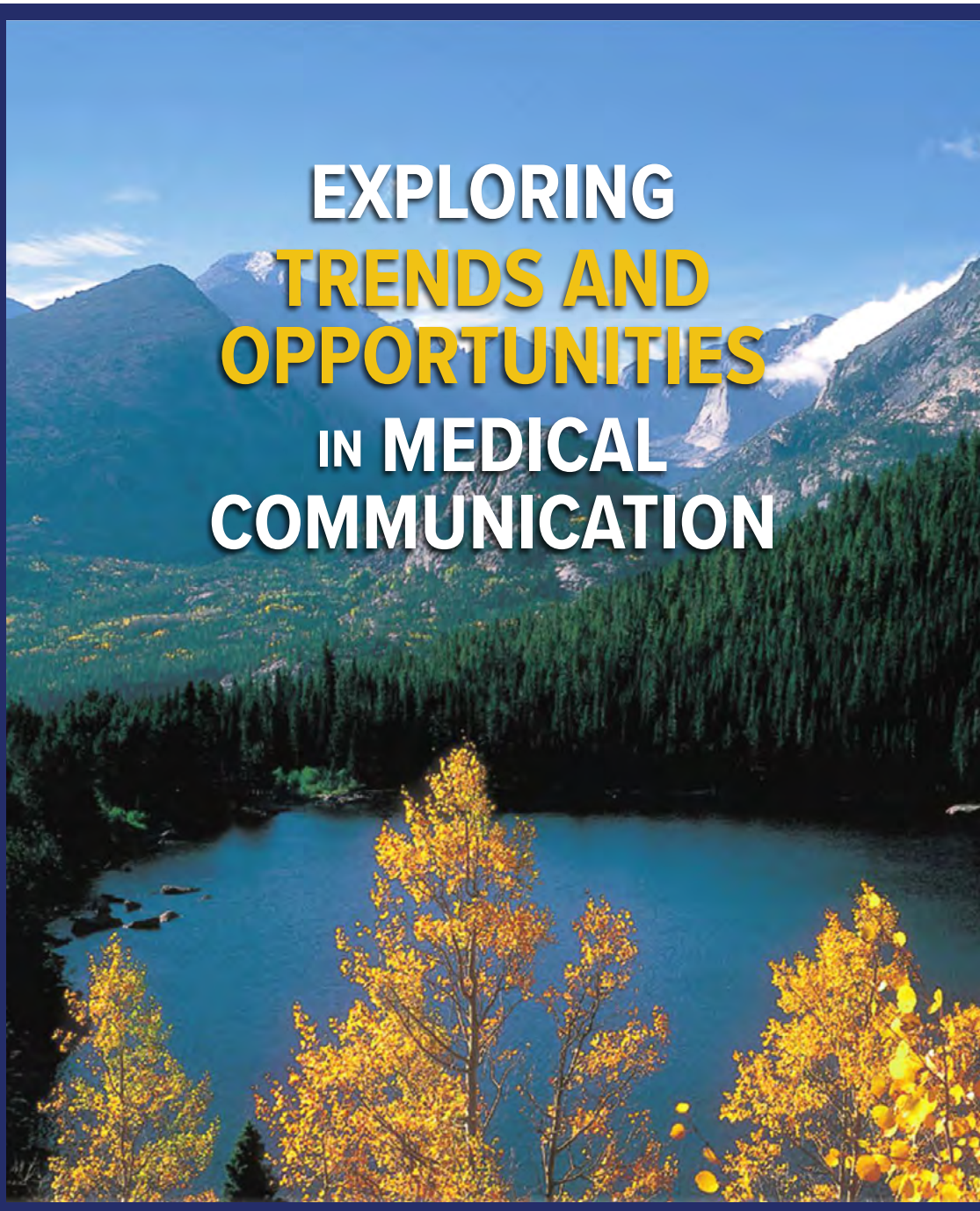
AMERICAN MEDICAL WRITERS ASSOCIATION
WWW.AMWA.ORG

Volume 38 Number 1 / Spring 2023

AMWA JOURNAL

INSIDE



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

TriloTalk

A **podcast** to discuss topics important for the profession of **medical writing**

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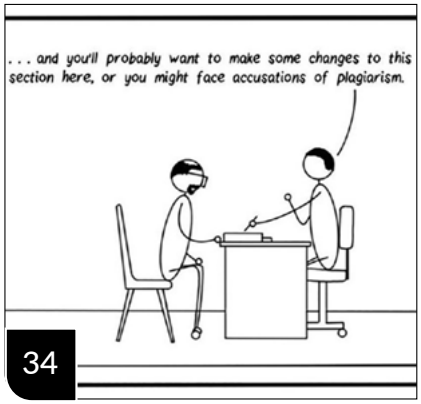
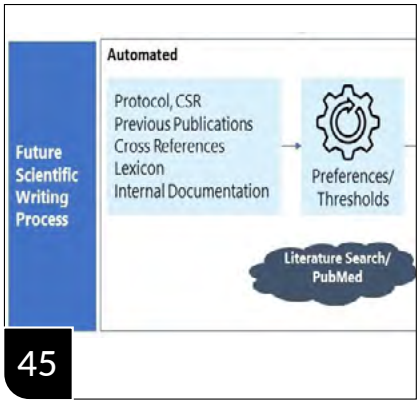
Contents

V38 N1
SPRING
2023





MORE Contents

AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL
V38 N1 / 2023

***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.

EDITORIAL OFFICE: ManagingEditor@amwa.org. Instructions for authors available at: www.amwajournal.org.

ADVERTISING: Contact marketing@amwa.org or (240) 239-0940. All advertising is subject to acceptance by AMWA and should be for products and services relevant to professional medical communicators. AMWA is not responsible for the content of advertising and does not endorse any advertiser or its products or services.

SUBSCRIPTION: The *AMWA Journal* is published quarterly. Subscription is included with AMWA membership. Nonmember subscriptions cost is $75 per year.

CONTACT: American Medical Writers Association, 30 West Gude Drive, #525, Rockville, MD 20850-4347. Phone: (240) 238-0940; Fax: (301) 294-9006; Email: amwa@amwa.org.

The *AMWA Journal* is in the MLA International Bibliography and selectively indexed in the Cumulative Index to Nursing and Allied Health Literature (CINAHL) print index and the CINAHL database.

ISSN 2163-5315

FROM THE EDITOR

Michael G. Baker, PhD
Editor-in-Chief

Following a welcomed return to the in-person format of the AMWA Medical Writing & Communication Conference in November of 2022, the Spring 2023 issue of *AMWA Journal* is dedicated to exploring trends and opportunities in medical communication. This also marks the one-year anniversary of the journal's transition to a digital platform, which by all accounts has been well received.

In the current issue, among other topics, we explore the use of artificial intelligence and machine learning in clinical research and health care, updated guidance on reporting race and ethnicity, the value of medical writers in continuing education for health professionals, and we provide session reports from the annual conference.

In subsequent issues this year, the themes will be Publications (Summer 2023, led by Guest Editor Qing Zhou), Global Medical Communication (Fall 2023, led by Guest Editor Elizabeth Kukielka), and Ethics (Winter 2023, led by Guest Editor Julie Ravo). As always, we welcome your contributions as authors, whether for a regular section, on a theme topic, or otherwise. Please see the journal's website for instructions for authors.

Back by popular demand, we are excited to announce that we will resume a section on career development to address issues of interest to those wishing to break into the medical communication profession, as well as career advancement for mid-stage and experienced professionals. We are recruiting for a career development section editor, so please contact me at journaleditor@amwa.org if you wish to be considered for the role.

The *AMWA Journal* will continue to bring you great content every quarter, and on an ongoing basis, we invite your input on the digital format.

ISSN 2163-5315

AMWA JOURNAL V38 N1 / 2023

CONFERENCE

2022 Harold Swanberg Distinguished Service Award Address

Aspire to More: Raising the Bar on Medical Writing

Julia Forjanic Klapproth, PhD / Owner and Senior Partner, Trilogy Writing & Consulting GmbH, Frankfurt, Germany

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

I am greatly honored to even have been considered for this award, and I want to say thank you to all those involved in selecting me for it.

When I received the announcement that I was getting the award, my first reaction was, "Oh wow…" followed quickly by, "So, why me?" As I tried to see myself from the outside, I realized that the thing that probably makes me eligible for this award is my ongoing, almost obsessive passion for medical writing and its importance to the pharmaceutical industry and the world.

Science is nothing without people thinking about what it means. Contrary to what people may say, data do not speak for themselves. We, as informed and skeptical creatures, look at the data and think about what they mean. As we begin to assemble each piece of insight, we put together a narrative and meaning. But that narrative only becomes powerful and has a transformative impact if it is communicated, and the knowledge is transferred from the few who are mining those nuggets of information to the rest of the world. Thus, science only begets progress if it is communicated effectively, and that's where we come in.

Without medical writers who understand how to take the data beyond just numbers on a page and turn it into a convincing narrative, progress will stutter. Whether we are regulatory writers crafting a document that succinctly expresses to the assessors why the benefit of a drug outweighs the risk or we are in the med comms space taking the science out to the public so that people can better understand their bodies and their illnesses and the available treatments, we are bringing the message to the world.

The better we do our job, the faster the messages of today will drive the science and developments of tomorrow and improve the lives of people throughout the world. We saw so clearly during the pandemic the importance of getting clear messages out to the world to avoid confusion and mistrust in science.

So, I honestly do not believe it is an exaggeration when I say that medical writers bring the light to the world. Hard-won light gleaned by researchers and doctors and patients who commit to research so we can learn more. But it is we who tell the world what has been learned, which is why it is our responsibility to get it right. To make sure that the texts we write are clear and focused on what matters. To ensure that no word is wasted and that we stand firm when teams start to veer toward text that merely repeats the data without any message, or long-winded, convoluted presentations for the public that confuse rather than inform. We can and must strive to show the teams we work with how much more our documents can be and why. Helping them understand the "why" is the key to achieving change.

ISSN 2163-5315

And yet, curiously, I hear over and over again from medical writers how medical writers have no authority on our teams. I don't believe that. In fact, I am of the opinion that if we believe we have no authority, we never will. Having authority has to do with belief in self, in how you enter a room, in how you engage with others. First, you have to believe you are legitimate and that what you bring to the conversation is equal in value to what anyone else brings to it.

But when I started out in the industry, I was afraid to speak up in meetings, afraid to ask questions. When I did, I would be so nervous that I turned beet red, and that really didn't help my self-confidence any! But two key things helped me understand that I could and should speak up.

First, I recognized something important. I noticed that when I was in meetings, I often had a question or thought about something people were discussing. But I wouldn't speak up because I thought, well, that is so obvious; if it made any sense, the other more experienced people in the room would already have said it. Right? So, I would sit in these meetings and watch conversations go around in circles, sometimes for an hour or more, and finally, somebody else would state what I thought of an hour ago or ask the question that I wanted to ask. And everybody else would go, "Oh yes, exactly, that's right!" What I realized was that maybe some of those "obvious" thoughts I was having weren't so obvious and not so silly, and if I would only raise them as soon as I thought them, I could actually contribute meaningfully to saving us all time and making progress.

But then I had to overcome my insecurity. Knowing I should say something was very different than being able to say it, let alone saying it confidently and without turning into a tomato. And that was where the second thing came into play that helped me gain the courage to speak with authority. I was lucky to have a strong role model in the room with me– Dr Barry Drees was one of the senior writers in my department, and we worked on several big projects together. If some of you are lucky enough to know Barry, you will know that he can speak about anything to anyone, anywhere, at any time. And that became my goal – to speak as freely and easily as Barry does.

So began about a 2-year journey. The first step was recognizing that I had something to say when I was in a meeting and was literally having heart palpitations in my effort to speak about it. But I would tell myself over and over, what would Barry do right now? He would be speaking. So I would think, "Why aren't you speaking? Open your mouth, girl! Speak!" And I would sometimes. I would turn beet red, and I was so nervous that what I said was stilted and uneven. But the more I spoke, the more people started to listen. And as I saw the impact of my input and practiced speaking up, there was a transformation, until at some point, I became the person I am now. I speak freely and frequently and have opinions on just about everything. Just like Barry!

The reason I am telling you this is because sometimes people think when I say that medical writers can have authority if they only step up and grab it that it's easy for me to say, or "I'm not like them." But that's not true. I was just lucky enough to have some good teachers and a good role model.

I personally connect strongly with Dr Swanberg's vision to create a curriculum for training medical writers. Without our teachers and role models, only a very few will find success and fulfillment.

Which brings me to the relevance of this award. Some of you may already know who Dr Swanberg was. But I suspect many of you are like I was when I found out about this award, and you don't know much about him and his importance to our career. Harold Swanberg was not only one of the founders of AMWA, he was an outspoken supporter of improving the education at all levels – from schoolchildren to medical writers, believing that offering everyone the opportunity of a good education would help society overall by helping people find fulfilling careers best suited to their abilities and predilections. He cofounded the AMWA Educational Committee in 1951, which focused on creating an appropriate curriculum for undergraduate and graduate programs in medical writing and editing. He also launched a manuscript editing service through AMWA to help physicians improve their documents. Dr Swanberg not only understood that there was a need for people to assist physicians in communicating their findings but that we should be cultivating this function as a career.

I personally connect strongly with Dr Swanberg's vision to create a curriculum for training medical writers. Without our teachers and role models, only a very few will find success and fulfillment. While Dr Swanberg brought

the idea to life of teaching people the essentials of medical writing in an editorial function, today the role of a medical writer has matured into much more. We are communicators, cat herders, solution finders, and leaders. Our training programs must serve all these areas, including teaching each one of us to believe in ourselves and not shy away from guiding our teams to producing documents that really communicate effectively. Medical writing is coming of age, and tailored, effective training is essential to raise the bar on the role and perception of medical writers in our industry.

So, to wrap up, I have to say that I am a bit dazed by getting this award. To be honored by your peers is incredibly rewarding, and I am very thankful for that recognition. But I accept this award with humbleness, for I stand on the shoulders of giants. From the inspired and tireless efforts of Dr Swanberg through the generations of champions of the medical writer's cause, I simply carry the torch further. I will do what I can to live up to what this award stands for. Thank you.

Acknowledgment

I thank Stephanie Vargas, MD, Principal and Medical Director, Med Ink Consulting, for her help in bringing the transcript to the page.

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

AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N1 / 2023

CONFERENCE

2022 John P. McGovern Award Address

Global Vaccines and Vaccinations: Science Vs. Antiscience

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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.

Thank you very much for the honor from AMWA and the opportunity to be able to speak with you. This means a lot to me, not only as a science communicator, but also because I've been writing books about the geopolitics of vaccines and global infectious diseases. Having this kind of recognition, for me, is particularly special. I'm sorry I can't be there with you in Denver, but please understand how important this honor is for me and my association with AMWA.

My career as an MD/PhD vaccine scientist is an interesting one and has kind of a dual aspect to it. For the last almost 40 years now, since I started as an MD/PhD student in New York in the 1980s, I've been working to develop vaccines for poverty-related neglected tropical diseases as well as viral infections. I'll talk about our work to develop a new COVID vaccine now in use in India, Indonesia, and elsewhere.

The other side is because I have four adult kids, including Rachel—who has autism and intellectual disabilities—and wrote a book a few years back called *Vaccines Did Not Cause Rachel's Autism* because that was kind of the phony assertion from antivaccine groups. Going up against them, by default, I became an expert not only in the vaccine science but the antiscience. I've been writing and speaking about that.

Today, what I want to do is speak to you about both aspects: the positive side and fight for developing vaccines for poverty-related diseases as well as coronaviruses, but, at the same time, increasingly I'm being called out to combat widespread antiscience activism and antiscience aggression.

To start out on the positive side, I'm a professor at Baylor College of Medicine, where I'm also the dean of our School of Tropical Medicine. Together with my science copartner for the last 20 years, we cohead the very interesting Center for Vaccine Development that has been making vaccines for parasitic infections in Africa, Asia, and Latin American countries, such as schistosomiasis, hookworm, Chagas disease, and leishmaniasis. Then, about 10 years ago, we started developing coronavirus vaccines for SARS and MERS and, ultimately, COVID-19. The Center for Vaccine Development is based at Texas Children's Hospital (coheaded by myself and my science partner for the last 20+ years, Dr Maria Elena Bottazzi), part of our enormous Texas Medical Center, which is the world's largest medical center.

We sometimes call our vaccines for parasitic diseases antipoverty vaccines because they're vaccines for disease that not only affect health but also trap people in poverty through their effects on child development, work or productivity, and pregnancy outcome. The vaccines also are a potent antipoverty tool, so we call them antipoverty vaccines. I first wrote about them in my first book, which is called *Forgotten People, Forgotten Diseases*.

One of the things that we do at our Center for Vaccine Development—it's not a typical academic center and is actu-

ISSN 2163-5315

ally developing the vaccines—is we use technologies, whenever possible, that are compatible with those used by vaccine producers in low- and middle-income countries (LMICs) that have banded together to call themselves the Developing Countries Vaccine Manufacturers Network (DCVMN). There are about 40 of these institutions in Asia, Africa, and Latin America. One of the common technologies that is widely used is microbial fermentation in yeast to make recombinant protein vaccines, which is the technology used to make the recombinant hepatitis B vaccine. For instance, countries like Bangladesh, China, India, Indonesia, etc., all make their own recombinant protein hepatitis B vaccine. If you want to plug and play into the system so that vaccines could be made locally in LMICs, this is a pretty good technology to use. Another aspect is that it's a vegan technology—no animal cells, human cells, animal proteins, or human proteins—so it has the capacity, for instance, to be made as a halal vaccine for Muslim-majority countries, which is also extremely helpful at times.

Our parasitic disease vaccines include vaccines for human hookworm infection and schistosomiasis, which is in phase 2 clinical trials. There's a lot of interesting science behind it that I won't go into, but we're trying to develop and distribute vaccines on the African continent, Southeast Asia, and Latin America. The point is if you were the CEO of a biotech, this would probably not be the map you want to have in your business plan because most of the pharma industry and biotechs are focused on the Global North, meaning North America, Western Europe, and Japan. So, the science that we're doing is interesting, but we're also trying to identify sustainable financial models for them to recognize that the return on investment is going to be very modest compared with vaccines intended for North America or Europe or Japan.

Our vaccine for schistosomiasis, which is in phase 2, is also helping a major problem of women's reproductive health, that is, female genital schistosomiasis, which affects 40 million girls and women on the African continent.

Our Chagas disease program targets a parasitic infection in the Latin American region that affects about 6 to 7 million people living with Chagas disease, of whom about 20% to 30% can go on to develop heart disease, Chagasic cardiomyopathy, which is caused by the parasite depositing, inducing the formation of collagen and fibrotic deposition as well as inflammation. This happens even despite antiparasitic chemotherapy. Dr Kathryn Jones, who heads our Chagas disease pathogenesis program, has been working with our vaccine center to develop a new prototype Chagas vaccine that will go into phase 1 clinical trials in Mexico next year.

This gives you an example of the type of parasitic disease targets that we're interested in. Of course, the problem with COVID-19 vaccinations was that the mRNA vaccines developed by Pfizer and Moderna were not readily available for LMICs. All the doses got swept up pretty rapidly by North American and European countries. This left a huge unvaccinated population gap, so huge numbers of people went unvaccinated on the African continent and in India and Southeast Asia.

A consequence, unfortunately, other than the obvious humanitarian concern, was that Delta arose out of an unvaccinated population in India and South Asia and Omicron out of an unvaccinated or undervaccinated population in Southern Africa. These were vulnerabilities that were created because of this vaccine equity gap, so our plan was to say, "Look, we've developed this low-cost technology that we think works as well for SARS and MERS vaccines; we can now do the same for COVID-19." In fact, we've actually done this now—we transferred the technology (without patents) to India and other countries where they've scaled up production. In India, the vaccine has been produced at scale by Biological E, a vaccine manufacturer based in Hyderabad that has produced the vaccine that they call Corbevax. So far, it has gone into more than 75 million adolescent arms in India and now is being used as a booster for adults. Biological E owns the technology, so it's a way of decolonizing the vaccine ecosystem by transferring ownership to an LMIC vaccine producer. We provide a proof of concept that you do not have to be a multinational pharma company to do big things. We did this through our academic home at Texas Children's Hospital and Baylor College of Medicine, our Center for Vaccine Development, in partnership with LMIC vaccine producers. We're hoping to hit the 100 million–dose threshold by the end of 2022 or early 2023.

One of our major activities is vaccine diplomacy, working to do the technology transfer of our vaccine technology—without a patent, in this case—to countries such as India, Indonesia, and Bangladesh and Botswana in Southern Africa. We've been doing this largely without a lot of public support in terms of the fact that we were cut out of Operation Warp Speed from the US government and have not really gotten that much support from the G7 countries; we are trying to do this with local governments as well as private philanthropy.

Corbevax was approved for emergency use authorization last year and first went into adolescent arms starting on March 15th. As I mentioned, now we've reached over 75 million doses in adolescents 12 to 14, and the numbers are going up; we're hoping soon for World Health Organization approval. Biological E, which owns the vaccine, is now pursuing its possible uptake in other LMICs. In parallel, we've done a similar vaccine antigen in Indonesia with their big vaccine producer, BioFarma, and it was just announced that this vaccine has been approved for Indonesia, where they

call it IndoVac. Because it's a vegan technology, this will be one of the first halal vaccines for Muslim-majority countries, which we're extremely excited about.

Now, that's the good-news aspect of the story. The not-so-good news is the fact that, because of 21st century social determinants as well as climate change, we are slowing, halting, or, in some cases, even reversing our global gains, both for control of neglected diseases as well as vaccine-preventable diseases. I've written about this in my last book, called *Preventing the Next Pandemic: Vaccine Diplomacy in the Time of Anti-science*. One of the forces I'm particularly concerned about is the rise in antivaccine/antiscience activism, which is really turning out to be aggression.

Let me give you an example that we've seen in this time of COVID-19. The official number of deaths for COVID is roughly around 5 to 6 million, but some estimates from the Institute for Health Metrics and Evaluation, *The Economist*, and others say up to 20 million deaths. The World Health Organization is now saying 15 million deaths. In the United States, we've had 1 million deaths, second only to India. The figure shows the familiar pattern of deaths that many people will recognize that goes through various peaks and valleys as we course through the pandemic.

The first peak was 2020 in New York, followed by the summer in Texas and the southern states; the big Alpha wave was in that terrible winter of 2021, and the Delta wave was in the last half of 2021, followed by the Omicron wave; then, there's a big blue arrow in the figure. That big blue arrow points to May 1, 2021, which is the date that the Biden administration announced that anyone who wanted to get a COVID vaccine could do so, but you can see that the deaths continued afterward. These were individuals who were defiant and refused to get vaccinated because they were victims of antivaccine activists.

My estimate is around 200,000 Americans needlessly lost their lives because they refused the COVID vaccine and became tragic victims to these new, very dark antivaccine activist forces. I want to go there next to explain what's happening with antivaccine/antiscience activism and aggression because people too often think it's just some random events that occur on the internet or social media, but it's far more deliberate than that. Let me take you through how I see that the antivaccine/antiscience ecosystem has evolved or devolved.

Again, I got involved in this being the parent of four adult kids, including Rachel, who has autism and intellectual disabilities, and explaining why vaccines did not cause autism, which was version 1.0 of the movement. Then, about 7 or 8 years ago, it became more of a political movement rallying around this banner of health freedom/medical freedom, and now it's become a full-on globalized empire. I want to finish up by taking you through versions 1.0, 2.0, and 3.0 to help you understand what's happening with antiscience (Box 1).

