Peter Hotez to debate R.F.K., Jr on the topic of vaccines. This proposition suggests that these men's arguments will be equivalent, despite one man drawing from decades and decades and decades worth of scientific data and the other man using cherry-picked in vitro data and conspiracy theories.

Two other contributors to misinformation within science and health communication are the oversimplification of science often perpetuated by clickbait headlines and the use of correlative data instead of causality.

People often ask Jessica and me why we care so much about correcting scientific misinformation. We care so much because of the harms that may result if people fall prey to such misinformation. We see direct harm to individuals. For example, some people don't believe in cancer therapies, but they get an IV of 5,000 mg of vitamin C. They subject themselves to a potentially acute toxic level of vitamin C, but they forego real medical treatment.

Harms may not be limited to a single individual opting out of a vaccine, for example. Harms may be community wide or global in scope.

Steier: Andrea, another good example to give here relates to organic foods. People have built up organic foods as being superior to conventional foods. Of course, we know that organic food comes with a much higher price tag, which means that a lot of people cannot access those foods. Therefore, people who fall into lower SES [socioeconomic status] categories simply go without eating fruits and vegetables altogether because they think that conventional produce is going to be harmful to them.

Love: Right.

Steier: This exacerbates food deserts and reduces access to healthy foods.

Love: Yes. Misinformation surrounding dietary fiber also causes harm. Some people who are already at higher risk for poor health outcomes because of their economic status adhere to the carnivore diet or a fad diet; they avoid eating fiber. However, a lack of fiber in one's diet causes additional health consequences, such as cardiovascular disease and diabetes. Health problems of at-risk populations increase as a result of misinformation.

Scientific misinformation also causes psychological harm. We get messages every single day from people who are scared to go to the grocery store because they have been convinced that ingredients and preservatives like sodium benzoate are toxic, are killing their kids, are harming them, and are causing premature puberty. People have health anxiety all the time due to this huge risk perception gap.

In addition to physical and psychological affects, misinformation leads to economic consequences. The health care burden increases when people do not opt into preventive health treatments and vaccines. The promotion of glorified snake oils increases the amount of money being spent on these items.

Misinformation may cause people to reject expertise, reject science on the whole, and mistrust regulatory and scientific agencies. Therefore, Jessica and I want people to realize that individuals who promote these alternatives that are often ineffective have a profit motive. Are they selling their quick fix? Are they selling their supplements? Are they selling a course you can take? Are they selling a book? You always want to look at that as well.

Steier: They're not working for hugs, right?

Love: Yes.

Steier: Before we go on, we need to acknowledge that the American health care system is not perfect. There are some very real issues that are systemic in our country and in others that are contributing to this. For instance, when I tried to make an appointment with a specialist, I was told, "Oh sure, no problem. It will just be 8 months from now." That is not helpful; I am dealing with a health issue now.

When people receive such a response, what happens? They go to the emergency room or urgent care. This behavior pressures the ER doctors to see as many patients as possible as quickly as possible. So, doctors have 30-second encounters with the patients. As a result, patients do not feel heard. A lot of these patients, especially those who are dealing with chronic illness or chronic pain, then switch to alternatives. While we understand why some people think they have no other options besides alternatives, we know that this turn toward alternatives is contributing to a general sentiment of mistrust and distrust of the scientific and medical establishment.

Love: Jessica and I created a toolkit of tips that allows us to effectively frame and communicate our message. First, we meet people where they are. We seek to understand people's objection to a particular piece of information and why they have this objection. We try to find out their educational limit or the amount of fundamental scientific knowledge that they have. We always want to listen to people. We listen with empathy and without judgment. We listen in a way that allows us to collect and source information. We then

reframe our message or find a path on common ground. We want the person to be open to the information we provide to them.

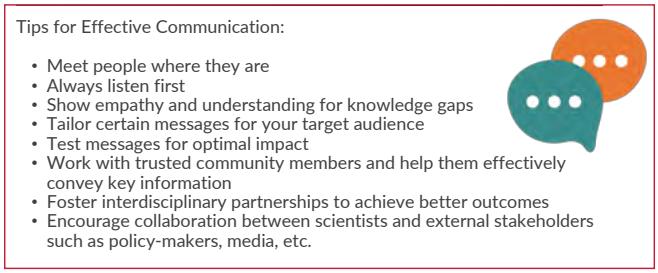

Figure 2. The unbiased science toolkit.

Steier: Another tip of effective communication is "show empathy." If we approach people from a place of judgment, those people are going to shut down immediately. We must be mindful that people come from different cultures and have different backgrounds and different levels of scientific education. So, there should be no judgment. The fact that we both have doctorates does not make us better than anyone; it makes us experts in our respective fields and gives us the authority to speak on certain topics. If one were to build a house, they would call an architect and a carpenter, experts in that line of work. Similarly, we want people to see us as helpful experts, not as threatening scientists who weaponize our credentials or talk down to people. That would be a very ineffective communication strategy.

Love: And of course, we need to tailor our messages to our target audiences. We're going to illustrate this in a moment. If you're in a regulatory field, you write for regulatory agencies. If you're in a publication area, you write articles for scientific peer review. Others of you write for the general public or for health care providers. Health care providers are often incorrectly conflated with scientists. Often, gaps exist between what health care providers communicate to their patients and what the science says. So, we science communicators must seek to bridge this information gap between scientists and health care providers.

Steier: It is also important for an effective communicator to test the message. Time and resources are not always available to do this, but this testing practice helps one to predict what the impact of their message will be.

Love: A lot of times, objections to our scientific messages are based on systemic or cultural differences, particularly with regard to certain communities. We cannot just enter as an outsider with the mindset of "I am a scientist. I am going to tell you what's what." We have to get buy-in from entities that are trusted by our target communities. Get them to be the conduit of our information. Therefore, we must convey our information to these trusted sources in a way that resonates with them so that they in turn are able to communicate it with others.

We have to work together across all segments, with organizations, governmental entities, private industry companies, the general public, and media outlets. The communication effort has to be interdisciplinary. We want the trusted entities to be the conduit of our information. Collaboration is really essential. Without it, we have the content, but we do not have the delivery method.

Steier: In the interest of time, we share with you just 3 examples of our more playful graphics. Sometimes we are technical, scientific, and didactic. But that does not always resonate with folks, especially people who are not scientifically minded.

The first example is a post encouraging people to eat fruits and veggies regardless of whether they are conventional or organic. Just eat them. I hope that everyone appreciates the pop culture reference to Schitt's Creek in the infographic. We say we're into the produce, not the labels.

Figure 3. Playing with messaging styles, techniques. and modalities. Example 1.

The second infographic (on next page) is a play on the Got Milk campaign, which was very popular. We used it to kick off a series on dairy and health implications, environmental implications, animal welfare, and more.

The third infographic is a comedic example of our snarky side. It illustrates that we should not conflate correlation with causation. The rise in ice cream sales does not cause a rise in shark attacks. Instead, the hot summer is the most

Figure 4. Playing with messaging styles, techniques, and modalities. Example 2.

popular time for people to eat ice cream and to go swimming in the ocean. So there you go. We get a little playful sometimes.

Figure 5. Playing with messaging styles, techniques, and modalities. Example 3.

Love: On a more serious note, last year we implemented a social media campaign related to the flu vaccine. The goal was to educate people and dispel misconceptions related to flu vaccines, because unfortunately the uptick in the number of flu vaccinations every single year is much lower than we and public health agencies would like.

Steier: I'll be pretty brief because I know we are short on time. We conducted surveys, hosted focus groups, and interviewed key informants within the public and among health care providers. We sought to identify the information gaps and the groups who are the most hesitant to get their flu vaccines. Two main groups emerged. One group was Black Americans of any age and gender, and the other group was young White males living in rural areas, particularly in the South and Midwest regions of the US.

These groups' reasons for hesitancy were completely different from each other. Among the Black Americans, it was a very understandable mistrust of the scientific and medical establishment based on historical events. They were scared. They feared chemicals, needles, and what was being injected into them. Whereas for the young white men, it was more about autonomy and distrust of the government. They refused to take something that was FDA-approved.

So, we developed a campaign with 2 different types of messaging that was tailored to these 2 audiences. We did some message testing: could we improve the messages?

Love: We created podcast episodes. We made infographics. We produced some video reels. We even conducted a live Q&A with a pediatrician.

Steier: The takeaway is that we reached an audience of 1.3 million individuals, which was amazing. A huge chunk of those individuals—over 300,000 of them—were clinicians, because HCPs [health care professionals] comprise a big chunk of our audience. This is great, because physicians are often our conduit for getting information directly to the public.

Amazingly, when we evaluated the impact of our flu vaccine campaign, we discovered that over 11,000 people changed their minds to get vaccinated based solely on the information that they received from our education campaign.

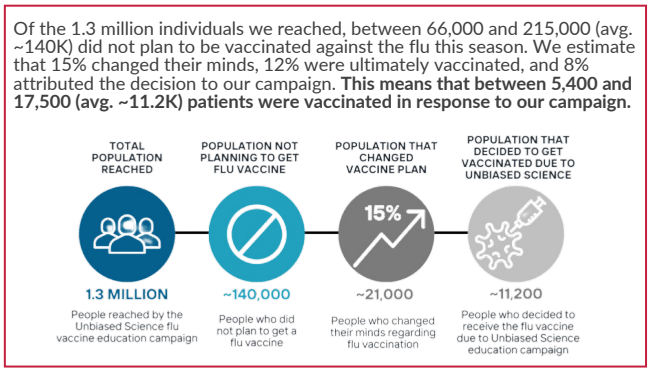

Figure 6. Reach and impact.

Love: We are working on writing up these campaign results and submitting them for publication, because I think there

needs to be more peer-reviewed data that underscores the importance of using social media for altering health outcomes. And of course, we have a lot of quotes that we included as well.

We conducted a similar study and educational campaign on menstrual hygiene misconceptions. There's a lot of fear-mongering within the menstrual health world around hormones, menstrual bleeding, and menstrual products. One theme that emerged from our study is that women routinely score lower than men on tests of one's baseline scientific knowledge. A lot of systemic reasons explain this finding.

In this campaign, we focused on 2 buckets of information: those related to medicine and health, and those related to chemophobia. We addressed medical and health topics by answering questions such as "Why do I poop more on my period?", "Why does the color of menstrual blood change over time?", and "Is it safe to sleep in a tampon overnight?" We approached the chemophobia-geared topics by answering questions like "Is titanium dioxide safe in my tampon?" and "Why are all these chemicals in my tampons?" Again, we tried to keep our communication playful but informative. We dissected the anatomy of different menstrual products, including tampons and pads. We explained the purpose of each ingredient in them, and we addressed common misconceptions about those ingredients. And of course, we talked about period poop.

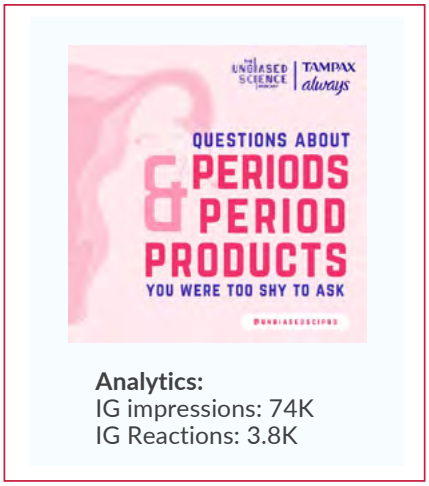

Figure 7. Reach and impact (IG only).

Love: People love to talk about poop. In our infographics, we included an image of a little wombat, because it has cube-shaped poop. I don't know if you knew that, but now you do.

We sought a similar reach to the flu vaccine campaign for our menstrual hygiene campaign. We created podcast episodes on menstrual myths and hygiene, made infographics, and produced additional reels. And we had a lot of reach.

So, what's next for us?

Steier: We want to grow. Science communication is more important than ever. We are all, everyone in this room, fighting an uphill battle. In the age of social media, misinformation supposedly travels 6 times faster than factual information travels. Everyone in this room is doing such meaningful work. We need more of it.

We want to expand our reach and our brand recognition. We want to make sure that this type of scientific information is being integrated into childhood education, undergraduate and graduate education, professional medical education, and scientific education.

Love: We want to create a kind of brain hub of interdisciplinary experts: not just scientists, not just health care providers, not just writers, not just media outlets, not just regulatory individuals. Cross-pollination is important, because if we do not communicate across different sectors, the messages will not reach the necessary audiences. We want to work with community leaders in order to understand why certain communities have poor health outcomes. We want to be a conduit of information that can be delivered through a trusted source. We also want to work with legislators to help them make policy decisions informed by science rather than by personal opinions or biases. Red dye no. 3 in California, I'm looking at you right now.

Steier: We would like to grow Unbiased Science and make it our main gig because "science is not finished until it is communicated." We are trying to figure out how to make science communication sustainable for us. Unfortunately, we have bills to pay, and running Unbiased Science takes a lot of time, energy, and expertise. We are open to ideas and collaborations and hope to speak with some of you after this talk.

Love: It's hard to have 2 full-time jobs.

Thank you all for your attention. Thank you so much for this honor. We will treasure this McGovern Award. Again, thank you so much.

Steier: Thank you. Thank you all.

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CONFERENCE

2023 Walter C. Alvarez Award Address

Building Trust in Public Health: Integrating Communication Every Step of the Way

Katelyn Jetelina, MPH, PhD / Founder and Publisher of *Your Local Epidemiologist*, Senior Scientific Consultant to the Centers for Disease Control, Atlanta, GA

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

Good afternoon, everyone. Thank you for this honor, I'm incredibly excited to be here. And I know it's going to sound a little cheesy, but it is also an incredible relief to learn about AMWA. The reason for that is that I am an epidemiologist; I am a scientist, at least that's who I was during pre-pandemic times. When the pandemic hit, I really stumbled upon scientific translation and scientific communication. I always loved teaching, but this was different. It was more human. It was more interacting with communities. It was a lot of listening.

And so my journey over the past 4 years in building a public health newsletter has been every emotion. It has been rewarding, it has been exhilarating, it has been humbling, it has been very scary, and it's also been quite lonely. I have always told people that I feel like I am in the middle of the forest with a machete, trying to find my way. Mainly, I think this is because this isn't what public health really did; it isn't what scientists are supposed to do. It's not how we get tenure, it's not how we get a Nobel Peace Prize, and, in fact, at least in public health, it's not even how you gain respect from peers. And I think this is the core reason why public health failed the biggest test we've had in the past 100 years: we failed at communication. And so when I got this award, I told my husband I found my people.

It was a huge sigh of relief. And when I started learning more about Dr Walter Alvarez, I even got more excited because our paths are actually pretty darn similar. He is a Californian; I am too. He had a lot of kids, 4 kids; one of his kids actually won the Nobel Peace Prize. My kids are toddlers drawing on walls, but maybe one day. We're both scientists; he's a medical scientist, I'm an epidemiologist, those are close enough. But what he did was bring awareness and advocate for public health, like sanitation and vaccination. He even challenged myths and misconceptions about health and disease, and that is a lot of what I have been doing as well.

And after he retired, he actually even wrote a medical column for newspapers. Maybe, I think, he should have called this "My Local Medical Doctor," but he also had a method to reach the layman, the community. And so this got me thinking. Alvarez broke the status quo in medicine. We need to break the status quo in public health, and it's incredibly important to do that right now. Why? Well, because we are seeing trust in public health declining.

There's been a loss of trust in institutions overall; this has really started since about 2016, across both aisles but mostly Republicans. I could go on for an entire day's lecture on why we lost trust, but that's not the point of this. If we continue this trajectory, the ramifications are going to be dramatic, they are going to be far-reaching, and they are going to be deadly. This will only be supercharged in the years to come given rising skepticism in institutions, given artificial intelligence developments, and even given climate change and the ramifications it has for new public health threats.

So what do we do? Public health, I think, needs to redefine its role in the twenty-first century. There is a lot to do on this list, but communication touches every single one of these things on this list. We play an integral role in this, and if we succeed, we will save lives. So I wanted to walk you through this checklist and show you, and try to convince you, how communication is an integral part in building trust in public health.

So this is my checklist; there are 5 things. The first thing is to become visible. What does this mean? Well, public health has always had this idea that we work in the background. In fact, we even have a saying that goes "public health is working if it's invisible." Think about seatbelts; we never really think about seatbelts when we put them on. The statistic of 3 million lives saved from vaccines during the pandemic is hardly known. It is invisible when it works. And we have to get out of this mindset; we have to refuse to be invisible.

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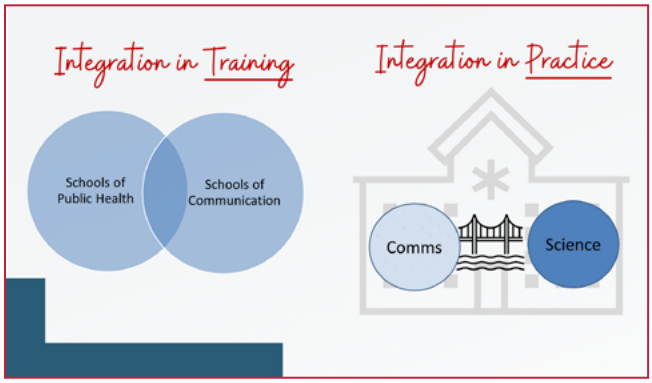
So how do we do that? We just need to start talking, start communicating, and start working with communities and not with each other. Public health scientists, scientists, and medical doctors are really good at talking to each other. It's another pathway taking scientists directly to community.



One integral way to do this is that we need to integrate communication into public health training. I was never trained in scientific communication; it's not viewed as a core. But this is a really low-hanging fruit of how we can integrate schools of public health with schools of communication to leverage all of the advantages both of us have. The other part of this is integration into practice. For many organizations and a lot of local health care departments, it means just creating a scientific communication core. It is recognizing that the leadership needs to recognize that it is an essential part of their mission, it is an essential part of their time, and it needs energy and resources allocated.

A lot of my work, though, and something I've discovered working with the Centers for Disease Control and Prevention (CDC) and the White House, is that a lot of the time there are 2 great teams: there's a great communication team and great scientists. However, the bridge between the 2 has been eroded. If there is a bridge there, it is very difficult to get across due to clearance processes that need to be dramatically thinned. Onerous clearance processes discourage frequent information sharing and inadvertently erode trust.

