INSIDE

HIGHLIGHTS FROM #AMWA2020

October 22, 2020 - Plenary Session
11:15 AM ET/8:15 AM PT

Executive Commentaries – Starting Soon!

Joan Affleck, MBA, ELS
Vice President, Head of Medical Writing, Merck & Co., Inc.

Heather Abourjaily, PharmD
Head of Global Scientific Communications – Pipeline, Vertex Pharmaceuticals

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

FROM THE PRESIDENT

Gail V. Flores, PhD / 2020−2021 AMWA President

Welcome to the 2021 Spring issue of the *AMWA Journal*. As I write this, AMWA is in the final stages of selecting the *Journal*'s new Editor in Chief (EiC), who will be in place at the time this issue is published. I hope you are as excited as I am to "meet" the new EiC in the next issue and see how they will work with the editorial board to help guide and shape the *Journal* in the coming years.

In this issue, you will find both articles featuring 2020 AMWA award winners and session reports from AMWA's successful 2020 Annual Medical Writing & Communication Conference. Despite this event being held virtually, attendance was high, and attendee reviews have been excellent. Once again, the volume of rich content included in the plenary sessions, open sessions, and roundtables was too large to capture in a single issue—so be on the lookout for other content inspired by our conference presenters as upcoming AMWA Webinars, Knowledge Builders, and other activities in AMWA Online Learning.

Speaking of AMWA Online Learning, have you checked out the catalog lately? Our education department has been very busy, continuing its momentum from 2020 into the new year by delivering fresh content and developing new webinars, Knowledge Builders, and other offerings. And the valuable opportunities to learn are not just limited to the Online Learning catalog! New posts are continually being added to the AMWA blog (https://blog.amwa.org), and AMWA's *Medical Communications News*, which is delivered to your inbox on a regular basis, has recently gotten a new look. Did you know that AMWA has a YouTube channel (https://www.youtube.com/c/AmericanMedicalWritersAssociation) that houses videos highlighting members discussing trends in medical writing and the features of AMWA? Be sure to open your emails from AMWA and follow AMWA on social media so you don't miss any of this valuable content!

When this issue is published, it will mark about a year since our daily lives were changed dramatically due to COVID-19–related stay-at-home orders. For those of who have lost loved ones or whose lives and livelihoods have otherwise been forever changed, please accept my condolences. I never expected my term as AMWA President to start entirely from my home, without a single in-person interaction or hug. Yet I've so enjoyed the smiles I get from my AMWA colleagues at virtual chapter networking events and governance meetings, as well as chatting on Engage, on LinkedIn, and in the conference platform. Thanks once again to our chapter leaders for keeping the online networking and programming going so that AMWA members can continue to feel like a part of the amazing community that is AMWA.

Yours,
Gail

Jam Session for Seasoned Freelancers

Brian Bass, with commentary from Cathryn D. Evans, Sherri Bowen, Melissa L. Bogen

The Jam Session for Seasoned Freelancers was born of the realization that when experienced freelancers get together and "talk shop," the topics of interest and concern are often much different from those of both new and less-experienced freelancers. The open session is typically conducted with participants seated in a large circle where everyone is equal, and everyone is invited to ask questions and offer advice. Moving in 2020 to the virtual format proved that this open and interactive (gently controlled) session fluidly translates to the virtual environment.

As always, the Jam Session (held virtually in 2 smaller sessions instead of 1 large session) elicited a lot of important and insightful discussion. Several themes rose to the top: finances, contracts, and life after coronavirus disease 2019 (COVID-19). In this article, members of the Freelance Forum have joined virtually to add their comments to the topics that were discussed.

FINANCES

Enacted and pending state legislation regarding how independent contractors are defined by law (and for tax purposes) was a hot topic. The issue began in California, where poorly worded legislation intended to protect certain gig workers like Uber and Lyft drivers engulfed nearly anyone who works for themself. While many states have jumped on the bandwagon, a glimmer of hope has emerged. California is relaxing its law so freelancers who truly work independently can continue to do so. Hopefully other states will follow suit.

In other great news on the financial front, some freelancers have applied for, and actually received, Paycheck Protection Program loans amidst the pandemic crisis. It was noted that thanks to restricted travel and face-to-face interactions, freelancers' expenses are way down, while for many, their workload is way up. This is a good time for freelancers to raise their rates. One session attendee shared that a client actually asked whether they're paying her enough!