Box 1. The Antivaccine Ecosystem in the United States

V.1.0 Vaccines and Autism
V.2.0 Vaccines and "Health Freedom"
V.3.0 Globalization

Version 1.0, vaccines associated with autism itself, has a lot of complexities. The original assertion, back in a paper published in *The Lancet* in 1998, claimed that the measles/mumps/rubella (MMR) vaccine had the ability to replicate in the gut of kids, and then that led to autism—or what, at that time, was called pervasive developmental disorder. The scientific community responded in a big way, showing that kids who got the MMR vaccine were no more likely to acquire autism than kids who didn't.

That was very, very important for debunking the assertion, and you would have thought that would be the end of it. But antivaccine groups grew in strength and size and kept on switching up or moving the goalpost in terms of what the actual assertion was; they switched it over to thimerosal preservative in vaccines, spacing vaccines too close together, and alum in vaccines. For a while, they even switched out of autism and said it was the HPV vaccine for cervical cancer or other cancers that was causing infertility or autoimmunity.

If that sounds familiar for COVID-19 vaccines, that's where they got it from—they just copy/pasted the false assertion onto COVID-19 vaccines. As I said, I got involved in this, having Rachel as my youngest daughter, and I detail this in the book, *Vaccines Did Not Cause Rachel's Autism*, which was published by Johns Hopkins University Press. It does a deep dive explaining the science of vaccines and the evidence showing there's no link with autism, but also what autism is and how it begins in early fetal brain development through the action of autism genes. Through Baylor College of Medicine Genetics we actually did a whole-exome genomic sequencing on Rachel, and my wife and I and were able to identify Rachel's gene associated with autism; it's involved in neuronal communication, which makes a lot more sense for something like autism.

Of course, I was heavily targeted by antivaccine activists because of that. They began calling me the OG villain—I had to look it up—the original gangster villain. I think it did have some effects on taking some of the wind out of the sails of antivaccine groups, but they found a way to reenergize about 9-10 years ago in a way that I not necessarily would have predicted. It began in Southern California, where so many parents had opted their kids out of getting vaccinated that, not surprisingly, it led to a large breakthrough

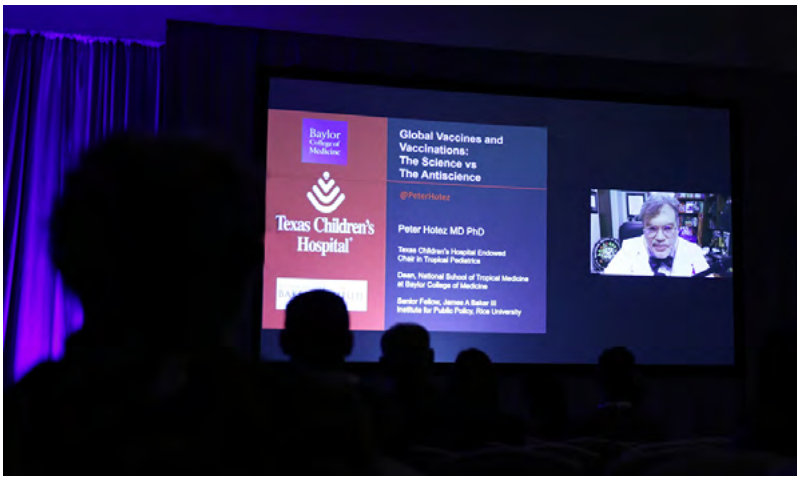
measles epidemic in 2014–2015. The California legislature responded appropriately by shutting down vaccine exemptions, and I supported that, but it also led to a backlash under this banner of medical freedom and health freedom, with people saying, "Hey, you can't tell us what to do in terms of vaccinating our kids."

That was fairly disturbing, but it's what took off, especially in states like Texas, where this idea of health freedom or medical freedom got adopted by the Republican Tea Party, and they formed their own political action committee around not getting vaccinated. There was pressure put on the state legislature to make it harder and harder to vaccinate our kids and easier and easier to opt out. As a result, we're up to almost 100,000 kids not getting all their vaccines in the state of Texas, especially around the Austin area, and this doesn't even account for the more than 300,000 homeschooled kids. We have a huge problem now in states like Texas, where too many kids are not receiving their vaccines required for school entry.

It's taken this very dark turn in Texas and elsewhere. At one point, antivaccine activists paraded with yellow Jewish stars at rallies and actually, in my opinion, mocking the Holocaust and using words like NO VAX in letters that look like Hebrew letters. I think it's incredibly offensive and divisive, and yet this is what's been going on here in Texas and elsewhere. And now, in this time of COVID-19, it's accelerated even further among this banner of health freedom/medical freedom to protest social distancing, contact tracing, and wearing masks. We've had some podcasters weigh in, and it's created quite a dark environment around getting vaccinated, and, of course, this has extended now to COVID vaccination.

In Texas, COVID vaccinations have higher rates along the border and some of the cities of the Texas triangle, but in the conservative areas of central Texas and the panhandle of east Texas, there are some of the lowest vaccination rates in the country. It mirrors the political map of Texas. The higher-vaccinated areas are in the more liberal/Democratic areas, whereas the low vaccination rates are in the more conservative/Republican strongholds. It's really quite striking, and this is what we're seeing now happening nationally.

Studies from Charles Gaba, the health analyst, as well as *The New York Times*, *Axios*, National Public Radio, and other groups show how in the last half of 2021, the deaths are overwhelmingly in red states, and the redder the county, the lower the vaccination rates and the greater the deaths, so much so that *The New York Times* actually calls it "Red COVID." This partisan divide of politicization of people not getting vaccinated is something, for me, that's been one of the hardest things I've ever had to talk about because all our training, as physicians and scientists, says you're not really



supposed to talk about Republicans and Democrats or liberals or conservatives. But I've not found a way to talk about it other than to talk about it in a quest to save lives.

Everyone's entitled to their conservative views, but please don't adopt this one because it's leading to my estimate that 40,000 Texans (and possibly up to 200,000 Americans) may have died unnecessarily during this Delta wave, and the numbers are continuing among the unvaccinated in the Omicron wave. It's extending now to all childhood vaccinations. There's a survey looking at how the distrust of COVID vaccinations along the partisan divide is extending to all childhood vaccinations, so I'm quite worried about the return of measles and pertussis and other childhood infections.

Another big concern I have with this is not only the rise of antivaccine activism, but how it parallels antisemitism as well; this has been reported by multiple outlets with people circulating antisemitic flyers blaming Jews for COVID-19. Because I'm Jewish, I'm aware of it more than others, and I'm frequently targeted not only for being a scientist but in particular for being a Jewish scientist. The emails that I'm getting are pretty frightening, and they often take a very violent tone, such as that I'll be charged with treason and other crimes against humanity and many expressing their desire to see me executed by various measures. There is also a lot of Nazi imagery. I'm sometimes compared to Dr. Mengele, the infamous Nazi doctor who experimented on humans.

This has been present not only with me but also my other colleagues—this idea that not only the science is being targeted but the scientists themselves. It's incredibly offensive stuff, very racist, and white supremacist in nature, with threats the army of patriots will come and hunt me down, very much leaning toward political extremism on the right. This is the new aspect of antivaccine activism—this adoption by far-right extremists—but it's also coming out of the Conservative Political Action Conference (CPAC). We

heard it multiple times that first they're going to vaccinate you, then they're going to take away your guns and your Bibles (https://www.newsweek.com/madison-cawthorn-says-door-door-vaccines-could-lead-taking-guns-bibles-1608503).

As ridiculous as that sounds to us, there's a segment of the country who believes it, or members of the House Freedom Caucus and the US Congress comparing people, like myself, whom they call medical brown shirts, using Nazi paramilitary analogies. Of course, it's revved up every night on Fox News by the nighttime Fox News anchors specifically targeting scientists, and these kinds of threats tend to ramp up every time. I'm particularly targeted on Fox News. They target Dr. Fauci a lot, of course, but when they get tired of beating up on Tony, I tend to be Fauci Lite. These are the kinds of threats that I'll often get after a prominent conservative news site picks this up or if it's amplified on Fox News.

So, the question is, what are we facing? What can we do, and what can AMWA's contribution be? Well, it's not easy, because this really does go outside the health sector. It's become a political problem. But I think it's important that we at least recognize the problem and its potential for unraveling our biomedical infrastructure. It's not only vaccines; it gets to COVID origins and COVID conspiracy theories, and we need to recognize that it's not an academic discussion—lives are being lost—and this goes way beyond just a theoretical discussion. Science and scientists are under attack, and it's deliberate and organized. These are not random events on the internet.

Proposing solutions, as I've mentioned, is not so straightforward, because so much of this has gone beyond the health sector. The US Surgeon General has tried to address this by talking to social media companies, such as Meta and Twitter, and I think that's useful, but it doesn't really get to those generating the content, and that's the problem. I think we need expertise in political science and other disciplines outside the traditional biomedical sciences to get some help.

Unfortunately, now it's going global. We're seeing this extend up into Canada and into Western Europe. *The New York Times* and BBC report it has been linked to QAnon and even neo-Nazi groups. This is a globalizing force. My worry now is that with the disruptions from the COVID-19 pandemic, we have seen a decline, for the first time, in childhood immunizations. We saw the largest drop in the last 30 years, and we're even seeing breakthrough polio cases in New York and elsewhere. My worry is that we're not going to come back to baseline—that something permanent and wrenching has happened.

The targeting of scientists, from my view, increasingly looks like what we saw during the '30s and '40s in the Soviet Union under Stalin—this kind of targeting of individual scientists seen as enemies of the state. And finally, I think this US-style antivaccine activism—and I've written about this in *Nature Reviews Immunology*—could start reversing global gains and global goals for vaccinating the world's children. I think this is starting to happen now on the African continent and elsewhere. I think we're going through a very dark period, with a lot of it coming from authoritarianism on the far right in the United States, but we're also seeing some of this now among authoritarian regimes in Brazil, Hungary, and elsewhere.

This is a time to recognize the politicization of health, but it's much more than that. It's specifically the targeting of scientists and, in the United States, prominent US scientists. I know it's not the happiest note to end on, but I think it's an important one. Until we can describe it and put our arms around it, it's hard to combat it. I think, for too long, we've seen this as random events on the internet or not really having a huge public health or geopolitical impact, and it's clear that now it does.

Thank you, again, for the recognition and the opportunity to speak with you. I look forward to a long association with AMWA. Thank you so much.

Acknowledgment

I thank Kelly Byram, Writer, Editor, and Founder of Duke City Consulting, LLC, for her help in bringing the transcript to the page.

Author declaration and disclosures: *The team of scientists at Texas Children's Hospital Center for Vaccine Development including its co-director, Professor Peter Hotez, is a co-inventor of a COVID-19 recombinant protein COVID vaccine technology owned by Baylor College of Medicine (BCM) that was recently licensed by BCM non-exclusively and with no patent restrictions to several companies committed to advance vaccines for low- and middle-income countries. The co-inventors have no involvement in license negotiations conducted by BCM. Similar to other research universities, a long-standing BCM policy provides its faculty and staff, who make discoveries that result in a commercial license, a share of any royalty income. To date, BCM has not distributed any royalty income to the co-inventors on the COVID-19 recombinant protein vaccine technology. Any such distribution will be undertaken in accordance with BCM policy. He is also an inventor on non-revenue-generating patents for neglected tropical disease vaccines. Prof. Hotez is also the author of several books published by Johns Hopkins University Press and ASM-Wiley Press and receives royalties from those books.*

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AMWA JOURNAL V38 N1 / 2023

CONFERENCE

2022 Walter C. Alvarez Award Address

Emerging Issues Following COVID-19: Public Health Communication

Leana Wen, MD, MSc, FAAEM / George Washington University, Washington, DC

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.

Hello everyone, it's a pleasure to be with all of you. And as I start, I want to first of all acknowledge the people who've made this AMWA conference possible and the annual conference chair, Dr Kimberly Korwek. I'd also like to thank the AMWA executive director, Susan Krug, and all of you at the American Medical Writers Association.

All of you at AMWA have also been on the frontlines in this confusing and frightening time. We are working with incomplete information, interpreting new science, helping people with news that they need to use in their daily lives to navigate huge uncertainty and protect themselves and their families, and to understand changing policy implications that often are changing by the minute. All of you are on the frontlines, not just with COVID, but also with all other aspects of health and wellness. Your work is so important, and I want to thank you for what you are doing every day.

I'm also delighted to join virtually another award winner, my colleague, Dr Peter Hotez, who as you know, is being honored for his exceptional work in medical communication and is a superb clinician and researcher, and who, along with his colleagues, has developed a COVID-19 vaccine. So, what great company we are all in.

Well, in my presentation today, I would like to talk about communicating public health in times of conflict and controversy, and my discussion is going to be in 2 parts. First, I want to talk about what we have learned from COVID-19, touching on the role of journalists, medical writers, and communicators, and then I want to discuss what we can do moving forward. And for each of these 2 categories, I want to give 3 lessons and move from less controversial to more controversial. And I look forward to engaging with all of you during this event and going forward as well.

So, first category of what we have learned from COVID, 3 things. The first—and again going from the more obvious, less controversial to perhaps more controversial—the first is that there are many neglected issues that have been bared for everyone to see. Not a surprise to any of us who work in health, but I think these may be some issues that much of the American public may not have had as much awareness of—for example, health disparities. Disparities did not start with COVID, but COVID certainly amplified them.

We saw this early on in terms of who has the ability—the privilege of social distancing, and who does not. We also saw this in the way that vaccine distribution first occurred, and when something was in extremely short supply like COVID vaccines, it was those who were able to get their smartphones and have all their friends and family start finding vaccine appointments who were able to get them first. Now, we also see those disparities don't go away on their own, and we're now seeing many of these same disparities playing out in monkeypox. We're seeing the same disparities playing out in virtually every other health issue that we can think of. But that, I think, is a neglected issue that more people are seeing now more than ever.

ISSN 2163-5315

Similarly, with the concept of social determinants of health. Now again, all of us working in health and in health care know that you can't separate someone's health outcomes from the housing that they have access to, from the food that they have access to, or from working conditions, but I think those issues also really played out during COVID in a way that shed awareness for the first time for many individuals.

One more issue, too, is that this country is really lacking in public health infrastructure, and one could even argue that we don't have any kind of functional public health infrastructure. It was mentioned that I ran Baltimore's health department. And I saw for myself every day how it was all about robbing Peter to pay Paul, that already—those of you who have a public health system for local and state health departments across the country know what I'm talking about here—people are already wearing multiple hats. The same people working on school health are also being pulled to staff shelters for individuals experiencing homelessness in the winter. And then you have something like COVID come along, and those same people are being moved from school health to now working on setting up vaccine clinics or setting up testing. And then now there's monkeypox, or now there's the reemergence of polio, and now these people are being pulled off these other crucial priorities to emerging issues, too. And I think this has been another issue bared for everyone to see, that there is no face of public health.

Now, by definition, public health works when we are invisible. But the problem when we're invisible is that public health becomes the first thing on the chopping block when it comes to budget time, and as a result, we're seeing the consequences of neglecting public health throughout. Well, I just hope that we have learned from all of this that the cost of doing nothing isn't nothing. Just something that my former mentor, the late Congressman Elijah Cummings, used to say, "the cost of doing nothing isn't nothing." Now, when we neglect public health, there are severe consequences, some of which we have seen during COVID.

The second lesson that I believe we've learned from COVID is that public health depends on public trust, and when that's eroded it's very difficult to get back. When I look back at the very beginning of the pandemic—I think in retrospect with 20/20 hindsight—things could have been done differently. And actually, probably the top thing that I wish that I and others had done a better job of communicating early on and throughout is that change is to be expected. Actually, change is the bedrock of sound public health policy when you're in the middle of an ever-changing situation like a new virus and a new pandemic.

Now, when you look at many of the arguments against vaccines or various COVID protocols, it's that public health officials are accused of being flip-flopping, but it's not flip-flopping when circumstances change. In the beginning, as you all remember, we didn't know that COVID was airborne. We were really worried about surfaces, and we were advising people to wipe down groceries. There were no recommendations for masking early on because we just didn't know about transmission, and then we recommended masks. But then, it looks like flip flopping even though it was that the science evolved, and also that circumstances changed.

Similarly, when vaccines first came about, we believed that in addition to preventing severe illness, they also prevented infection. Well, that changed with evolving time, with the arrival of the Omicron subvariants that the vaccines were less protective against infection during Omicron spread. And so, there is less a case for mandates than there were before, and so recommendations have to change with those growing circumstances with those changing circumstances in mind.

And that's actually something that in clinical medicine is really apparent because, in clinical medicine, you would absolutely expect that if you're treating a patient with cancer, as an example, and there's a new chemotherapy regimen that comes out, you would absolutely expect that your clinician is going to be offering that new regimen. You want your doctor to stay up to date with the science. And also, changing circumstances matter too. Using the same analogy, if someone's body is responding one way to one treatment and not responding as well as it should maybe to another, you would expect those recommendations to evolve.

Well, that should really be the case when it comes to public health policy as well. And again, looking back, one thing that I wish we had done a better job of is to communicate that change is the bedrock of good public health policy. And I think by communicating the change, communicating not just what changed but why, over and over again, I think that is going to be crucial to reestablishing trust.

The third lesson that I believe that we've learned from COVID is that public health has become very polarized. Now, my great concern prior to COVID was that people were not thinking about public health. Now, we had to make the case for why public health matters to public safety, or why it matters to education, and why it matters to the economy. But it was a fairly neutral topic—it just wasn't something that people really thought about. And a major concern, having run a local health department, was that public health was always underfunded.

Well, I have a different concern now, and I think it's an even more significant concern. Let me take you back to a

focus group that I had the opportunity to participate in for the Bulwark, and we did a podcast based on this. But the focus group was looking at the various mitigation measures, and they were interviewing Republicans, Democrats, and Independents, and what really came through in the focus groups was that masks and vaccines means something other than what they are, which are public health measures that help to reduce virus transmission.

For one group, and you can guess which group, but for the group that's anti- these measures, they see masks and vaccines as being about control, about government control over individuals. This was a fight for individual liberty, versus for the other group that very much wanted masks and vaccines—one would argue perhaps even want mask mandates and vaccine mandates still. For the other group, it was almost a reaction to that first group, and masks and vaccines equaled caring for others and equaled not being part of that antimask, antivaccine "Republican" group.

And so, I bring this up because I really worry about this. I mean, public health has always been hard because it's about balancing individual liberty versus what's best for all and protecting the most vulnerable. It's not clear where that pendulum is going to be, someone is always going to be accusing you no matter what policy you set of having the balance wrong. You're either weighing more toward individual liberty or more toward doing something that protects all but at the cost of individual liberty, and that's not an easy balance to strike.

I mean, even thinking about something as basic as whether somebody with multidrug-resistant tuberculosis should be required to quarantine or be required to isolate for the duration of their illness. I mean, even something like that that I think for most of us in public health would be pretty easy to say, "yes, that person should be in isolation." But enforcing that, especially against that person's will, that's still a matter of saying what's best for people—for all people, is going to outweigh individual liberty. So that balance has always been hard to strike.

But I would say now that balance is many times harder to strike because we are now seeing a substantial backlash against public health in a way that we have not before. We have more than half of states passing laws and legislatures passing laws that restrict public health authorities in some way. That's not just going to affect COVID, but many other issues down the line. For example, if there is a bill that prevents local health authorities from issuing mask mandates in the future, a patient with multidrug-resistant tuberculosis, or somebody with measles, which is a most contagious illness—things like that will also be affected as well.

We know that routine childhood immunizations are falling, and that's something that's also very concerning. We're seeing that immunizations that previously were just accepted as something that children should do, was an opt-out. Now a lot of parents are beginning to question whether certain immunizations should go forward or not.

And I have this very significant concern that the backlash against COVID restrictions, because of how politicized COVID has become, is now bleeding into these other things, and there are really significant consequences here. We're talking about infectious diseases, but we're also talking about other aspects of public health. Again, if public trust is eroded, it's very difficult to get back. And I'm very concerned that we're going to lose trust from the public for the next virus that could be a pandemic, or we could even lose trust from the public for other routine public health matters that previously were not questioned.

Now, it's unfortunate that many public health officials and experts during COVID have been attacked for our views. Dr Hotez is certainly one who's come, unfortunately, under attack. I have had similar experiences, and I would just say that from my standpoint, I think there is a reflex—sometimes blame, if you will—of saying, "well, it's one side. It's the antimaskers or the antivaxxers who are attacking us for our views." But I actually think that these attacks come from all sides.

And again, this backlash I really fear is going to hurt what public health is able to do in the future. And so, here's the controversial statement that I'm going to state and leave us on before we move to the second part of this conversation. And the controversial statement that I have is that the more we keep focusing on COVID, the more it's going to bleed into and have consequences on other aspects of public health.

And I actually believe that when restoring trust in public health, we have to recognize that good health is not just the absence of COVID, and we have to recognize that, like it or not, COVID has been inserted in the middle of culture wars. And that if we are going to have any chance of depoliticizing public health and bringing public health back to this nonpartisan state that it should be in, I believe that we need to put the focus away from COVID and more on other health issues that also very much impact health and well-being but are not subject to that same polarization as unfortunately, COVID-19 has been.

I now want to move to the second part of this discussion, which is "What can we do moving forward as medical communicators, as journalists, and as people who are public-facing?" And here, I have 3 recommendations, and

they're going to move again from more obvious and less controversial to perhaps a bit more controversial. So, 3 things on how we can propel the conversation forward.

The first is that we need to be transparent and intellectually honest with the public. Let me explain to you what I mean here by giving you an example of something that happened at a conference several months ago. I went to a conference that was a lay audience conference, was talking about COVID, and at that time just doing an explainer on boosters, vaccines, and immunity. And at the end of the conference, 3 people came up to me and almost whispered a question, and it was said to me as well, basically, "I didn't want to raise this issue in this forum in front of everyone, but I want to ask you about natural immunity—is that a thing?"

And I believe that our duty, as communicators, has to be to give the full truth, not just the truth that we think others can handle. Because if we do that, if we try to limit the truth and censor those who are trying to tell a fuller story, then I believe we're actually undercutting public health further and eroding trust further.

Of course, it is a thing. I mean, it is true that there is such a thing as "natural immunity," also referred to as immunity after recovering from COVID or from other infections. I think what's happened, and the reason why these very well-educated individuals who are very much pro-vaccine were afraid to ask the question, was that they feared a backlash. They feared a public response of other people in that audience accusing them of being antivax for asking the question about whether natural immunity exists.

But you know what? It does exist, and I think if we are not honest about it with individuals. Because look, I understand all the reasons at the beginning of the pandemic—I think especially right after vaccines first came out—I think there was this fear that if you talked about immunity after recovering, that people are not going to want to get vaccinated. But the thing is, you can say 2 things are true are once.

It is true that you have some level of immune protection after getting infected. It is also true that you could get even better, more robust, and more lasting protection if, in addition to recovery from infection, you also got vaccinated. And, in fact, we have many studies now showing that this hybrid immunity conveys probably the most durable, the most consistent, and the strongest level of response.

But acknowledging natural immunity isn't being antivax, and actually, not acknowledging it makes people think that you're hiding something from them and that you're not being intellectually honest. And so, I think part of this is what we can do, I believe, as medical communicators are really being honest even when that topic is nuanced and difficult.

Now, we talked a little bit about masks earlier. I think that one of the reasons why the World Health Organization and the Centers for Disease Control and Prevention were not recommending masks early in the pandemic, very early in the pandemic, was that there was a very limited number of masks, especially N95 and new prevalent masks. And I think that we should have been honest and said masks could be helpful. We're not sure because at that point in the pandemic—we're talking March of 2020—we didn't know exactly how helpful they were, but we could have said, "They probably are helpful, but right now we need to save them for health care workers." I think that that type of intellectual honesty would have also avoided some of the accusations against flip-flopping later.