Second on my checklist is placing "public" back into "public health." Communication is core to this because it means that it's opening up a 2-way street. As epidemiologists and health officials, we've been doing a lot of telling, telling, telling, and it's important during a pandemic because time is lives. But we really need to stop and listen. And listening is very different than hearing.

Hearing is much easier because it's involuntary and no conscious effort is required. But it's really important to recognize that legitimate concerns do exist in the community, that we have failed in the past, especially with certain groups, and we need to approach it from a place of empathy and not only listen to questions but go actively look for questions. Open a tip line. During my time the last 4 years, I was getting so many questions, emails, and messages that I actually had to start creating a program that could start finding themes in the emails I was getting, so I could help address as many people as possible. And then also to know where people are talking and go to that place, and I'll get to that soon.

Another piece of opening up a 2-way street is also being there and listening during nonemergency times, which is what I call "peace time." In public health, there's always going to be a challenge to communities, so we need to listen to the communities to understand what their concerns are, not just our priorities in public health but their priorities, and this will build trust.

We also need to learn how to translate in public health. One really big challenge during the pandemic was this idea that scientists were saying something and the public was hearing something else. They were apples to oranges. We need to learn how to translate. People do not know what myocarditis means, they do not know what bivalent vaccine means, and they don't have to. But they do need to learn, and they have the right to understand, so we need to think big picture. One quote I love is attributed to Albert Einstein: "If you can't explain it simply, you just do not understand it well enough."

As public health officials, as scientific writers, we have a very deep knowledge in particular subjects, and sometimes the knowledge is too much that we get into these weeds of nuance. But really, scientific communication is this art that is a balance between nuance and readability. And so we need to teach people how to do this as well as partner with them.

Another part of putting "public" back in "public health" is equipping trusted messengers, realizing that sometimes it's not best that the ivory tower is communicating. In fact, a lot of people do not listen to the ivory tower; they don't listen to Katelyn Jetelina on *PBS NewsHour*. What they do listen to is trusted messengers; these are pastors, these are educators, these are physicians. And so we need to help equip these trusted messengers.

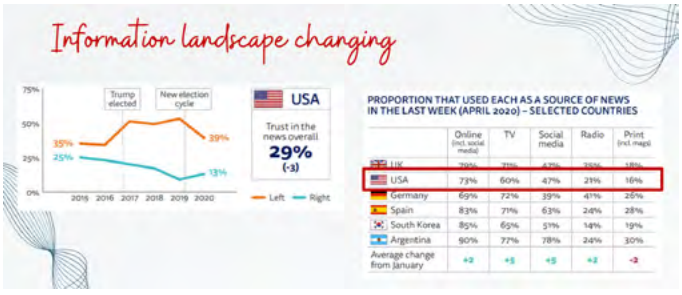
One of the biggest discoveries during my time at *Your Local Epidemiologist*, my newsletter, was I always assumed, in the beginning, that I was talking to Joe on the corner. So, I did a survey, and 77,000 people answered this survey. What

I found was that I wasn't talking to Joe on the corner; I was translating science to trusted messengers: those at the White House, NASA scientists, neighbors, education boards, or physicians. They would translate the information that I provided and spread it to others. And then people eventually got this information in their homes to make evidence-based decisions. This is an example of a small node in this huge grassroots network of information diffusion.

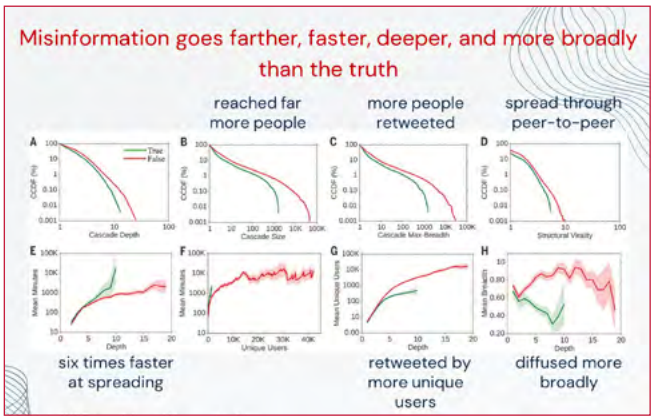
Another part of putting "public" back in "public health" is also to recognize not just what to say but how we say it, to be inclusive, because how we communicate the right information matters. The words we use matter, the tone we use matters, and the details matter.

Johnson and colleagues did this fantastic social network analysis early in 2020, around April 2020, right when the pandemic was taking off, and they did a number of computer simulations on Facebook pages.[1] A figure from their article shows the following: red dots are anti-vaccination pages, the blue dots are pro-vaccination pages, and the green dots are undecided, like your Parent Teacher Association. And what this found is many things. One, there's a clear echo chamber: the red dots are clearly separated from the blue dots. But I think even more importantly, the red dots, the anti-vax pages, are more closely aligned to the green dots than the blue dots are. So, pages that explain the benefits of vaccination are largely disconnected from the main battlefield of sentiment. We are talking to each other. We are not being inclusive, we are not reaching out, and we need to change this figure.

Part of being inclusive is, again, recognizing what you say matters, especially to people who are vaccine-hesitant or believe in conspiracy theories. This means we can't be condescending, we cannot be alienating, and we have to be empathetic. That means not using words like "insane" or "dumb" or "whatever." Because all we're doing when we say these words is challenging their worldview, and people will double down because their worldview is linked to their identity. And we need to build new foundations of trust.



Next is that public health needs to get with the times. What do I mean by that? Well, the information landscape is rapidly changing, and we have not kept up in public health. People no longer get their information from the news. In fact, only 30% of Americans trust the news overall. We have social media, and it's a huge part of how people get their news. Over 70% of Americans find health information on social media. So we need to be in this information landscape.



Source: Voshoughi, Roy, Arab. (2018) The spread of true and false news online. Science

Part of getting with the times is also recognizing mis- and disinformation, false information, and the power it has. This is a study done in 2018, before the pandemic.[2] They looked at 3 million tweets on Twitter and found that misinformation or false news goes faster, farther, deeper, and more broadly than the truth. False news reached far more people than the truth, was more retweeted than the truth, and spread through more peer-to-peer interactions than the truth. False news was 6 times faster at spreading than the truth, was retweeted by more unique users, and was diffused more broadly. These findings shed new light on the fundamental aspects of our online communication ecosystem, and we need to get up with the times and react to this.

And we are. There are a lot of resources going into this right now, particularly on the federal level. There are bills. The Food and Drug Administration has said they have a plan for mis- and disinformation. We have libraries and schools getting involved by teaching kids about misinformation. We have a proposed zero draft by international Member States to combat misinformation. And if you asked me probably a year ago, I would agree with this. Let's throw everything at this, it's the only way, end of presentation.

But there's always going to be bad actors. There's always going to be opinions, and it's always going to be a game of whack-a-mole. So how do we get ahead of it? I think part of getting up with the times is that we need to prevent it. We need to focus on proactive communication, not just this reactive communication of mis- and disinformation.

What is proactive communication? Well, in crisis communication, as you know, it's "be first, be right, be credible." The biggest gap right now is timeliness with public health communication. Messaging is too slow and too scant to meet the need of the public to make decisions today. Public health officials must get more comfortable communicating quickly, continuously, and with empathy.

We have to anticipate concerns to be proactive. It still amazes me that we took 9 months to create this

life-changing vaccine, and we did not prepare the communication or the education on it on the front end. We needed to anticipate concerns. We needed to answer concerns and questions from a place of empathy because a lot of people wanted to know, "Does mRNA change our DNA?" and we could explain that, and we needed to get ahead of it. Instead, we are playing a reactive game still to this day.

Being proactive is also bringing people along for the scientific discovery ride. What do I mean by that? It's telling people what we do know, but more importantly, it's telling people what we don't know and how we are trying to find an answer. If we are able to do this, particularly during an emergency in real time, people will be able to pivot more easily. You don't need to wear masks, you do need to wear masks, you don't need to wear masks if you're vaccinated, now you need to wear masks. It's really important that we continue to bring people along for that scientific discovery ride.

Fourth on the list is to embrace politics. There's a strong desire in science and medicine, and a lot in public health, to avoid politics. But responses, like a pandemic, are human endeavors put in place by people through political processes. It is inherently political. Where communication is so important, though, is how we talk about public health and how we talk about issues. Take, for example, these 2 buzzwords: "inequities" and "harm reduction." This works really well on one side of the aisle; however, you'll need to change your frame to reach the other side of the aisle, like a biosecurity threat. Knowing our audience and being smarter about how we talk about data and public health is so important to get anything done in this space.

Last on my checklist is to innovate. In order to reach every single household in the country, we need to build the capacity to communicate more effectively and timelier, and this is done on the backs of innovation. For example, we can innovate using public–private partnerships. Can the CDC, for example, work with a company to better tell their data story? Another example is we need to innovate through entrepreneurship. Entrepreneurship is not necessarily a thing in public health. It has always kind of lived in government. But we can launch creative innovation incubator design studios dedicated to health communication so that we can increase capacity and reach every single household.

Another way to innovate, and this is where I'm putting a lot of my time today and into the future, is innovating in the infrastructure. What do I mean by that? Well, creating something or somewhere for public health communication to live. One of the biggest frustrations I have right now is that everyone's looking to someone else to figure out public health communication, and that's because a lot of institutions are permeable to external pressures. For example, the federal government is permeable to politics; they have confusing guidance, and they have a lack of communication.

We also have academia. Academia is very difficult for the community to understand, and it's also slow, particularly during a public health crisis. And then we also have for-profits. The problem or the challenge with for-profits is that the general public thinks that they're partisan or at least have conflicts of interest. And to me, my biggest question is, "Where does public health communication live?" I think it's a space that we can all create together, some space not in these 3 buckets but somewhere else where we can start building trust, being nimble, being responsive—somewhere that is like a community of practice where there's this information exchange hub that can then be disseminated and leveraged through a number of networks that reaches everyone.

So this is my checklist, 5 things, and this is how we are going to save the world. No, just kidding, but it really is something that public health needs to start chipping away at. And I hope that you can see that communication is an integral part in every single step, whether that's becoming visible, putting "public" back in "public health," getting with the times, embracing politics, or innovating. There is a lot of red text on this slide, and it represents all of us. It's all of us communicators and scientific translators that can help that movement go forward.

So I invite you to insert yourself into any one of these aspects. Ruffle feathers. Help change the status quo in public health. Change ideas, come with big ideas. The only way we improve trust in public health and, ultimately, save lives going forward is by us working together and improving public health communication. Thank you.

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Session Report

Next-Level QC Review and Editing in Medical Writing

Speaker
April Welch, ELS
Vertex Pharmaceuticals, Boston, MA

By Angela Trenkle, BS

When working in quality control (QC) in medical writing, it can be helpful to learn ways to ensure that all mistakes are caught. In this education session, April Welch shares some of her tips and tricks for taking your QC reviewing and editing to the next level.

KEEP TRACK OF COMMON ERRORS

April began by sharing some examples of common errors while also emphasizing that although these examples are specific, she wanted the audience to take away the concepts behind them and how they might show up in other ways in any documents the audience members review. The concepts behind these examples included being aware of absolute statements in your writing and trying to find exceptions, keeping an eye out for missing units and information, and figuring out ways to change statements from vague to specific. She then went over some of the more common grammar and punctuation errors and inconsistencies that she notices the most when editing and gave the audience a refresher on some of these rules. These included commas, hyphens, colons, and abbreviations.

THINK LIKE A WRITER

April began by mentioning that it's important to think about the way the document was written, whether it was from a template, an approved document of the same type in a different therapeutic area, or a global module with some country-specific updates, because it can help you get into the mindset of thinking like a writer. She then went over particular things to keep an eye out for in each of these document types. These included template text that contradicts de novo text, incorrect key terms, including the therapeutic area, and checking items such as dosing and endpoints because they can vary depending on the country.

ERROR-PROOF YOUR PROCESS

April began by stating that the best way to error-proof your process is to follow a consistent process that plays to your strengths and allows you to move through a document quickly and consistently. She then talked about making use of the electronic tools at your disposal, including customizing the Word toolbar, using keyboard shortcuts, and getting autocorrect to type your frequent comments for you. She then brought up the topic of checklists and touched on how to use them to your advantage and the importance of keeping track of certain metrics within these checklists and what they can be useful for.

BE CURIOUS AND OPEN TO FEEDBACK

April began this section by showing a table that showed 3 categories for training options that can be helpful for both new hires as well as seasoned veterans in the QC field: Collaborative, Self-Study Essentials, and Self Study Over Time. After going over the various choices under each of these categories, she delved into the Lessons Learned training option under the Self Study Over Time section and recommended doing this by meeting as a team and going over the processes together. She then emphasized the importance of being curious and included ways that you could build upon your skillset with things that you can do before and after document review as well as various helpful topics to delve into to expand your knowledge. She then closed the presentation with some call-to-action items for specific issues that may come up and what you can do to fix these for the future.

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CONFERENCE

Session Report

Roads Leading to Approval: The Right Level of Detail for CMC Submissions

Speakers
Helen (Nellie) Forwood, MA, RAC, CQE
Associate Director Regulatory Writing, Certara, Rockland, DE
Carlos Rousselin, BS
Associate Principal Regulatory Writer, Certara, Nashville, TN

By Sidonie Jones, MA, MPhil, PhD

What is the right level of detail for submissions? Too much detail in submissions can make post approval changes a nightmare. Too little detail can lead to refusal of your application. How do you determine the right level for your submission? There are many considerations to be made when completing a new drug application (NDA) or a biologics license application (BLA).

Forwood began by discussing the right level of detail for an NDA. Every submission has a unique level of detail required. The following points are considerations when deciding the appropriate level of detail:

- Items discussed in your presubmission meetings with the US Food and Drug Administration (FDA). Make sure your submission covers any points discussed by your FDA manager in meetings for the investigational new drug application (IND), NDA, or BLA.
- Understand which modules are regulatorily binding. These are modules that will require a post approval submission if changes are made to them. Having too much detail in these modules can adversely impact your ability to make post approval changes to your product.
- Develop a relationship with the FDA manager for your project. This relationship can help with making submissions geared toward the FDA reviewer.
- Comparability protocols (to be discussed later).

The right level of detail is dependent upon the complexity of the product. The higher the complexity, the more detail is needed to demonstrate the details of the product. Small molecule drug products are more well-known and usually require less detail than large molecule products (eg, vaccines, biologics, and gene and cell therapy products).

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q12, Jan 2020, Appendix 1[1] (ICH Q12) is the guidance used to give examples of typical regulatorily binding modules. Forwood reviewed several examples the electronic Common Technical Document (eCTD) Module 3, which details typical regulatorily binding modules (established conditions) from the ICH Q12. Forwood also discussed post approval changes in manufacturing, all of which must be reviewed by someone in Chemistry, Manufacturing, and Controls (CMC) Regulatory Affairs to determine if there is a change in the established conditions in the existing application(s). She discussed the different pharmacopeia (ie, the books describing drugs, chemicals, and medicinal preparations as the standard in each region): the United States Pharmacopeia (USP), European Pharmacopeia (Ph. Eur.), British Pharmacopeia (BP), and Japanese Pharmacopeia (JP). There are differences between the USP, Ph. Eur., BP, and JP; however, ICH is working on reducing these differences.

Rousselin spoke on submissions of large molecules (biologics) and vaccines. Biologics are grown and harvested rather than synthesized, which poses issues. Biologics are exponentially larger than small molecules, which makes them harder to identify, characterize, and isolate. They are also susceptible to contamination, which presents regulatory challenges. There is increased detail necessary for large molecule applications, and these applications can be as much as twice as long as those of small molecule applications. Rousselin discussed the increases required in regulatory detail for biologic applications. He specifically spoke of ICH Q12 module 2.3, which is quality overall summary. He also discussed some parts of module 3 that could have increased regulatory detail for a biologic application. Contamination and stability are very important to consider, and process validation is a requirement for a BLA. There is a level of redundancy between modules 2 and 3 that can be required for large molecules. Finally, the ICH Q12 module 3.2.A, appendices are to show how effective your aseptic quality controls are.

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Rousselin then detailed the regulation of vaccines, which has similar content requirements to that of a BLA. Most vaccines have long development times that increased from the 1990s to the 2000s[3]. Barriers to vaccine development and approval include limited return on investment in both industry and academia, and limits of healthy individuals to take the vaccines. There have been less than 25 vaccines licensed by the FDA over the last 10 years. However, the FDA has instituted regulations to accelerate approvals for serious conditions. These lead to accelerated approvals, fast track evaluations, and breakthrough therapy designations. Two FDA regulatory programs authorize access pre-FDA approval: Expanded Access (Compassionate Use)[4] and Emergency Use Authorization[5]. This has accelerated approvals to approximately 1 per year in recent years.

Vaccines have 3 classes: viral vector, mRNA, and DNA. mRNA vaccines could be the dawn of a new age because they have certain advantages: they are easier to manufacture, are noninfectious, and they have versatility across many therapeutic areas, including cancer and gene therapy. These new therapeutics will require new approval protocols.

Forwood then spoke on comparability protocols (CPs), a comprehensive written plan to assess the effect of potential or known changes to be made post approval. CPs may be submitted as part of the original application or as a post approval change. CPs assist the applicant with knowing what studies and tests are needed when post changes are to be made. CPs can help with these post approval submissions by having an agreed-upon list of what will be needed, what will need to be contained in the submission, and they may even reduce the regulatory burden for post approval submissions.