Speaking of being paid enough, it was universally agreed by session attendees that a freelancer who both edits and writes shouldn't charge different rates for those services. It was aptly noted, "Your value is your value no matter what you're doing."

I did not apply for a Paycheck Protection Plan loan for my business, nor did I apply for unemployment, despite having some "down time" during the quarantine, but am very happy to hear that many AMWA members were able to benefit from these programs.

As far as the idea of sticking rigidly to your hourly rate regardless of the type of work ("Your value is your value no matter what you are doing"), I do not agree with this. While I certainly respect those who feel this way, I do not share this point of view.

I certainly would not hire someone to do a simple copyediting or proofreading job and pay the same amount that I would pay an experienced medical writer. Why would I? I can hire someone else at half that amount, perhaps even less. (Note, however, that when I perform editing functions on a project I was hired to write, I do not lower the hourly rate for that part of a project; the rate for editing is lower specifically when I have accepted an "editing job.")

Personally, I charge various rates depending on the job. For example, for Project Management, my rate is higher than for writing, and I charge more for writing than for editing. My rate for performing a Quality Control (QC) review of a regulatory document is slightly less than what I charge to write the document itself because this is not a mere "proofreading" job—the QC reviewer needs to know as much about drug development, regulatory guidelines, and complex format requirements as does the medical writer. On the other hand, if I hire someone to do an "editorial edit" and straight proofreading of a regulatory report, I will pay significantly less than the medical writer's or the QC reviewer's rate. Moreover, I sometimes have discounted my rate for a guarantee of a certain volume of work over an extended period. Finally, sometimes I charge less for a nonprofit organization than for a corporation, hospital, contract research organization (CRO), or drug company.

Probably the best I can say is that there are not and perhaps should not be any absolutes in this regard. I believe we need to be flexible depending on the situation.

—Cathryn D. Evans

CONTRACTS

There was a rousing discussion about protecting client information. While none of the session attendees reported experiencing a security breach, freelancers must be watchful for security language infiltrating their contracts. Case in point, there may be a

contract clause requiring the freelancer to pay to protect the client's data. The group agreed such language should be stricken from the contract, and there was discussion around the value of professional liability insurance in providing financial protection in the event a security incident is encountered.

Freelancers need to be careful and thorough when reviewing all types of client contracts. For example, there may be a purchase order for a project with a hidden twist: a link to a 20-page contract filled with fine print. Freelancers must be vigilant. The time to discover language that binds you isn't after the project has been delivered.

Jam session point: Freelancers need to be careful and thorough when reviewing all types of client contracts.
Yes, please read contracts very carefully!! In at least 3 recent draft contracts for my services, there have been clauses to the effect that payment will only be made for "satisfactory" work, for example, "work that has been performed to COMPANY'S satisfaction and in accordance with the terms of the applicable Statement of Work" or "COMPANY will pay all undisputed invoices for services satisfactorily completed." (Underline emphases are mine.) These are untenable clauses without explicit, specific details about what constitutes "satisfactory" (and when I pushed back on this, none of the clients had any such list of details). A client could say your work is "unsatisfactory" if you made a typo or forgot a comma! And if there are no clauses or details about what, exactly, could or would be "disputed" in an invoice or how notification of, defense of, or any mediation of what might be disputed is handled, then this is a red flag, and you should either ask for those details or (better) just strike through that language in the draft contract. Additionally, be sure to always, always, get reciprocal indemnification wording (each party holds the other harmless…).
—**Sherri Bowen, MA, ELS**

Key Message: Always check contracts for double indemnification, and if the indemnification is one-sided, ask for double indemnification.

Contracts often have a paragraph on indemnification, which may look like this:

"[FREELANCER] will indemnify, defend, and hold harmless [CLIENT] from and against any loss, cost, liability, or damage of any kind arising out of all reasonable claims by a third-party made against [CLIENT] arising from the Services of this Agreement to the extent arising out of [FREELANCER's] (a) negligence or willful misconduct, (b) infringement of any third-party intellectual property, or (c) breach of this Agreement."

The indemnification clause is an attempt to shift potential lawsuit costs from one party to the other. Indemnification protects the indemnified party (in this case, the CLIENT) against

losses from third-party claims related to the contract. Such clauses are often used in medical writing/editing agreements because the risks associated with a party's nonperformance, breach, or misconduct are high.