Similarly, with monkeypox vaccines, I think we should have been honest to say that they need to be rationed when there's a limited supply and a lot more people interested in getting the vaccines than the supply initially was for. I know that rationing is a bad word, but it's also the truth that at that time rationing had to occur.

I think sometimes in communication in general, there is a need to try to simplify for our audience—and look, I'm not saying that this is easy at all. But I also think that our audience deserves the truth from us, and the truth is that science isn't always clear-cut, and that medicine exists in the area of gray.

Two things—or multiple things—can be true at once. For example, mitigation measures can and do reduce the spread of the virus, but they all come at a cost. Telling people, for example, to not gather with one another, having physical distancing, even mask-wearing—yes, they reduce spread, but they also have a cost. And so, I think those people who are trying to again get people to do something that they don't want to do and follow mitigation measures sometimes feel like, well, we have to emphasize only the benefit. But then, I think we're not being intellectually honest if we don't also talk about the cost.

And I believe that our duty, as communicators, has to be to give the full truth, not just the truth that we think others can handle. Because if we do that, if we try to limit the truth and censor those who are trying to tell a fuller story, then

I believe we're actually undercutting public health further and eroding trust further.

The second thing, and again, 3 things here on things that we can do differently. The first is to be transparent and intellectually honest. The second is to acknowledge that following science is not a sufficient motto—that public health is, of course, based on the science, but ultimately, it's about values. There's been a lot of discussions now as we are moving through the emergency phase of COVID-19 about when mitigation measures end, and that is in some ways based on the acceptable number of infections, acceptable number of hospitalizations, and acceptable number of deaths.

Some people might say that as long as hospitals are not getting overwhelmed again, then mitigation measures can end. Others will say that as long as infection levels are high, as long as there is long COVID, then we need to keep up mitigation measures. I mean, these questions are based on the science because modeling, for example, can help us to understand where we're at and where we're going. But this is not just a scientific question, this is a question just as much societal value. I think it's important for us to again be intellectually honest about that.

We also, crucially in public health, have to consider where the public is at. There is no point in recommending something if people literally won't follow it. My sister's partner is Dutch, and we were recently having a conversation about how in the Netherlands bike helmets are not required, and very few people are actually wearing bike helmets. And for us, in this country, it seems rather shocking that you have all these people biking but with no helmets. And the point that my sister's partner was raising is, well, let's say that you actually are now saying that helmets are going to be required, but if half or more of the population literally are not using helmets, it's going to be impossible to enforce. And then if people start questioning this law or this regulation, you may have the issue of the boy who cried wolf. If they don't trust you on this, and this thing cannot be enforced, then why trust you on other issues?

And I think that's been one of my considerations in thinking through when our mitigation measures need to end. It's a values question, but the value also has to take into consideration where people are already. If most people are already not wearing masks, if most people have already returned to going to indoor restaurants and going to travel, it's not going to work to say, "oh no, don't do those things." Rather, we need to work on, in a sense, harm reduction.

We need to help people to do the things that they want to do and make it safe for other individuals who are more vulnerable, so doing things like recommending same-day testing for individuals before they go see their elderly relative in a nursing home or making sure that people have access to vaccines and boosters. And that we're also making treatments readily available and reducing all barriers to treatments and making sure that there are lots of other treatments that are actually hugely underutilized like Evusheld, the preventive antibody—for example, it was hugely underutilized.

How can we make sure that those things are pretty low-hanging fruit? I mean, these are not things that there is a societal objection against, but they are things that as a policy matter, we can try to make them more available. And I think that that's one way of considering where the public is at and knowing that you're not going to force people to do something that they don't want to do. But you can still work around where people are to get to the point that we all need to get to, which is protecting the most vulnerable.

This is another call for understanding and accepting the nuance that circumstances have changed. And I think part of this nuance is accepting that just because most individuals have returned to normal doesn't mean that some individuals haven't, and it also doesn't mean that societal change has to stop.

Sometimes, especially when you look at social media, it seems like there are people who want to simplify and say, "well, if you are in favor of people returning to normal, that means that you don't acknowledge that COVID is real, or you don't acknowledge the more than a million deaths from COVID, or that you don't acknowledge the toll of long COVID." I think both of those things can be true at once: I think it can both be true that COVID has had this huge, terrible societal impact and continues to have an impact, and we need to address societal policy issues like improved ventilation, and paid sick leave, and aiming for universal access to health care.

You can aim for societal change, but at the same time also acknowledge that Omicron COVID is going to be with us for the foreseeable future, and that we need to emphasize returning to normal in order to get people to see that good health is not just the absence of COVID—both of those things can be true at once. And I think we as communicators should really push back against those who seek to simplify and further polarize where we're at in this discussion.

And so, that makes me move to the third thing. After being intellectually honest and talking about values, we need to embrace our role to seek the hard truths and to act with fairness and empathy. All of you as communicators and journalists, you are finding these neglected issues that

we begin our conversations with. You are the ones who are finding out about health disparities, and you know that if you don't dig around for those data often, they're not being produced. And so, I want to commend you for what you're doing in this sense to really shed light on disparities, on social determinants, and on these other neglected issues.

You also have such a crucial role to play as a communicator in accountability. How is the funding that's being allocated being spent? There was funding going to classrooms for improving ventilation, and all this money going to local health departments. Well, where is that money and how is it being spent? You are also the ones helping to make the connections on these various issues related to social determinants of health, and I think that your role here is so important.

We started this conversation, too, by talking about conflict and controversy. Well, I want to put another plug in for how a lot of that conflict and controversy is manufactured. Often, it's someone taking one sentence out of context, and that they want to make you, or me, or all of us about one or the other. And I think that our role as communicators also has to be honest and fair and to really point out when something is being taken out of context.

I believe, too, that we have a role to be decent to one another, and when we fight among each other there is a potential harm that it erodes trust for all of us. And frankly, there are so many more issues that we must address together. We have the reemergence of polio, we have routine childhood immunizations falling off a cliff, and we have the opioid epidemic driven by fentanyl that's gotten worse now more than ever. We have women's health at a crossroads that's being threatened across the country, and we have mental health that's long been neglected and getting worse at this time. And, of course, we have this issue of robbing Peter to pay Paul and not having sustainable infrastructure for public health. There are so many issues that we need to address together.

And I hope that coming out of COVID, we're able to come together and address these other issues, digging up data where needed, and holding people accountable where needed, but also trying to take away that level of anger from the conflict and controversy. We're trying to depoliticize public health and getting us all back to the place where we're able to work together on these difficult issues.

Now, the work ahead, no doubt, is very challenging. I want to end with a quote and an appreciation for all of us who work in public health and communication. And this quote is by Dr Harrison Spencer, a former leader in public health—as you will see from this quote. And Dr Spencer says that "Public health is filled with heroes, both well-known and unknown. They are visible on the national or international stage, or they work quietly in communities with families and individuals. When they do their job, they often become invisible."

Well, I believe that that is the job that you all do in AMWA every day—you help to make the invisible visible, and you help people to navigate their lives at very challenging junctures. And you're also helping us to push forward to a time where we're able to really value public health as the crucial aspect of our overall national security and our well-being, and you're helping to lay bare all these crucial issues that many people unfortunately are neglecting. And I truly believe that when the long arc of history is written, you will be the heroes, and I am so honored to join you at AMWA today.

Thank you.

Acknowledgment

I thank Kavita Garg, Director of Medical Writing at Saliegral Global, for her help in bringing the transcript to the page.

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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CONFERENCE

Session Report

Attention!: How to Harness It for Productivity and Deep Work

Ann Winter-Vann, PhD
Director of Medical Writing Services, Whitsell Innovations, Chapel Hill, NC
Kelly Kilibarda, PhD
Manager of Medical Writing, Whitsell Innovations, Chapel Hill, NC

By Allie Boman

Dr Kilibarda started out by declaring that, although she and Dr Winter-Vann created it themselves, she was unhappy with the title of her presentation. The word harness, she said, implies that attention is outside of yourself and you need to catch it. Rather, like happiness, attention is already within you. Thus, a better title would be "How to Cultivate Attention for Productivity and Deep Work."

Dr Kilibarda, and later Dr Winter-Vann, presented a curated set of attention theories and practices, rich with lived experience and tangible ideas for implementation.

First, Dr Kilibarda challenged the idea that work and play exist on opposite sides of the spectrum of unenjoyment to enjoyment. She decried this idea as a false binary and encouraged a more holistic view of work as expression and productivity.

We can increase the enjoyment and fulfillment of our work by cultivating our attention. In doing so, we create contexts in which we access and produce the best we have to give.

Without some intentionality, however, we may remain in shallow work—tasks that require little cognitive power but take time—for most of the day or week. Shallow work is often visible to others and holds some value, but it can easily be replicated by others.

In contrast, deep work provides a context for enjoyable, fruitful productivity. Summarizing Cal Newport and others, Dr Kilibarda described deep work as a distraction-free state requiring cognitive power, concentration, and endurance. By training ourselves to regularly enter into deep work, we access and produce that which we alone can contribute. We create space for offering our true value.

Dr Kilibarda explained that the sweet spot for deep work is 90 minutes without interruption. It takes training and practice to be able to concentrate for this long, but learning to do so is key to contributing our best work. She stated that the average worker wants about 8–10 hours of uninterrupted deep work per week. However, managers and teams tend to undervalue long periods without interruption because it appears as though little is being accomplished. Therefore, maintaining this practice at work requires self-advocacy.

Dr Winter-Vann built on the theory of deep work, covering how to cultivate attention practically.

HOW TO CULTIVATE DEEP WORK

- **Prioritize** tasks using Eisenhower's urgent/important matrix
- **Plan** time blocks, building space in your schedule for deep work
- **Communicate** when you are entering a deep work block, so people won't expect an instant response from you
- **Enforce boundaries**—don't agree to meetings during your planned deep work times
- **Shut off notifications** (use "do not disturb" on your devices, etc.)
- **Create a routine** around deep work sessions (signal to your brain that it's time to do deep work; similar to bedtime rituals for children)
- **Rest** between sessions of deep work
- **Audit your time**—how does what you did compare with what you planned to do?

HOW TO MINIMIZE SHALLOW WORK

- **Automate/delegate** low-importance tasks
- **Set reminders** to release yourself from needing to remember details (e.g., set an alarm for when it's time to leave work to pick up your kid from school)
- **Compress** the time allotted to answering emails, etc. (e.g., plan a 30-minute session for responding to messages)

ISSN 2163-5315

- **Normalize** unavailability—counter the expectation that you will respond to messages immediately

Dr Kilibarda emphasized the value of getting into a flow state via deep work. The idea is to be so immersed in your work that time disappears. Some tedium is required for reaching this state, partially because we are used to dopamine fixes: when we rely on instant rewards through easy tasks and distractions, we are feeding our brain dysfunction. So part of mastery in deep work is getting used to boredom, which Angela Duckworth says is very tiring! This is why rest after a session of deep work is crucial, even if it doesn't look like we've accomplished much.

Finally, Dr Winter-Vann reiterated the difference between shallow and deep work: Shallow work doesn't take much skill. It might require a few weeks to train someone to do it. (In fact, you might consider training someone to take over some of your shallow work!) Deep work, however, accesses the skills and knowledge that you have developed over months and years. It is in this context that you bring forth your unique value on the job and in your world.

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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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AMWA2022

Julia Forjanic Klapproth, PhD (left) receives the 2022 Harold Swanberg Distinguished Service Award from Sarah Dobney, MPH.

Brian Bass, MWC is our 2022 Golden Apple award winner!

Kelly Byram, MS, MBA, ELS (left) receives the 2022 AMWA President's Award from Katrina R. Burton, BS.

AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N1 / 2023

CONFERENCE

Session Report

DIY Graphics for Medical Writers

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By Jerm Day-Storms, PhD, MWC

Successful medical writers can clearly communicate a message to the intended audience. Many times, the written word alone may not be the most effective method of communication. The client may even ask the medical writer for help in designing a visual aid or presentation. Graphic design tools are available, but they may be cost-prohibitive or have steep learning curves for mastery. Instead, medical writers can use a familiar tool, Microsoft PowerPoint, for graphic design.

WHAT IS GRAPHIC DESIGN?

Graphic design is the art of visual communication using text, images, and symbols. Medical writers use the 3 aspects of graphic design—layout, color, and typography—to help convey the message of the project. The layout consists of how the information is organized as well as how visual elements are placed on the page or slide. The colors and typography used can enhance the visual appeal of the work.

Graphics work by medical writers can be diverse. Medical writers may be asked to format, lay out, or design slides or posters for presentations. They may create specific visual elements, such as charts, graphs, or diagrams. Typically, a client provides a template and color palette, but a medical writer may be required to design a simple color palette and template. Medical writers often transfer graphics from one format to another. For example, a single graphic element may be required to be transferred across manuscript, slide, and poster formats.

When designing graphics, medical writers must

- keep it simple by sticking to the main points,
- remove superfluous information,
- avoid an overwhelming number of objects and colors, and
- use a logical order to make the story easy to understand.

CHOOSING THE RIGHT TOOL FOR THE JOB

Deciding which graphical element best explains the data is important. Will the intended audience understand the story better if conveyed as a table, graph, diagram, or chart? Sometimes, text is the best option if it is formatted to make it visually appealing, such as by varying color or font. Other times, a medical writer may transform one less effective method into a better one for a particular point. For example, a table comparing 2 different treatments may be easier to understand as a graph.

Because medical writers must use graphics in a variety of projects, it is important to delve deeper into different types of graphics that can be produced using tools from the Microsoft Office suite.

Tables

Tables are the simplest graphical elements created by medical writers. For manuscripts, tables are created in Microsoft Word using the Table function of the Insert menu bar. Likewise, for posters and slides, tables are created in PowerPoint using the Table function. Tables created within either Word or PowerPoint are easily transferred by copying and pasting as a table with reformatting, as necessary. Tables never need to be recreated when information is moved from one format to another.

When using tables as a visual element in a project, it is best practice to keep color formatting consistent. For example, in a presentation or poster, the control group should be presented in tables as one specific color and the experimental group(s) in another throughout the project to increase the visual appeal and flow. Another option is to use different background shades (from the same color palette, of course) for the control and experimental groups.

Tables can also be used to make text easier to read. Data from bulleted lists can be transformed into a table with horizontal lines and light background, creating a visual element that is more scannable. Similarly, tables can be used to simplify potentially complex topics by using different shades and/or symbols to help classify groups of data (Figure 1).

ISSN 2163-5315

Drugs Class	Weight change
Secretagogues	↑
Thiazolidinediones	↑
Insulin	↑
DPP-4 inhibitors	↔
Colesevelam	↔
Bromocriptine quick-release	↔
α-Glucosidase inhibitors	↔
Metformin	↓ or ↔
GLP-1 receptor agonists	↓
SGLT-2 inhibitors	↓
Amylin mimetics	↓

Figure 1. The table as a visual element. Tables can be used to create visual elements for classifying data by using shading and/or symbols.

Figures

PowerPoint offers built-in Excel functionality, including the ability to create visually appealing charts and diagrams. For figures that are data-driven, such as graphs and charts, the data are stored within the embedded spreadsheet. The data can be easily updated in the spreadsheet with the changes automatically reflected in the slide's graph. Also, the graph can be reformatted within the slide.

Figures created within one presentation can easily be copied across different platforms, including manuscripts using Word or posters using PowerPoint. When copying a figure from a slide into a manuscript, it is best to paste the figure as a picture to lock in the formatting. When copying the figure into a different PowerPoint file, do not paste the figure as a picture. From the Paste Options menu, choose "Keep Source Formatting & Embed Workbook" for data-driven graphs. For any figures that are not data-driven, choose either "Keep source formatting" to keep the graph formatting the same as in the original file or "Use destination theme" if the desire is to have the format match the new file.

Resizing figures can be simplified by using the sizing function for uniform resizing. Locking the aspect ratio maintains the same proportions of the original objects. It also allows for resizing multiple figures to precisely the same size.

Available figure options include traditional bar graphs, scatter plots, line graphs, and pie charts. Additionally, more complex biostatics charts, such as Forest plots and Box and Whisker plots, can be created or modified to help explain data. Labels can be added to the data even for select data points, if desired. Background shades or use of shapes can help highlight important data.

Creative use of shapes, graphs, and gradients can be used to visually tell a story. For example, a pie chart with a subchart can further sub-divide data into groups (Figure 2). This example is created using 2 pie charts connected by a trapezoid filled in with a gradient to indicate a faded zoom.

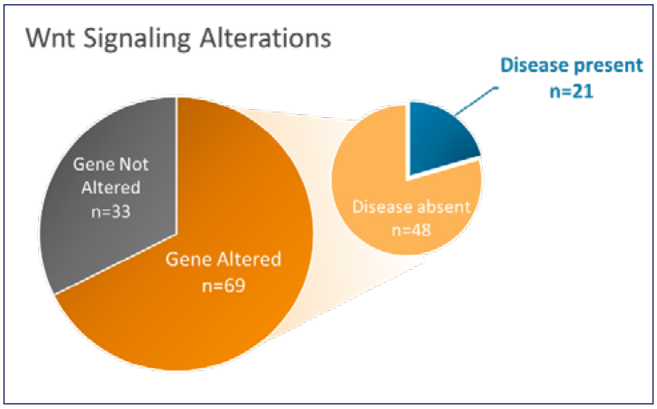

Figure 2. Complex figures to depict data. Using graphs and charts with shapes and gradients can help tell the story of complex data.

Slides

PowerPoint's reputation for creating robust slide presentations is well-known and well-documented. Generally, the basics of any slide presentation consist of template, color, and graphics. The client will usually provide the medical writer with a slide template containing the approved color palette and appropriate layouts. Occasionally, the medical writer may be tasked with developing a template which can be accomplished either by using or modifying one of the many theme templates from Microsoft or by creating a template within the Slide Master menu of PowerPoint.

Color can be used to organize information throughout the presentation to aid in the flow and to make it easier for the audience to understand. Colors can be chosen from a list, gradient, or wheel, depending on the chosen menu. It may be difficult to precisely match 2 colors. Each color has a unique six-digit hex code. If the hex code is known, it can be entered in to choose a color. However, if the hex code is unknown, the eyedropper tool can easily be used to select and match a desired color. This is helpful, for example, when trying to match legend colors to specific colors within a figure.

Slide presentations should be visually appealing, so graphical elements should comprise at least 2 out of every 3 slides. Keep text at a minimum by converting as much text as possible to graphical elements. Keep any bullet points to a single line of text, and do not use more than 2 levels of bullet points on a single slide.

Boring bullet point slides can be transformed into visually appealing graphical elements. For example, the bullets

could be changed into vertical boxes with different shades of color to help each point stand out. Rather than having a bulleted list of dates or events, a timeline figure can be created from the simple chevron shape in PowerPoint. Insert the chevron and stretch it out to create a timeline figure. The figure can even be filled in with a gradient of colors to help emphasize the passing of time or events. Likewise, lines and icons can be added to the timeline. The color of icons can even be altered to match the timeline color. Also, a simple bulleted list can be turned into an eye-grabbing visual aid with the addition of color and stock figures. For example, see how the following list is radically changed (Figure 3).

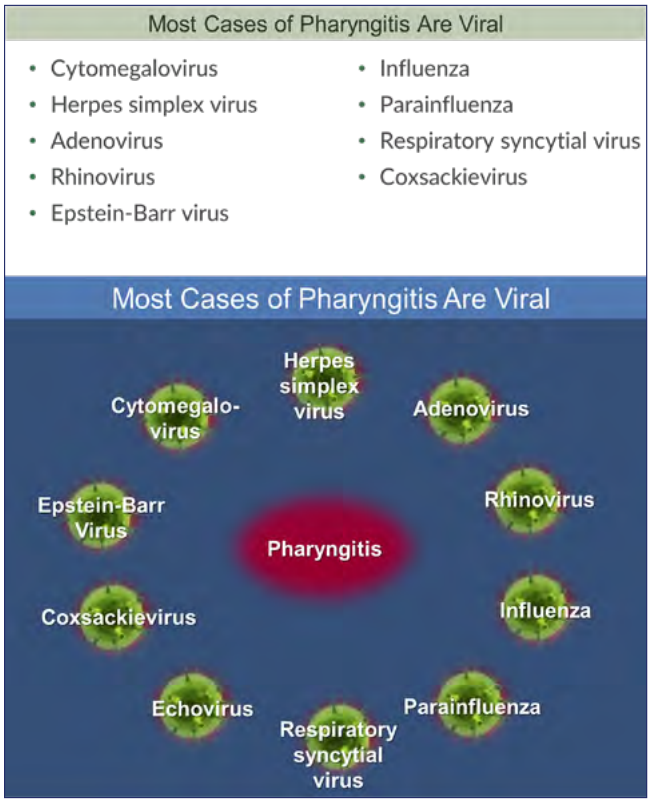

Figure 3. Transforming bullets. Simple bulleted lists (top) can be transformed into visually appealing graphical elements by using color and images (bottom).

Slide animations should be used sparingly. Do not use animations as devices to transition from one slide to the next, such as the spinning slide, because it can distract from the presentation rather than enhance the story. Only use animation to help the audience follow the story. For example, a build can be used to show progression or highlight important trends. If a graph, gel, or image contains large amounts of data, then an animation can be used to help the audience digest the information in smaller pieces.

> When creating graphics, remember to keep it simple so that the intended audience can follow the story and to not distract from the message by overloading with graphical elements or an overabundance of colors.

Posters

Poster presentations can be created using PowerPoint's Slide Size menu function in which the poster is created on a single slide of the appropriate poster dimension. The poster layout, which plays a vital role in the presentation organization, may be either portrait or landscape. For portrait posters, the presentation is divided into horizontal sections whereas it is divided into vertical sections for landscape posters. Regardless, the largest section of the poster organization should be reserved for the results. The title and authors are always listed across the top of the poster. Additional poster sections include introduction/background, methods, and conclusions/summary. One way to economize space, if possible, is to move any acknowledgments, references, and disclosures to the bottom of the poster in a smaller font. Posters should be saved as a PDF.

Like a slide presentation, color is an important aspect of the graphic design. Use one main color with 2 accent colors chosen from the color palette. Some graphs or figures that contain more data may require additional colors. The colors should be used consistently throughout the poster to maintain clarity and flow.

Poster content should primarily be visual elements with text at a minimum. The graphs, tables, and figures should be easy to understand without requiring extraneous textual details. Section headings, such as background and results, should be one color with any subheadings in an accent color to help visualize hierarchy.

MEDICAL WRITERS DO NOT NEED EXPENSIVE TOOLS FOR DO-IT-YOURSELF GRAPHICS

Visually appealing, easy-to-follow graphical elements add clarity to a presentation or manuscript. Medical writers can successfully create their own graphics without using expensive tools because Microsoft PowerPoint with its built-in Excel function can create high-quality, editable visual elements. Usually, clients are familiar with Microsoft Office

products and are happy that the graphics can be easily transferred from one format to another. When creating graphics, remember to keep it simple so that the intended audience can follow the story and to not distract from the message by overloading with graphical elements or an overabundance of colors. By knowing which Microsoft Office product can be used to create the project and how to transfer it (Figure 4), medical writers can design their own graphical elements or projects at lower cost and lower learning curve than an expensive graphics program when using a platform that most clients use.

	Manuscripts	Posters	Slides
File type	Word	PowerPoint	PowerPoint
Graphics software	PowerPoint	PowerPoint	PowerPoint
Paste figures as	Picture	Graphic object	Graphic object
Submission/ presentation	Word	PDF	PowerPoint

Figure 4. Do-it-yourself graphics for medical writers. Medical writers can use inexpensive tools, such as Microsoft PowerPoint, to create, transfer, and present graphical elements.