Forwood spoke lastly on drug master files (DMF(s)). When there are 2 or more manufacturing partners; a DMF allows each party to protect their intellectual property. The DMF holder files the DMF with the FDA and includes a letter of authorization (LOA) in their DMF (or may amend an existing DMF with an LOA), allowing the partner submitting the NDA (or supplemental NDA) to reference the information within the DMF. There are currently 4 different types of DMFs:

1. Type 2 Drug Substance, Drug Substance Intermediate, and Material Used in Their Preparation; or Drug Product;
2. Type 3 Packaging Material;
3. Type 4 Excipient, Colorant, Flavor, Essence, or Material Used in Their Preparation, and;
4. Type 5 FDA-Accepted Reference Information.[2]

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CONFERENCE

Session Report

Shackleton's Ghost Writer: Navigating the Landscape of Appropriately Acknowledging Authors

Presenter
Art Gertel, PhD
MedSciCom, LLC, Lebanon, NJ

By Lara Burgess, PhD, RAC

Sir Ernest Shackleton was an Anglo-Irish explorer who led several expeditions to the Antarctic in the early 1900s. After returning from his adventures, Shackleton enlisted Edward Saunders, a reporter from New Zealand, to help him write a book. Saunders took Shackleton's journals and listened to his stories and ultimately wrote 2 books: *The Heart of the Antarctic* and *South*. The latter described the Imperial Trans-Antarctic Expedition of 1914 to 1917, better known as the Endurance expedition, with the crew somehow surviving for 497 days in the Antarctic environment. However, Shackleton is listed as the only author in both books. Saunders was given a small acknowledgment in one of the books and is not mentioned in the other. Saunders later wrote of *South*, "If I said that any chapter was entirely mine, I should be telling an untruth. My work was complementary to his. I could say that Shackleton had a remarkable gift of literary suggestion…"

Comparing and contrasting the different standards for authorship between scientific/medical publications and popular literature, Dr Art Gertel posed the question of how Saunders should have been recognized for his contribution in *The Heart of the Antarctic* and *South*. In this surprisingly suspenseful session, Art provided the framework to systematically determine authorship in the 2 contexts.

The foremost authority to set the present-day standard for authorship of scientific and medical publications is the International Committee of Medical Journal Editors (ICMJE). The ICMJE developed criteria for authorship[1] that distinguish authors from other types of contributors, and compliance with the IMCJE recommendations is required by most leading biomedical journals.

According to the ICMJE, there are 4 criteria that an individual must meet to qualify as an author:

1. Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; AND
2. Drafting the article or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Individuals who meet all of these criteria should be identified as authors. Individuals who meet some of the criteria should be acknowledged as nonauthor contributors.

In 2022, Good Publication Practice (GPP) guidelines[2] were updated to emphasize the listing of medical writers as authors if they qualify based on ICMJE criteria for authorship. According to GPP, if medical writers do not meet authorship criteria, their contribution should be disclosed in the acknowledgment section (eg, as a nonauthor contributor). Practices such as ghost writing (ie, failing to list qualified authors as such), ghost authorship, guest authorship (ie, giving authorship credit to those who do not meet appropriate criteria), and relinquishing authorship (ie, forcing otherwise qualified authors to opt off bylines to accommodate academic authors) are inconsistent with GPP. Companies may reimburse authors, but any such payments must be fully disclosed and comply with applicable regulations and company, institutional, journal, and congress policies.

According to GPP, medical writers should be appropriately acknowledged and not treated as ghost writers. To avoid potential conflicts related to authorship, a professional medical writer should have the following in writing before beginning work:

- The authors will control and direct the content of the publication or presentation.
- All authors have agreed to the writer's involvement.
- All authors have a documented agreement with the sponsor that identifies their respective rights, roles, and responsibilities.
- The authors will disclose, at a minimum, the writer's name, professional qualifications, affiliations, funding source, and any other information required by the journal or congress.

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Although medical writers typically do not meet ICMJE authorship criteria #1 (ie, substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data), medical writers working on other types of publications like literature reviews may qualify as authors.

So, should Saunders have been recognized for his contribution in *The Heart of the Antarctic* and *South*, if ICMJE or GPP standards were applied? According to ICMJE and GPP, it seems that Saunders likely met ICMJE authorship criteria #2, #3, and #4. Therefore, he should have been recognized for his role as a writer but not as an author. However, given that the 2 books would be considered as popular literature, these standards would not apply, leaving it up to Shackleton to determine the degree of acknowledgment due to Saunders.

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2023 AMWA BALTIMORE

Golden Apple recipient Hope Lafferty, AM, ELS, with AMWA Member Recognition Committee Chair, Abbie Miller, MWC

AMWA President's Award recipient Don Harting, MA, MS, ELS, CHCP, with AMWA 2022-2023 President, Elise Eller, PhD

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CONFERENCE

Session Report

Social Media Continuing Medical Education: Next Steps

Speakers
Cindy van Dijk
Principal, Scientific Communications
Allison Kickel
President and Founder, Bonum Continuing Education

By Laura Tibaquirá, MA, ELS

Continuing medical education (CME) refers to educational activities designed to help physicians maintain, develop, or increase their knowledge and skills. CME credits are required by different medical specialties to ensure professionals are up-to-date with the latest advancements and practices.

Cindy van Dijk and Allison Kickel's presentation at the AMWA's 2023 Medical Writing & Communication Conference provided an overview of how medical communicators can use social media (SoMe) to take CME to the next level.

SoMe AND CME

"Name one useful thing you have learned from social media." With this statement, the presenters invited attendees to share their experiences with SoMe and how it is used to gather and share knowledge. They reflected on how health care professionals (HCPs) can now harness the potential of SoMe and actively use it for training, timely CME, and ongoing professional development.

BENEFITS

In the busy world of clinical medicine, there are distinct advantages to using the SoMe CME to engage physicians.

- **Available on demand:** Physicians can arrange their ongoing educational opportunities around their schedule.
- **No discussion restrictions:** HCPs can engage in open and unrestricted discussions, allowing a free exchange of ideas and enabling participants to ask questions, challenge concepts, and share their perspectives.
- **Content validation:** SoMe CME adheres to all the same guidelines as regular CME and includes academic and practicing clinicians in the development and delivery of the programs. Established mechanisms maintain the credibility and reliability of the information presented.
- **Adherence to regulations:** The Accreditation Council for Continuing Medical Education sets CME standards to ensure content delivered through SoMe is compliant with recognized academic and professional standards.
- **Peer-to-peer and networking opportunities:** HCPs can connect and network with their peers from different specialties, institutions, and geographical locations.
- **Spaced learning and measurement over time:** Learning activities can be posted over time, allowing for better retention and reinforcement of knowledge.
- **Cost-effectiveness:** Professionals can access educational content, engage in discussions, and expand their knowledge without high expenses or registration fees.

TYPES

There are many types of educational formats and platforms and, as Cindy and Allison explained, their use depends on the communicator's objective, the audience, and the type of content. Here are the most popular types:

- **Webinars:** Live or taped-to-live online educational presentations. Commonly used platforms: YouTube, Facebook Live, Instagram, and X/Twitter
- **Online communities and discussion forums:** Specific spaces to share opinions, interact, and connect. Commonly used platforms: Facebook, SERMO, and Doximity
- **Blogs and vlogs:** Articles and personal commentaries on a specific topic. It is a vlog if it contains video material. Commonly used platforms: WordPress, Blogger, LinkedIn Pulse, and YouTube
- **Journal clubs:** Groups that meet regularly to evaluate academic literature. Commonly used platforms: X/Twitter, Facebook groups, and Slack
- **Tweetorials:** Threaded tweets with a concise overview of a topic, including pretest and posttest questions. Commonly used platforms: X/Twitter

KEYS TO SUCCESS AND RULES OF ENGAGEMENT

Each SoMe platform has distinct capabilities and unique benefits and downsides, so developing hosted SoMe CME can be a bit overwhelming. Some of the keys to success are to think differently and be open to change, know the target

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audience, focus on the educational value of the content, and understand the dynamic nature of SoMe. Most important of all is to stay active and expect the unexpected.

Sharing medical education on SoMe should consider a number of factors depending on the platform and audience. Here are a few planning-to-execution tips:

- Consider the dynamics and limitations of the platform (character limits and the use of emojis, images, hashtags, and polling questions).
- Gather supporting references.
- Validate content with other professionals.
- Test the content before posting it.

FINAL CONSIDERATIONS

SoMe CME media is constantly evolving; it offers unique opportunities for HCPs to enhance learning, connect, and collaborate, but it also poses challenges and requires more robust risk management strategies than traditional CME. HCPs need to critically evaluate content to ensure accuracy, protect patient information, adhere to ethical guidelines, and be mindful of potential biases.

Cindy and Allison reminded us that as HCPs and communicators, we can embrace SoMe CME as a valuable addition to our continuous learning journey, working together to shape the future of medical education and, ultimately, improve patient outcomes.

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Session Report

Strategies to Prevent Medical Writer Burnout

Speaker
Nidhi Johal, BSc (Hons)
Medical Writing Director, Trilogy Writing & Consulting

By Sophie Ash, BSc (Hons)

In the dynamic field of medical writing, burnout has been an ongoing concern, prevailing even before the recent surge labeled as the "great resignation." The World Health Organization (WHO) acknowledges burnout as an "occupational phenomenon," attributing its origin to persistent workplace stress: a challenge notably experienced by medical writers.

Nidhi Johal has over 11 years' experience in the medical writing industry, having worked on a variety of clinical and regulatory documents across multiple therapeutic areas. She is passionate about creating positive workplace cultures that value employees' wellbeing and presented on the topic at the AMWA Annual Conference in October 2023.

Nidhi established the following learning objectives for her presentation, entitled "Strategies to Prevent Medical Writer Burnout":

- Build awareness of the various factors that affect the document authoring process.
- Manage team and stakeholder expectations and set clear boundaries.
- Identify tools and methods to manage the document authoring, review, and editing processes more effectively.

Understanding the nuances of burnout and recognizing its early signs are crucial. Nidhi encourages medical writers to pay attention to signs of burnout, such as increased sick days, reduced work quality, behavioral changes, and disengagement. Furthermore, withdrawal, lack of focus on professional development, and noticeable stress are additional red flags that demand one's attention.

Nidhi believes that adopting proactive measures is essential when it comes to counteracting burnout effectively. This involves a holistic approach encompassing self-awareness in addition to catering to one's physical and emotional needs. Prioritizing workloads, seeking additional resources, establishing clear boundaries, and requesting help when necessary were some of the key strategies put forward. Nidhi stresses that the gradual implementation of changes in work patterns is pivotal in mitigating the risks associated with burnout.

Effective collaboration within medical writing teams is fundamental in burnout prevention. To achieve this objective, Nidhi suggests building trust through facilitating team member introductions, understanding each team member's roles and responsibilities fully, and fostering open communication to create a cohesive work environment that minimizes burnout risks.

Nidhi encourages all medical writers to thoroughly prepare before they dive into any new project. Essential preparatory steps include things like understanding project specifics, aligning with client expectations, and scrutinizing project timelines. For example, facilitated kickoff meetings allow team members to gather crucial information pertaining to a project as well as to discuss document authoring processes and collectively establish timelines.

> "Educating teams on effective review practices before a document is reviewed is pivotal for improving overall efficiency."
>
> – Nidhi Johal, Medical Writing Director, Trilogy Writing & Consulting

Throughout her medical writing career, Nidhi has also found comment resolution meetings (CRMs) to be extremely helpful in getting team members aligned such that documents can continually progress more easily. Nidhi suggests having CRMs after each reviewed draft of a working document to keep everyone on the same page. It's generally easier to schedule CRMs well in advance to ensure that team members are available to participate.

"Lean authoring" is an approach to medical writing that encourages the delivery of essential information in an easily accessible format, as opposed to bulky documents that are hard to decipher. Nidhi is a huge proponent of organizations adopting a lean authoring attitude as she's seen it shorten

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review times considerably, freeing up writers' time to complete other tasks.

To ensure every meeting is purposeful and productive, Nidhi encourages medical writers to carry out meticulous planning beforehand, keep meetings concise wherever possible, and make sure someone takes responsibility for keeping to the agenda and wrapping up on time. She also advises professionals to be mindful of team members in different time zones or with upcoming vacation time or "out of office" dates. All in all, the more considerations are made ahead of time, the more smoothly meetings are likely to go, minimizing friction, stress, and fatigue among employees.

> "Your job as a manager is to get better outcomes from a group of people working together."
>
> – Julie Zhuo

Outside of the workplace, Nidhi recommends developing and strengthening complementary skills, such as self-discipline, nurturing a positive mindset, implementing self-care routines, and setting healthy boundaries. Other helpful skill sets for preventing burnout include getting more comfortable asking for help, breaking problems down into more manageable chunks, taking regular breaks, and talking things through with trusted advisors, colleagues, or friends.

Nidhi considers supportive managers to be indispensable in helping to prevent medical writer burnout. If you manage a team, try to foster an empathetic work environment in which you check in regularly with team members to offer constructive advice and support. Keeping an eye on each person's workload to make sure it is manageable is paramount, and celebrating team achievements will help boost morale and productivity.

Before wrapping up, Nidhi shared a concept from the book *Multipliers: How the Best Leaders Make Everyone Smarter* by Liz Wiseman and Greg McKeown. "There are two types of leader: Multipliers and Diminishers," she explained. "Multipliers bring out the best in people, whereas Diminishers do not." In the book, Multipliers are described as leaders who create a safe space for employees to share struggles with them, such as feelings of burnout. Conversely, Diminishers are leaders who micromanage team members, acting like tyrants and know-it-alls, making workers feel small and unappreciated. Nidhi encourages managers to engage in open dialogue with their team wherever possible, taking a "Multiplier's" approach to leadership to create a healthier work atmosphere.

In conclusion, adopting a multifaceted approach that integrates individual well-being, effective team communication, skill development, and robust managerial support is imperative to prevent medical writer burnout. Implementing these strategies comprehensively can significantly contribute to creating a mutually beneficial and more productive work environment in the medical writing profession.

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SCIENCE SERIES

The Gut Microbiome–Human Body Symbiosis: Relevance of the Ubiquitous Microbial Community on Health and Development, Part 2

Smitha S. Dutt, PhD / Freelance Medical Writer, Editor, and Translator, Montreal, Canada

ABSTRACT

The human gut microbiome, comprising a range of microbial species (~100 to 1,000), is an extremely malleable ecosystem. It originates around the time of human birth and evolves as the infant grows until it matures into the relatively stable adult gut composition. Through this dynamic evolution, the composition of the gut microbiome is influenced or altered by factors such as diet, environment, mode of birth, genetics, infections, and medications. Strong associations between such alterations (dysbiosis) and diseases have led scientists to develop therapies that target a malfunctioning gut. Research is now focused on the microbiota or their associated metabolites as potential therapies. Treatment options explored include prebiotics, probiotics, postbiotics, synbiotics, fecal microbiota transplants, and live biotherapeutic products. The gut microbiome is not a panacea for all health issues; rather, it is part of a large network of interconnected operating systems within the human body. As communicators of scientific data, medical writers play a vital role in educating the public on the merits and limitations of gut microbiome therapeutics. Popular discourse, however, can be influenced by misinformation. With the ever-growing influence of social media, the lay reader must learn how to critically appraise the health information propagated by these sources. This second part of the gut microbiome series explores the association of the gut microbiome with human disease and the role that social media plays in influencing the popular perception and understanding of the importance of the gut microbiome. Approved and experimental therapies using the gut microbiome will be discussed.

Social media pundits and science communicators are extremely important in monitoring the quality and integrity of discourse on the impact of the gut microbiome on human health.[1-3] Microbiome researchers set out to confirm the association of gut dysbiosis (Box 1) with many chronic diseases. However, a decade later, it is becoming increasingly difficult to conclusively link gut dysbiosis with specific diseases due to the vast heterogeneity of the human microbiome.[4] The gut microbiome is so vital to our existence that it is referred to as the second genome.[5] Genetics and the living context define the healthy equilibrium between the gut microbes and the body.[5,6] The dynamic evolution of the gut microbiome from birth to adulthood ensures diversity in the

Box 1.

Microbiome
A microbiome is an ecosystem of microorganisms (eg, bacteria, viruses, phages, fungi, archaea), their genes, and metabolites in a particular environment.

Microbiota
Microbiota are microorganisms (eg, bacteria, viruses, fungi, archaea, and phages) that live in a particular environment.

Dysbiosis
Changes to the composition of the gut microbiome (eg, function and taxonomy) cause dysbiosis. Drastic disturbances to the gut microbial balance are linked to inflammatory bowel disease, obesity, type I diabetes, asthma, autism spectrum disorder (ASD), and allergies. Gut dysbiosis causes inflammation and immune reactions.

Epigenetics
Epigenetic changes modify gene expression by acetylation or methylation of DNA in the absence of changes (eg, insertions, deletions, duplications) to the DNA sequence.

Interactome
An interactome is a biological community that functions on the basis of an interactive network of human genes, epigenetic modulation, environmental features, and the microbiome.

Metabolome
A metabolome is the comprehensive collection of metabolites in a system (eg, body, cell, organ).

Xenobiotics
Xenobiotics are chemicals (eg, industrial pollutants, drugs, fertilizers, or pesticides) that are not naturally found within a biological system and are metabolized by microbes.

Circadian cycle
A circadian cycle is a 24-hour cycle that governs the metabolic, physical, behavioral, and mental signaling networks within the body.

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gut microbial community.[7,8] The gut microbiome is part of a complex network or interactome consisting of the metabolome (Box 1), the gut–organ axes, environment, genetics, and epigenetics.[9] A disruption to any part of the interactome could alter the crosstalk and result in disease.[9] Diseases manifest when there is a shift or change to the microbial diversity in gut microbiota (dysbiosis) due to infections, stress, intake of antibiotics and other medications, age, exposure to xenobiotics (Box 1), seasonal changes, circadian rhythms, an unhealthy diet, industrialization, exposure to pets, use of chemical disinfectants, or type of birth.[10,11] This review will discuss ways in which gut dysbiosis affects health and how the gut microbiome can be manipulated as a target for promising new treatments.[4,12,13] As medical writers, we should proceed cautiously when promoting the health benefits of the gut microbiome.[14,15] By reporting evidence-based information, medical writers should also have an obligation to counter social media's exaggerated claims of the gut microbiome as a panacea of health.[2,3,16]

THE GUT MICROBIOME IN DISEASE

In healthy humans, there is a bidirectional crosstalk between the gut microbiota, the immune system, and the intestinal mucosal surface.[10] In a disease state, this crosstalk is affected.[10] It is unclear if gut dysbiosis either causes or is caused by diseases.[9,12] Gut dysbiosis manifests as a result of an unhealthy diet, environmental changes, type of birth, and antibiotic use, among other factors.[17] Gut dysbiosis favors the proliferation of pathogenic gut bacteria.[9,10] This results in inflammation that triggers an immune response.[9,10,17,18] Inflammation increases the permeability of the intestinal epithelial membrane.[10,18] This allows pathogenic gut microbes and metabolites to translocate through the membrane and travel via the systemic circulation and the respective gut–organ axes to target organs.[9,17] The circulation of these pathogenic gut microbes and their metabolites can all activate or enable epigenetic modifications. Individually or jointly, these factors can impact human disease (Figure 1).[10,11,17-20] The role of gut dysbiosis in diseases will be elucidated in this section.