In the clause above, the client is protected from the freelancer's negligence. As the freelancer, protect yourself from client negligence by checking contracts for double indemnification. If the indemnification is one-sided, ask for double indemnification.

With double or mutual indemnification, both parties agree to pay the other party for losses arising out of the agreement to the extent those losses are caused by the indemnifying party's breach of the contract.

One way to handle double indemnification is to have 2 paragraphs in the indemnification section of the contract. To use the clause above in double indemnification, add a second paragraph in which you switch the names [FREELANCER] and [CLIENT].

Alternatively and more simply, the double indemnification can be worded in 1 paragraph something like this:

"Each party will indemnify, defend, and hold harmless the other party from and against any loss, cost, liability, or damage of any kind to the extent arising out of its breach of this Agreement, and/or its negligence or willful misconduct."
—**Melissa L. Bogen, ELS**

LIFE AFTER COVID-19

As mentioned earlier, many seasoned freelancers have experienced increased workloads since the pandemic began in March 2020. This is great news for our bank accounts. But there's concern that the volume and velocity of work isn't sustainable. Freelancers are grateful to be very busy through these unprecedented times, but too much of a good thing can burn a person out. That's exactly how a lot of seasoned freelancers are feeling these days. The increased workload, and opportunities to take on still more work, isn't likely to ebb any time soon.

Ironically, considering the Jam Session was held virtually, the "Zoom Boom" was identified as another aspect of the age of COVID-19 that has become at times overwhelming. Unnecessary and unwelcome are other words that come to mind. Videoconferencing is a good way to "meet" clients one would otherwise likely not get to see even without travel and gathering restrictions. But between the exploding number of videoconference platforms, the number of different ways in which videoconferencing is used, and the number of clients a freelancer might have who all want to videoconference, this has also become too much of a good thing.

I have not experienced a huge increase in volume of work during 2020. But I have seen a rather notable increase in headhunters calling me to see if I am interested in a full-time job. Thus, I have the distinct impression that there are many drug companies and CROs hiring full-time writers over the last year. Opportunities seem abundant for those who wish to be an employee, even if working remotely. I suspect this is directly related to the increase in research for vaccines and potential treatments for viruses, especially COVID-19.

On the other hand, I have found myself being quite flexible during this time, undertaking a variety of activities. For instance, rather than focusing on "medical writing" per se, I have done QC reviews, editorial review/critique of papers, copyediting as well as substantive editing, mentoring for prospective medical writers (especially those who wish to work in pharma/biotech), and a certain type of spiritual/psychological counseling for people undergoing extreme stress during this time.

I rather like this expansion of types of work, despite the fact that not all of them pay as well as medical writing in the pharma/biotech industry! I also like not having to travel to meet people—Zoom is just fine, thank you. This medium saves time and money for the medical writer as well as the client; I hope it continues even when travel and maskless socialization become routine again. I do agree with others that participating in too many Zoom meetings per day is quite tiring, so we need to use good sense when scheduling such meetings.

—**Cathryn D. Evans**

Key Message: Remember to stick to your business model. Take care of yourself so you don't get burned out.

I have been working from home since 1997. My business model did not change because of the pandemic.

However, work environments for my clients changed dramatically. Nearly all of them had to set up home offices and then juggle schooling and office space with spouses along with their pre-pandemic responsibilities. They have more demands on their time and more stress.

I am maintaining the key attributes that my clients have come to expect from me: high quality, dependability, flexibility, and affability. Additionally, I am keeping my business boundaries top of my mind. What does this look like?

I continue to meet client deadlines. I email periodic status reports so clients know how their project is progressing. I don't work weekends unless I have miscalculated how long projects would take. I am taking on less work and leaving more time to regain mental balance. I continue to refer clients to a select cadre of AMWA colleagues I know and trust. When I am feeling "Zoomed out," I say no to virtual meetings and give myself a break from online technology.

—**Melissa L. Bogen, ELS**

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

WALTER C. ALVAREZ AWARD ADDRESS

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.

Every Person Is a Patient: Finding the Story in the Science

Mary Elizabeth Williams / Journalist and Author, *A Series of Catastrophes and Miracles: A True Story of Love, Science, and Cancer*

Hi, everybody. When I was first contacted by the American Medical Writers Association way back on February 18th and informed that I was the recipient of this year's Walter C. Alvarez Award, I was so excited and honored and surprised and immediately eager for the day when we could all be together. I ended my email, in fact, by saying ,"I can't wait to see you."