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

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AMWA JOURNAL V38 N1 / 2023

CONFERENCE

Session Report

Inclusive Language: Best Practices and Practical Applications For Medical Writers and Editors*

Speakers
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By Rebecca Moran, MD

Medical writers are uniquely positioned to help address inequities and bias in medical research and reporting by adopting best practices for use of inclusive language. Writers who embrace inclusive language strive to focus on the perspectives and voices of those who have traditionally been marginalized or stereotyped and aim to avoid expressions that exclude groups of people who have historically faced discrimination. Although the inclusive language umbrella encompasses a variety of groups and people, this presentation specifically focused on inclusive language as it applies to race, ethnicity, gender identity, and sexual orientation. To aid in the audience's understanding of these concepts, the speakers provided definitions of several key terms (Table 1).[1]

GOOD FOR SCIENCE, SOCIETY, AND BUSINESS

Adopting principles of inclusive language makes data stronger. It recognizes that people use different terms to self-identify based on their race, ethnicity, gender, gender identity, and/or sexual orientation. When surveys or other research tools use generalizations or stigmatizing terms, study participants might feel confused, negated, or "othered." As a result, they may feel unable to accurately complete a survey or be unwilling to participate in the study at all. Using inclusive language increases the likelihood that a diverse array of people will participate in research, which in

Table 1. Definitions of Key Terms

Diversity	Focuses on identities that correspond to societal differences in power and privilege and therefore the marginalization of some groups based on specific attributes; involves the representation of various social identity groups
Race	Generally regarded as a means of differentiating between people by phenotypic characteristics such as skin color; it is a societal construct that has historically been used as a tool for oppression
Ethnicity	A multifaceted component of one's identity that can encompass the nationality, tribal affiliation, religion, language, and traditions of a particular group, among other aspects; as with race, it has been a basis for discrimination
Unconscious bias	Social stereotypes about certain groups of people that individuals form in an unconscious manner
Othering	To view, treat, depict, and/or refer to a person or group of people as intrinsically different from or inferior to oneself using an "us versus them" mentality
Gender	A set of sociocultural norms and expectations about behaviors and characteristics regarding what is considered "masculine" or "feminine" in a given society or context
Gender identity	One's innermost concept of self as male, female, neither male nor female (eg, nonbinary), a blend of genders, or no gender; how one identifies based on these characteristics (eg, gay, lesbian, bisexual, pansexual, queer)
Sex assigned at birth	The assignment (male, female, or intersex) that a doctor or midwife uses to describe a child at birth based on anatomy and chromosomes
Sexual orientation	Emotional, romantic, and/or sexual attraction

Adaptation of Emery and Hicks[1] reprinted with permission from RTI.

* *This manuscript is based on a session from AMWA's 2022 Medical Writing & Communication Conference.*

ISSN 2163-5315

turn impacts health equity. It also signals to clients that you have expertise in this skill and that you (or your company) are keeping up with evolving terminology standards.

HOW TO START USING INCLUSIVE LANGUAGE

To start using inclusive language, the speakers encouraged all medical writers to ask themselves the following questions when writing or reviewing documents: is the terminology or language used relevant, accurate, inclusive, respectful, and thoughtful?[2] If it does not meet all 5 criteria, Hicks asked writers to consider whether it belongs in the document at all, and if so, can the language be massaged to meet these criteria? She goes on to note that "Incorporating inclusive language into our work requires conscious decisions that call for conscious actions."

Table 2[1] lists specific examples provided by the speakers of language that is generalizing and stigmatizing, as well as their recommendations for preferred alternatives.

Emery and Hicks provided additional advice on how writers can start using inclusive language in their work, including

- Respecting how individuals self-identify and allowing them to select more than one race and/or ethnicity when possible.
- Creating an inclusive language style guide that offers alternatives to generalized terms such as "minorities" and "non-White."
- Being aware of stigmatizing language such as "mixed race" or "at-risk patients."
- Avoiding "othering" language by expanding race, ethnicity, and gender identity response options in surveys.
- Changing "Other" to "A race or ethnicity not listed" or "A gender identity not listed."
- Alphabetizing survey options to avoid creating a perceived hierarchy among surveyed groups.

Table 2. Examples of Preferred Terminology

Avoid	Preferred
At-risk patients, at-risk youth, at-risk communities	Patients at risk of developing… (a specific disease, such as diabetes) Communities of color at risk of developing… Black patients at risk of developing…
Minorities, minority	Best practice is to name the specific group(s) being referenced
Minority communities	Communities of color Historically underserved communities Historically marginalized groups
Mixed race	Biracial Multiracial
Non-White(s)	Best practice is to name the specific group(s) being referenced If the group is unknown, use the above alternatives for "minority communities"
Homosexual(s)	Be specific when possible (eg, "men who identify as gay") Members of the LGBTQ+ community People who identify as LGBTQ+
Sex change	Gender-affirming surgery Gender-affirmation surgery Gender-confirmation surgery
Sexual preference/ lifestyle	Sexual orientation "Preference" and "lifestyle" erroneously suggest that sexual orientation is a choice
Transgendered (used as an adjective)	Transgender (used as an adjective, eg, "a transgender patient")

Adaptation of Emery and Hicks[1] reprinted with permission from RTI.
Definition: LGBTQ+, Lesbian, Gay, Bisexual, Transgender, Queer, and many other terms.

OFFERING FEEDBACK AND MANAGING CLIENT CONCERNS

Efforts to employ inclusive language are relatively new, and you may find yourself in the position of needing to offer feedback regarding it to clients, colleagues, or other writers. The speakers offer several tips on how to approach this in a thoughtful and nonjudgmental way, including:

- Being constructive and collegial.
- Approaching the interaction as a learning opportunity.
- Thinking about how terminology is perceived by the reader.
- Collaborating with your client to create an inclusive language guide for the project.
- Linking to appropriate resources, such as the *AMA Manual of Style* 11th edition section on inclusive language.
- Keeping a log of frequently used feedback to use as stock text.
- Customizing software (such as PerfectIt) to scan for keywords or phrases for use in every project.

Additionally, clients might be concerned about unintentionally offending others or that the language is not inclusive enough. Emery advised writers to express confidence in being able to handle the client's inclusive language concerns, to be humble, and to "recognize that you're human, and the client is too. Inclusive language practices are new to many people, and we are all co-learning."

THE IMPACT OF CHANGE

If Emery and Hicks made one concept exceedingly clear, it is this: words matter. Words have the power to draw us together or rip us apart, and medical writers can help achieve a more equitable, diverse, and inclusive society by adopting the principles of inclusive language. They summarized the enormous potential impact of embracing inclusive language by sharing an eloquent sentiment that appeared in a journal editorial on racial and ethnic disparities in research: "Scientists and scientific journals have the opportunity to facilitate best practices and ultimately impact racial and ethnic disparities. The written interpretations of science by a few shape the future creation of history and science for many."

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Common Acronyms

ABIDE: Accessibility, Belonging, Inclusion, Diversity, and Equity
DEI: Diversity, Equity, and Inclusion
EDIB: Equity, Diversity, Inclusion, and Belonging
JEDI: Justice, Equity, Diversity, and Inclusion
RJE: Racial Justice and Equity

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AMWA JOURNAL V38 N1 / 2023

CONFERENCE

Session Report

Moving From Worst to Best in Medical Writing for Continuing Education in the Health Professions

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Continuing education in the health professions (CEHP), including continuing medical education (CME), is a vitally important and fast-changing field in which medical writers can find challenging and rewarding work. The field draws its importance from the way all stakeholders work together to provide clinicians with the up-to-date knowledge and skills they need to improve patient health outcomes.

CEHP providers include a broad range of organizations, including health systems, medical schools, and government agencies, but freelance medical writers most often work with private medical education (med-ed) companies and medical specialty societies.

CEHP is a growing industry. According to statistics kept by the Accreditation Council for Continuing Medical Education (ACCME), the industry reported $2.81 billion in total income in 2021. Of that amount, $895 million came in the form of commercial support from large pharmaceutical and medical device companies, a sharp increase from $723 million the previous year.[1]

MEDICAL WRITERS HELP PRESERVE INTEGRITY

To distinguish it from advertising, CEHP instructional content must be accredited by a third party, such as the ACCME at the national level or one of its designees at the state level. Individual med-ed companies may also apply to the ACCME for the right to bestow continuing education (CE) credit upon clinicians who complete their courses.

The ACCME endorses a system for the commercial support of CEHP that aims to protect its integrity by erecting a firewall between commercial interests and the expert faculty who deliver instruction to learners. In Standard 2 of its Standards for Integrity and Independence in Accredited Continuing Education, the ACCME states, "The accredited provider must ensure that all decisions related to the planning, faculty selection, delivery, and evaluation of accredited education are made without any influence or involvement from the owners and employees of an ineligible company."[2] In this system, pharmaceutical companies and medical device companies are ineligible to award CE credits, but they are free to provide commercial support so long as they comply with ACCME standards.

The medical writer provides services to the med-ed company developing the accredited program. This program includes a curriculum overseen by expert faculty. The medical writer must not be influenced by any commercial supporter so that the integrity of the program remains intact at each step of the content development process, from the grant proposal to the outcome report.

Before a program can be developed, a proposal is written and submitted to obtain funding. The proposal must justify why the commercial supporter should give money to the med-ed company or specialty society. A typical proposal consists of a program agenda, an outcomes measurement plan, a budget, a delivery schedule, credit information, an audience generation plan, and a needs assessment (NA).

Med-ed companies often outsource these NAs to freelance medical writers. A strong NA is usually built around a core literature review, but it may also include several other types of evidence showing why clinicians need to learn about a particular topic. The narrative of a well-written NA will describe one or more gaps between optimal clinical practice (e.g., as laid out in practice guidelines) and actual clinical practice as observed in the field. The NA serves as the basis for developing the learning objectives for the proposed program, and these objectives in turn justify the agenda, instructional content, and faculty selection.

After a proposal is funded, medical writers typically work with expert faculty in developing content that may include test questions, case studies, monographs, and slide decks. Additionally, medical writers may draft outcome reports for supporters, text to be used with infographics, or conference posters. Well-established medical writers may

ISSN 2163-5315

even write scripts for interactive patient case simulations or publish outcome reports in peer-reviewed journals.

WORST PRACTICES IN WRITING NAs

Though they may work from home offices spread out across the United States, freelance medical writers who develop NAs for CE grants nonetheless form a tight-knit community of practice. Members of this community often call themselves CME writers. From 2014 to 2019, several CME writers carried out an annual survey aimed at identifying best practices for writing NAs. The survey was publicized and supported by both AMWA and the Alliance for Continuing Education in the Health Professions (ACEHP or Alliance). These surveys resulted in several posters, an article jointly published in the *AMWA Journal* and the Alliance *Almanac* in 2019,[3] a mini-tutorial offered to all AMWA members, a presentation at the ACEHP national conference in 2020, and a workshop at the 2022 AMWA Medical Writing & Communication Conference.

Within the 2018 survey, one question inquired about any poor practices that survey respondents might have observed in NAs written by others. Of the 104 writers responding that year, 67 reported a wide variety of poor practices. Two independent reviewers, one from AMWA and one from ACEHP, sorted these complaints into categories. The category with the greatest number of complaints was "sources and referencing," such as outdated research, lack of proper citation, and insufficient support for gaps in education.

FOCUSING ON WRITER-RELATED SOLUTIONS

What are possible solutions to remedy these worst practices? CME writers face many challenges that may impair the quality of their work. Training programs, either employer-based or university-based, are scarce. Moreover, system-related problems, such as labor market supply and demand, industry expectations, or standard project lead times, may lie beyond the control of the individual medical writer. Rather than trying to solve these macro-level problems, it may be more beneficial to focus on micro-level problems that lie within the control of writers, such as improving their professional knowledge, skills, and attitudes as well as learning how to deliver the types of assignments that are in high demand among CEHP providers. In other words, writers can choose to focus their efforts on becoming more competent.

DEVELOPING A COMPETENCY MODEL

Although a 2-part competency model for regulatory writers has been published[4,5] and a training outline for future regulatory writers has been developed,[6] there is no similar model or outline for CME writers. Yet, executives at med-ed companies have stated anecdotally that a competency model to address what they say is a lack of qualified CME writers would be beneficial. Clinicians and former clinicians who are seeking to transition into the field have also shown a strong interest in specialized training opportunities. To meet these needs, a research project using the Delphi method is currently in progress. The project has 2 primary goals:

1. Identify knowledge areas, skills, and attitudes necessary for the next generation of CME writers to excel
2. Identify deliverables that the next generation of CME writers should be able to develop

The Delphi method uses an iterative process of sending successive questionnaires to an expert panel of key stakeholders to forge consensus. In this case, the Delphi panel consists of 22 experts, balanced among writers, teachers, and company executives. Over a series of 3 rounds of questionnaires, the panelists are asked to rate a preliminary set of competencies and to suggest any additions. The competencies span the domains mentioned above: knowledge areas, skills, attitudes, and deliverables, or KSADs. Each successive round of questions contains controlled feedback in the form of ratings of the KSADs as well as rationales for these ratings. Panelists, whose identities are protected from disclosure during deliberations, are free to change their ratings between rounds if they are persuaded to do so after reading their fellow panelists' rationales. A predefined group rating of 4 or higher (out of 5) indicates consensus that a given KSAD should be included in the model. Statistical analysis will be used to test for the stability of responses between rounds and to analyze for any differences between subgroups.

HELPING WRITERS MOVE FROM WORST TO BEST

The ACCME has set high ethical standards aimed at protecting the integrity of accredited instructional content for health professionals. Medical writers are involved in many stages of the content development process and are uniquely positioned to add or subtract integrity. Unfortunately, medical writers often come to this task unprepared because expectations are high yet adequate educational or training programs are limited. This situation leaves many medical writers with no choice but to muddle through and figure things out on their own. A competency model, developed by consensus among key stakeholders in CEHP, will help the next generation of writers approach this important task

more professionally and systematically. Indeed, a competency model may encourage these future writers to pursue excellence in developing high-quality, ethical, and engaging instructional content that will help clinicians, in turn, to develop the competency they need to improve patient health outcomes.

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N1 / 2023

CONFERENCE

Session Report

The Use of Artificial Intelligence and Machine Learning in Clinical Research and Health Care

Speaker
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Founder and CEO, Duke City Consulting, LLC, Albuquerque, NM

By Noelle Ochotny, PhD

Artificial intelligence (AI) projects are becoming more common assignments for medical communicators. In fact, a show of hands in this session revealed that approximately one-third of us have worked on a project involving AI and, among those who had not, many anticipated they would in the coming year.

The presentation was organized into 3 sections. The first discusses the basics of AI and machine learning (ML) technology. The second describes how AI tools are developed and implemented. The third identifies and provides examples of the current and emerging applications of AI in clinical research and health care.

The session's focus is on narrow AI, specifically, on a type of ML called supervised learning. It is important to note that not all the AI health applications discussed in this session are implemented in health care yet.

ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING TERMS

Artificial Intelligence (AI): Leverages computers and machines to simulate the problem-solving and decision-making capabilities of the human mind.

Weak AI, also called **Narrow AI:** This type of AI is limited to a specific task or narrow area.

Strong AI: An AI that has mental capacities and flexible intelligence that mimic the human brain. This type of AI is also sometimes referred to as artificial general intelligence, artificial consciousness, or sentience.

Machine Learning (ML): An AI technique that teaches computers to learn from data.

Algorithm: A set of instructions. In ML, the algorithm learns and evolves without human intervention based on the data it processes. The algorithm builds on commonly used models such as linear regression, logistic regression, Bayesian algorithms, and decision trees. The terms algorithm, model, and tool are sometimes used interchangeably.

Deep Learning: A type of ML that uses an artificial neural network (ANN). ANNs are layers of connected nodes designed to emulate human processing of information.

WHAT ARE SOME CHALLENGES ASSOCIATED WITH AI?

ML model creation requires data and computing resources. Creating the complexity required for a valid ML model can require extensive resources. There are also issues with trust in the ability of the model to make correct decisions that are for the benefit of the patient. Therefore, data and privacy security need to be robust. Having strong data and privacy security can help build trust in the ML model.

CATALYSTS FOR THE DEVELOPMENT OF ML

Recent developments have catalyzed the development of ML models and include

- Big data, which provides the necessary data and resources.
- Cloud storage, which enables organizations to store, access, and maintain large amounts of data required for ML model development. Also consider that the volume of medical data doubles every 8 to 12 months, which requires a lot of storage.
- Powerful computing is essential. ML can be a computationally intensive process, so a powerful computer is needed to handle the load.
- Parallel processing, which allows the ML model to be deployed across multiple processors. This is necessary for the ML algorithm to perform large amounts of computation on large data sets, especially in the deep learning context.
- Maturation of statistics and mathematical methods, which underlie ML.

ISSN 2163-5315

TYPES OF ML

There are 3 common types of ML models, supervised, unsupervised, and reinforcement learning.

Supervised learning uses labeled training data that pairs inputs with outputs (input-output pairs are called examples; a collection of examples is a data set). An application of this type of learning might be an application that predicts if a specific type of tumor is likely to be malignant or benign based on its size, for example. Algorithm training, validation, and testing require a data set be subdivided into a training data set, a validation data set, and a testing data set. Supervised learning occurs via a training loop (Figure).

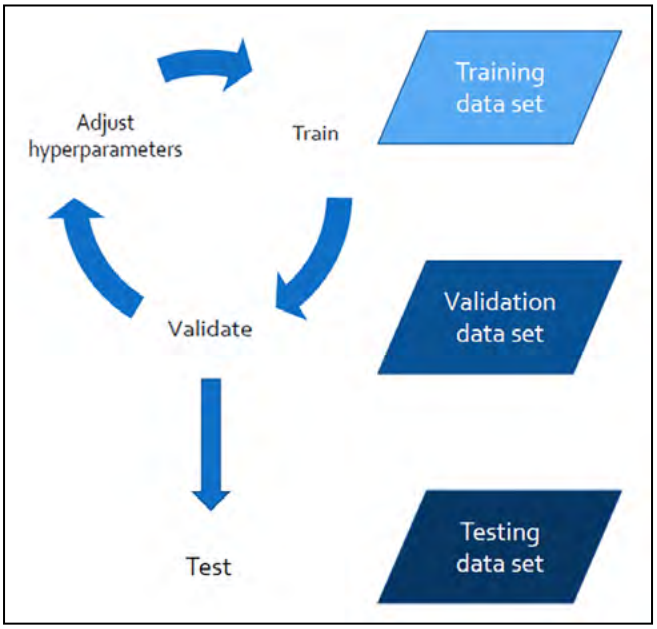

Figure. Supervised learning training loop. Copyright 2022 Duke City Consulting, LLC.

In supervised learning, the percentage of the data set dedicated to each function depends on biostatistical calculations that will inform this decision. This can be similar to the sample size calculations used to determine the sample size in clinical trials. It is important that the data sets are representative of the population so that the resulting ML model is generalizable.

Unsupervised learning uses unlabeled training data—rather, the computer looks for patterns in the data. Some examples of this type of learning are images and pathology data. Used for clustering, segmentation is an example of how this type of learning can be applied.

Reinforcement learning is a reward-and-penalty type of learning beyond the scope of this session.

Deep learning has more complicated models composed of nodes organized in layers. Each layer transforms information and passes it to another layer. The term "deep" refers to the number of layers through which the model operates. In this type of learning, the model can learn from itself to create new features. Ground truth information is fed back into the model to enable the deep learning model to learn from itself. (Ground truthing is a term used in ML that means checking the results of machine learning for accuracy against the real world.) An example of deep learning is facial recognition. Deep learning requires a vast number of resources.

WHAT ARE SOME ML MODELS BEING DEVELOPED IN HEALTH CARE AND CLINICAL RESEARCH?

1. Risk assessment and prevention. The patient completes a questionnaire that includes a personal and family history, and the algorithm can calculate the patient's risk for cancer. To do this, the algorithm uses guidelines such as the National Comprehensive Cancer Network guidelines to determine a patient's risk for certain cancers. The algorithm then goes on to suggest risk reduction strategies and treatment plans for that patient. Is there a role for medical writers? Consider that there are patient-facing and clinician-facing aspects related to the model. Medical communicators may develop information regarding risk reduction, testing, and treatment options that is provided to those audiences. The medical writer can communicate what is going into the model and what is coming out of the model using language specific to the 2 audiences: clinicians and patients. In addition, trust in the model is an ongoing issue. The medical writer plays an important role to develop trust.

Attendees were interested in whether there are guidelines in place on how to communicate the risk assessment and prevention tools to patients in order to obtain informed consent. These tools collect sensitive data from patients and their families, so the patient and the family need to provide informed consent.

The attendees were also interested in whether medical students and residents are receiving training on AI and ML. One attendee reported that their institution, the University of Florida, launched a curriculum on AI development for physicians and clinicians. AI and ML models may affect how medical students and residents receive training. For example, a radiologist has seen thousands of images, and current medical students may not get that experience.

2. Clinical decision support software. There is an ongoing debate about which software is regulated as a device. The United States Food and Drug Administration (FDA) issued a guidance[1] regarding Clinical Decision Support Software to describe the FDA's regulatory approach to Clinical Decision

Support software functions. Consult the guidance for a complete discussion and examples.

Keep in mind that if the software contains ML, then the FDA considers it to be a device. The FDA consistently updates guidelines for AI/ML applications.

3. Diagnosing retinal disease. This is a fast-growing market that includes diabetic retinopathy, a common complication of diabetes. To diagnose retinal disease, a camera takes an image of the patient's retina that is then analyzed using ML. Several papers reported an AI detection rate of retinal disease that is better than the detection rate of clinicians. However, the AI performed worse at diagnosing negative cases.[2,3]

4. Reading and segmenting medical images. Several ML tools are being used in the radiology field. Radiologists who used ML to read medical images worked 65% faster.[4] It is important to note that the use of ML tools improves workflow but does not replace the radiologist.[4] Many of the ML tools listed on the FDA website as being approved are developed for radiology.

5. Predictive modeling. These models help predict outcomes like who will require readmission to the hospital within 30 days of discharge, among others. Predictive modeling can be added to a hospital's electronic health record package. The process to add predictive modeling to an electronic health record package is straightforward because there are vendors who can add the models. For example, the tracking of fall risk, heart failure, and early detection of sepsis can be electronic health record add-ons. However, it is vital that these add-ons meet guidelines requiring model reporting, be useful, fair, and reliable, and are generalizable and transparent. A lack of transparency in an AI model can pose a significant barrier to gaining the trust of patients and clinicians.

6. Drug discovery and development. DeepMind's AlphaFold 2 can predict how a protein folds with an accuracy rate similar to crystallography, but in hours rather than months.[5] AlphaFold 2 radically shortens the identification and development cycles for new drugs, a great boon to biomedical researchers.

7. Nanotechnology. There is hope that this emerging technology field can be applied to cancer diagnostics and cancer therapeutics; however, intratumor and interpatient heterogeneity have posed significant barriers in this area. Application of AI methods to the design and analysis of outcomes have met with some success.

WHAT IS GENERATIVE AI?

Generative AI is a type of ML algorithm that is designed to generate new data based on what it has learned from the data that it has been trained on. This can be used to create new images, text, or other forms of data that mimic the characteristics of the training data. For example, AI can create images of people that look real but who do not exist.[6]

WHAT ARE FUNDERS AND THE FDA LOOKING FOR?