Metabolic Syndrome

Metabolic syndrome encompasses nonalcoholic fatty liver disease (NAFLD), diabetes, obesity, hypertension, and cardiovascular disease.[6,8,12,21-24] Antibiotic use in infants appears to be associated with the risk of developing these diseases in later life.[9,25-29] Obesity in metabolic syndrome results in part from gut dysbiosis from a high-fat, sugar-concentrated, and low-fiber Western diet, genetics, sedentary lifestyle, maternal gestational diabetes, and the circadian cycle (Box 1).[8,12,23,24,30-32] In patients with type 2 diabetes (T2D) (Table 1), gut dysbiosis is associated with a Western diet, obesity, persistent inflammation, and an increase in the concentration of branched-chain amino acids in the serum.[12,23,24,31]

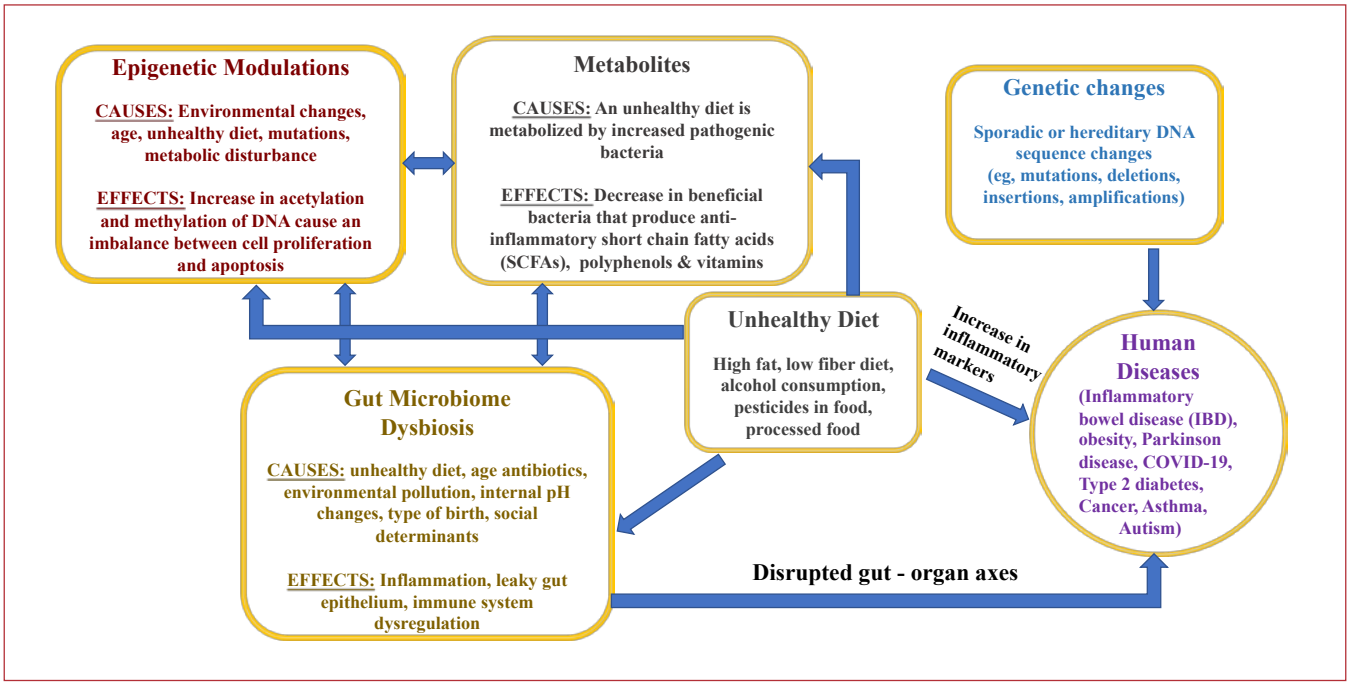

Figure 1. Potential Pathways to Human Disease. Interconnected pathways associated with human disease. Dysbiosis results from epigenetic modulations, pathogenic microbes, and metabolites released from an unhealthy diet, use of antibiotics, and environmental triggers, among others. Gut dysbiosis along with an unhealthy diet and gene sequence changes can disturb the usual homeostatic balance in the body, which is linked to disease.

Cardiovascular Disease

Studies, although inconsistent, have found that high plasma trimethylamine N-oxide (TMAO) levels are associated with a risk of cardiovascular disease.[8,24,42,43] This microbial metabolite is the byproduct of a low-fiber, meat-oriented Western diet.[8,24,42,43]

NAFLD

In NAFLD, gut dysbiosis or fat accumulation in the liver inflames the liver and other organs comprising the gut–liver axis. Inflammation increases intestinal wall permeability that allows pathogenic microbes (Table 1) and their metabolites to reach the liver through the portal vein or systemic circulation.[8,38,44,45]

Gastrointestinal Diseases

Inflammatory Bowel Disease

Inflammatory bowel disease (IBD) is an umbrella term for the group comprising indeterminate colitis, ulcerative colitis, and Crohn disease.[24,46] Research has convincingly shown microbial perturbations in the gut in those with IBD, although it is not clear if gut dysbiosis is a cause or an effect of IBD.[24,46,47] IBD has been associated with gut dysbiosis, inflammation of the intestinal mucosa, lesions in the gastrointestinal tract, genetics, environmental influences, and immune system perturbations.[9,15,24,46,48]

Malnutrition

Inadequate or overnutrition causes malnutrition. Dietary supplements alone rarely correct malnutrition. However, research has shown that a diet of peanuts, bananas, and chickpeas may modify the gut microbiomes of malnourished children by encouraging the growth of age-specific bacteria.[49-51]

Neurological Diseases

It has been postulated that gut microbes exert an influence on emotions, processing capabilities, and even behavior.[52-54] Research now shows associations between gut dysbiosis and mental disorders, such as anxiety, epilepsy, autism, depression (Table 1), sleep irregularities, Parkinson disease, and Alzheimer disease.[6,36,55-59] The gut microbiota communicates with the brain through the gut–brain axis.[60] Intestinal microbiota translocate across the permeable intestinal wall and migrate to the brain where toxic metabolites, inflammation, and oxidative stress damage the integrity of the blood–brain barrier.[61]

Dermatological Diseases

Dysbiosis in the gut–skin axis is associated with psoriasis, acne vulgaris, alopecia areata, and atopic dermatitis, among others.[62-66] Diet, genetic susceptibility, and hygiene influence the bidirectional communication within the gut–skin axis.[65,67-70]

Respiratory Conditions

Asthma

The risk of developing asthma has been attributed to a Western lifestyle, the mode of birth (eg, cesarian section), industrialization, and the use of antibiotics.[24,71,72] Although genetics may be involved, environmental changes that reduce gut microbial diversity increase the susceptibility to airway inflammation.[72,73] Changes in the gut microbiome (Table 1) are reversible and dynamic. Replenishing the gut microbiome with health-promoting bacterial strains helps to reduce airway inflammation.[24,73]

COVID-19

The SARS-CoV-2 virus infects the gastrointestinal (Table 1) and respiratory tracts of humans with associated inflamed lungs and colon damage.[18,74] Fecal sampling studies have shown reduced gut microbial diversity, decreased commensal species that maintain intestinal equilibrium and regulate host immunity, increased bacteremia-associated bacteria, and other distinct differences in infected patients compared with healthy individuals.[18,34,75]

Cancer

The role of the gut microbiome in colorectal cancer and gastrointestinal cancer has been documented.[10,41,76-78] Genotoxins secreted by *Escherichia col*i (colibactin) and

Table 1. Microorganisms Associated With Diseases

Diseases	Causative Bacteria or Microorganisms
T2D[12,33]	↓ *Faecalibacteria*, ↓ *Bacteroides*, ↓ *Akkermansia*, ↓ *Bifidobacteria*
Obesity	↓ *Bacteroides*,[23,24] ↓ *Akkermansia*[24]
Atopic Asthma	↓ *Akkermansia*,[24] ↓ *Lachnospira*, ↓ *Faecalibacterium*[24,25]
ASD[24]	Bacteria: ↑ *Corynebacterium*, ↑ *Lactobacilli*, ↑ *Colinsella* Fungus: ↑ *Candida*
COVID-19[34,35]	Bacteria: ↑ *Actinomyces viscosus*, ↑ *Clostridum hathewayi*, ↑ *Bacteroides nordii*, ↑ *Enterococcus*, ↑ *Enterobacteriaceae*, ↓ *Faecalibacterium prausnitzii*, ↓ *Roseburia*, ↓ *Lachnospiraceae*, ↓ *Eubacteria* Fungi: ↑ *Aspergillus flavus*, ↑ *Candida albicans*, ↑ *C. auris*
Depression[36]	↓ *Bifidobacteria*, ↑ *Streptococcus*, ↑ *Klebsiella*
NAFLD[37]	↑ *Enterobacteriaceae*, ↑ *E. coli*,[38] ↓ *F. prausnitzii*
Cancer	↑ *Helicobacter pylori*, ↑ *Fusobacterium nucleatum*, ↑ *Bacteroides* fragilis, ↑ *Shigella flexneri*,[39,40] ↑ *Escherichia coli*[40,41]

↓ Reduced microbial levels; ↑ Increased microbial levels; ASD, autism spectrum disorder; NAFLD, nonalcoholic fatty liver disease; T2D, type 2 diabetes.

Morganella morganii (indolimine) act in distinct ways to damage DNA and cause genomic instability that gives rise to benign and metastatic tumors.[41,77] Pathogenic bacteria (eg, *Fusobacterium nucleatum, Bacteroides fragilis, Shigella flexneri*) inhibit the immune response to tumors and potentially contribute to carcinogenesis.[41,77]

TREATMENT STRATEGIES

The purpose of gut microbiome therapy is to restore the appropriate age-related microbial diversity associated with optimum health (eubiosis).[17,26,79] The gut microbiome can be a target of treatment, or it can serve as a source of biotherapeutics.[80] As clinical biomarkers, microbial signatures associated with symptoms can indicate the effectiveness of personalized treatment, for example in COVID-19 or neurovascular disease.[4,35,81-83] Researchers are looking into ways to modulate the impact of therapies by manipulating the gut microbiota.[10,77] The heterogenous gut microbiota can change the potency of drugs and their subsequent actions by binding and altering their conformation, metabolizing them, modifying liver or mucosal barrier function, or regulating gene expression.[10,77] This section discusses different forms of experimental microbiome therapies. Large-scale clinical studies are necessary to verify their impact on human health. Currently, fecal microbiota transplant (FMT) is the only US Food and Drug Administration (FDA)-approved microbiome therapy for *Clostridioides difficile* colitis infections.[4]

Prebiotics

Prebiotics are fermented, nondigestible food ingredients that are selectively utilized by host microbes and provide health benefits by enhancing the growth of one or more bacteria in the colon (Table 2).[12,18,60,81,84,86] Prebiotics regulate enzymes that modulate xenobiotics, inhibit pathogen growth, and modulate immune responses.[18,81,86] Although preliminary studies reveal positive effects of prebiotics in depression, colorectal cancer, schizophrenia, anxiety, and stress, large randomized controlled studies are required to confirm these positive effects.[12,52,87-90] Prebiotics can be administered directly to the skin and vagina or taken orally to reach the intestines.[18]

Nutrients or Dietary Interventions

Diet plays an important role in shaping gut microbiome composition.[9,17,19,24] In premature infants, breastmilk, human donor milk, and formula impact gut flora and the developing immune system.[91,92] Indigestible dietary fiber and complex carbohydrates (human milk oligosaccharides) are metabolized by commensals in the large intestine to produce short chain fatty acids (SCFAs) that help to prime the immune response and reduce inflammation in the host.[34,93]

Probiotics

Probiotics are defined as "live microorganisms that, when administered in adequate amounts, confer a health benefit to the host" (Table 2).[12,81,94] Their use is still in the experimental stage. Large-scale studies are required to confirm the positive impact of probiotics as treatment.[14,86] Most probiotics are bacteria and yeast.[14,46,86,95,96] Among the panoply of effects, probiotics can prevent colonization by pathogenic bacteria, improve gut microbiome diversity, regulate the immune system, and prevent allergies.[12,17,18,91,97,98]

The FDA and European Food Safety Administration consider live biotherapeutic products, probiotics used to treat specific diseases, as drugs that require stringent regulations before they can be sold in the market.[12] Beneficial effects of probiotics have been observed in diabetes, depression, cancer, ulcerative colitis, autoimmune arthritis, multiple sclerosis, and rotavirus diarrhea.[12,17,18,36,87,91,97-105] In premature infants, probiotics modify gut microbiome diversity that appears to improve host immunity and reduce feeding intolerance as well as mortality.[15,91]

Most probiotics are considered safe as food supplements although patients who are immunocompromised should not use them.[39,86] Probiotics are commonly found as ingredients in fermented products, for example, yogurt, cheese, and fermented soy.[86,94] The efficacy of probiotics depends on the stage of the disease when the probiotic is administered, the dosage, dietary modifications suited to the requirements of the introduced probiotic, the overall health of recipients, and the duration of treatment.[18,24,81] As part of a personalized approach to treatment, identifying the microbial signature of the gut will influence the selection and efficacy of the appropriate probiotic.[24,91]

Synbiotics

Synbiotics are defined as "a mixture comprising live microorganisms and substrate(s) selectively utilized by host microorganisms that confers a health benefit on the host."[94] For example, the prebiotics fructooligosaccharides enhance the growth of probiotic Bifidobacteria, which help to prevent necrotizing enterocolitis, COVID-19, and antibiotic-associated diarrhea.[57,81,106] Probiotics combined with wheat aleurone (dietary fiber) help to reduce the risk of colon cancer by improving intestinal health.[86] Synbiotic treatment has been effective in treating T2D, NAFLD, depression, and irritable bowel syndrome.[81,87,99,107-109] Prebiotics supplement the action of probiotics to inhibit the activity of angiotensin-converting enzyme-2 when they are used together in patients with COVID-19.[106] Combined use of prebiotics and probiotics appears to reduce symptoms of depression and anxiety.[52]

Postbiotics

Postbiotics are "a preparation of inanimate microorganisms and/or their components that confer a health benefit to the host" (Table 2).[21,94] Postbiotics are nontoxic, found in high concentrations, ubiquitous in the human body, stable when introduced into the circulatory system, and can be administered through multiple routes.[13,111,112]

Enterosynes

Enterosynes are diverse molecules that function as bioactive lipids or peptides, microbiota, hormones, immune molecules, and nutrients.[37] Strategies that target enterosynes could potentially treat diseases like T2D.[37]

Phage Therapy

Phages are viruses that infect bacteria.[13] Phage cocktails have been found to be safe for patients.[13] In a recent study, a combination of 5 phages had an immunosuppressive effect on patients with IBD, and in a phase I human clinical trial, phages suppressed Klebsiella pneumoniae, a common pathogenic bacterial strain in IBD.[112,113] Fecal virome transplantation studies have been deferred due to controversies over the safety of phages as therapeutic agents.[12] Large randomized, controlled studies are needed to confirm the impact of these new biomolecular therapies.[12,21,37,114]

FMTs

FMTs improve microbial diversity in a dysbiotic gut.[61,81] In FMT, preprocessed stool in a capsule or in liquid form is transplanted from a healthy donor into the colon of an individual with a disease.[12,17] In addition to microbiota, an FMT contains vitamins, SCFAs, and bile salts.[17] FMT therapy has shown promise in neurological conditions (eg, autism spectrum disorder, Parkinson disease), obesity, gastrointestinal disorders, blood disorders, diabetes, and liver diseases.[4,8,13,17,24,115-124]

In September 2022, the FDA approved FMT to treat *Clostridioides* (old name: *Clostridium*)[12] *difficile* colitis.[4] Additional approved therapies include Vowst, an oral drug containing fecal microbiota spores,[125] and Rebyota, a live microbiota-based FMT.[4,126]

The quality of the donor microbiome is an acknowledged risk of FMT. Donor selection depends on factors, such as the type of birth (caesarean vs vaginal), smoking history, and prior antibiotic exposure.[13,24,81,116] There is a risk, especially in patients who are immune-compromised, of transferring resident pathogens, multidrug-resistant bacteria, or infection via the donor microbiome.[13,24,81,116]

ROLE OF BIOMEDICAL WRITERS IN COMMUNICATING HEALTH INFORMATION

Enthusiasm for gut microbiome research has propelled a flurry of books, articles, and videos on the medicinal properties of foods, diets, and food-related therapies.[2,55,127] However, the promise (beneficial effects) and peril (harmful effects) of manipulating the gut microbiome have often been exaggerated and misinterpreted (Table 3).[16,127-130]

The social media landscape is a vast, fertile ground for the dissemination of information.[3] YouTube and TikTok are some of the sites where videos generate interest and find viewership. Many advocate home remedies while quoting purported beneficial effects of the bacterial constituents on our health. These benefits are claimed to be based on data from research studies.[16,129,130] Amid all the hype, it is necessary to approach gut microbiome-linked health information with caution (Table 3).[2,130] Social influencers and celebrities seek to promote gut microbiome-inspired therapies as part of the wellness industry.[3] Unfortunately, government

Table 2. Examples of Prebiotics, Probiotics, and Postbiotics[13,15,18,84,85,86]

Microbe-Associated Potential Therapies	Source	Examples
Prebiotics	Vegetables (eg, broccoli, onions), grains (wheat), fruits, nuts, or as purified dietary supplements.	Psyllium, oligosaccharides, fructooligosaccharides (eg, banana, chicory root, asparagus, garlic), human milk oligosaccharides, lactosucrose, xylooligosacharides, polyphenols, galactooligosaccharide, mannan oligosaccharide, resistant starch, polyunsaturated fatty acids, arabinooligosaccharides, dietary fibers.
Probiotics	Microbes in fermented foods (eg, kefir, yogurt), also available as nasal sprays or oral supplements.	*Lactobacillus rhamnosus*, *L. helveticus*, *L. casei*, *L. acidophilus*, *Streptococcus thermophilus*, *Lactococcus lactis*, *Enterococcus fecalis*, *L. bulgaricus*, *L. paracasei*, *L. plantarum*, *Bifidobacteria longum*, *B. bifidum*, *Bacillus coagulans*, *Faecalibacterium prausnitzii*, *Akkermansia muciniphila*, *Lactobacilli reuteri*, *L. brevis*, *B. breve*, *Bacteroides fragilis*, and *L. gasseri*.
Postbiotics	Nonviable microbial cells or cell fragments.	Cell byproducts (SCFAs), TMAO, cell components (eg, proteins, endo- and exopolysaccharides), enzymes, microbe-targeted toxins, bile acids, acetic acid, tryptophan, lactic acid, vitamins, peptidoglycans.