It is very bittersweet to be with you today in this format, in my bedroom. Again, still, where I have spent so much time over the past several months looking at these 4 walls and that pile of laundry, right over there, that I will get to later.

I have changed. And I'm sure that you have changed as well. We've changed in ways that are unique to every single one of us and we have changed collectively. Some of those changes have revealed themselves very slowly over time and some of them have been quite abrupt.

I happen to know about both of those things, and so I thought maybe we could spend a little time today talking about that. Talking about those moments that define us and who we are. The ones that we see ourselves in terms of the before and the aftermath of. That first kiss, the loss of a parent, the birth of a child, an act of violence, a report on the news, a phone ringing in the middle of the night, or ringing in the middle of the morning.

I'm going to tell you about the phone call that changed my life. This, as we say at the beginning of every comedy movie from the last 25 years or so, is me. Just a normal person on a summer day, maybe a little bit of an overachiever, maybe a little bit of a type A, because what good comedy doesn't start with someone like that? Taking my first and what turned out to be my last trapeze lesson.

This is me, less than a week later, on another summer day. I don't think that I look very different, certainly not to a casual observer, although I see the changes. I see my older daughter, age 10, happy to have a day out, but I wonder what she was thinking. And I see my younger one, age 6, with her arms around me, and holding me protectively. And me holding her. I'm wearing a brand-new hat. It's ridiculous, and I don't like hats.

I see something inscrutable in my face because I look at the camera and I know that this might be my last summer. Let me take you back a few days. It was 10:30 in the morning, August 11th. I was on a deadline for a story and it was my dermatologist. I had been in her office a week before to have her look at a weird scab on my head. I had not been worried about it at all.

The first thing she said to me was "I'm so sorry." So, I grabbed a piece of paper and I started writing. *Malignant melanoma*, underlined. *Meet with* and then, nothing, because I think she said the doctor's name too quickly. *Lymph node biopsy*. I didn't really know at that point what lymph nodes are. I'm still a little unclear. I do, however, know that I am very ticklish when my lymph nodes are checked.
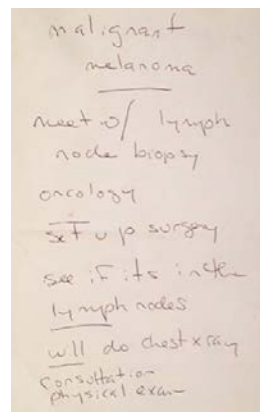
Hello, this is your life now.

Oncology, that is a word I do know, so I underlined it. *Set up surgery. See if it's in the lymph nodes*. To my everlasting shame I wrote *it's* without the contraction, and that is very unlike me. *Lymph* I underlined again, *will*, underlined, *do chest x-ray. Consultation, physical exam*.

At the end of that phone call, I was someone else. I was a patient. The following day, I met my brand-new oncologist because I was a person with an oncologist. And a few days after that, I had surgery. I had a couple of centimeters taken off the top of my head and with it the hair. I ever since have had a big old bald spot on the top of my head, and I have learned a lot about combovers.

As you can see from this photograph, I also learned that if I thought my other hat was ridiculous, I was entering a whole new world of ridiculous hats.

I recovered. I found out that people have a lot of opinions when you get sick. Some of them are very helpful, some of them are not. And I began yet another new life, this time, as a "cancer survivor."

This was my life for a while. Three months to the day after I was diagnosed with cancer, my best friend was diagnosed with ovarian cancer. My father-in-law died of colon cancer. I went to the Rocky Mountains with a friend. I went to Orlando with my family, and we saw Hogwarts and drank butter beer and things were good, for a time.