The main concerns of funders and the FDA are found in the Good Machine Learning Practice for Medical Device Development: Guiding Principles document.[7] The concerns that some application developers tend to neglect, in Byram's experience, are included in the following list. Of particular focus is improving the performance of the human-AI team. Another concern is that models degrade over time and need to be retrained.

Key takeaways from this guideline include

1. The multidisciplinary team should work together throughout the total product life cycle to ensure that the AI remains relevant.
2. Make sure that clinical study participants and data sets are representative of the population, so the models developed on them are generalizable.
3. Be sure to emphasize the performance of the human-AI team.
4. Ensure that deployed models have the capacity to be monitored with a focus on improved safety and performance, and appropriate controls are in place to manage retraining risks.

Attendees were curious about the intersection of privacy laws and training data sets. Attendees indicated that, in their experience at their institutions, the patient provides consent for their data to be used in data training sets. To build and maintain trust with the patient, the consent form should include a statement that all patient data will be kept secure, and the data used for ML is deidentified using Protected Health Information guidelines.

CLOSING

Byram closed the presentation by emphasizing the importance of being aware of the FDA and funder guidelines and to consult the references provided in the presentation for further guidance.

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

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N1 / 2023

CONFERENCE

Session Report

What *Is* Plagiarism? Putting Out Fires Around This Hot Topic

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Andrea Klingler
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By Eloise DeHaan

If I were to write this piece without crediting medical editor Vee White and medical and science editor Andrea Klingler for their research and presentation, it would be plagiarism.

The two shared their expertise about plagiarism at AMWA's Medical Writing & Communication Conference, November 3, 2022, in Denver.

Plagiarism is "[when] an author documents or reports ideas, words, data, or graphics, whether published or unpublished, of another as [their] own without giving appropriate credit or attribution" (*AMA Manual of Style*, 11th edition, Section 5.4).[1]

Between 2019 and 2020, White and Klingler surveyed 260 writers, editors, and publishing professionals about plagiarism. The largest proportion of responses came from the United States, Canada, and the United Kingdom but included widespread places such as Japan, Cyprus, and Uruguay.

The survey found that writers fear plagiarism's consequences most (Figure). Among 38 medical or science writer respondents, the largest proportion, 84%, thought the biggest consequence of plagiarism was that they would lose their job.

Gaps were obvious between how confident publishers were in writers' and editors' ability to produce plagiarism-free product and the confidence of editors and writers themselves to do so, with publishers being more skeptical.

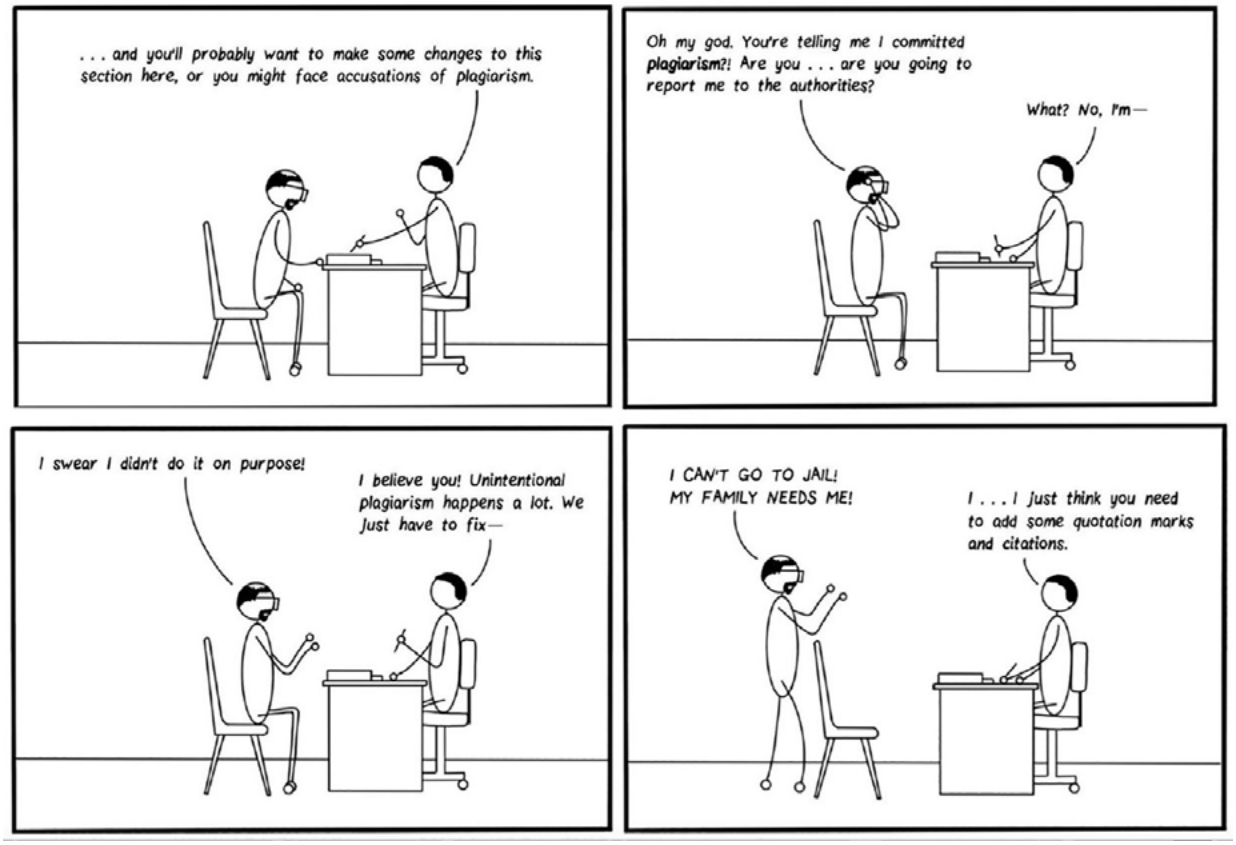

Figure. The Plagiarist. Cartoon reprinted with permission under a CC-BY NC license from Iva Cheung.[2]

ISSN 2163-5315

Furthermore, among the subset of 79 medical/science communicators who were "extremely or very confident in their understanding of and their ability to avoid/identify [plagiarism], 26 (33%) had no or intentional-only training."[2]

The presenters explained that intentional plagiarism is knowingly taking credit for someone else's work. It is presenting someone else's words, sentence, structure, or idea as your own. Unintentional plagiarism is done without intention and can be the result of poor paraphrasing, careless work like forgetting to insert a citation, or cultural differences.

Publishers' top tactic for avoiding plagiarism in new content was to put clauses about the issue into their contracts with writers (71% of publisher respondents chose this option). For catching plagiarism in existing content, publishers depended on an editor's keen eye (82% of respondents) and plagiarism-detecting software (74%).

Although the survey respondents tended to be highly experienced in their occupation, most reported receiving training on this subject in an academic setting, some as far back as in grammar school. Minimal anti-plagiarism training seems to be offered to writers and editors. With even less training in unintentional plagiarism, editors lack knowledge of this issue. Editors do, however, implement specific strategies to identify plagiarism.

White and Klingler offer tips to help writers avoid plagiarism[2]:

- Keep copied verbatim text separate.
- Remember to cite public domain and unpublished material too.
- Summarize, analyze, and synthesize.
- Remember that plagiarism includes more than words.
- Be careful when reusing your own previously published material.

They also counsel editors on how to help writers when plagiarism is an issue[2]:

- Prepare with concrete examples.
- Start the conversation with a different word.
- Ask questions.
- Avoid assumptions.
- Open discussion before deciding next steps.

See the Plagiarism Survey Project's website at www.veewhite.com/plagiarism-survey.

Eloise DeHaan is Medical Copyeditor and Stakeholder Engagement Coordinator, Horizon Scanning, at ECRI, Plymouth Meeting, PA.

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

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N1 / 2023

TOPICAL FEATURE

Updated Guidance on the Reporting of Race and Ethnicity in Medical and Science Journals

Tracy Frey / JAMA Network, Chicago, IL

ABSTRACT

The language used to describe study participants in the medical literature is of paramount importance. The objective is to use the terms that people use to describe themselves while also being sensitive and consistent, supporting diversity, and conveying respect. It is also important to medical editors that a style guide reflects their responsibilities and need for clear guidance. To this end, the *AMA Manual of Style* committee reassessed our guidance on race and ethnicity soon after its release in February 2020 because we realized that our guidance already needed to be updated. We started with some small steps, like deciding to capitalize all racial and ethnic categories including *Black* and *White*, and then ended up dismantling the entire section in our quest to develop more robust, comprehensive, and thoughtful guidance. After almost a year of research, updates, external review, and further revision, we published our efforts to garner public feedback, which was successful and led to further revision and review. When we were confident that our guidance met our objectives, we published our revision in August 2021. Our updates include definitions of commonly used terms associated with race and ethnicity, concerns and controversies in health care and research, racial and ethnic collective term usage, alphabetization of racial and ethnic categories, and geographic origin and regionalization considerations, and we provide examples to help guide authors and editors. Our current guidance is more reflective and complete, and we plan to make further revisions as the language and culture evolve.

The 11th edition of the *AMA Manual of Style* was published in February 2020, but we made a major update to the section on race and ethnicity a year and a half later because we realized that our guidance needed to be updated to reflect ongoing understanding and the need to report sociodemographic information more accurately, sensitively, and consistently. Our goal was to provide recommendations and suggestions that encourage fairness, equity, consistency, and clarity in reporting of race and ethnicity in medical and science journals. "Terminology, usage, and word choice are critically important, especially when describing people and when discussing race and ethnicity. Inclusive language supports diversity and conveys respect. Language that imparts bias toward or against persons or groups based on characteristics or demographics must be avoided."[1]

PROCESS

As we have done with all *AMA Manual of Style* revisions, we looked at the current guidance on reporting race and ethnicity to determine what was missing and what we wanted to add or change. The *AMA Manual of Style* committee began reassessment in the spring of 2020 and talked about what the plan would be.

After an 8-month process of research, updates, external review, and more revision, we published our initial guidance in February 2021 as an editorial in *JAMA*[1] with an invitation for wider public review and feedback, hoping to capture the expertise of people we did not seek out initially. This was a first for us and successful because we had dozens of individuals in academia, publishing, and government with expertise in reporting race and ethnicity and diversity, equity, and inclusion reach out with suggestions and advice. It was a lot to sift through, and we encountered several topics for which people outright contradicted one another, but the feedback was invaluable and helped us to build a stronger, more comprehensive section. We sought review once more, and then the final version was published in *JAMA* on August 17, 2021.[2] A week later, the content was live and freely available in the online *AMA Manual of Style*.[3]

KEY PRINCIPLES IN THE UPDATED GUIDANCE

Our revised guidance followed 5 key principles. First, we acknowledge that race and ethnicity are social constructs. Race is a created concept, not a biological category defined by genetic traits or biological differences. Racial and ethnic

ISSN 2163-5315

categories are social constructs with limited utility in understanding medical research, practice, and policy. However, the terms may be useful as a lens through which to study and view racism and disparities and inequities in health, health care, and medical practice, education, and research. The indistinct construct of racial and ethnic categories has been increasingly acknowledged, and concerns about use of these terms in medical and health research, education, and practice have been progressively recognized.

Second, we knew there would be historical sensitivities and controversies related to the language used to describe race and ethnicity and associated nomenclature in medical and health research, education, and practice, including the intersectionality of ancestry and heritage, social determinants of health, and other socioeconomic, structural, institutional, cultural, and demographic factors.

Third, race and racism do not exist in isolation, and therefore, racial and ethnic descriptors should not be reported alone. Other sociodemographic factors and context should be included as much as feasible, if reporting race assists in the study of disparities and inequities in health, health care, and medical practice, education, and research. Language and terminology must be accurate, clear, and precise, and must reflect fairness, equity, and consistency in use and reporting of race and ethnicity.

Fourth, it should be abundantly clear, particularly in research, what the origin of the categories is. Who classified individuals, what categories were available, and how these determinations were made should be clearly described (eg, self-report or selection, investigator observed, database, electronic health record, survey instrument). Reporting of race and ethnicity should not be considered in isolation and should be accompanied by other sociodemographic factors, social determinants, and the intersectionality of race and ethnicity with these other factors.

Finally, and most important, the guidance we have put forth in the manual is not final. The dialogue continues, and we will collect feedback and experience with implementing our guidance, which will allow us to make further updates to it. Continual review of the terms and language used in the reporting of race and ethnicity is critically important as societal norms continue to evolve.

GUIDANCE COMPONENTS

The revised guidance includes definitions of commonly used terms associated with race and ethnicity and acknowledges that these terms and definitions have changed, that some are out of date or should not be used, and that the nomenclature will continue to evolve.

We address concerns, sensitivities, and controversies in health care and research and provide guidance on the reporting of race and ethnicity in research articles, with the understanding that editors are working with the data that researchers collected. We also provide guidance for capitalization; adjectival, punctuation, and abbreviation usage; and what order to present categories, as well as examples of collective or umbrella terms for racial and ethnic groups.

Examples are included to help guide authors and editors, and we will continue to collect feedback and more examples to help. In addition, a quiz has been developed on race and ethnicity at the *AMA Manual of Style* website[3] to help editors identify potential issues in reporting and explain the rationale for the correct quiz answer, of which in some cases there is more than one.

SUMMARY OF APPROPRIATE TERMS WHEN REPORTING RACE AND ETHNICITY

The following is a summary of the preferred terms to use when reporting race and ethnicity in medical and science journals. Complete guidance is available at the online *AMA Manual of Style*,[3] and a summary table of appropriate terms is available in the Instructions for Authors for *JAMA* and the JAMA Network journals.[4]

1. All racial and ethnic categories, including *Black* and *White*, should have initial capitalization, except when capitalization could be perceived as inflammatory or inappropriate (eg, "white supremacy"). Race and ethnicity categories should be listed in alphabetical order, not in order of proportion, and "other" and "unknown" should be listed last. The categories included in "other" groups should be defined and reported. Authors should be as specific as possible when reporting on racial and ethnic categories (even if these categories contain small numbers). If the numbers in some categories are small enough to potentially identify study participants, the specific numbers and percentages do not need to be reported provided that this is documented. For cases in which the group "other" is used but not defined, the author should be queried for further explanation.

2. Race and ethnicity terms should be used as adjectives, not nouns. They can be modifiers (eg, Asian patient, Black individual, White populations) or predicate adjectives (eg, patients who are Asian, Black, or White).

3. Most combinations of proper adjectives derived from geographic entities are not hyphenated when used as noun or adjective formations, so do not hyphenate these

terms and similar combinations as nouns or compound modifiers (eg, African American patient).

4. Generally, abbreviations of categories for race and ethnic-ity should be avoided unless necessary because of space constraints (eg, in tables and figures). If used, any abbre-viations should be clearly explained parenthetically in the text or in the table/figure footnotes or legends.

5. Authors use many collective terms when describing racial and ethnic minority groups. Many of these terms carry negative connotations, may be inaccurate or stigmatizing, and may be "too inclusive," to the point that they erase differences among specific groups.[5-8] These terms include *mixed race*; *minority* and *minorities* used as nouns; *people of color*; *brown*; and *Black, Indigenous, and people of color* (BIPOC), *Black, Asian, and minority ethnic* (BAME), and *Black and minority ethnic* (BME). These terms should be avoided unless they were specifically used in data collection, and in those cases, the term should be defined, if possible.

a. The terms *multiracial* and *multiethnic* are preferred over *mixed race* in reports of studies if the specific categories these terms comprise are defined or if the terms were predefined in a study or database to which participants self-selected.

b. We recommend using the collective terms *racial and ethnic minority groups* and *racial and ethnic minority individuals*, in which *minority* is used as a modifier and not as a stand-alone term. Terms such as *underserved populations* (eg, when referring to health disparities among groups) or *underrepresented population* (eg, when referring to a disproportionately low number of individuals in a workforce or educational program) may also be used as collective terms provided the categories of individuals included are defined at first mention. The term *minoritized* may be acceptable as an adjective provided that the noun(s) that it modifies is included (eg, "racial and ethnic minoritized group"). *Groups that have been historically marginalized* may also be suitable at times if the rationale for this description is provided. However, preference is for the specific racial or ethnic categories included or intended to be addressed instead of using a collective term.

c. The terms *Hispanic*, *Latino* or *Latina*, *Latinx*, and *Latine* are preferred to the term *Spanish speaking*. Avoid reflexively changing *Latino* and *Latina* to *Latinx* or *Latine* or vice versa and follow author preference. Authors of research reports, in turn, should use the terms that were prespecified in their study (eg, via participant self-report or selection, investigator observed, database, electronic health record, survey instrument).

d. Description of people as being of a regional descent (eg, of African, Asian, European, or Middle Eastern or North African descent) is acceptable if those terms were used in data collection. However, it is preferable to identify a specific country or region of origin when known and relevant to the study. It is generally preferable to describe individuals of Asian ancestry according to their specific country or regional area of origin (eg, Cambodian, Chinese, Indian, Japanese, Korean, Sri Lankan, East Asian, Southeast Asian). Similarly, study participants from the Middle Eastern and North African region should be described using their nation of origin (eg, Egyptian, Iranian, Iraqi, Israeli, Lebanese) when possible. For individuals of various ancestries living in the United States, do not reflexively add "American." However, there are times it is appropriate. For example, individuals of Middle Eastern and North African descent who identify with Arab ancestry and reside in the United States may be referred to as Arab American. Similar construction would be applicable for other groups such as Asian American, Indian American, etc.

e. In reference to persons indigenous to North America, *American Indian* or *Alaska Native* is generally preferred over *Native American*. However, the term *Indigenous* is also acceptable. There also are other specific designations for people from other locations, such as *Native Hawaiian* and *Pacific Islander*, *Indigenous people*, *Indigenous peoples of Canada*, and *Aboriginal people*. If appropriate, specify the nation or peoples (eg, Inuit, Iroquois, Mayan, Navajo, Nez Perce, Samoan).

f. Avoid collective reference to racial and ethnic minority groups as "non-White." If comparing racial and ethnic groups, indicate the specific groups being compared. Researchers should avoid study designs and statistical comparisons of White groups with "non-White" groups and should specify racial and ethnic groups included and conduct analyses comparing the specific groups. If such a comparison is

justified, authors should explain the rationale and specify what categories are included in the "non-White" group.

g. There are similar concerns about dichotomized comparisons of only 2 racial or ethnic groups (eg, Black vs White patients). If such a comparison is justified, authors should explain the rationale for this focused comparison limited to only 2 groups.

UPDATE TO JAMA NETWORK JOURNALS' INSTRUCTIONS FOR AUTHORS

In addition to updating the style manual, we also updated the Instructions for Authors for *JAMA* and the JAMA Network journals[4] with regard to the collection and reporting of demographic data on race and ethnicity. We specify that the Methods section should include an explanation of who identified participant race and ethnicity, the source of the classifications used, and the reasons why race and ethnicity were collected for a study. We clarify that specific racial and ethnic categories are preferred over collective terms, when possible, and that authors should report the specific categories used in their studies and define categories included in groups labeled as "other." The *Results* section should report the race and ethnicity categories of the study population and categories should be listed in alphabetical order in the text and tables.

FUTURE GUIDANCE

Our next step is to update the sections on sex and gender, sexual orientation, age, socioeconomic status, ability, and persons with diseases, disorders, or disabilities. As with race and ethnicity, we recognize that our guidance in these sections may be dated, inadequate, and sometimes confusing, and we are working to change that. Our revision for sex and gender and sexual orientation is in process, and we will soon have our draft updated guidance reviewed by internal and external experts on diversity, equity, and inclusion to ensure we recommend using clear, concise, consistent, appropriate, and inclusive language.

Some of our interim guidance appears in the Instructions for Authors for *JAMA* and the JAMA Network journals[4]:

> The term *sex* should be used when reporting biological factors and *gender* should be used when reporting gender identity or psychosocial/cultural factors. The methods used to obtain information on sex, gender, or both (eg, self-reported, investigator observed or classified, or laboratory test) should be explained in the Methods section. The distribution of study participants or samples should be reported in the Results section, including for studies of humans, tissues, cells, or animals. All participants should be represented, not just the category that represents the majority of the sample. Studies that address pregnancy should follow these recommendations, and if the gender identity of participants was not assessed, use the terms "pregnant participants," "pregnant individuals," "pregnant patients," etc, as appropriate.

CONCLUSIONS

Our race and ethnicity guidance is freely available on the *JAMA* website,[1] at the online *AMA Manual of Style*,[3] and is linked from the *JAMA* and JAMA Network journals' Instructions for Authors.[4] This guidance is not intended to be final but is presented with the understanding that monitoring will continue, and further updates will be provided as needed. Continual review of the terms and language used in the reporting of race and ethnicity is critically important as societal norms continue to evolve.

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

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N1 / 2023

TOPICAL FEATURE

Common Grantsmanship Hurdles of Early Career Clinician-Scientists and How a Medical Writer Can Help

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ABSTRACT

Researchers with medical training and clinical experience bring essential perspectives to academic medicine. Compared with their nonclinician, PhD-trained peers, clinician-scientists typically have less training in grant writing, and their time for this work is even more constrained. Medical writers can help clinician-scientists understand and fulfill the expectations of funding organizations and review panels, and ultimately, help them compete more successfully for funding. Based on the literature and personal experience in this role, I propose 4 grantsmanship hurdles that often confront clinician-scientists: (1) identifying funding opportunities that fit, (2) mastering the unique language and integrated narrative style of a compelling grant proposal, (3) turning ancillary documents from drudgery into assets, and (4) shedding the "bunker mentality." This article surveys practical strategies by which medical writers can foster time efficiency, mitigate experience gaps, and help clinician-scientists develop persuasive grant proposals effectively tailored to the relevant audience.

Medically-trained faculty at academic medical centers play essential roles in the advancement of biomedical research. Clinician-scientists bring the perspective to recognize knowledge gaps that impede progress in patient care and translation of discoveries to the clinic. Although they are well-positioned to enroll patients and coordinate clinical trials, early career clinician-scientists often receive minimal training in crucial research and grant writing skills and have heavy clinical duties that dominate their time. Although junior faculty can seek didactic research training, it is often more effective and efficient for them to consult a medical writer with expertise in writing and grantsmanship. Some academic institutions employ such consultants under job titles such as grant writer, scientific editor, or medical writer.[1] An individual investigator might engage a freelance writer for similar support. This article discusses several grant writing hurdles facing clinician-scientists and details tools and strategies by which a medical writer can help them clear the hurdles and gain professional skills.

CLINICIAN-SCIENTISTS

Clinician-scientists are biomedical researchers who have formal training and credentials in a clinical discipline. Although many clinician-scientists are physicians, the category also includes pharmacists, nurses, advanced practice providers, dentists, dietitians, and other medical professionals. Clinician-scientists are sometimes categorized by how much of their professional effort is spent in clinical practice compared with research.[2] The diverse backgrounds, job descriptions, and goals of clinician-scientists correspond with diverse funding objectives. Those with a primary focus on research usually pursue federal funding along a prototypical path that aims for mentored career development grants (eg, National Institutes of Health [NIH] K awards), then research project grants large enough to support a research laboratory or larger clinical trials (eg, NIH R or U awards).[3] Others see themselves as clinicians first and have a complementary research portfolio that can be integrated with their clinical practice.[2,4,5] Critical funding for these individuals may come from subcontracts on federal grants, industry sponsorship of multisite clinical studies, or small grants from foundations, professional societies, or intramural funds.