SCFAs, short chain fatty acids; TMAO, trimethylamine oxide.

Table 3. Recommendations for Responsible Dissemination of Gut Microbiome Research

Current Trends in Dissemination of Gut Microbiome Research	Suggestions for Medical Writers for Responsible Dissemination of Gut Microbiome Research
The lay public has limited awareness of the role played by the gut microbiome in gut health within the human body framework.[2,9]	The concept of the gut microbiome should be presented as a unique ecosystem of microbial communities that is indelibly interwoven within the cellular organization of each individual and evolves from the combined influence of the environment, diet, medications, social determinants, and industrialization.[9,12]
Disease results from a disruption in the biochemical network within an organ system. Research now indicates that diseases occur when associations between biochemical networks of different organ systems including the gut are disrupted.[9]	Association data should be interpreted to show that there is a complex interactome at work in a disease.[9] The biochemical network of the gut microbiome should also be considered as affected during disease along with the biochemical network of the affected organ.[9]
Microbiome hype is mediated by popular health articles and social media, including YouTube videos by celebrities with promises of instant cures from diseases.[1,3,16]	Plain language patient education materials and videos by trusted sources, such as scientists and health professionals, could help to educate the public on the advantages and disadvantages of manipulating the gut microbiome, thus preventing the spread of misinformation.[2,3]
The representation of the gut microbiome in the public domain involves opposing concepts. For example, personalized nutrition companies confidently project gut microbiome therapies as a panacea for good health. In contrast, they provide disclaimers that the results obtained using their personalized nutrition technology should not be considered in place of a medical expert's opinion.[5]	Companies should explain the effects of the gut microbiome on human health to enable the consumer to make an informed decision on accessing personalized gut microbiome treatment for a given disease.[5]

websites or research articles are dense in information and are not reader-friendly for the lay public.[2] The lay public is not inclined to absorb information from these resources, especially when social media provides this information in attractive formats.[2,3] Medical writers, in their role as educators, should understand the current information landscape and utilize popular channels of public information to communicate effective and credible information to the lay public.[3]

It is the responsibility of science writers, medical communicators, and health experts to interpret and disseminate evidence-based factual information about popular health trends, such as the use of pro-, pre-, or postbiotics so that the public can make educated decisions regarding their use.[2,3] In this way, medical writers, health writers, and communicators can influence the discourse of scientific information in the public domain.[2,3] The lay public, in turn, will learn to recognize and trust the information from reliable science communicators and websites.[2,3] This will improve the influence of credible science in the public domain.

CONCLUSION

Microbial signatures could serve as personalized biomarkers to distinguish a healthy individual from someone with a disease.[12,59,82,83] And yet, there has been limited success in treating diseases on the basis of this core belief. This does not diminish the value and importance of the gut microbiome. On the contrary, research has revealed that the gut microbiome is one of many players in the complex interconnected biological network (interactome) within the human body.[19,131] Similarly, we can foresee a future of personalized treatment in which disease is always assessed simultaneously by a cohort of physicians specialized in fields related to the interactome that includes the gut microbiome. When data from large randomized controlled studies are positive and consistent on the benefits of the gut microbiome as treatment, then the lay public can utilize this information with confidence. Science writers, medical communicators, and health experts have a responsibility toward the public in interpreting and disseminating vital information on the impact of the gut microbiome on human health and well-being.

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CREATIVE WRITING

Harmonies of Justice: Reflections on Virtue and Equality

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Justice, in Aristotle's words profound,
Should honor virtue, merit, and moral ground.
To give each person what they truly deserve,
The essence of justice in things we preserve.

For equals, equal shares should be assigned,
But what defines equality in kind?
On the goods we distribute, we must reflect,
In allocating flutes, who should we select?

The merit for flutes lies with the best player,
Aristotle affirms, and we concur there.
Discrimination in justice finds its place,
Yet relevance to excellence we must embrace.

To allocate flutes based on color's shame,
Would be unjust, a travesty to claim.
Birth and beauty may outshine flute's sweet sound,
But to the best player the flute should be crowned.

The search for the best flute player, we must shift,
To seek the best musicians, that's the gift.
For flutes are meant to be played with great skill,
To offer music that hearts and souls fulfill.

As a Black man, my skin's not my own choice,
Yet I'm punished for it, confronting biased voices,
Philosophically pondering this plight,
Prejudice's weight casts a somber light.

Amidst this sea of bias, I stand tall,
Against racism's tides, I hear the call.
To challenge injustice with swift resolve,
In poetic waves, our stories evolve.

In hospitals and schools, the echoes sound,
Where doctors of color are rarely found.
Patients suffer, lacking care they require,
Their voices silenced, their pain not heard higher.

Enslavement's scars remain, clear and deep,
Injustice haunts students, robbing their sleep.
In halls of white, their struggles concealed,
Their pain and hopes, often unconcealed.

A world we yearn for, where diversity thrives,
Where healthcare's fairness is true in our lives.
A place where bias and neglect are banned,
And equitable care is given a hand.

Diverse voices, united we shall be,
Revolutionizing a system we see,
Where patients and doctors blend as one,
Healthcare's victory, for all, shall be won.

So let us heed their cry, feel their pain,
Stand with people of color, their strife disdain.
Together, we'll forge a path toward change,
In a world where medicine's fair, not strange.

Diversity's embrace shall illuminate,
Our healthcare system, no longer to frustrate.
With doctors and patients as partners aligned,
A world where health for all is truly enshrined.

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FREELANCE FOCUS

Nourish Your Niche: The Rewards and Risks of Specialized Medical Writing

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What is a niche? What are the rewards and risks of nourishing a niche? How do you find a niche? As freelance medical writers, or writers considering freelance work as an option, we have to ask ourselves what kind of medical writing we are going to do. Are we going to offer a broad mix of services or tap a specialty niche? This article will help you weigh the pros and cons of whether to specialize as a freelance medical writer and how you can get started.

FROM GENERALIST ROOTS TO SPECIALIST BRANCHES

At the beginning of a freelance medical writing journey, it's common for writers to take on different types of work and to work for different types of clients. I did this too. In the early years of my freelance medical writing journey, I edited, wrote, researched, and synthesized information for a range of deliverables, including white papers, reports, needs assessments, slide decks, monographs, manuscripts, book chapters, and more. My clients included nonprofit organizations in public health, startups in biotech, providers in continuing medical education/continuing education for health professionals (CME/CE), academics, and individuals who contracted me via guru.com.

Taking on a broad spectrum of work in the early days of freelancing often stems from uncertainty about how and where to start. So we start anywhere. This is no bad thing in my book. By casting your net widely, you'll find what fits your interests and your preferred style of writing. You'll learn which clients and medical writing sectors align with your values and the life you want to lead. You will develop a broad knowledge and skill base as well as flexibility to respond to different situations.

Yet there's a tradeoff in confidence and competence from being a generalist. Each fresh project or new client can unleash a cascade of anxieties about whether we're up to the task and potentially leads us down seemingly endless research and pre-writing rabbit holes. At some point, we begin to harbor a sneaking suspicion that we have spread ourselves thinly across therapeutic areas, specialties, and project types. To switch metaphors here, we can end up feeling less like fisherfolk (casting the net, remember?) and more like goldfish, darting around trying to find bites here and there for our business. Frustration, overwhelm, inconsistent revenue, and cognitive overload ensue.

NICHE BENEFITS

In contrast, nourishing a niche (or two) is a way to funnel your energy and target your resources to ensure sustainable revenue for your business. A niche is simply a specialized segment or service offering within the broader field of medical writing. A niche can be directed toward serving particular client or project types, therapeutic areas, disease states, and more. Niches are not carved in stone and evolve over time. Over the last 2 decades I have personally cultivated niches in developing white papers and education outcomes manuscripts (project-based), working with medical specialty societies (client-based), and conducting qualitative evaluations of CME/CE programs (skill-based). Here are some specific advantages of nourishing a niche.

Crack the Client Mindset Code

Clients often say they prefer to work with specialists. They believe that writers with a greater understanding of a disease state, therapeutic area, or deliverable type means they will already know what to focus on for a given project. In my generalist phase of freelance writing, prospects that did not convert to clients often told me that they needed writers with deep knowledge of a subspecialty area. Similarly, clients who contact me now for CME/CE specialist writer recommendations tell me they prefer to work with writers who can use their deep knowledge to quickly distill what is important in a new clinical study, provide appropriate context, and succinctly summarize a topic in bullets for a slide deck or in concise sentences for a narrative. Client mindset about the value of specialists versus generalists can be a redoubtable rockface to scale. Nourishing a specialist niche is an efficient way to climb with ease.

Streamline Your Client Acquisition

A well-nourished niche provides a solid platform to help you nurture repeat business. When you establish clients that already know, like, and trust you and your work, they are more likely to offer not only repeat work but also pull you into projects that stretch you. A 2019 American Medical

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Writers Association (AMWA) survey showed that 60% of freelance writers (105 of 175) reported that repeat business accounted for more than 75% of their work.[1] This has been my experience too. For instance, I started writing education content for a national membership organization in oncology in 2015 and knew they were developing quality improvement initiatives with a qualitative outcomes component. Qualitative research and analysis is a skill-based niche for me, and so I gently pitched my services in this area. The client hired me 2 years later to run focus groups and conduct member interviews for end-of-year reports and other deliverables. Same client, different service, no hustle.

Build Your Authority

When you develop a niche, you will also deepen your knowledge and skills. Your subject matter expertise and familiarity with terminology, audience, or deliverables will make it easier to establish credibility with prospects and clients and enhance demand for you as the "go-to" writer in your selected niche. Word of mouth will work in your favor, and your reputation will lead you to better clients, more substantial projects, and repeat business.

Generate Higher Revenue

Your specialized skills and niche concentration increase your ability to generate more revenue for your business. Specialists generally command higher compensation than generalists. This point can be tricky to substantiate because of limited data. However, anecdotal commentary suggests that when generalist medical writers niche down, their revenue grows considerably.[2] The 2019 AMWA Medical Communication Compensation survey also suggests that the greatest percentage of income for freelance writers comes from working in some type of niche (eg, regulatory, continuing education).[3] As a niche specialist, you will also indirectly generate higher revenue. You will spend less time on research and pre-work for any given project, and it will also be easier for you to stay updated in your specific niche.

Optimize Your Marketing

Nourishing a niche is the secret sauce that helps you market your services. When you know your niche, you are better equipped to identify and target prospects in language and contexts that resonate with their needs. As marketers say, when you talk to everybody, you talk to nobody. So when you are clear about your niche, your marketing will be crystalline and more consistent.

Selectivity

Nourishing a niche means building awareness about what matters to you in your work and life so that you can be selective about client, projects, and experiences. When we are not selective, we are reactive and not fully present in our business and work. When you are selective, you can give more of yourself to each moment, conserve your cognitive energy, and show up for the people and projects that bring you joy, satisfaction, and revenue.

THE FLIP SIDE OF NOURISHING A NICHE

Generalist medical writers often say they thrive on client, project, and deliverable diversity and assume that a niche will narrow their client pool, potential for professional growth, and content scope. It is true that when you nourish a niche, you are definitely saying no to a broad, undefined pool of potential clients. You will always see appealing opportunities that make you feel as though you are missing out. Nourishing a niche can lead to content repetition or to projects that lack variety and bore you. If your niche is well established, over time, you could hit a rate ceiling. Your skills could stagnate, and it could prove challenging to move out of your niche. Your niche will also be subject to the vagaries of market demand and could even become obsolete.

However, when you say yes to every project under the sun and you follow your interest to take on projects that whet your appetite or tickle your fancy, in the short term your appetite will be whet and your fancy will be tickled. In the longer term, you'll end up feeling scattered, frazzled, unanchored, and exhausted. My guess is that you'll also be undercharging and your bank account will suffer.

HOW TO FIND A NOURISHING NICHE

You do not have to scramble to find a niche that works for you. Rather, niches are refined out of your existing skills, talents, and interests. Chances are you are already working in a specialized area, like consumer health or patient education. Perhaps particular deliverables form a core component of your revenue. So start from where you are, what you enjoy, and what generates revenue for your business. Remember that success doesn't come from pursuing every opportunity. It comes from intentional focus on opportunities that align with your skills, energy, and values. In the end, a niche does not have to be narrow. It just has to be focused.

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TECHNOLOGY TALK

Generative AI in Clinical Research: Regulatory Submissions, Clinical Data Management, and Beyond

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ABSTRACT

Artificial intelligence and its subsets, such as generative artificial intelligence, have been making headlines due to their potential to accelerate the growth and expansion of various industries, including healthcare. However, the majority of application areas in healthcare revolve around diagnosing diseases, finding lead molecules for potential treatments, optimizing hospital operations, and other related aspects. This means that there are areas where the potential of these technologies is still to be realized. Examples of where such technologies could produce a significant impact across multiple elements are clinical research and its related domains, including regulatory submissions, clinical data management, clinical documentation, and other closely related areas. When artificial intelligence and its related technologies are utilized in these areas, they yield unparalleled outcomes regarding efficiency, consistency, and reproducibility. This, in turn, supports professionals involved in clinical research, like medical writers, statistical programmers, and other stakeholders, to drastically improve the speed by which they produce the initial drafts of various outputs, reduce the risk of errors that could lead to submission rejection, and optimize the overall clinical research workflow. Despite the potential of this area, the number of available solutions that support the aforementioned domains remains low. This is further complicated by the fact that there are even fewer numbers of working solutions.

The release of the generative pre-trained transformer 3 (GPT-3) language model in 2020, and more recently, the chatbot ChatGPT, have sparked considerable interest in the potential applications of artificial intelligence (AI) in various fields, including health care.[1,2] Despite the vast uses of AI in this area,[1,3] its potential in automating regulatory submissions, such as those submitted to the Food and Drug Administration (FDA), remains underrepresented. Other growth areas in which generative AI and its related technologies could provide significant value include clinical data collection, management, analysis, postmarketing surveillance, pharmacovigilance reporting, and other areas.

Automating regulatory submissions, such as clinical study reports (CSRs), which are part of the electronic common technical document (eCTD), is challenging because large clinical studies generally yield incredibly complex and copious amounts of data points around participants. This is where the current GPT-3 and -4 technologies fail because they were not designed nor optimized to understand this specific activity and how those particular data sets relate to each other. Moreover, they are not clinically trained; they are prone to errors and hallucinations, negatively impacting their validity. Indeed, such challenges are evident in complex therapeutic areas, like oncology and studies with a higher number of subjects.

For example, patient narratives,[4] a key component of CSRs, examine serious adverse events that are fatal, life-threatening, or of special interest, among others. Usually, medical writers (MWs) could spend days preparing drafts of a few patient narratives because these narratives could be tens of pages long in treatments that address rare or difficult-to-treat conditions. This would require additional effort in studies with a higher number of participants. Before getting to the writing step, statistical programmers and other stakeholders involved in clinical research are required to prepare the files that MWs will use. This job could take weeks or even months of work and is prone to human errors due to the vast sizes of the data sets that need to be handled.

With the use of AI, the first step to preparing the initial draft of patient narratives requires establishing relationships between the proper data points within complete databases. Only then may the creation of narratives incorporating all the aforementioned types of adverse events be automated using natural language processing (NLP) and natural language generation (NLG) models. NLP and NLG are subsets of AI, and when combined with a well-structured data modeling technique, they work not just to process the data, but to also highlight interdata relationships and highlight key components within the data that afford higher accuracy for the narratives. This approach may save MWs hundreds (or even thousands) of hours and cut submission cycle durations significantly.

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It is important to note that the use of AI and its related technologies, such as NLP and NLG, in automating regulatory submissions like CSRs is meant to augment the potential of MWs by helping them reduce the time spans needed to create initial drafts and modify them in a much shorter time frame. Otherwise, MWs would spend a significant amount of time preparing the drafts and updating their content upon request from the sponsor.

In addition to generative AI potential in CSR authoring, other automation tools have also shown significant value in accelerating regulatory submissions. For example, automating Tables, Listings, and Figures (TLFs), which are documents created by statistical programmers and other stakeholders and are used by MWs to populate CSRs, have proven to be of significant value to MWs and programmers alike. TLF automation reduces the time needed to author CSRs and improves the quality assurance process by flagging potential errors, inconsistencies, or missing data in the databases used. By automating TLFs, documents submitted to the FDA will inherently have higher data quality and be devoid of errors, resulting not only in faster approval times but also significantly lessen the chances of rejections due to errors.

When viewed from the perspective of time and quality, adopting AI in creating, validating, authoring, and submitting regulatory documents decreases the man-hours spent across the spectrum of these processes by at least several months or more. The quality of the submitted documents is also much improved. Ultimately, this translates into cost and time savings. In addition, it would increase the availability of personnel resources, such as MWs, statistical programmers, and other stakeholders involved in creating eCTDs, freeing them up to attend to more critical processes that require substantial human input.

Currently, there are only a handful of AI-driven regulatory automation solution providers. Those with actual working and proven solutions are even less common. Notwithstanding, organizations that have managed to perfect CSR automation have witnessed increased demand for services from parties involved in clinical research.