Regardless of career trajectory, early career clinician-scientists face 2 particularly difficult headwinds. First, clinicians who assume junior faculty positions often start with limited research mentorship and hands-on research experience.[5-7] In the sphere of grant writing, they may be unfamiliar with the structures, norms, and vocabulary that more experienced researchers take for granted. A clinician developing a grant might need guidance on how the review process works so that they can write with the true audience in mind. Second, clinical duties increasingly dominate their time,[4] so clinicians with thriving research programs often rely on a cast of trusted collaborators and team members working around them. A medical writer with expertise in grant writing who fosters effective communication and

ISSN 2163-5315

efficiency is an invaluable addition to these teams and can help clinician-scientists capitalize on scarce research time.

GRANTSMANSHIP HURDLES FOR CLINICIAN-SCIENTISTS

Most grant writing challenges common among early career clinician-scientists are also familiar obstacles for their PhD-trained peers, so the advice offered here might help a researcher in either category. However, training gaps and patient care duties for clinician-scientists often accentuate the following hurdles. By helping them clear these hurdles, medical writers can foster both professional achievement and progress in medicine.

Hurdle 1: Identifying Funding Opportunities That Fit

Funding agencies post funding opportunity announcements (FOAs) using a variety of channels, and the window of time between the FOA and submission deadline can be as short as several weeks. Investigators who passively wait for relevant opportunities to present are prone to discovering them too late or not at all. Medical writers can assist by designing a robust search strategy, of the sources below and others, and perhaps even take responsibility for maintaining the search and alerting their clinician-scientist colleague(s) to possible matches.

Federal Funding Agencies

FOAs for federal grants are relatively easy to track because sponsors disseminate them through well-maintained Web resources. The comprehensive database at Grants.gov is populated with links to FOAs from NIH, the Centers for Disease Control and Prevention, other arms of the Department of Health and Human Services (HHS), the Department of Defense, and other agencies with missions extending widely across medicine and beyond. Search filters allow users to focus on chosen agencies, funding categories, dates, and other variables. NIH- and HHS-sponsored opportunities also appear in the dedicated NIH database at NIH.gov, which features more agency-specific search and filter functionality; for example, you can filter results by activity code (eg, K08, R01) or by institute. In either of these databases, the *Save Search* function allows the user to set up automated email alerts about relevant FOAs in the future.

Private Funding Agencies

Societies and foundations represent the spectrum of clinical disciplines, medical conditions, and patient advocacy themes, and they issue a vast range of FOAs. Although many of these FOAs are relevant to clinician-scientists, their configuration and dissemination vary widely. Some private grant programs are offered on a regular annual or semiannual cycle, but in many cases the timing is unpredictable or a specific FOA happens only once. Because these FOAs are invariably posted on the respective organization's website, clinician-scientists or a medical writer could proactively monitor the websites of relevant organizations for new FOAs. A few such organizations simplify this task by offering an electronic mailing list. However, neither method is very efficient if an investigator needs to monitor multiple organizations, or if a medical writer is assisting multiple investigators at once.

One-Stop Solutions

Clinician-scientists and their grant writing consultants who are interested in diverse funding sources should consider accessing a subscription-based, comprehensive grants database (Table 1). These continually capture new opportunities from thousands of private funding organizations, federal and state government agencies, and international entities. Search filters and periodic email alerts make it possible to track opportunities in any sector that match an investigator's research interests and project parameters (eg, submission deadline, budget size, geographic focus). Investigators or consultants can begin by checking what access they may already have through institutional subscriptions. Individual subscriptions to some of these services are also available.

Table 1. Subscription-Based Grants Databases

Database Name	Web URL	Individual Subscriptions
Funding Institutional	fundinginstitutional.com	
GrantForward	grantforward.com	
GrantScape	thegrantscape.com	√
GrantSelect	grantselect.com	√
Pivot-RP	pivot.proquest.com	
SPIN	spin.infoedglobal.com	

Hurdle 2: Mastering the Unique Language and Integrated Narrative Style of a Compelling Grant Proposal

Clinician-scientists tend to be goal driven and action oriented. In the process of developing a research proposal they are generally most comfortable explaining their plan to attain new knowledge and drive clinical innovation. Less intuitive for the grant writing novice are how to craft the multiple application sections in a way that inspires urgency about a stated knowledge gap, curiosity about the scientific hypothesis, and confidence in the applicant's capacity to achieve the objectives. In most successful grants, these pieces all begin to crystallize in the specific aims page and are emphasized in each subsequent section. A medi-

cal writer can help the clinician-scientist ensure that these facets are consistently, concisely, and effectively conveyed throughout the full proposal.

Medical journals have recently published several excellent articles that speak specifically to clinicians about writing effective grant proposals.[8-16] These are easy resources to share with investigators, and medical writers can mine the articles for new ideas and language that might resonate with investigators who are getting used to this genre. In one article that focuses on how to write an effective specific aims page, Monte et al[10] argue that a grant proposal is equivalent to a business pitch:

> *We define the goal of grant writing as gaining financial sponsorship for planned work; like sales, a proposal requires marketing, tailoring, and a value proposition… The aims page is the point of sale for planned science and is written with the goal of research sponsorship.*

These authors describe their formula for writing a persuasive specific aims proposition in 4 paragraphs from defining a critical need to demonstrating the potential return on investment. Two other articles also dissect the specific aims page, offering similar instruction and borrowing colorful idioms from humanities and mathematics.[8,14] Certain articles contain rubrics for objective evaluation of a specific aims page that may be valuable tools for a consulting medical writer.[8,10]

This "make the sale" mindset is beneficial throughout the grant writing process. Reviewers are drawn to a grant proposal if it convinces them that (1) the investigator has delineated an urgent problem, (2) they have an innovative and scientifically credible idea to address the problem, (3) the proposed plans are well designed to test the great idea, and (4) the investigative team and research environment display the capacity to execute the plan. Each of these parts is fulfilled through multiple sections of the application (Figure). A clinician-scientist may feel most engaged and confident in describing the core idea or innovative elements of their plan, whereas certain sections (eg, budget, biographical sketches) may seem like mere boxes to check. However, a medical writer who helps them integrate all 4 major elements improves the probability of an outstanding impact score from the review panel.

For an inexperienced applicant who lacks fluency in the jargon and expectations of grants, the instructions and review criteria found in an FOA are often opaque. A medical writer can help not only by decoding the requirements but by checking the application against the FOA for completeness and fulfillment of the specified review criteria ("responsiveness"). A simple way to help the clinician-scientist stay on track is to create a checklist early in the writing process and keep it updated as a dashboard while completing the application. The AMWA Member Resource Library features a template for a detailed grant checklist and schedule of milestones.[17]

Hurdle 3: Turning Ancillary Documents From Drudgery Into Assets

For some clinician-scientists, the list of required supporting documents is a daunting barrier. Often, an investigator either spends many precious hours producing these from scratch or hurriedly produces subpar documents that likely dampen reviewers' confidence. A medical writer can help elevate the application by introducing resources that lighten the investigator's learning curve and boost document quality. Sometimes useful tools are readily available, and we may just need to point the investigator in the right direction. For example, the National Center for Biotechnology Information provides a free online app called SciENcv, which helps investigators build a complete and compliant NIH-style biosketch.[18]

Another way to help address this barrier is by encouraging smart use of institutional boilerplate text. Many universities seek to help their investigators with grant applications by maintaining boilerplate that describes facilities, resources, expertise, and administrative structures. Although these resources can be a good building block, beware of 2 possible flaws.

First, watch for text that has grown stale after a couple of years on the shelf, both to eliminate outdated information and to ensure inclusion of newer resources. If the clinician-scientist is unsure about key details, reach out to the relevant core facility or office to ask for a fresh review of the information. A medical writer employed at an academic institution can benefit all affiliated investigators by maintaining a current boilerplate library.

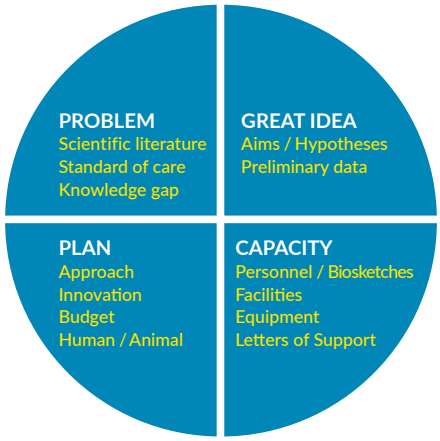

Figure. Four main elements of a grant proposal that the investigator must illustrate for reviewers. Multiple sections of the proposal combine to build confidence in each element.

Second, no matter how complete and current the information is, applicants should not simply copy unmodified generic boilerplate text into an application. Coherence among the many pieces of an application signals to reviewers that the investigator has given careful thought to everything that needs to work together to achieve the research aims. Therefore, resources that have no relevance should be deleted, and the generic text should be enriched with tailored sentences or phrases that emphasize relevance to the project (Table 2).

Table 2. Examples of Tailoring Verbiage to a Specific Proposal

Grant Section	Points of Emphasis	Tailored Sentence Example
Facilities/ Resources	Access, relevance	Dr Smith has an agreement with the Gait Analysis Lab to support monitoring participants' fluidity of motion post-surgery (see letter of support).
Equipment	Location, features, purpose	The PI's division houses a PET/CT scanner (make/model) with respiratory and cardiac gating to reconstruct phase-matched images. It will be used to screen study enrollees for lung cancer recurrence.
Biosketch–personal statement	Commitment, role	As a co-investigator, I will coordinate the key informant interviews in Aim 2, to include securing IRB approval and ensuring protocol-adherent interviews, transcription, and coding.

PI, principal investigator; PET/CT, positron emission tomography/computed tomography

An excellent way to demystify the components of a complete application is to provide examples of proposals that were funded in the past. Ideally, an investigator has mentors who will share recent grants as models. A staff medical writer can facilitate the sharing process by gathering and managing a small library of model proposals from willing faculty. Furthermore, multiple NIH institutes provide online access to lightly redacted copies of grant proposals they have funded.[19] Examples of applications to other funders can be more difficult to find; however, one online resource, Open Grants,[20] maintains an open repository of proposals submit-ted to a variety of public and private sector organizations.

Hurdle 4: Shedding the "Bunker Mentality"

Clinician-scientists are often forced to fit their grant writing into odd pockets of time around their more rigid clinical schedule. Those who have received minimal research mentorship may not fully appreciate the benefits of robust initial review by a colleague before a proposal goes to an anonymous review panel. Consequently, grant writing tends to be a solitary endeavor; this "bunker mentality" can deprive proposals of objective external feedback and editing. Medical writers can help investigators resist this bunker mentality by encouraging them to seek the following kinds of feedback.

Program officers working in the NIH institutes are known for the constructive advice they offer investigators. They are often helpful in identifying programs and study panels in which a research idea would find its best fit, sharing the upcoming release of new FOAs, explaining the grant review processes, and decoding reviewers' critiques.[21] In most cases, an NIH FOA lists contact information for the appropriate program officer(s). Alternatively, a great resource for identifying program officers (as well as institutes and review panels) relevant to the clinician-scientist's project idea is the Matchmaker search tool at the Research Portfolio Online Reporting Tools website.[22] Although program staff in other agencies or organizations may be less visible, it is worth trying to identify them for similar assistance. An investigator should initiate the conversation about their proposal concept by email, share a draft of the specific aims, and propose setting up a call or virtual meeting for feedback. Many clinician-scientists seem reticent to reach out for this help; a writing consultant can provide critical assistance in facilitating this process and eliciting valuable feedback.

Peers and colleagues are an invaluable source of grant feedback for investigators at any career stage. Fellow researchers can provide insight from various angles, such as: Has the investigator made a persuasive argument for an important knowledge gap that must be filled? Does the proposed approach stand up to technical scrutiny? How well does the proposal address review criteria found in the FOA? Medical writers bring legitimate insight into these questions as well, but peers can take it to an important next level. Sometimes part of our role is to encourage seeking that help from a couple of trusted individuals and plan it into the writing timeline.

Many institutions seek to elevate the presubmission grant review process by organizing internal mock review panels often targeted toward their junior faculty and trainees.[23,24] Not only does this facilitate feedback from 4 or 5 reviewers at once, but it also introduces the dynamic of a live panel discussion. Data collected at one institution demonstrated the effectiveness of internal review for increasing success of submissions to NIH.[24] The greatest challenge in leveraging this resource is proactive planning. An investigator must request review by a mock panel and supply a draft of at least the specific aims page, several weeks before the funding agency's deadline. When such an opportunity exists, medical writers should encourage working far enough ahead to secure this assistance.

Finally, medical writers can play the role of document editor to help maximize a proposal's clarity, completeness, conformity to instructions, and professionalism. This service may range from early partnership in the conceptual stages to copy editing at the final stage. It is important to remember that many early career clinician-scientists are looking for more than a batch of corrections. We can create a true professional development experience if we partner with our clinician-scientist colleagues and help them think through the communication strategy. A 2020 post to the AMWA Blogs cogently described the editing technique of providing "informational support,"[25] that is, you "focus on an author's development by explaining why changes are being suggested and offering to answer questions about editing recommendations/comments." A sense of partnership and a supportive tone help ensure investigators will return for assistance with resubmissions and future proposals.

CONCLUSION

Grant seeking is an integral part of the landscape in academic medicine. Clinician-scientists who aim to advance their research programs and find backing for their ideas will continue to need skilled grant writing assistance. Medical writers can add value across the full scope of documents needed in any given proposal. We can also help our clinician-scientist colleagues see the finished product from the vantage point of funding organizations and peer reviewers. This will not only increase the likelihood of a funded proposal, but also cultivate a clinician-scientist's grantsmanship expertise for future applications.

Acknowledgment

I thank Heather C. McNeill, MA, ELS, and Jennifer K. Peterson, PhD, for their constructive reviews of the article.

Author declaration and disclosures: *The author notes no commercial associations that may pose a conflict of interest in relation to this article. The author received partial salary support from NIH funding for the Nebraska Pediatric Clinical Trials Unit (UG1 OD024953). Contents of the article are solely the responsibility of the author and do not necessarily represent the official views of NIH.*

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N1 / 2023

ARTICLE

Leveraging Artificial Intelligence, Natural Language Processing, and Natural Language Generation in Medical Writing

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ABSTRACT

Medical writing is a process that generates a variety of documents in the biomedical domain, including but not limited to clinical reports, regulatory reports, protocol documents, patient narratives, plain language summaries, and so on.[1] Medical writing is complex and time-consuming because a writer must refer to multiple sources, sift through a large volume of documents, maintain data integrity, perform review of literature, do interpretation of results, summarize, and so on.

These challenges can be addressed and minimized substantially by adopting artificial intelligence, specifically cognitive search, natural language processing (NLP), and natural language generation (NLG) models and other techniques. Given the recent advances in language models for NLG, the time is ripe for a product in the medical writing domain that integrates and automates search capabilities, provides cognitive processing, and generates content using NLG.

This white paper takes scientific manuscript writing as an example to provide insights into the way NLP and NLG can augment, automate, and expedite the process of writing a wide variety of biomedical documents. It looks at the current limitations of technology and ways to address those. Finally, it provides recommendations on how these technologies can be used to create a single system or product. Such an approach has the potential to expand into multiple areas in the biomedical domain, with medical writing as the first challenge.

GLOSSARY

Natural Language Processing (NLP): The branch of artificial intelligence (AI) that enables computers to process human language and understand the meaning, intent, and sentiment of the text, much like a human being can.

Natural Language Generation (NLG): The branch of AI that enables computers to produce human language that approximates content generated by a human being.

Recommendation Model: A system that uses machine learning to predict content that is relevant for a user in a given context. The predictions are often combined with a ranking system that enables users to see the most relevant recommendations first.

Named Entity Recognition (NER): A process by which text is classified into predefined categories like drug name, disease name, location. Also, depending on the context, it can differentiate between "apple" (fruit) and "Apple" (corporation).

Large Language Model (LLM): Large Language Models (LLMs) are artificial intelligence tools that can read, summarize and translate texts and predict future words in a sentence letting them generate sentences similar to how humans talk and write.[11] Eg., GPT-3, GPT-J, BART, BERT, t5.

Natural Language Query Understanding (NLQU): This is a capability of the search system to understand a search query written in natural language. This is achieved by LLM based search systems. Eg. "What is the second largest land animal in the world?"

INTRODUCTION

CURRENT MEDICAL WRITING MARKET

According to Grand View Research, the global medical writing market size that was valued at US $3.4 billion in 2019 is expected to expand to US $7.77 billion by 2027 at a compound annual growth rate of 10.9%.[2] The cost spent on content generation continues to rise.

EXISTING MEDICAL WRITING PROCESS

Medical writing is a complex and manually intensive process. The process of medical writing involves the following steps

a) Understanding the content brief
b) Review of literature
c) Collation of the results, methods, and discussion sections

ISSN 2163-5315

d) Authoring the manuscript and maintenance of data integrity in the process
e) Reviewing the authored content
f) Copy editing
g) Approval and sign off
h) Electronic publishing

Medical writers spend 2 to 3 weeks researching across multiple data sources and a large corpus of documents (nearly 1 million new articles are added yearly to just PubMed).[3]

The review of literature is the most time-consuming step in the medical writing process. This requires a domain expert to first search for and then read through the text of the articles on a particular subject area. The goal of this step is to synthesize the existing knowledge in a particular subject area. In the case of writing a scientific manuscript for a clinical trial, the review of literature must cover several subtopics in the therapy area of concern. All the subtopics require individualized search strategies irrespective of the therapeutic area. Medical writers use several literature databases like PubMed, Scopus, Ovid, and Cochrane. This also introduces the risk of missing out on relevant literature, making this task not only time-consuming, but also error-prone. The aforementioned tasks require multiple individuals to complete it in a reasonable amount of time, each one concentrating on a particular subset of the overall document.

The final challenge lies with the summarization step, when information gleaned from several published articles is summarized. The risks here are missing the important points as well as accidentally not including a relevant reference.

In writing the results section of a manuscript, data may need to be collated from a source document like a clinical study report (CSR) and adding it to the manuscript in a particular format. This can involve aggregating and summarizing the data, creating plots, or writing a narrative for a particular set of data. A great example are the tables for adverse events. This step may introduce quality issues if not done carefully. Obviously, the power of using a computer to automate data analytics is well known, and natural language generation (NLG) provides tools to create narratives summarizing tabular data accurately.

Products with authoring workflows that allow collaboration on a single document by multiple people have been in use for more than a decade.[4] In addition to these, functionalities like referencing and text formatting according to journal requirements have also been in use. These capabilities can come from various tools and techniques, which would require integration of many products or tools into a single system.

ROLE OF ARTIFICIAL INTELLIGENCE IN MEDICAL WRITING

A system that can automate and assist with these tasks would help mitigate many of the challenges and risks described before. Artificial intelligence (AI) has several interesting possibilities for transforming any industry. Nowhere are its applications more relevant than for life sciences and pharmaceutical, regulatory, and medical writing for creating documents such as scientific manuscripts, fact sheets, literature reviews, disease awareness, and oral posters.

A canonical use case for the application of AI is the process of the review of literature that is done as part of research work. In the review of literature process, the researcher is required to use their language and domain knowledge to summarize the various published articles on a topic. This is done to summarize the state of the art in the field. NLG models are being used to automate this step; at the same time, manual intervention is required before the machine-generated text can be submitted for publication.

Many functionalities are required to automate the medical writing process that are elaborated on in the following sections.

Cognitive Search for Literature Survey and Recommendation

The review of literature requires multiple subtopics in a disease/therapeutic area to be comprehensively covered. This requires individualized search strategies for each subtopic, with the search itself carried out across multiple databases. The next task is to read through the top hits for each subtopic to identify the relevant content in that published article.

AI or machine learning (ML) can help in automating the literature search, content extraction, content enrichment (which includes named entity recognition [NER]), and intent detection in the context of life sciences and pharmaceuticals. This enables advanced unified searching across multiple data sources and databases.

Secondly, once trained, the recommendation models are used to identify the relevant sentences or paragraphs in the articles. Automation of this step can enhance efficiency of the most time-consuming component in the literature review process. In addition to automation, the system can perform citation management, an essential part of any medical or technical document.

Narrative Generation

The generation of narratives from structured data by applying NLG has been in the life sciences domain for more than a decade. Previously, it was done using hardcoded text as part of code, and now, NLG models can generate text up front for the structured data that is being processed. The text or narrative generated by the NLG model can, depending on the models used, involve ML algorithms (deep learning) or preset parameters. The output from either of these or a combination of both is a narrative as would have been written by a medical writer.[5]

Summarization

The most recent developments in the NLG space have enabled models to summarize large texts. The initial models were trained and built using news articles because they provide human-generated text and summaries. Now, models are being trained on the published medical corpus available as peer-reviewed scientific articles. Further refinement of the models specific to diseases and drugs are needed in automating medical writing.

There are 2 types of summarization techniques possible using NLG models: extractive and abstractive.

Extractive summarization involves identifying important subsets of sentences from the original text in toto and forming a summary comprising such sentences. This type of summarization is useful if the author decides to select multiple sources from the recommendations and to rewrite the text on their own after the summary gets generated.

Abstractive summarization reproduces important material in a new way after examination and interprets the text using NLG capabilities, simulating how humans do a review of literature.[6,7]

Abstractive summarization mimics how an author would write a synthesis of existing literature in their own words along with the references used. Examples of such models include GPT-3, t5, BERTs, and BARTs.[8] Abstractive summary is useful when the authors want an abstract of the selected recommendations. This kind of summary, along with reference metadata, addresses issues related to plagiarism because this is not an exact reproduction of text from the sources but a generation of original text.

Figure 1 depicts one such example of extractive and abstractive summarizations.

KEY CHALLENGES IN APPLYING AI TO MEDICAL WRITING

The key challenges to applying AI in medical writing include

- Ingesting documents from diverse sources and variety of formats. Apart from a pharmaceutical company's internal data sources, there are multiple external sources like PubMed articles, regulatory documents, clinical trial documents, protocols, clinical study reports, and press releases. This necessitates dealing with different document formats and structures like native PDFs, Docx, XML, HTML, and scanned documents.
- Understanding document semantics and content, extracting key entities unambiguously, capturing synonyms based on scientific ontologies, identifying contexts and intents from medical content in the context of life sciences and pharmaceuticals. This requires compositional semantic analysis that includes word sense disambiguation and relationship extraction that is relevant in biomedical literature.
- Reranking cognitive search results for better search relevance. This requires adoption of learning to rank

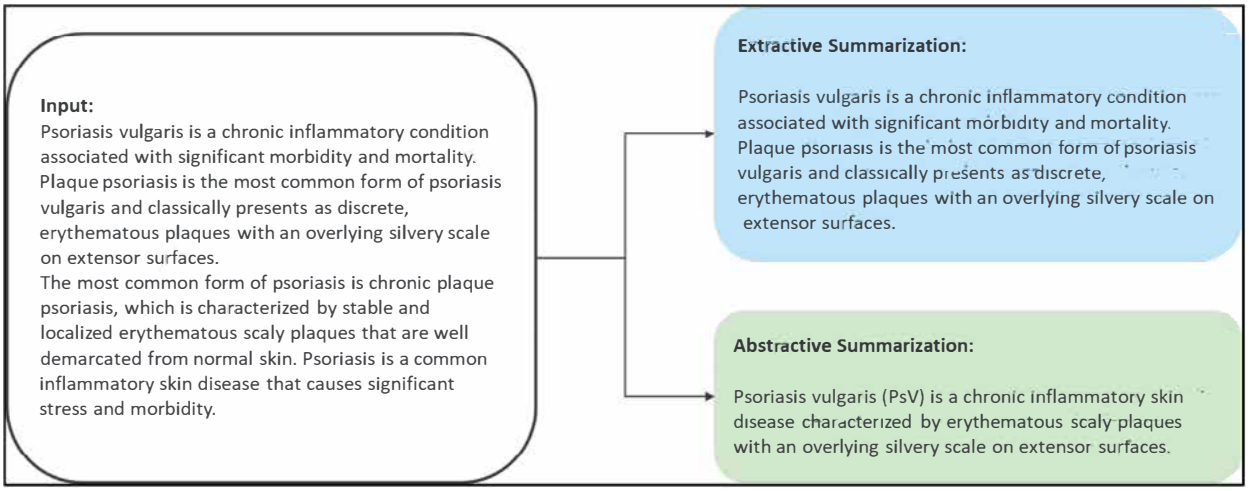

Figure 1. Extractive and abstractive summaries from given input text.

also know as machine-learned ranking. This process re-ranks results from search engines in the medical writing context for content such as the mechanism of action for drugs or disease epidemiology, etc.[9]
- Combining multiple modes of intelligence such as natural language processing (NLP), NLG, deep learning, language models, lexicons, and ontologies into a state-of-the-art AI-based platform for medical writing.
- Removing biases from algorithms. Potential biases can creep in at various steps, from the curation of training datasets, to feature engineering, model choice, and implementation. Detecting and removing algorithmic biases will entail evaluating it via a thorough understanding of the algorithm's role and the context in which it is deployed.

BRINGING IT ALL TOGETHER

As discussed earlier, one of the objectives of this article is to define the architecture and components of a system or product that will automate the process of medical writing significantly. Such a system should have the end-to-end ability to ingest documents, identify the entities in those documents, provide them as search results based on user queries, and generate summaries based on user-selected documents. These features require adoption of the various AI techniques discussed previously.

AI horizons have seen a strategic shift from conventional ML (with a focus on augmenting intelligence) to deep learning (enabling higher accuracy and predictability), and now to the responsible, transparent generative AI.

The key emerging trends for language processing and generation include

- Adoption of deep learning and transfer learning architectures driving accuracy, performance, and speed.
- The NLP shifts from extraction of isolated entities to abstractive reasoning and language models.
- Using models for text critiquing, information retrieval, question answering, summarization, gaming, text generation, and translation.

With state-of-the-art pretrained language models (eg, GPT-3, GPT-J, BART, BERT) that can be fine-tuned for the biomedical domain, the system can generate human-like summarizations and narratives.[10] Consequently, the text summarization exercise and the final document generation can be reduced to a few days rather than a few weeks, even after accounting for the final manual review and approval processes.

Moreover, with all workflows automated, the scope of error is minimized, contrasted with the current manual process (Figure 2).

To bring about these efficiencies, the AI-led platform for life sciences is envisaged to encompass the following key features:

- Unified search across multiple internal and external databases
- Built in deep learning models for article recommendation in the context of pharmaceutical clinical trials, regulatory intelligence, and medical research
- State-of-the-art language models fine-tuned for life sciences for text summarization and NLG tasks
- Real-time data ingestion of structured or unstructured documents from varied data sources (scientific articles from PubMed, regulatory sources like the US Food and Drug Administration (FDA), European Medicines Agency, CSRs, and protocol documents, etc)
- NLP-based automatic document structure extraction, content enrichment, and sentiment analysis
- Dynamic document editing features leveraging scientific lexicons and ontologies
- Workflows for collaborative medical authoring
- Content citations (ability to refer to original sources from a machine-generated summary)
- Templatization of the final document based on the need

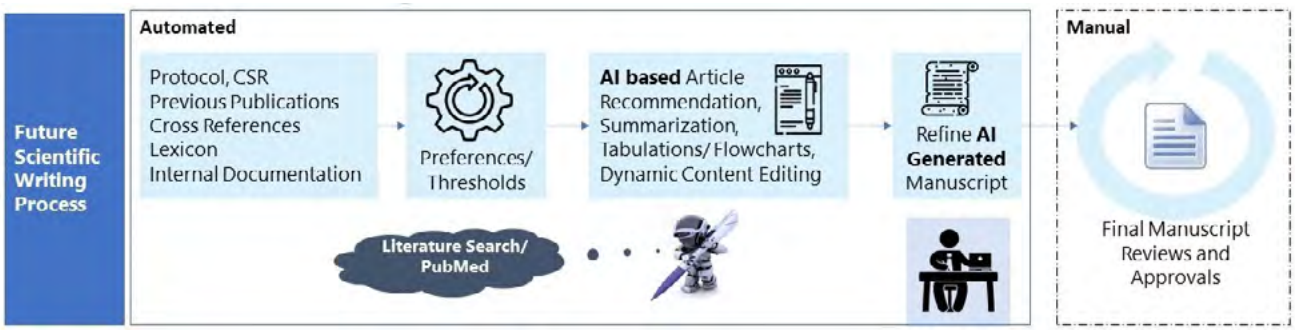

Figure 2. Automated process of medical writing. AI, artificial intelligence; CSR, clinical study report.

Medical writing typically involves authoring contents like medical manuscripts, posters, or clinical study reports with predefined templates for each content type. An authoring template is not just a bare-bone skeleton for content authoring but a composite of individual sections, the onboarding of which entails data ingestion, article recommendation, and content summarization steps (Figure 3).

Let us illustrate this through an example of the introduction section of a typical manuscript. This section includes content primarily from PubMed articles contextualized for disease description, epidemiology, burden of disease, and a drug mechanism of action.

The following activities are required for the generation of an introduction section of the manuscript.

- For data ingestion, PubMed articles are considered, and indexing is configured for relevant article sections like "Abstract" and "Introduction." NLP pipelines are used for the classification of sentences as belonging to categories like "description of disease," "burden of disease," "disease epidemiology," and "mechanism of action." These create labels and do NER for diseases, drugs, molecules, and so on.
- For article recommendation, natural language query understanding pipelines for intents like classification contexts are defined. Search ranking rules and boosting criteria are refined as required.
- For content summarization, based on the section specific summarization or narrative needs, the platform evaluates the available language models. For configuration initial training, samples are curated for platform-suggested language model fine-tuning, and pipelines are defined for subsequent active learning.

Figure 4 provides a schematic view of the platform architecture. The document sources will not only be external in nature like PubMed, Ovid, and ClinicalTrials.gov, but also

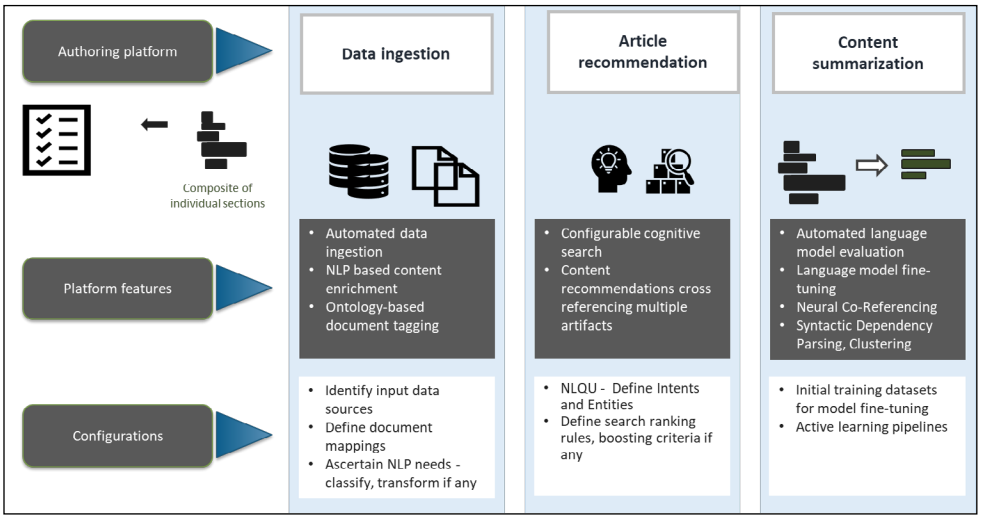

Figure 3. Section onboarding in medical writing platform. NLP, natural language processing.

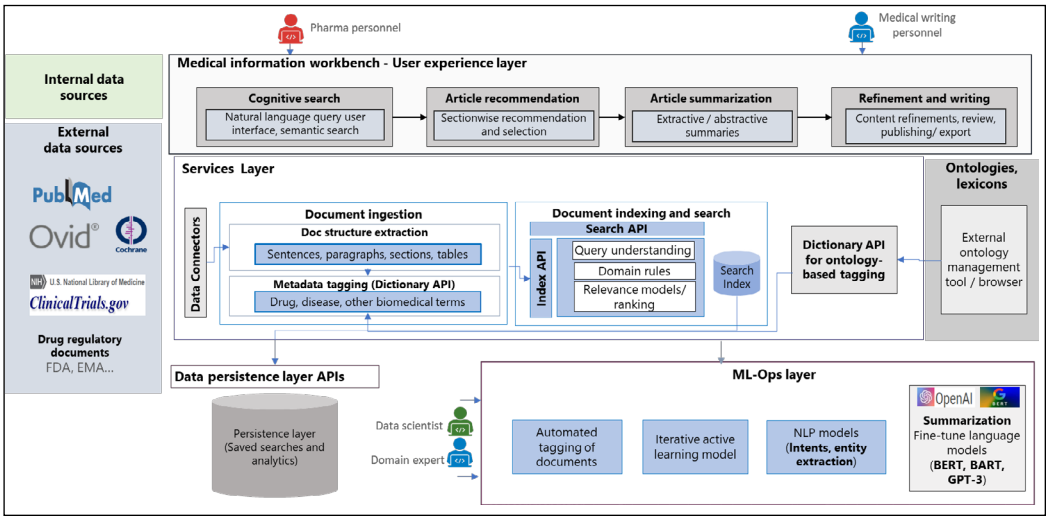

Figure 4. A schematic view of the platform architecture. API, application programming interface; EMA, European Medicines Agency; FDA, United States Food and Drug Administration; ML, machine learning; NLP, natural language processing.

regulatory documents like those published by the FDA and document sources that are internal to any organization deploying the platform.

During the ingestion of the documents, document structure is extracted and tagged with metadata that helps in indexing and classifying the content for future use. Such extraction includes classification of sentences and paragraphs and sections as dealing with different drugs, diseases, and other biomedical terms.

When a user searches for documents, the questions posed by the user in plain English are translated into machine-readable queries that are then searched against the indexed documents. The results are then ranked according to the rules and boosting criteria used and returned to the user as recommendations.

Once the user selects the documents identified for summarization, NLG is used to generate extractive or abstractive summaries of the selection.

CONCLUSION

AI and ML, combined with NLP and NLG, promises to benefit the medical writing process by reducing the manual aspects of the work by automating many steps, in addition to improving quality and reliability. The time and effort thus saved can be substantial to large organizations that often spend a considerable amount of both during the lifecycle of a drug.

Author declaration and disclosures: *The authors acknowledge the team's learning from building the Cognitive Search and Medical Writing Platform at Infosys.*

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FREELANCE FOCUS


Melissa L. Bogen


Lori De Milto


Cathryn D. Evans


Gail V. Flores

Q1: In the age of LinkedIn, how important is a website for a freelancer? What are the key elements that should be included in developing a website?

Initially, I thought my answer to this question would be quite brief: I don't think websites are important for freelancers, since I've never had one yet have had a successful freelancing career. Upon reflection and discussing this with other freelancers at a local AMWA chapter event, I realize this answer is very specific to the type of writing I do and at this particular time in my career. I almost exclusively write educational materials for pharma/biotech sales representatives and medical science liaisons, none of which ever enter the public domain. Although a website can include writing samples and links to published works that can be very helpful for many freelancers, I don't have any samples or links that can be publicly shared. After 20+ years as a freelance medical writer, I feel like LinkedIn is currently a better way for me to market than a website. However, I can't rule out that I missed out on great potential clients earlier in my career because I didn't have a website.

—Gail V. Flores

Although LinkedIn has become increasingly important for freelance medical writers and editors, you still need a website too. Clients use LinkedIn to search for freelancers and also to check us out to decide whether to contact us. But you have to follow LinkedIn's format for the content and design of your profile.

A professional, client-focused website helps you stand out from other freelancers and persuade clients that you're the right freelancer for them. Your website highlights your key marketing messages in a compelling and visually engaging way and shows clients that you're running a professional freelance business.

The two key elements of a freelancer's website are (1) content that's compelling, clear, and focused on client needs and (2) design that's visually engaging, clear, and easy to navigate. In your content, quickly tell clients

- what you do (your services),
- who you do it for (your target clients), and
- how what you do benefits clients.

If you already have a client-focused LinkedIn profile, then you should have much of the information you need for your web content. Write client-focused marketing messages and conversational, concise, and scannable content. Include the essential web pages for freelancers.

Use heads and subheads to highlight the benefits clients get when they work with you. Heads and subheads also make your content concise and scannable. Write your content like you're having a conversation with a client.

The essential web pages for a freelance website are

- Home (the most important part of your website),
- About,
- Services,
- Samples, Portfolio, or Work,
- Testimonials, Clients, or Testimonials and Clients, and
- Contact.

You can combine and organize Services; Portfolio, Samples, or Work; and Testimonials, Clients, or Testimonials and Clients in different ways. If you're a new freelancer, you can add testimonials and information about clients later.

Hiring a professional designer is one of the best investments in your freelance business you can make. If your design isn't visually engaging, clear, and easy to navigate, then clients will move on to the other freelancers on their list. Also, a good designer will guide you through the process of developing your website.

—Lori De Milto

* * *

Q2: What are your favorite web conferencing platforms and why?

My favorite web conferencing platforms are GoToMeeting and Zoom. I like GoToMeeting because it's extremely user-friendly. I can easily split the window so that the meeting

ISSN 2163-5315

slides are on one of my monitors and the meeting participants are on a second monitor. I can also quickly use the camera icon to take a screenshot of the slides being presented instead of having to manually take screenshots. However, to my knowledge at this time, the accessibility f eatures for GoToMeeting are behind those for Zoom; some of my colleagues have informed me that many screen readers are not compatible with GoToMeeting, and the closed captioning feature is not as robust as the one used in Zoom. For these reasons, I prefer Zoom.

I'm not a fan of either Microsoft Teams or Google Hangouts. Although I use Microsoft and Google apps and platforms all day every day in my work, I find their web conferencing platforms to not be as easy to use as those discussed above.

—Gail V. Flores

Other than Skype and FaceTime, the only two web conferencing platforms I have used (or attempted to use) are Zoom and MS Teams. The latter was not compatible with my iMac 27" desktop computer; the client's IT person tried three times to enable me to log on to MS Teams, over the phone and within my computer—this person was not successful. The person said it is "supposed to be" compatible with Mac but obviously wasn't able to make it so. Thus, I opted out of joining meetings via MS Teams (which, being a Microsoft product, is of course more compatible with MS Windows than with Mac). Zoom, on the other hand, is simple and works easily on the desktop, iPad, and iPhone. Since the pandemic shutdown, I have participated in somewhere between 5 and 8 Zoom meetings every week, except when out of town—with no complications.

—Cathryn D. Evans

* * *

Q3: What are the etiquette rules for web conferencing platforms that you follow? Camera on or off and when?

I'll start by saying that I believe that nobody should ever feel like they have to be on camera. In addition to not being comfortable with being on screen, many valid reasons exist for not being on camera. Personally, mine have included very early meetings, feeling unwell due to illness, and being upset after receiving bad news. It's OK for people to have offscreen days—after all, in each meeting, there always seems to be at least one other person who is offscreen because they are traveling, driving, or their webcam has stopped working. Furthermore, my projects went well for 20 years before the pandemic just through teleconference calls, so video isn't a must for project success.

However, there are also valid reasons for being on camera. I think it helps build a rapport with my clients, particularly during initial or project kickoff meetings. I also enjoy the social aspect; I often feel isolated working from home, and I enjoy interacting with others besides my family members, even if it's just onscreen.

With respect to etiquette, I believe that cameras should be off when people are eating or are using exercise equipment, such as a treadmill or stationary bike. Wardrobe is up to each person. For me, I might wear something nicer for a new client and something more casual for someone I've known for a while or for an internal team meeting. Finally, if you need to respond to an email from a client or a text from a family member, I recommend turning the camera off, since it's difficult to hide that you're not paying attention to the speaker.

—Gail V. Flores

For the most part, on-camera participation is something I do for only the first meeting with a particular group so that we all get to know one another and have a visual impression of one another; after that, I use an icon/photo when attending a Zoom meeting. Exceptions occur, but my general rule is to be off camera.

Obviously, the most important "etiquette" rule is to listen to others and pay attention just as dutifully as when you meet in person. Second (especially when meeting on camera) it is simple courtesy and common sense not to eat, read other materials, leave the room unless absolutely essential, answer the phone and carry on a sideline conversation, or do anything that might be considered rude or untoward. Drinking water, coffee, or tea seems to be acceptable. Third, "mute" yourself when you are not actually speaking. Finally, do not allow boisterous or barking dogs—or other potentially distracting background activities—to take place.

—Cathryn D. Evans

Virtual meetings have become especially popular during the COVID-19 pandemic. Because web conferencing takes the place of in-person meetings, I dress and behave as if I'm in the room with my work colleagues. Here are my best practices for virtual meetings:

- Wear business-casual attire, including shoes, in case you stand up and your legs or feet become visible.
- Ensure you have drinking water nearby so you don't have to leave the meeting to get it.
- Blur the background to draw attention to your face and away from your surroundings.
- Absolutely no other people (eg, household members) should be visible in your background if they are not a

conference participant. If you cannot conduct the web conference in a dedicated space to ensure privacy and confidentiality, blurring the background is especially important.

- Keep the camera on and look at the speaker so it's clear you're paying attention. If it's a small meeting and your clients have their camera off, you can turn your camera off to match them. I like to show my face at least initially so they know what I look like and that I am prepared to have our meeting.
- If you need to move away from the camera—either quickly to close a door or window shade or longer for a bathroom break—turn the camera off temporarily so that walking away and coming back doesn't distract the other participants.
- In Zoom (and perhaps other platforms), add a business-casual photo of yourself to your profile so it appears when the camera is turned off. Using a photo is not essential, but this is a nice practice to keep some humanity in the virtual meeting.
- As a label for your face or photo, use your complete business name and perhaps add your pronouns in parentheses.
- Keep muted except to talk.

—Melissa L. Bogen

AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N1 / 2023

CONSCIOUS WRITING

The Intrinsic Story Structure of Original Research Manuscripts

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The first scientific journal, *Philosophical Transactions*, was founded in 1665.[1] At that time, and for more than 2 centuries thereafter, scientific manuscripts did not have a standardized form or style. However, in the 1940s, a standard structure began to emerge. Decades later, in the 1980s, a standard structure was widely adopted for original research manuscripts in the sciences.[2,3]

Most research manuscripts are now written in a standard structure known as IMRaD (Introduction, Methods, Results, and Discussion).[2,3] In this structure, the Introduction describes the background of the study, the Methods describe how the study was carried out, the Results report what the study found, and the Discussion explains what the study findings mean.

This standard IMRaD structure makes the process of developing and publishing manuscripts more consistent and easier to manage. This structure helps authors organize their ideas and ensure they include all the important elements of the study. The IMRaD structure also helps editors and reviewers evaluate manuscripts more easily. And the structure helps readers to quickly locate specific information without going through the entire paper.[3]

The IMRaD structure has another valuable feature. This structure helps authors to tell a story with the most common story structure: the three-act structure.

THREE-ACT STORY STRUCTURE

The three-act structure contains 3 acts separated by 2 plot points (Figure 1A). In Act 1, the story starts with the Setup, or exposition, which is when readers learn about the setting and characters in the story. At the end of Act 1 is Plot Point 1. Here, readers encounter the Tension, or an inciting incident. This tension engages readers' curiosity, excitement, or other emotion so that they want to keep reading the story.

Act 2 is the Action in the story. The Action builds momentum, further engaging readers as the story approaches Act 3. Near the peak of the Action, the story hits Plot Point 2. At this point, readers reach a cliffhanger that heightens their emotions to entice them to keep reading the story.

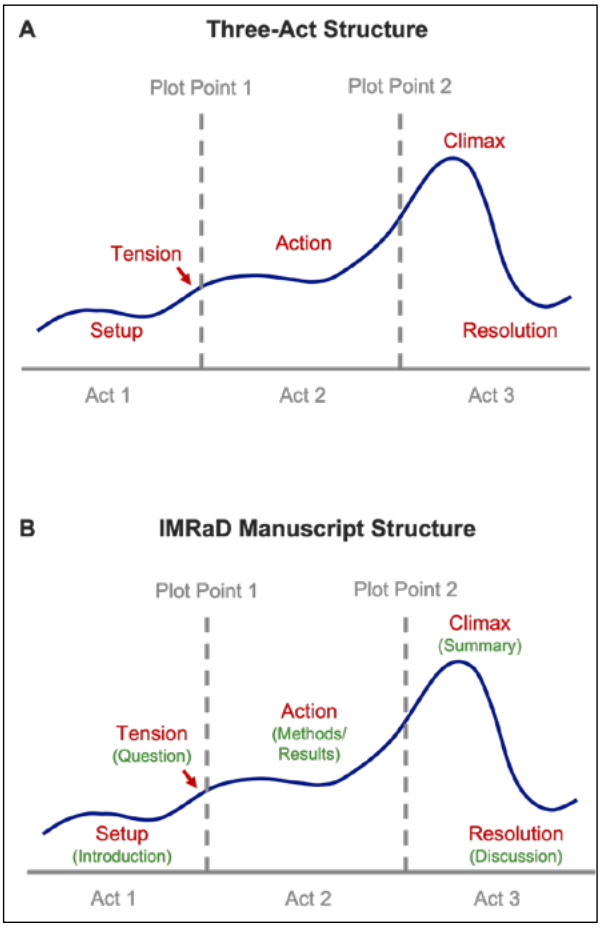

Figure 1. Three-act story structure in original research manuscripts. A) Three-act structure commonly found in stories. B) Three-act story structure found in original research manuscripts that follow the standard IMRaD (Introduction, Methods, Results, and Discussion) structure.

In Act 3, the story peaks at the Climax and then ties everything together in the Resolution, or denouement. In this way, Act 3 relieves the tension, or the heightened emotions, created at the end of Act 1.

THREE-ACT STORY STRUCTURE IN MANUSCRIPTS

The IMRaD structure of manuscripts maps onto the three-act story structure (Figure 1B).

ISSN 2163-5315

Act 1

Setup

In a research manuscript, Act 1 is the Introduction section. This section is the exposition of the story, when readers learn about the characters and setting of the study. For example, the characters in a manuscript might be proteins, drug compounds, diseases, or patients. And the setting might be a particular cell type, organ, hospital, or population.

Act 1 also includes any other background details that might be important for readers to know to understand the story in the study. For example, readers may need to know statistics about a particular condition, why existing drugs are ineffective, or how the structure of a mutated protein influences a particular disease state.

These background details help to frame the purpose of the study—what problem the study aims to address. This purpose helps readers understand the relevance and significance of the study. And it helps to frame the Tension.

Tension

The Tension in a manuscript is the research question at the end of the Introduction. This question describes what the characters need to accomplish in the story. In other words, how can the characters help to solve the problem you framed in the Setup?

The Tension also needs to state what specific question the study proposes to answer and how that question is connected to the problem framed in the Setup. For example, does the new drug need to slow disease progression? Or does the gene mutation need to improve organ function? This framing sparks curiosity and excitement in readers to entice them to keep reading into Act 2.

Act 2

Action

In a research manuscript, the Action includes the Methods and Results sections. The Methods section starts the Action by describing what happens to address the question in the story. In other words, what approach was used, what experiments were carried out, what data were collected, and what analysis was done in the study?

The second part of the Action is the Results section. This section builds on the momentum created in the Methods section by reporting the findings in the study. These findings build on each other as the story approaches Act 3. At this point, readers learned the study findings, but they may not yet have a clear understanding of whether the findings answered the study question. This moment creates a cliffhanger that propels readers into Act 3.