The potential of generative AI and related technologies extends beyond the realm of regulatory submissions. For instance, in clinical research—more specifically clinical trial data collection, management, and analysis—the use of AI can potentially flag inconsistencies related to the same entry across multiple databases. For example, recorded information concerning adverse events in a patient is captured in both the safety and efficacy databases. Although the former mostly holds serious adverse events, the efficacy repository contains both serious and nonserious adverse events, plus more. The use of two separate databases has been shown to cause inconsistencies in entries due to human error. This could negatively affect the evaluation of the safety and efficacy of a biopharmaceutical or medical device product. Another example of a challenge in which generative AI and related technologies can help is one in which case report forms do not have cross-form consistency. For instance, the concomitant medication used to treat an adverse event could be written manually, making it liable to typos, nonstandard abbreviations, or include terms that are not necessarily aligned with those in the Medical Dictionary for Regulatory Activities. Moreover, dates entered in the "date" field might appear like actual dates, but there are no time-consistency checks, leading to the loss of the cause–effect link. When implemented, AI could flag such inconsistencies in entries, helping stakeholders correct these errors beforehand. In this area, the use of AI not only ensures consistency but also upholds quality because the human eye could easily miss such errors due to the sheer size of the databases.

Automation of data analysis with AI could offer significant value across other areas in clinical research conduct and reporting. In postmarketing surveillance, the use of AI could help scan, collect, and organize safety signals from various sources like clinical studies, adverse event reporting forms, scientific literature, and other sources. Additionally, generative AI and related technologies could help automate pharmacovigilance efforts by identifying and tracking safety trends and generating reports that revolve around those safety signals. Similarly, the same technology could be utilized in cross-reporting, allowing standardization, efficient data collection, analysis, and reporting.

In conclusion, the use of AI in regulatory submissions, cross-reporting, and the other aforementioned areas is still marginal, even in the literature. Nevertheless, pharmaceutical companies, clinical research organizations, and other stakeholders could gain substantial advantages through AI adoption—most notably with regard to time saved. This ultimately allows for the introduction of life-saving treatments sooner than would otherwise transpire.

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TOPICAL FEATURE

Using Innovative Tools and Lean Writing Workflow Processes to Accelerate Regulatory Document Writing*

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ABSTRACT

Lean writing workflow processes can streamline development of complex documents, including protocols and other regulatory submissions.

This paper outlines standard development timelines and describes useful lean writing workflow methods and tools to reduce protocol development timelines without sacrificing document quality.

We present the results of a survey completed by 75 Medical writers (MW) that reveal the strategies used during document preparation and use real case scenarios (protocol development) that illustrate how innovative tools and approaches can be efficiently used to create a lean writing workflow process.

Software tools (e.g., proofreading assistance, citation manager, collaborative authoring and reviewing) were widely accepted and used during protocol development according to the MWs surveyed. Most of the surveyed writers (62%) hypothesized a reduction in production time by about 25%. Efficient collaborative work across different time zones had a marked impact on shortening timelines while maintaining production of high-quality documents.

Real case scenarios were used to illustrate how innovative tools and approaches can positively impact timelines and efficiently create a lean writing workflow process regardless of therapeutic area.

The real case scenarios showed that protocol development time can be decreased by about 26% without compromising the quality of the document. This shows that software tools, templates, checklists, and collaborative writing were more impactful than hypothesized by the MWs included in the survey.

With clear workflow processes, roles, and responsibilities backed by innovative software applications, template guidelines, and collaborative work processes, MWs can overcome common development challenges and improve their lean regulatory writing skills.

Aspects of this work were disclosed as a poster presentation at the 2022 AMWA annual conference in Denver, CO, November 3-6.

INTRODUCTION

Every clinical investigation begins with the development of a clinical study protocol, which conveys the design and methods for conducting a clinical study. Protocols are written by a multidisciplinary team that normally includes a medical and clinical pharmacology expert, a statistician, a pharmacokinetics expert, regulatory consultants, a study manager, a project manager, and a MW. It is the role of the MW to coordinate the input of all involved experts to compile the protocol.[1,2]

MWs routinely face accelerated timelines to complete drafts, and realistic schedules are often a luxury. Lack of coordination among team members or any lag during document development could lead to a cascade of events potentially resulting in study delay. Therefore, sufficient time needs to be invested in the development of the protocol to account for multiple reviews, edits, and adjustments after reviews. To produce a document that is clear and concise with a well-organized message, a lean writing process that emphasizes timeliness and quality is beneficial.[3] When sufficient time for completing writing processes, particularly lean writing, is not allotted, protocol development is likely to become excessively long. This is because truncated initial timelines require more extensive editing and/or review. Similarly, protocol content could be repetitive, verbose, ambiguous, inconsistent, and riddled with errors, negatively affecting protocol quality.

Given that writing and reviewing compete for time, how can MWs use tools that support both practical timelines and high document quality standards? What can be done to ensure that the time writers spend on protocols is more focused on the quality of the content than on the search for errors and common mistakes?

Here we describe useful lean writing workflow processes and innovative software tools to reduce protocol development timelines without sacrificing document quality.

STANDARD TIMELINES

To effectively manage and coordinate the multidisciplinary

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team involved in preparing a protocol, clear descriptions of the roles and functions of each team member are vital. These descriptions are crucial not only so that each team member understands the contribution required of them but also to determine the amount of time necessary to complete their contribution to the protocol effectively. Along with the multidisciplinary team that contributes to the content of the protocol work, the editorial and regulatory publishing teams manage the redactional quality of the final document. Defining a standard, full process timeline streamlines every part of the process: from synopsis preparation to study design; from assessment planning to text, table and figure quality; from the science to published document, a standard timeline guarantees fewer process conflicts (Figure 1).

Standard full-process timelines have evolved over time, with each step further refined by the collective experiences of colleagues across diverse departments and functions. Standard timelines have built-in flexibility to account for variable workloads as each team member may simultaneously work on multiple projects. Each step of the protocol development is divided into rounds. Each step can be fulfilled in the allotted time depending on individual workload. In general, development proceeds from drafting to review and/or quality control (QC) and then to drafting again, where review comments can be addressed. As mentioned above, standard timelines may require additional flexibility; for example, an ad hoc meeting may be necessary to address any unresolved issues. The drafting step ends with the approval of the protocol, which is followed by the publishing of the common technical document (CTD) in a format consistent with the regulatory submissions (e.g., the ICH CTD format).[4]

Standard ICON protocol development timelines include 10 to 15 days to prepare the synopsis, 47 days for the body of the protocol, and 3 days for the publishing of the CTD-ready document (Figure 2). Synopsis preparation may not always be required, as the client may have prepared the synopsis during conceptual development of the study. Additionally, the client may prefer to publish the protocol using an alternative publishing service. In these cases, our standard timeline would only include the 47-day protocol preparation. The addition of a synopsis and publishing would not change the protocol development process, only the timeline.

In this report, we only discuss the preparation of the protocol and compare our standard timelines with case studies in which we have successfully accelerated protocol writing timelines using the innovative tools described below.

Figure 1. Document preparation process, an outline. QC=Quality control.

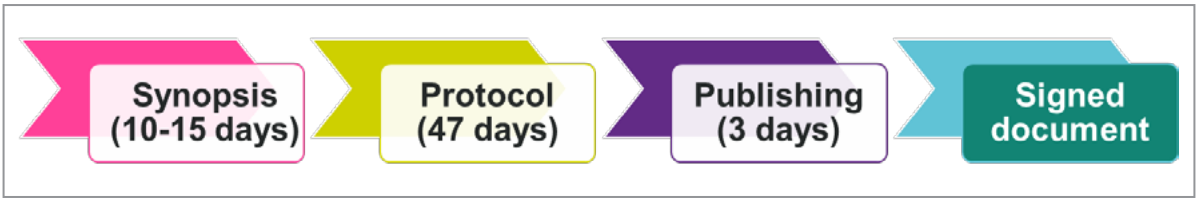

Figure 2. Standard protocol development timelines.

We also present the results of a survey completed by 75 MWs that reveal the strategies used during document preparation that illustrate how innovative tools and approaches can be efficiently used to create a lean writing workflow process.

THE SURVEY

A 10-question online survey was designed to understand which timeline-saving tools and approaches are most used by MWs. The survey was administered to 75 writers both internal (54) and external (21) to ICON. Of those who completed the survey, 41% were early phase MWs, 37% were late phase MWs, and 21% were MWs specialized in other areas (ie., manuscript writing).

The majority of MWs surveyed said they required 5 to 7 weeks (49%) or more than 7 weeks (35%) to develop a protocol, including draft preparation, review cycles, administrative tasks, and finalization. For each review cycle, 51% of MWs claimed they allocated an average of 3 to 4 days, while 46% required 5 days or more (Figure 3). Only a small percentage (3%) required 1 to 2 days.

To meet aggressive timelines, 50% of MWs have worked collaboratively across time zones to develop a protocol and believed that the approach had a positive impact on reduction of development timelines. The key factors for a successful collaborative approach as selected by the writers were: continuous work around the clock, parallel and continuous QC of the work, and a good relationship among the authors (Figure 4). When writers were asked about the factors that could negatively impact collaborative writing, the responses indicated that lack of communication, conflicting opinions, and lack of flexibility were the primary factors.

Software tools are widely accepted by MWs. Most of the surveyed writers at ICON use PerfectIt (91%), EndNote or another reference management software (49%), and PleaseReview (53%) during protocol development. Whereas outside ICON, EndNote is the preferred tool (63%), followed by other software and PleaseReview (37% each), and PerfectIt (16%). These differences likely reflect the different company preferences. Of the MWs who leverage one or more of these tools, 45% believe an application such as PleaseReview is a more helpful tool than the others surveyed for protocol development and reduction of timelines (ICON 52% [50 MW] and outside ICON 29% [21 MW]) (Figure 5). This is likely because when used within a lean workflow process, PleaseReview directly addresses 2 of the

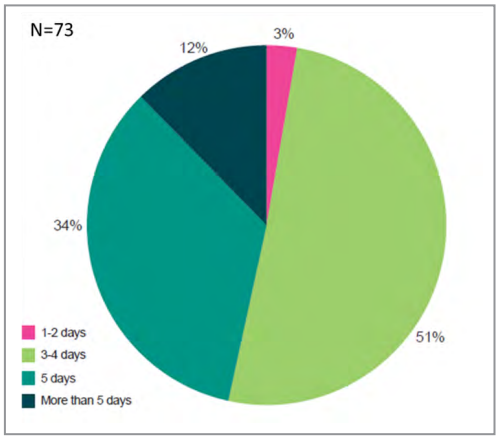

Figure 3. Survey question: On average, how many review days are included in your timelines for each review cycle? Answered, N=73; Skipped, N=2.

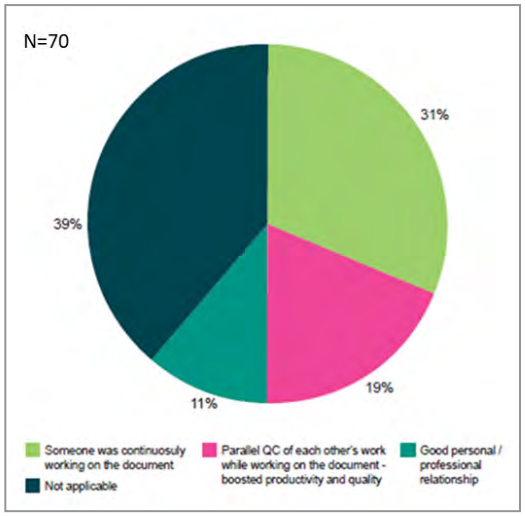

Figure 4. Survey question: If collaborative work positively impacted your timelines, please select the most important factor contributing to timeline reduction. Answered, N=70; Skipped, N=5.

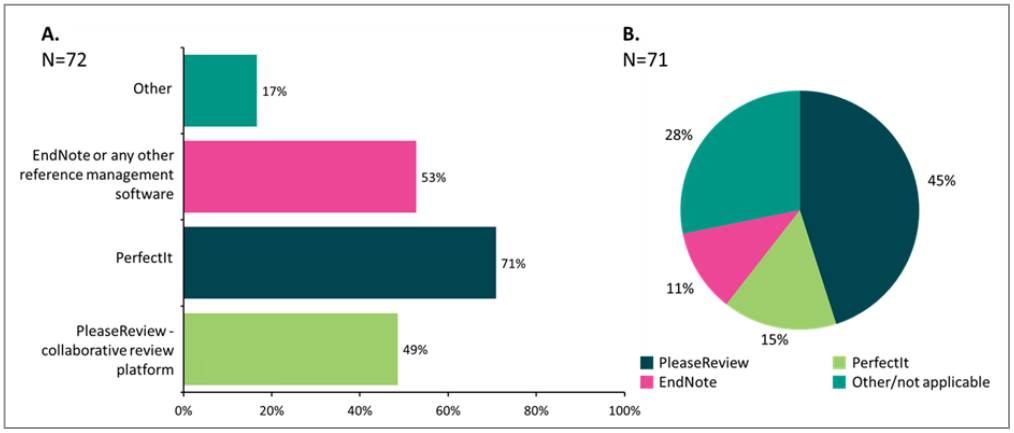

Figure 5. Survey questions:
A. Do you use any of the following tools for protocol development? Answered, N=72; Skipped, N=3.
B. Which of the following tools do you consider more helpful for protocol development and reduction of timelines? Answered, N=71; Skipped, N=4.

negative factors identified by MWs: conflicting opinions and communication.

According to the surveyed writers, when taken together, these tools can help to reduce up to 35% of the time required for development of a protocol (Figure 6). The different software tools can efficiently identify grammar, style, and content errors; save time by automating citation updates; and provide a mechanism for simultaneous review and consolidation of reviewer comments.

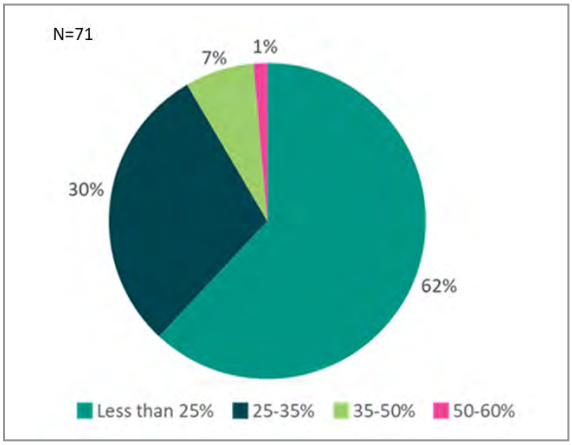

Figure 6. Survey question: On average, how much time can these tools save? Answered, N=71; Skipped, N=4.

REAL CASE SCENARIOS

In ICON's day-to-day practice, the medical writing team regularly responds to sponsors' requests to compress standard timelines and deliver high-quality protocols sooner. We use the tools, templates, and checklists described above and work collaboratively across geographically dispersed teams to expedite development. To demonstrate how these tools and a collaborative approach can positively impact protocol development, we analyzed the results of five real case medical writing scenarios to compare our writing process across standard and reduced timelines with a heterogenous group of MWs. All scenarios were Phase 1 study protocols of varying study designs: 2 drug-drug interaction studies; 2 single-ascending/multiple-ascending dose studies; 1 food-effect study, and all were of moderate complexity. A collaborative writing approach was used in all the studies. The writers involved in these scenarios had 5 or more years of experience and used 1 or more of the previously described tools.

Our real case scenarios showed that protocol development timelines can be decreased by about 26% without compromising the quality of the document (Figure 7). This shows that software tools, templates, checklists, and collaborative writing were more impactful than hypothesized by the MWs included in the survey. Most of the surveyed writers (62%) hypothesized a reduction in production time by 25% or less; meanwhile, our real case scenarios show a 26% decrease.

MASTERING THE TOOLS FOR LEAN WORKFLOWS

As the number of content contributors on a team increases, so does the potential for inconsistencies and errors, which in turn affects the efficiency of the document review and the overall project schedule. Document review and QC checks can take hours, days or even weeks to complete depending on the complexity and quality of the document. Such checks are typically the most expensive and time-consuming part of the protocol development process. Employing lean writing

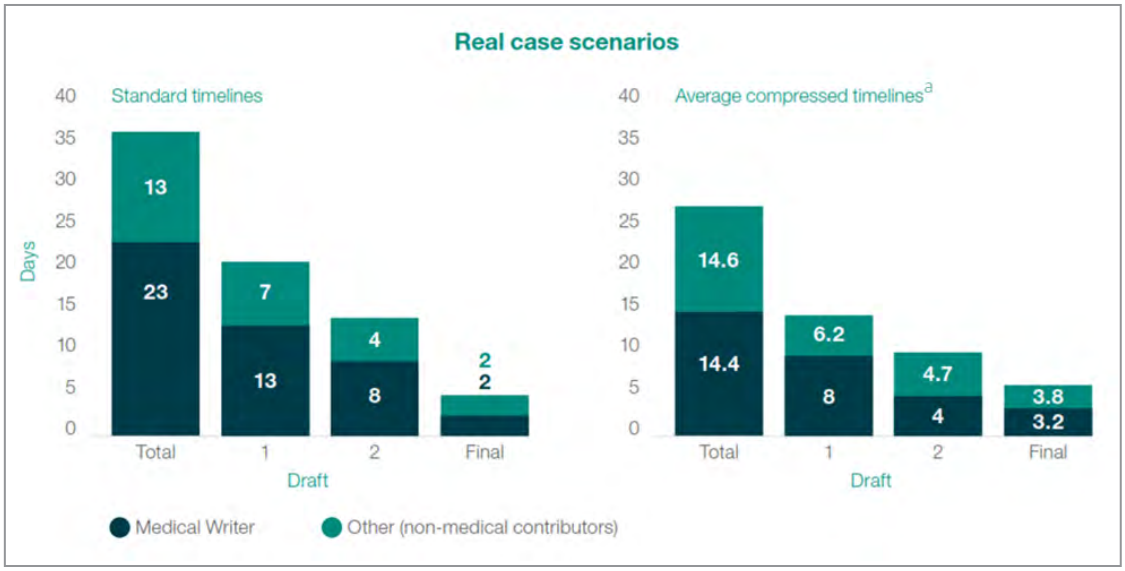

Figure 7. Time required to prepare a protocol under standard and reduced timelines. [a]*Average of 5 reduced timelines was 26.5 days (range 18, 33 days).*

workflow processes and innovative software applications can mitigate potential time loss in the document review process without sacrificing document quality.