Act 3

Climax

The Climax is the first paragraph of the Discussion section. This paragraph describes whether the characters answered the question raised with the Tension. To maximize the impact of the Climax, this paragraph needs to remind readers of the study question, summarize the key findings of the study, and state how those findings answered the question in the Tension. This structure reinvigorates and then satisfies readers' curiosity and excitement about the study.

Resolution

Act 3 also contains the rest of the Discussion section, including the final conclusions paragraph. The Discussion section explains how the characters and their setting changed as a result of the Action in the study. In other words, how do the findings fit within the existing body of literature? Do they support or contradict findings published in other studies? And, importantly, how do the findings advance the field?

At the end of Act 3 is the Conclusions paragraph. This paragraph is the denouement of the manuscript that ties the entire study together by (1) reminding the reader of the problem in the Setup, (2) reiterating the question that creates the Tension, (3) highlighting the main study findings in the Action, (4) stating how the findings answer the question in the Climax, and (5) emphasizing how the study advances the field in the Resolution. In this way, the Conclusions paragraph leaves readers with a clear concept of the overall relevance and significance of the story in the study.

BUILDING THE STORY

The three-act story structure includes 5 stages—Setup, Tension, Action, Climax, and Resolution—that can be condensed to form the abbreviation STACR. Each of the STACR elements has an important function in a story that helps to engage readers and keep them reading. These STACR elements also map onto the IMRaD structure of original research manuscripts, creating a built-in story structure that engages and informs readers about a research study.

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

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N1 / 2023

IN THE SERVICE OF GOOD WRITING

Paragraph Structures

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Bad writers write badly for 2 simple reasons: they choose the wrong words and put them in the wrong order. As a result, they write bad sentences. Then, they usually put those bad sentences in an order that makes no sense. A good writer writes good sentences and puts them in a meaningful order, so that the writer's ideas flow smoothly from the page into the reader's mind (see Key Points). Good writers also break up their text into manageable chunks, called paragraphs.

Writing guides often tell you to use the paragraph as the unit of composition. Each paragraph can focus on a particular topic or idea. The break between paragraphs gives readers a chance to rest, to think about what they have just read. The break also alerts the reader that there may be some shift of focus.

WHAT IS A PARAGRAPH?

The word paragraph came from the roots *para-* (meaning beside) and *graphein* (literally, "to write"). In ancient Greek punctuation, a paragraphos was a punctuation mark, derived from the letter gamma (Γ), that was used to mark a division in text (such as between speakers in a dialogue). The paragraphos was the only punctuation mark that the Greek philosopher Aristotle mentioned, and he took a dim view of it. In his *Rhetoric*, Aristotle argued, "A sentence should break off with the long syllable: the fact that it is over should be indicated not by the scribe, or by his period-mark in the margin, but by the rhythm itself."[1] This advice may have made sense in ancient Greek, but it is utterly useless in English.

By the Middle Ages, scribes were using a *paragraphus* (the Latinized version of *paragraphos*) to mark the beginning of a new section in a discourse. They often used a capital C, which stood for capitus (head). For clarity, they started putting a single vertical line through the C, then 2. Eventually, the sign developed into our modern pilcrow symbol (¶), which word processing programs still use to indicate the end of a paragraph.[2] (The word *pilcrow* is a corrupted version of the word *paragraphus*.) Meanwhile, the word *paragraph* started to mean the block of text that was set off in some way, such as by adding a line of space between paragraphs by indenting the first line of the new paragraph, or by adding a large initial capital letter to the beginning of the new paragraph. In typeset text, you can use a dingbat (eg, ■) to signal a paragraph break that occurs when you cannot use a line return.

PARAGRAPH STRUCTURES

You probably learned in school that every paragraph should have a topic sentence, and that the rest of the sentences in the paragraph should support or build on that topic sentence. Plenty of paragraphs do have that structure, but many well-written paragraphs do not. I don't worry about whether each of my paragraphs has a topic sentence. Instead, I try to put my sentences in a logical order and then make sure that I put in paragraph breaks wherever there is a big enough change of topic or focus. Nevertheless, I find that many of my paragraphs do have a topic sentence. Instead of worrying about how to generate a topic sentence for each paragraph, think about the purpose of the paragraph. If a paragraph is well written, its structure will generally reflect its purpose.

To Tell Part of a Story

A narrative is a story, an account of a series of related events. Events are facts that have some restriction related to time: events have a before, a during, and an after. Each paragraph can tell a portion of the story. A narrative might not have a topic sentence in each paragraph. Instead, a paragraph may contain a series of sentences of equal importance, each describing a particular event: this happened, this happened, this happened, and so on. Each of these sentences may be equally important. However, you might find some places in which there is a natural break in the action (eg, "On the following day, …"). Those are good places to insert a paragraph break.

In a narrative, you may need to add some sentences that provide commentary to explain the context or meaning of a particular event. The sentence that recounts the event and the sentences that provide commentary about that event can be set apart as a separate paragraph.

In a simple narrative, you can recount a series of events that happened one right after another. But to tell some

ISSN 2163-5315

stories, you need to use a nonlinear timeline. For example, you may have to recount the events in the order that you learned about them instead of the order in which they happened. You may have to describe events that overlap each other, or events that happened simultaneously in 2 different places ("meanwhile, back at the ranch…"). You may have to describe the same event as seen from several points of view (as in the famous movie Rashōmon). Thus, you may have to depart from a simple chronological account. Instead, you may have to write subnarratives that you must then weave into the larger narrative.

When writing a simple or complicated narrative, you can use a paragraph break whenever you need to signal a discontinuity in the action or a shift in topic, setting, or perspective. If you need to make a larger break in the narrative, you can use a text break (signaled by white space and perhaps a printer's ornament) or start a new chapter.

To Give Instructions

Instructions are a series of commands, sometimes interspersed with explanations. You can usually put the commands in the order in which they are to be followed. However, in an ordinary recipe, you may need to refer to a separate recipe for how to prepare one of the ingredients. For example, a recipe for sourdough bread would call for sourdough starter. Thus, there is generally a separate recipe for how to make and maintain the starter. For this reason, the timeline in a recipe might not be strictly linear.

In a recipe or any other set of instructions, you can use paragraph breaks to separate major steps in the process. For example, when writing about how to perform a surgical procedure, you might devote the first paragraph to the options for anesthesia, the second to patient positioning, the third to the initial incision, etc. You might also need to write a separate set of instructions for the anesthesiologist.

To Describe or Explain Something

A paragraph that describes or explains something may have a topic sentence that defines what the thing is and several other sentences that give more information about that thing. When you need to shift topic or emphasis, add a paragraph break. Note that in the passage below, there is a clear topic sentence in the first and third paragraphs, but not in the second paragraph:

> Insulin is the hormone that allows the body to react to a meal [topic sentence]. Insulin is a peptide hormone that is secreted by the beta cells in the islets of Langerhans in the pancreas. During fasting, these cells release only a small trickle of insulin (basal or constitutive insulin secretion). Various stimuli that are associated with a meal cause a burst of insulin secretion. These stimuli include hormones released by the gastrointestinal tract in response to feeding, as well as the rise in blood glucose that occurs after a meal. Insulin then acts on cells throughout the body, to stimulate them to react to the meal.
>
> Insulin's most familiar actions are on blood glucose levels. Insulin stimulates liver and muscle cells to convert glucose to glycogen for storage. Insulin also stimulates heart and muscle cells to express GLUT4 transporters, thus allowing those cells to take in more glucose to use as an energy substrate. These two effects cause a reduction in blood glucose. However, insulin also stimulates adipose cells to store the fat that is being absorbed from the meal. It also stimulates cells throughout the body to use amino acids to synthesize proteins. Thus, insulin is an anabolic (growth promoting) hormone. Insulin also crosses the blood–brain barrier to enter the brain, where it has effects on cognition and behavior. Crucially, insulin also acts on the alpha cells of the pancreas, to suppress the release of glucagon.
>
> Glucagon is the hormone that opposes the actions of insulin, promoting mobilization of stored nutrients as opposed to the storage of circulating nutrients [topic sentence]. Thus, it allows the body to survive a fast. Like insulin, glucagon is a peptide hormone….

The second paragraph does not have a topic sentence. Instead, it provides more commentary on the topic sentence from the first paragraph. The paragraph break is useful because the first paragraph focuses on insulin secretion, whereas the second paragraph focuses on insulin's effects. The third paragraph does more than shift focus. It changes the topic to a different hormone: glucagon. Depending on the overall structure of the piece, you might insert a new heading before the third paragraph.

To Explain How Parts Make Up a Whole

You can use a paragraph to give an overview of a structure. The topic sentence will say that the whole consists of several parts. Other sentences may address each individual part. If you have a series of parallel sentences, you might want to present them as a bulleted list. Note that the bulleted list makes a long paragraph easier for your reader to digest:

> The pancreas has exocrine and endocrine functions [topic sentence]. An exocrine gland is one that secretes products through a duct [definition]. The pancreas secretes digestive enzymes (e.g., amylase, lipase, and proteases) through a duct that empties into the duodenum, which is the first few inches of small intestine. In contrast, endocrine glands release their

products directly to the bloodstream [definition]. The endocrine functions of the pancreas are performed by the islets of Langerhans, which are small clusters of hormone-producing cells that are scattered throughout the pancreas. Although these islets make up only about 1% to 2% of the mass of the pancreas, they receive 10% to 15% of its blood flow. Several different kinds of cells are found in the islets, each producing a different hormone or hormones:

- Alpha cells produce glucagon
- Beta cells produce insulin and amylin
- Delta cells produce somatostatin
- Epsilon cells produce ghrelin
- Gamma cells, also called F or PP cells, produce pancreatic polypeptide.

To Say That Something Is True

According to the Greek philosopher Plato, knowledge is justified true belief.[3] Suppose that you want your paragraph to persuade someone to accept a claim as truth. You can state the claim in a topic sentence, which often ends up at the beginning or the end of the sentence. You can then add a sentence or 2 to define your terms or clarify what you mean by the claim. Then, you write one or more sentences that provide evidence to support the claim. You might also add a sentence or 2 to explain why the evidence justifies your claim. In the following paragraph, the claim is the final sentence:

> Pre-eclampsia is defined as hypertension that starts after week 20 of gestation [definition]. All of the features of pre-eclampsia represent either the effects of poor circulation (e.g., poor placental development, intrauterine growth restriction, and the HELLP syndrome [hemolysis, elevated liver enzyme levels, and low platelet levels]) or the body's attempt to compensate for or correct low blood volume (e.g., robust activation of the renin-angiotensin-aldosterone system, leading to hypertension and edema) [evidence]. Aldosterone promotes retention of salt and water; but if the woman does not have enough plasma protein to hold the extra fluid within the vascular space, it will migrate to the intracellular space. Thus, the extra fluid will produce edema instead of expanding intravascular volume. Pre-eclampsia is most common among women who are prone to hypoproteinemia and thus to hypovolemia (e.g., undernourished women and women with gestational diabetes) and among women who are carrying more than one fetus (and thus need a greater expansion of blood volume) [evidence]. Pre-eclampsia can be managed with careful use of intravenous colloids (albumin or hetastarch) to expand blood volume [evidence]. All of this evidence supports the same conclusion: pre-eclampsia results when the woman does not have enough plasma protein to expand her blood volume enough to meet the demands of pregnancy [claim].

This is a long and dense paragraph. You might be tempted to split it into 2 paragraphs, just to give the reader a break. But if you do that, then the reader might not be sure what you mean by "all of this evidence." To solve this problem, you might put the claim after the definition and then offer the evidence. If so, you will have to reword the claim, "Pre-eclampsia occurs when a pregnant woman does not have enough plasma protein to expand blood volume sufficiently to meet the demands of pregnancy."

To Offer Advice

Whether you are expounding truth or offering advice, your argument may follow a similar structure. The difference is the mood of the verb in the topic sentence: to state what is true, you use the indicative mood, which is a realis modality. But to give advice or commands, you use an irrealis modality. The advice may be in the form of a command (imperative mood) or a deontological statement (what should or must be done or what you think is needed). The advice could be implied by a conditional statement, which is a statement about what would or can happen, if a condition is met. (For more information on linguistic modality, see Shoulda, Woulda, Coulda![4]). The topic sentence that offers the advice could come at the beginning or the end of the paragraph, or even somewhere in the middle. Some of the other sentences could clarify the advice or explain why the advice is sound:

> To prevent pre-eclampsia, we must provide nutritional support for undernourished women and nutritional counseling for overnourished women [topic sentence: advice]. Pregnant women with protein-energy malnutrition are at risk for pre-eclampsia because they convert too much of their blood proteins to glucose, for use as an energy substrate [explanation]. These women simply need more food [advice]. In contrast, overnourished women are at risk for pre-eclampsia because a high-calorie, high-fat diet promotes insulin resistance, which leads to oversecretion of glucagon, which promotes the excessive conversion of plasma protein to yield excess blood glucose [explanation]. When added to the physiologic insulin resistance of pregnancy, the insulin resistance resulting from overnutrition can lead to gestational diabetes, which is a temporary form of type 2 diabetes during pregnancy [explanation]. Fortunately, the insulin resistance from

overnutrition can be rapidly corrected by a change to a low-fat, high-fiber, high-carbohydrate diet [advice].

Notice that the paragraph has the same basic structure as the topic sentence: we must do A and B. The other sentences in the paragraph provide clarification and justification for A and then B. This is the order that the reader expects from having read the topic sentence.

RELEVANCE AND ORDER

To use the paragraph as your unit of composition, you need to do more than add hard returns every so often. You must analyze how the sentences in the paragraph fit together. Thus, you might ask yourself the following questions:

- Does the paragraph contain all of the information that I need to make this particular point? If not, what must I add (eg, a definition of an uncommon word)?
- Does the paragraph contain any sentences that are not relevant to the point that I want the paragraph to make? If so, do I move those sentences to another paragraph or delete them?
- Are the sentences within my paragraph in the right order? Would the writing make more sense if I put the sentences in a different order?
- Are my paragraphs in the right order? How does each paragraph fit into the overall structure of the piece?

COHERENCE

When you study grammar, you focus on individual sentences. When you study writing composition, you learn to pay attention to the relationships between sentences. The goal is to learn how to achieve coherence in your writing: a logical, orderly, and aesthetically consistent relationship of parts. Even if you put your sentences in the right order, you need to pay attention to words that provide connections between sentences and that clarify the relationships between ideas. These include repeated words, demonstratives, pronouns and possessive adjectives, and conjunctive adverbs.

- The infection produces *inflammation*. This *inflammation* then.... (repeated word and a demonstrative [*this*])
- *Elizabeth Blackwell* was the first woman to receive a medical degree in the United States. *Her* acceptance letter to Geneva College was intended as a practical joke; but *she* earned the respect of professors and classmates, graduating first in *her* class. (*She* is a pronoun, and her is a possessive adjective.)
- All men are mortal. Socrates is a man. *Therefore*, Socrates is mortal. (*Therefore* is a conjunctive adverb. For more information on conjunctive adverbs, see Meanwhile, Back at the Ranch[5]).

KEY POINTS

- Write good sentences.
- Put your sentences in an order that makes sense.
- Use paragraph breaks to signal a shift in topic, emphasis, or point of view.
- You don't have to have a topic sentence in each paragraph.
- Paragraphs that serve a particular purpose will tend to have a corresponding structure (eg, a topic sentence that expresses a claim and other sentences that provide supporting evidence).
- If you cannot see the whole paragraph at once on your computer screen, it is probably way too long. Look for reasonable places to break it up.
- To indicate a paragraph break, you can use a space between lines or an indentation of the first line of the new paragraph.
- In a typeset piece, if you cannot use a line return to signal the end of a paragraph, use a dingbat (eg, ■).
- To indicate a larger break in a narrative, such as in a work of fiction, you can use white space and perhaps a printer's ornament.
- You can also break your text into sections, each of which contains a series of paragraphs.
- Section headings will help your readers navigate within the piece and may even help your readers find your piece online.

IGNORE BAD ADVICE

If you read about how to write good paragraphs, you will find some pieces of advice that I never follow.

Primer Language

Many writing guides tell you to avoid "primer language" (ie, short, simple sentences). Ignore that advice. Instead, we must struggle to keep our sentences as short as possible. As medical writers, we must explain complex ideas. To do that, we must often write complex sentences, which are long and hard to read. Meanwhile, everyone wants us to produce readable text. Writers for federal government agencies must follow the Federal Plain Language Guidelines.[6] Likewise, corporations also want us to produce text in plain language. Readable text appeals to consumers and ranks higher in search engine results.[7]

Sentence Variety

Some writing guides say that it is bad to have a string of sentences that all have the same grammatical structure. For this reason, they urge you to alter the structure of some of your sentences, for the sake of variety. Yet that method leads to madness. The structure of a sentence should be based on

the structure of the underlying idea. If your ideas vary naturally in structure, your sentences will also vary naturally in structure. By fixing the grammatical problems (eg, problems with modifier placement) that occur in so many sentences, you will automatically create variety in sentence structure. Conversely, if you have a series of ideas that are parallel in structure, the sentences that express them will naturally be grammatically parallel. When that happens, you can set those parallel sentences out in a bulleted list. The items in a list are supposed to be grammatically parallel!

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

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AMWA NEWS

FROM THE PRESIDENT

Looking Forward

Elise Eller, PhD / 2022–2023 AMWA President

As I write this, it's January. There's snow on the ground, and now that I've gotten through the end-of-the-year deadlines and the holidays, I've had a chance to look back at our conference in Denver. I am so pleased that we were able to have our annual conference in person. I enjoyed talking with people face to face and attending the wonderful sessions that the 2022 Annual Conference Program Committee put together. (Note that for the first time this year we recorded select sessions, which are available for purchase through the end of March.) I got to meet up with fellow members of the Rocky Mountain Chapter for our chapter dinner, including several people I had seen only on Zoom. Best of all, I saw a lot of people, from newbies to old hands, enjoying their time at the conference.

In addition, our Medical Writing Executives Advisory Council had a successful Executives Forum at the annual conference. The Executives Forum offers programming to senior level pharma/biotech professionals whose responsibilities include recruiting, training, and managing medical communicators. A summary of what happened at this year's forum will be in the June issue of the *AMWA Journal*.

A new year has started, and we have a lot to look forward to.

Our Diversity & Inclusion Assessment Task Force is analyzing data collected from the survey that was sent out last summer to AMWA members. The task force will report back to the AMWA Board of Directors to advise on next steps. I am eager to discover how we can improve serving our members and make sure members with a variety of backgrounds and areas of expertise are heard.

One of our other great initiatives, the Value of Medical Writing Working Group, continues to make great strides in defining and quantifying the value of medical writing. Last year, the Working Group published a series of 3 articles in the *AMWA Journal*, and, at the annual conference in Denver, they presented 2 posters, one on empowering medical writers and the other on measuring the success of medical writing. The Working Group plans to continue to create and publish tools, resources, and articles to help medical communicators develop leadership and other important interpersonal skills to empower medical communicators. Look for Working Group updates in the *AMWA Journal* and at future AMWA conferences.

For those of you who like to stay connected throughout the year by attending AMWA's webinars, we are developing a great webinar schedule for this year. Webinars will be announced in the biweekly AMWA updates, so be on the lookout for those.

Finally, we're already gearing up for our 2023 Medical Writing & Communication Conference in Baltimore. We have a great location on the waterfront, and I have crab cakes and a Chesapeake Bay cruise on my personal to-do list. Our 2023 Annual Conference Program Chair, Michele Sequeira, writes more about this year's conference in this issue of the *AMWA Journal*. I hope you will be able to join me in Baltimore for what I am sure will be an excellent mix of educational content and networking.

ISSN 2163-5315

AMWA NEWS

Conference Preview: Homecoming in Baltimore

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

Save the dates, October 25 through 28, to join us in Baltimore, Maryland, for the 2023 Medical Writing & Communication Conference. We'll be at the Baltimore Marriott Waterfront Hotel, a spectacular location on — as its name says — the waterfront. We're looking forward to seeing you in person at #AMWA2023, your home for continuous learning and connection in the field of medical communication.

Photo by Brendan Beale on Unsplash

AMWA is committed to furthering the skills and knowledge of professional medical communicators. AMWA's Medical Writing & Communication Conference is the go-to event for our profession and focuses on trends and opportunities in medical communication. It's the premier place to find educational, professional, and networking opportunities.

The Annual Conference Committee has been working hard to develop a conference program that will appeal to the needs of our diverse members. Program topics cover professional focus areas such as regulatory writing, promotional writing, medical editing, scientific publications, and health communication. We're also including topics in career development; core knowledge and skills, such as science and medicine; writing and editing mechanics; technology; and work/life balance. We have aimed to include trendsetting topics such as data visualization, patient decision aids, plain language summaries of publications, and structured authoring. And we've worked hard to cover topics at a range of levels from beginning to mid-career to experienced medical communicators.

As in past years, the Medical Writing & Communication Conference will offer a variety of formats for learning and networking with peers. We'll offer the highly regarded AMWA workshops for additional fees for those who wish to learn specific topics in depth. And the conference will feature MedWrite talks, jam sessions, speaker sessions, roundtables, and poster and networking time to keep you refreshed and active.

The city of Baltimore offers a wonderful array of old and new, familiar and exotic. I encourage you to schedule your travel to take advantage of the city's unique culture. Sample local seafood; view the skyline from a harbor cruise or water taxi; or visit the Maryland Science Center, the National Aquarium, or the historic ships in the Inner Harbor. If you're a history buff, plan a trip to Fort McHenry at Baltimore's Locust Point; it's the site of the Battle of Baltimore that inspired Francis Scott Key to write "The Star-Spangled Banner." For me, personally, it's been more than 3 decades since I last visited, and I am looking forward to absorbing the vibe of Charm City again.

Baltimore is very close to AMWA's executive offices in Rockville, Maryland, hence the idea of "Homecoming" for this year's conference. In a time of rapid change and development of our profession, it's a great vantage point from which to look to the future.

Stay tuned for conference registration information. I look forward to seeing you in Baltimore in October!

ISSN 2163-5315

CALENDAR OF MEETINGS

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

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

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

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

Association of Independent Information Professionals
"#AIIP23: The Annual Conference for Info-Entrepreneurs"
In-Person: April 27- 30, 2023
Wrap-Around & Virtual Events: April 24-May 5, 2023
Milwaukee, WI
https://www.aiip.org/conference

Association of Clinical Research Professionals
"ACRP 2023"
April 28-May 1, 2023
Dallas, TX
https://2023.acrpnet.org/

Council of Science Editors
"2023 CSE Annual Meeting"
April 29-May 2, 2023
Toronto, Canada
https://www.councilscienceeditors.org/annual-meeting-2023

European Medical Writers Association
"55th Annual EMWA Conference"
May 9-13, 2023
Prague, Czech Republic
https://www.emwa.org/conferences/future-conferences

Regulatory Affairs Professionals Society
"2023 Euro Convergence"
May 10-12, 2023
Amsterdam, Netherlands
https://www.raps.org/events/2023-euro-convergence

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

Society for Scholarly Publishing
"Transformation, Trust, and Transparency"
May 31-June 2, 2023
Portland, OR
https://customer.sspnet.org/SSP/ssp/AM23/Home.aspx?hkey=22abbe1c-7a5d-45c5-9a39-183b3535d1b6

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

ISSN 2163-5315

2023 AMWA

Medical Writing & Communication Conference

OCTOBER 25-28, 2023
BALTIMORE, MD

Trends and Opportunities for Medical Communicators

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

SAVE THE DATE

https://www.amwa.org/conference