A variety of software tools are available to help medical writers[5] streamline the review process, and we will explore the benefits of a few popular tools below. Our study is not intended to promote any software but to highlight the importance of the tools themselves. There are several programs on the market that offer the same or similar tools to the ones referenced in this paper. The programs we mention in our study and survey are simply the software we use at ICON.

The findings of our study may largely pertain to the software applications and tools used by those MWs in the survey and in the case scenarios and may not generalize to other tools or software applications available on the market.

ASSISTED PROOFREADING

As previously mentioned, the more writers and reviewers involved in the development process, the more likely it is that inconsistencies in style appear along with repetition, verbosity, and data and grammar errors. To reduce these errors and optimize our specialists' time, we utilize PerfectIt™, a Microsoft Word add-in, as a proofreading application to manage some of the most tedious and time-consuming editing. It catches inconsistencies in hyphenation and numbers, checks punctuation and capitalization, automatically corrects double spaces, removes spaces after paragraphs and cuts spaces before punctuation. It is particularly helpful with abbreviations, as it ensures that every abbreviation is defined only once at its first presentation.

PerfectIt has saved time in hunting for typographical and grammatical errors and style inconsistencies, resulting in a higher-quality draft and reduced overall QC time.

AUTOMATED REFERENCE MANAGEMENT

MWs often work on large, unwieldy documents with large numbers of references which can be lost, moved, or unlinked from the document body. Style inconsistencies may also be introduced as the document evolves and multiple contributors add on sections.

The citation managing application EndNote™ and its Microsoft Word add-in is used to manage citations of published works and source documents. With EndNote, writers can insert in-text citations while the program automatically organizes references in a bibliography in the preferred style and also updates and crosslinks citations with references throughout document drafting. In EndNote, it is also possible to save bibliographies and literature in libraries that are easily searched and updated. Additionally, EndNote can save references from the major online scientific databases, such as PubMed or Google Scholar. Like PerfectIt, EndNote comes with default styles and customization options.

EndNote saved time by reducing the MWs referencing workload, including tracking and formatting citations throughout large documents. It has a robust citation library sharing capacity and integrated and up to date referencing to facilitate collaboration.

Box. Software Tools for Medical Writers

PerfectIt
https://intelligentediting.com

EndNote
https://endnote.com

PleaseReview
https://www.ideagen.com/products/pleasereview

STREAMLINED REVIEWING

A multiplicity of authors and reviewers can produce high-quality content, but it can also pose challenges in the review cycle. Reviewers may have conflicting comments and consolidating comments across multiple documents and controlling which edits are made is quite time-consuming.

To facilitate the collaborative review of documents, we use PleaseReview™, an online platform designed for co authoring, reviewing and consolidating comments. It allows teams to achieve faster turn-around times and meet tight deadlines for collaborative document development. Reviewers can review simultaneously, see each other's comments (single interface for all reviewers), and engage in discussion, facilitating comment mitigation.

Additionally, the entire review process is saved in an audit-ready review log. PleaseReview works directly with Microsoft Word, Excel, and PowerPoint documents, PDFs, images, and plain text files. Authorized persons can easily download the reviews and original documents, and the comments and proposed changes can be found in the Word file in tracked-changes.

Authors and reviewers can effectively collaborate and review in real time such that comments can be readily addressed. The author has full control over the proposed edits, and simultaneous review by many authors comes with no risk of losing any of the content, as changes and comments cannot be lost or overwritten by other reviewers. PleaseReview also gives a holistic overview of the process, which includes the review status for each reviewer, reconciliation reports, summaries of all comments and actions taken by the participants.

KNOWING YOUR TEMPLATE

It is the responsibility of the writing team at ICON to find an adequate protocol template to use as a basis for development. There exist several template options such as the TransCelerate common protocol template and National Institute of Health template, which incorporate feedback from multiple industry stakeholders.

Templates may vary depending on the foreseen study design, study population, and/or therapeutic area. A template usually contains already-approved regulatory language, standard laboratory assessments, inclusion and exclusion criteria, a study diagram, and schedule(s) of assessments. Sections are prefilled with the most common and routine assessments and language.

The need for a standardized template has been recognized by the ICH, and one is currently being developed. Most recently, ICH M11 promises similar efficiencies in protocol review and approval to those gained when regulatory approval applications were standardized by the eCTD template within ICH M4.[4]

To save time, it is recommended to develop standard templates that follow the regulatory guidelines. Also, a protocol checklist can be employed to reduce content errors across sections.

This checklist serves as a helpful tip sheet for MWs and peer reviewers working on early clinical protocols. The checklist can help ensure consistency in content across sections of protocols, help identify sections prone to repetition and reduce the likelihood of amendments.

MWs in our group authoring early clinical protocols use a checklist regularly to check their own work before the delivery of drafts for team review and as a last self-check for potential errors before finalization. The use of this checklist has proven to reduce time during document development and quality checks. Many of the tips in this checklist are based on actual inconsistencies that have been uncovered in past company protocols after finalization or raised during Informed Consent Form development.

ENGAGING COLLABORATIVE WRITING

The conventional sequential document development approach, with distinct cycles of authoring and reviews, has evolved toward a more collaborative, asynchronous process. This approach can take advantage of time zone differences for global teams or teams with a wide geographic distribution, thus maximizing development timelines. Instead of a restrictive linear, sequential development, collaborative writing allows authors to work on different sections while writers implement continuous QC checks. Collaborative writing can essentially continue around the clock when conducted across multiple time zones and in many cases may be the only way to meet aggressive timelines.

Successful collaboration requires effective communication, clear expectations, careful planning, and trust that each member will accomplish their tasks on time and to quality. When executed well, this method helps to build stronger team bonds, as remote teams develop an increased awareness of teammates' cultures, work styles, native language differences, and personalities. Although there are challenges to collaborative writing, the effective use of collaborative authoring tools (including those mentioned above) can enable this activity in ways that would otherwise be impossible.

TIPS FOR A SUCCESSFUL COLLABORATIVE WRITING SYSTEM

- **Effective Communication.** When working with a distributed team, effective communication is the most crucial success factor. Striking the perfect balance between online and offline methods of communication is key. While brainstorming is more effective in real time, using calls or instant messages, an offline approach allows collaborators to work autonomously, uninterruptedly, and more productively, giving focused attention to each document section.
- **A Clear Management Plan.** The lead MW must coordinate supporting MWs, direct questions to team members, keep the team informed of key decisions, identify critical updates and sections impacted, and delegate tasks. They must also identify the action steps required to move successfully from project start to finish, outline the various tasks relevant to document production, and clearly define roles and responsibilities to help the team focus on priorities and successfully complete the document.
- **Author Accountability and Cooperation.** Careful planning when assigning each author a section to complete promotes a sense of accountability and cooperation. Important aspects to consider for task allocation are the experience, background, and personality of the writer to maximize their expertise and productivity.
- **Problem-solving.** One of the greatest struggles in collaboration is the potential for disagreement. It is common for collaborating authors to have conflicting approaches to accomplishing work or presenting ideas. Authors must approach these differences collaboratively, with a problem-solving mindset, to share ideas, work toward a common goal, and make decisions together.
- **Embrace the Virtual Processes.** Virtual processes and

collaborative tools improve efficiency in the document development process. For instance, files can be stored in shared repositories for easy retrieval at any time. However, ensuring the team is aligned on the best practices and processes for these tools is crucial. A common version control system and standard naming convention ensures that documents are saved appropriately.

- **Flexibility.** The key to collaborative, asynchronous, and virtual document development is flexibility. The MW should be available to their collaborators to resolve issues and enable continuous progress. Instead of dividing authors into silos, knowledge-sharing among team members helps solve complex problems and enrich content. Similarly, this flexibility in the collaborative approach drives commitment among collaborators and fosters teamwork with a global perspective.

> "Great things in business are never done by one person. They're done by a team of people."
>
> —Steve Jobs[6]

CONCLUSIONS

Regulatory writing can be complex both in content and development processes, but with lean workflow processes and useful tools, MWs can reduce the amount of time and personnel hours attributed to each step. Software tools are widely accepted by MWs, and many already use the tools discussed above (92%, Figure 6).

Based on the real case scenarios examined, protocol development time can be decreased by about 26%, showing that software applications, templates, checklists, and collaborative writing are more useful than originally hypothesized by the largest group of surveyed MWs (62%).

With clear processes, roles, and responsibilities backed by innovative tools, MWs can overcome common development challenges and improve their lean regulatory writing skills.

Limitations

A limitation of this study is inherent to the survey sample size. Most respondents were ICON employees (54 out of 75 [72%]) and therefore the sample may not be a true representation of the medical writing community. However, this study was exploratory in nature and the results obtained were not intended to be extrapolated to the entire medical writing population. Future research could be undertaken to examine the strategies used by MWs from different backgrounds and levels of experience.

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V39 N1 / 2024

TOPICAL FEATURE

The Making of the International Standard for Writing in Plain Language ISO 24495-1: Its Usefulness, Content, and How It Came into Existence

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There is ample evidence across many domains that writing in plain language saves time or money or both for readers and organizations. Communication in plain language is generally more effective and produces better outcomes than traditional writing. In many contexts, readers prefer plain language over traditional writing styles, and use of plain language fosters the building of trust. Finally, the process of translating is usually more efficient for plain language documents.

In July 2023, after many years of development, discussion, and alignment, the International Organization for Standardization (ISO) published a standard for plain language.[1] This publication makes an internationally developed and agreed-upon standard available to all people interested in the use of plain language. It is an authoritative source developed by plain language practitioners, linguists, technical writers, designers, and text creators from many different countries. The standard will help all writers (authors) to make their texts (documents, web pages, etc.) most useful for the intended audiences (readers, users). It applies to most written languages and reflects the most recent research on plain language and the experience of plain language experts.

ADVANTAGES OF HAVING A PLAIN LANGUAGE STANDARD

We all benefit from the availability of technical standards in our everyday lives. They ensure that a plug bought in New York will fit a socket in Alaska and San Diego. International standards ensure that a product has the same specifications, regardless of where it is manufactured and used. Standardization fosters economic activity and growth. "Standards are the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent – people such as manufacturers, sellers, buyers, customers, trade associations, users or regulators."[2]

Medical writers appreciate the usefulness of standards in the realm of drug development. The many activities of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)[3] have led to a large set of standards that cover many aspects of drug development, including the definition of requirements on content and format of clinical documents, eg, structure and content of clinical study reports ICH E3 or the study protocol and investigator's brochure in ICH E6 on Good Clinical Practice. Many of these standards are subsequently transferred to company standard operating procedures and associated working instructions and hence have a direct impact on the work of medical writers. Also, the plain language standard provides a whole host of advantages:

> "All industries and sectors benefit from improved communication. Readers benefit when they can understand and use information. And organizations gain improved branding, efficiency, and effectiveness of communications products. A plain language standard provides all sectors, in nearly all languages, with a set of guidelines and strategies to make information more accessible and effective."[4]

Interoperability: The standard fosters the mutual understanding of what constitutes plain language. It provides a basis for discussion and serves as a basis for the use of plain language in special domains. The common standard allows integration of the various components developed in specialized domains.

Clarity and consistency: The standard provides clear guidance on how to develop texts in plain language that are easily understood by users. This reduces ambiguity and enhances the reliability of communication.

Cost efficiency and compliance: The standard will help streamline the processes of writing in plain language and thereby reduce costs. Both the generation of plain language texts and their efficiency can be evaluated against compliance with the guidelines, creating a useful measure for writers (authors) and readers (consumers).

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Collaboration and development: The availability of the standard facilitates collaboration among practitioners, allowing them to work in a common framework. This will accelerate development processes and exchange in the community of practitioners across languages.

Portability: The standard will enable the transfer of texts across different environments and languages. Texts and documents developed in compliance with the standard can be more easily translated without major modifications.

Structure of the plain language standard

- Foreword
- Introduction
- Scope
- Normative references
- Terms and definitions
- Governing principles
- Guidelines
- Annex A: Overview of principles and guidelines
- Annex B: Sample checklist

THE CONTENT OF THE STANDARD

At the center of the standard is the definition of plain language. It is characterized as communication in which wording, structure, and design are so clear that intended readers can easily

— find what they need,
— understand what they find, and
— use that information.

Consequently, the standard evolves around 4 principles that are elaborated on in separate subchapters:

Principle 1: Readers get what they need (relevant)

- Identify the readers
- Identify the readers' purpose
- Identify the context in which readers will read the document
- Select the document type or types
- Select content that readers need

Principle 2: Readers can easily find what they need (findable)

- Structure the document for readers
- Use information design techniques that enable readers to find information
- Use headings to help readers predict what comes next
- Keep supplementary information separate

Principle 3: Readers can easily understand what they find (understandable)

- Choose familiar words
- Write clear sentences
- Write concise sentences
- Write clear and concise paragraphs
- Consider including images and multimedia
- Project a respectful tone
- Ensure that the document is cohesive

Principle 4: Readers can easily use the information (usable)

- Evaluate the document continually as it is developed
- Evaluate the document further with readers
- Continue to evaluate readers' use of the document

For each principle, detailed guidelines are presented each with a small number of examples. Together with the definition of terms and 2 annexes, the standard provides comprehensive coverage of the key considerations for writing plain language texts that are useful for their audiences.

> "Plain language ensures readers can find what they need, understand it and use it. Thus, plain language focuses on how successfully readers can use the document rather than on mechanical measures such as readability formulas."[1]

AVAILABILITY OF THE STANDARD

The standards developed under the auspices of ISO or any national standard body are not free. They are therefore not freely available on the internet. They must be bought from ISO for a small fee; in the case of the plain language standard, the fee is 96 Swiss Francs (around $110). Clearly, this is a comparatively small sum that could be afforded by most. If the standard is used for professional purposes, this expense is usually tax-deductible. The money that is generated by selling the standards ensures that ISO remains independent of economic and political influences and can give full freedom to its communities of volunteers. Charging for standards allows ISO to "ensure that they are developed in an impartial environment and therefore meet the needs of all stakeholders for which the standard is relevant."[5]

THE MAKING OF THE STANDARD

Looking back, it is difficult to determine who exactly it was who came up with the idea for creating a universal definition of plain language and a standard across regions, let alone

finding out when and where it happened. However, the initiators and the people who over many years devoted their time and efforts to nurture the idea are still around. That said, they are usually too modest to brag about their involvement in the development of the plain language standard.

To fully appreciate this achievement, it is important to understand that all the definitory and alignment work in the field of plain language has been done by volunteers who are enthusiastic plain language practitioners and advocates. There was no institutional support from academia and no monetary support from governments for this initiative. However, some Northern European countries such as Norway have supported the cause by sending official delegates. Even so, the international plain language standard was developed by people who were prepared to spend many evenings and weekends discussing ideas and fine-tuning text proposals.[6-9]

It is difficult enough to develop a definition in a community of practitioners and to internationally align it. It is even more challenging to get a standard developed and adopted by the International Organization of Standards (ISO). It's not ISO that prompts the development of a certain standard. Rather, someone, usually industry or other groups of practitioners, approaches a national member organization of ISO which—if they see value in the proposal—brings it into the ISO system of expert groups. These groups are organized in larger groups called technical committees, or TC for short (there are about 250 TCs in ISO). These groups of experts negotiate and align on all aspects of the standard.[10]

The strength of the ISO process relies on its global scope, its representation of developing countries and consumer groups, and the principle of consensus. The latter ensures that all comments of all stakeholders are considered. Experts representing national standard development organizations need to be nominated by their countries' committee to work in an ISO working group.

Overall, it has taken some 16 years from the first public appearances of the idea of a plain language standard in 2007 to the release of the ISO standard in 2023.[11] The first 7 years, until 2014, were spent developing and discussing a definition of plain language. The definition was formally adopted by the International Plain Language Federation (IPLF) in 2014. Then, in 2017, the IPLF set up a committee to develop a plain language standard.

As is so often the case, it was the initiative of a small group of people, in this case, from the IPLF, led by Christopher Balmford, a lawyer by training, to approach Standards Australia and probe their willingness to take up the topic. He cold-called the relevant person at Standards Australia and met with him. Christopher's enthusiasm overcame the initially profound skepticism, and he convinced Standard Australia to take up the topic. Apparently, his cause was greatly helped by the fact that he incidentally mentioned that he and a friend had paddled a sea kayak the 150 miles from mainland Australia to Tasmania, island hopping on a 16-day trip. This demonstrated his tenacity, endurance, and dedication—all very much needed for bringing an idea to an adopted standard.

Standard Australia quickly realized that a plain language standard would be more effectively developed internationally, rather than nationally, and proposed the project to ISO. In 2019, ISO Technical Committee 37 (Language and Terminology) approved Standards Australia's initiative to develop a plain language standard globally. This was an enormous success because the standard could now be developed in alignment with all 35 national standard organizations that are members of the technical committee.

Subsequently, ISO TC 37 set up a working group (WG 11) to do the groundwork. The working group appointed a "drafting committee" of 8 members to do the initial writing of the many drafts and to discuss the feedback from both the national standard committees and other professional organizations such as Clarity, the Center for Plain Language, PLAIN (Plain Language Association International), the International Institute for Information Design, and the European Parliament.

The proposals of the drafting committee were then discussed and decided in the wider working group (WG 11), which comprised the delegates of the national standard bodies that had decided to become involved. Christopher Balmford was appointed Convenor and was tasked to lead the development and to ensure that the principles of ISO such as fairness, freedom of speech, equality, and consensus in all decisions were followed. The working group usually had some 30 delegates from 18 countries—from every continent except Antarctica—representing about 20 languages.

On a personal level, Christopher, being located in Australia, had to chair meetings starting at 11 PM and often continuing until 1 AM so as to accommodate the different time zones of the experts around the globe. Over some 4 years, there were many intense phases, particularly when revised drafts were due and when comments to drafts needed to be evaluated. Often, several hundred comments needed to be read, discussed, and decided upon. Each comment that had been made had to be responded to in writing!

LEADERSHIP, DEDICATION, AND COLLABORATION

Being a global endeavor, both the working group and the drafting committee comprised a wide range of different characters, all being experts in the field, each one of them enthusiastic about the topic, but each one with a well-formed and

well-articulated opinion. It was the task of the Convenor to ensure that everybody was heard, every contribution was discussed, and, most importantly, a solution was found to which everybody could agree (in line with ISO's consensus principle). The role was also administrative, ie, calling for the meetings and, very often, writing the minutes.

To successfully perform at the helm of such a diverse and lively group of experts, it takes a well-balanced, patient, and emphatic character with a detailed understanding of the topic. Most helpful was Christopher Balmford's ability to thoughtfully guide discussions to a fulfilling conclusion.

The majority of the conceptual work was done by the drafting committee, which, during the many very intense phases, often had several meetings a week. Although the composition of the drafting committee changed over time, key members who contributed over extended periods of time were Annetta Cheek (USA), Vera Gergely (Hungary), Angelika Vaasa, (Belgium), David Lipscomb (USA), Susan Kleimann (USA), Torunn Reksten (Norway), Machiko Asai (Japan), Rosa Margarita Galán Vélez (Mexico), and Andreas Baumert (Germany; also, the author of this article was a member of this group for several months in 2022, substituting for Andreas Baumert). Furthermore, editing was handled by Gael Spivak (Canada). Many of them are involved in one of the plain language organizations.

Although good leadership was of great importance, the development of the plain language standard was successful because of the collaborative, inclusive, sharing attitude of both the members of the drafting committee and the WG 11 over some 4 intense years!

ALL'S WELL THAT ENDS WELL?

Before the standard could be finally published, it had to undergo various steps of approval and discussion in ISO. One of them was approval by ISO TC 37. In preparation of the final vote, all national standard bodies represented in TC 37 were given the opportunity to review and comment on the final draft. This alone took several months because the national standard bodies needed to be given enough time for their review. However, after approval by TC 37, the final standard was published in June 2023. It is now available at the ISO website (see above). The IPLF has also developed a detailed list of frequently asked questions about the standard.[12]

Although the standard is adopted on international level, national standard bodies with their respective committees are working on the localization of the standard to their language and territory. The IPLF offers a guideline and a checklist for all those plain language practitioners who want to engage in the adoption of the standard by their national standard body.[13]

Building on ISO plain language standard part 1, there are 2 initiatives underway that aim to expand the standard into the realm of

- legal writing and drafting[14] and
- science writing (ISO/AWI 24495-3, *Plain Language — Part 3: Science Writing*).

Furthermore, because ISO is re-evaluating every standard in 5-year intervals, the preparations for the next update have already begun.

Christopher Balmford has meanwhile stepped down and Angelika Vaasa, from the European Parliament, has been appointed Convenor. However, given Christopher's enthusiasm for plain language, he will continue supporting the cause.


Christopher Balmford

The ISO plain language standard was initiated and developed by an international group of experts and enthusiasts over 4 years in a process that was based on respect and equality. The standard will help authors to write documents in which readers find what they need, understand what they find, and use that information.

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TOPICAL FEATURE

Understanding the Impact of Technology on Medical Writing: AMWA Survey Results from June 2023

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ABSTRACT

In July 2023, the American Medical Writers Association (AMWA) developed a survey to understand the impact of technology on the role of medical writers in clinical and regulatory document development. The survey was administered using SurveyMonkey to individuals responsible for leading, training, or developing a medical writing team. Respondents were mostly regulatory writers (96%) working in pharmaceutical/biotechnology/medical device or contract research organizations (88%). Most were using technology (65%) and almost all were planning to implement authoring technology (95%). New roles for medical writers, training methods for implementation of artificial intelligence (AI), and validation of the AI output were also discussed. Quality and accuracy of the AI output were the most important considerations of the respondents with transparency and disclosure as the least important. In general, the survey respondents felt that the impact of technology in the medical writing field was an important and timely topic for AMWA to address.

As the pace of artificial intelligence (AI) and related technology development and implementation increases in the medical writing field, the impact of this technology on the role of the medical writer is evolving. Global regulatory agencies such as the United States Food and Drug Administration,[1] European Medicines Association,[2] and Japan's Pharmaceuticals and Medical Devices Agency[3] are advancing positions and soliciting feedback on the use of AI in drug development.

Ultimately, the use of AI in scientific publications is likely to be dependent on the position of the editor(s) of the individual journals. To that end, journal editors are currently discussing the acceptable uses of AI in development of medical publications and requiring authors to attest to the use of technology when submitting manuscripts. The International Committee of Medical Journal Editors has added a section on the use of AI to its website defining the role of authors and contributors.[4] The American Medical Writers Association (AMWA) journal, along with other organizations, states that "AI tools cannot be listed as an author of a manuscript" and that "Authors should report the use of AI to create content or assist with writing or editing of submissions to the *AMWA Journal* in the Acknowledgment section."[5] Other professional medical writer organizations are publishing position papers on AI and discussing the use of AI by medical writers.[6-8]

The mission of AMWA is to promote excellence in medical communication and to provide educational resources in support of that goal.[9] Therefore, the AMWA Executive Advisory Council established a task force with the purpose of developing a survey to understand the evolving role of the medical writer in the face of AI technology advancements.

SURVEY PURPOSE AND METHODS

The overall purpose of the survey was to understand the impact of technology on document development to help ensure that medical writers acquire the skills to not only retain but also enhance their value. To make certain that all survey respondents were aligned on the terminology used in the survey, definitions (Table 1 on next page) were provided based in part on the definitions in the glossary of the US Food and Drug Administration's discussion paper *Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products*.[1] The survey was created, uploaded into SurveyMonkey, and distributed to AMWA members and other individuals who led, trained, or were developing a medical writing team in late July 2023.

SURVEY RESULTS

Respondents

Twenty-five respondents completed the survey. Most survey respondents (88%) were from pharmaceutical/biotechnology/medical device companies or contract research organizations/medical writing companies. Medical writing consultancies made up the remaining 13% of respondents.

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Table 1. Definitions of Technology Used in the Survey

Technology	Definition
Artificial Intelligence (AI)	A branch of computer science that focuses on building and managing technology that can learn to autonomously make decisions and carry out actions on behalf of a human being.
Bot	A computer program that can execute commands or automate certain tasks.
Machine Learning (ML)	A branch of AI and computer science that focuses on the use of data and algorithms to imitate the way that humans learn, gradually improving its accuracy.
Natural Language Processing (NLP)	The branch of computer science, specifically the branch of AI, concerned with giving computers the ability to understand text and spoken words in much the same way human beings can.
Assisted Authoring	A subset of NLP that generates human language text from data inputs.
Structured Content Authoring (SCA)	Structured authoring is a standardized approach to writing technical documentation in which the content is controlled by predefined rules.
Digital Data Flow (DDF)	Allows for information flow between systems or platforms eliminating the need for manual entry of data into documents.

The primary focus of most respondents (96%) was regulatory writing and communication; 4% were focused on scientific publications and other health communication. Most respondents (72%) worked in departments with ≥20 medical writers. More than half of the respondents (65%) were from companies using some form of technology to author content. Only 10% of respondents said that there were no plans to implement any technology in the next 2 years.

Technology Applications in Use

Respondents were asked what technology applications their organization was using or planning to use (within 2 years) to improve the efficiency or speed of medical writing. Almost all respondents (95%) cited the use of authoring technology. Around half of respondents (53%) cited formatting technology. A little less than half of the respondents cited applications that performed document review/editing (47%) or quality review (42%). Less than a quarter of respondents cited the use of intelligent searching (21%) and electronic protocol builders (16%).

Stakeholders Using Technology

Information technology (IT) was reported as the highest user of technology for automation (53%) in the survey. Biostats and programming were cited as users by 42% of responders. Next was data management (32%); other (21%); and data analysis, submissions, and clinical (16% each). Respondents identified structured content authoring and assistive authoring (65%) as the most significant technology applications for medical writers in the next 3 to 5 years, followed by automated quality review (40%), and intelligent searching or digital data flow (30% each) (Figure 1).

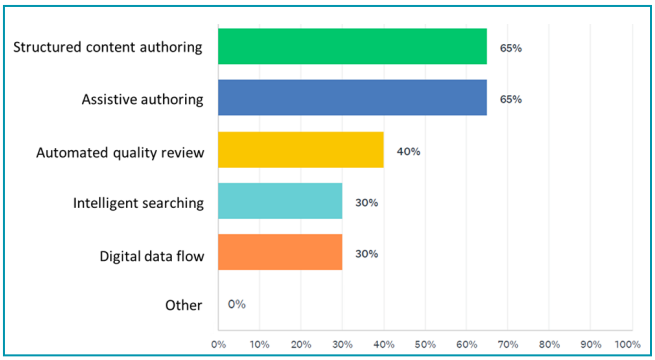

Figure 1. Future technology applications. Survey respondents were asked to select all technology applications that they saw as the most significant for medical writers in the next 3 to 5 years.

New Skills and Roles Medical Writers Need

The respondents identified training on and familiarity with the new tools/platforms as a need for medical writers to be successful in using technology applications for document development. Training that will be needed included how to use the tools and especially how to develop the appropriate prompts to produce the most relevant response. An understanding of how the tools work was cited as important to assess the accuracy and security of a new technology.

New roles will be needed for successful implementation and management of technology for document development. Effective trainers and implementation specialists who are experts in the technology (including software developers and IT support) were also deemed important and required for successful implementation and management of new technology tools. Quality control review of all AI-generated content was a critical component of necessary skills. Although the personnel for these roles may come from other disciplines such as IT departments, interested medical writers could also be trained to fill the new roles.

Validation of Technology

Human oversight was the most mentioned mechanism to validate technology. This included comparison of documents produced using AI, to manually generated documents, and development of standard operating procedures and processes based on ongoing experience with the tools. Some respondents said that there were no requirements or best practices (15%) for validation of technology or that

these were unknown (25%) in their organization. This illustrates the incredibly fast pace that technology is being developed and implemented in the medical writing field.

Training

Town halls, training sessions, and electronic communication were ways that management is approaching the implementation of new technologies used in document development. There was an interest in hands-on training for new technologies expressed by some respondents. No new or novel approaches to implementation were proposed by survey respondents.

Natural Language Generation and Assistive Authoring

Respondents suggested that the use of natural language generation and assistive authoring will enable medical writers to be more efficient, speed up the process of generation a first draft, decrease the time spent doing mundane tasks like copying and pasting, and increase productivity. This is predicted to shift the medical writer's time to evaluation of content.

Major Concerns and Considerations

One major concern expressed was that technology would be used without author input. Quality and accuracy ("hallucinations") of the output from these tools were also concerns along with protection of information and the integrity of information and/or data. Understanding the limitations of the tools and overreliance on the tools such that errors will be missed were also raised. Not fully understanding the critical need for medical writer review and quality control of the output was raised as a concern that could lead to unrealistic timelines. Some respondents also felt that company management may believe that these tools can replace medical writers, thus jeopardizing jobs.

Considering assistive authoring or other AI applications, survey respondents were asked to rank each item in order of importance or concern with 1 as the most important and 8 as the least important (Table 2). The top ranked concern was the accuracy of the generated content. Disclosure and transparency were ranked as the least important considerations.

DISCUSSION

Technology is here to stay and will provide benefits to medical writers. But it is clear that the medical writing community should be part of the discussion on what, how, and when to use technology. The respondents ranked the accuracy of the generated content as the most important consideration as AI is implemented in the medical writing field. The least important considerations were disclosure and transparency, likely due to the fact that these are currently being addressed by journal editors and regulatory agencies. The survey respondents called the use of technology in medical writing an important and timely topic for discussion within the medical writing community.

To understand role of AI in medical writing from a different perspective, the authors queried ChatGPT version 3.0 with the prompt, "What is the role of AI in medical writing?" The final paragraph of the output contained this disclaimer:

> *While AI offers numerous benefits to medical writing, it is important to note that human expertise and oversight remain crucial. Medical writers should use AI tools as aids and validation mechanisms, understanding their capabilities and limitations in the context of the specific writing task. Additionally, ethical considerations, data privacy, and regulatory compliance should be carefully addressed when integrating AI into medical writing processes.*

Table 2. Concern or Importance of AI Considerations

	Rank								
AI Considerations	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	Avg Score
Accuracy of generated content	47%	26%	21%	5%	–	–	–	–	7.16
Acceptance by regulatory authorities	21%	–	37%	16%	11%	11%	–	5%	5.47
Ability to protect confidentiality of company and patient data	5%	32%	5%	21%	16%	11%	11%	–	5.16
Traceability during audits or inspections	–	26%	5%	26%	16%	16%	11%	–	4.79
Developing processes to support the use of technology	16%	5%	16%	16%	16%	11%	5%	16%	4.58
Ethical considerations/legal concerns	5%	11%	11%	16%	21%	21%	–	16%	4.21
Transparency to other functions/communication of use across stakeholders	–	–	5%	–	21%	16%	47%	11%	2.68
Disclosing use of technology to stakeholders	5%	–	–	–	–	16%	26%	53%	1.95

Considering assistive authoring or other AI applications, survey respondents were asked to rank each item in order of importance or concern with 1 as the most important and 8 as the least important. Percentages are based on the 19 respondents who answered this question. AI, artificial intelligence; Avg, average.

This again illustrates that the medical writing community needs to be included in the development, deployment, and implementation of AI. Medical writers can increase their value by facilitating adoption of AI in the field, taking on new roles to support the use of AI in medical writing, and by working to improve the quality and pace of AI use to produce medical writing output.

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AMWA NEWS

FROM THE PRESIDENT

AMWA Has a Place for You

R. Michelle Sauer / 2023-2024 AMWA President

Howdy AMWA,

I have 2 children, and during this time of year, parents are asked to volunteer for career day. I don't know about you, but when I tell people I'm a professional medical communication expert, most have never heard of our profession. Doctors, nurses, and scientists have well-established roles in our society, but medical communicators still remain off the radar of most young people's career options. As I begin to describe what I do to my kids, their eyes often glaze over but, when speaking to friends and the public, many are interested and see the obvious value we, as communicators, bring to the health care fields and beyond. As I speak with students, scientists, doctors, nurses, and medical liaisons, I find myself telling them, "You are a medical communicator too."

As our field continues to grow and evolve, it's important that we continue to support, listen, and learn from each other. Over the next few months, you will receive email alerts to member surveys. In order to serve you best, we need to understand you, your needs, your opinions, and your professional goals. For those who completed the evaluation of the 2023 annual conference, I want to thank you. We look at every response and adapt to make sure each year continues to improve. Several of the sessions from our annual conference are included in this issue, and I encourage you to take the time and read them.

Plans for 2024 are already in full swing. I have no doubt that our annual conference committee and staff will exceed expectations. Do not forget to block out your calendar for October 23 through 26 so you can join us in person at the 2024 conference in New Orleans. In the meantime, please be sure to check out the many regional events scheduled for the spring. If you are not already a member of a chapter, or there isn't one nearby, I highly encourage you to check out Engage, our organizational platform for professional dialogue. If you have a question, there is a medical communicator out there with an answer.

As you read this issue of the journal, I hope you find an article interesting that would help a colleague. If you do, I have a request: please tell your friends. In my first column, I highlighted the fact that AMWA is NOT one thing. The expertise and foci of our membership vary and continue to grow and evolve. Over the past months, as I have taken a more visible role within AMWA, I have noted that many medical communicators have not heard of AMWA, or they say, "I am not a medical writer." To them, I respond, "I am not either, but AMWA has a place for all medical communicators." Our medical communication field is large, and it is not surprising that some have not found their "home" yet. So let's join together and welcome more of us into this amazing career field.

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

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CALENDAR OF MEETINGS

2024 AMWA **Medical Writing & Communication Conference**
OCTOBER 23-26, 2024
NEW ORLEANS, LA

Trends and Opportunities for Medical Communicators

American Copy Editors Society/ACES: The Society for Editing
"ACES 2024 San Diego: Unleashing Creativity"
April 4-6, 2024
San Diego, CA
https://aceseditors.org/conference/2024-san-diego-1

Association of Independent Information Professionals
"AIIP 2024 Symposium"
April 18-21, 2024
St. Louis, MO
https://aiip.org/annual-event/2024-symposium

The Association of Clinical Research Professionals
"ACRP 2024"
May 3-6, 2024
Anaheim, CA
https://acrpnet.org/event/acrp-2024/

Council of Science Editors
"2024 CSE Annual Meeting"
May 4-7, 2024
Portland, OR
https://www.councilscienceeditors.org/annual-meeting

Regulatory Affairs Professional Society
"RAPS Euro Convergence"
May 6-8, 2024
Berlin, Germany
https://www.raps.org/europe-2024/home

European Medical Writers Association
"Valencia 2024"
May 7-11, 2024
Valencia, Spain
https://www.emwa.org/conferences/conferences/valencia/

Society for Technical Communication
"STC Summit: Technical Communication Conference & Expo"
May 17-19, 2024
Minneapolis, MN
https://summit.stc.org/conference/

Society for Scholarly Publishing
"Inflection Point: Setting the Course for the Future of Scholarly Communication"
May 29-31, 2024
Boston, MA
https://customer.sspnet.org/SSP/ssp/AM24/Home.aspx

Regulatory Affairs Professionals Society
"RAPS Regulatory Intelligence Conference"
June 5-7, 2024
Linthicum Heights, MD
https://www.raps.org/events/raps-regulatory-intelligence-conference

Association of Health Care Journalists
"Health Journalism 2024"
June 6-9, 2024
New York, NY
https://healthjournalism.org/training-events/health-journalism-conference-2024/

Drug Information Association
"DIA 2024 Global Annual Meeting"
June 16-20, 2024
San Diego, CA
https://www.diaglobal.org/en/flagship/dia-2024

Regulatory Affairs Professionals Society
"RAPS Regulatory Intelligence Conference"
June 18-20, 2024
https://www.raps.org/events/regulatory-intelligence-conference

Asian Council of Science Editors
"ACSE 2024"
August 18, 2024
Dubai, United Arab Emirates
https://theacse.com/2024/

Academy of Communication in Healthcare/International Association for Communication in Healthcare
"International Conference on Communication in Healthcare – ICCH 2024"
September 9-13, 2024
Zaragoza, Spain
https://each.international/eachevents/conferences/icch-2024/

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