So record scratch, a year after my first diagnosis, I was diagnosed again. There had been some troubling spots in my lungs. I didn't know that when I went in for my surgery that I already had a presumptive diagnosis of stage IV. I didn't know that diagnosis carried a presumed 7 more months to live or that my odds of surviving 5 years were well below 10%.
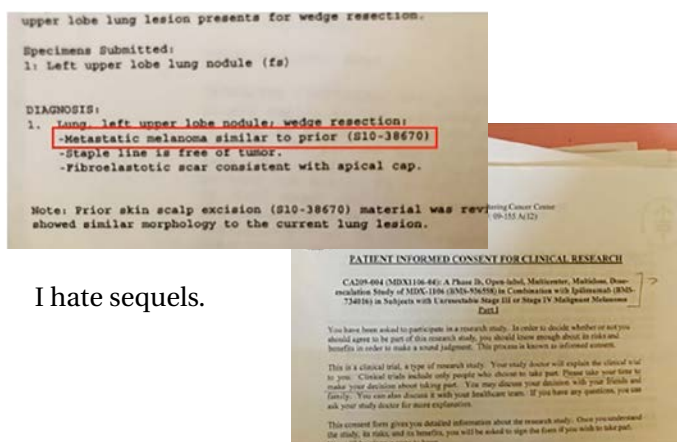
I hate sequels.

It was the beginning of the school year, and the likelihood that I was going to be around for the end of it was very slim. But I hit the jackpot. I became one of the first people in the world in a clinical trial for immunotherapy. I was one of the first 10.

I became one of the first people in that trial to present no evidence of disease. And yet, when I look at my informed-consent form, I see how little I understood. I understood maybe the word *melanoma* in that form. And as you can see, I put a question mark next to everything else.

That is unfortunate. It is unfortunate that the phrase *informed consent* rarely delivers on the first part, and then by consequence, it's very hard to get the second part. And I wish that that was different. And I believe that it can be, because we need to live in a world where information is clear, and consent is truly authentically possible.

I spent 2 years in my clinical trial. I spent a lot of time at the hospital. At one point, I had a nurse tell me she had never taken that much blood out of one person in a single draw. And I was doing all of this while I was still working and parenting and living my life. Because that's how it is. The experience of illness and treatment happens in our lives and our world. It does not occur on some separate plane in some other planet. And we are all seeing that in a very real way right now.

We have to have context for our conditions because they are not discreet, and they don't take place in a bubble.

These photographs were taken about 2 weeks apart.

[Editor's Note: Faces of two children in the photo on the right were blurred for privacy reasons]

You can probably guess the time of year. I took my daughters to meet Santa Claus and they asked me to come with them. I was really feeling the effects of my treatment at this point. It was pretty hard. And I was very tired. And my girls whispered something to Santa Claus, and when I asked my older daughter what they said, she told me, "I can't tell you or it won't come true."

And then a little while later, my family and I were with our cancer support group, and my phone rang, and it was my doctor. I had had my first set of scans that morning, and he told

me that I presented no evidence of disease. And I asked him, "Now what does that mean?" And then he explained it to me, and then I cried. And I went downstairs, and I told my daughters. They were in the midst of a birthday celebration. It was one of the happiest moments in, I think, all of our lives. And I took that photograph. That's the moment that my daughters learned that their mom was going to be around. And very shortly after that photograph was taken, the moms of the other 2 kids in that photograph died of cancer.

I have now been cancer-free for 8 years, but I am always a patient. And sometimes that is a real badge of honor, and sometimes I wish that people could see me as more than just a patient. My doctor and I used to do a guest lecture at a translational medicine class at a prestigious medical school every spring. And every spring, the physician who taught it would introduce my doctor by listing all of his achievements and experience, and then he would turn to me and say, "and a patient."

I don't think he ever bothered to learn my name. I don't think he ever saw me as a human being with a story to tell. With an experience that informed the process of research. I think he saw me as cells on a slide. But I'm very fortunate because he was an exception.

Which brings us almost to the present. I took this picture in Madison, Wisconsin. I was on a work trip and I stopped in for lunch before my flight home. It was the last time I was in a bar. It was the last time I had a conversation with strangers sitting next to me. There were 2 coworkers who came in from across the street for their lunch break and started talking. I had the grilled cheese with caramelized onions and fig jam. And a beer. And if I had known that I would not be doing this again for a very long time, I would have had dessert. It was the last time I was on an airplane. My life and the world have been very different ever since.

And when I look at that photograph of a bunch of taps, I see something that is part of a health care story that is part of

the story of 2020 and the pandemic that changed everything. I think I got a little bit spoiled being in a clinical research trial. On the one hand, yeah, I was a medical experiment, and I didn't know if I was going to live or die and I didn't know if the treatment itself might kill me, but on the other hand, I got to be part of the process. I got to be a reporter, which is completely in my wheelhouse.

I worked with a team of doctors and nurses and researchers who for the most part respected me and listened to me. I was a collaborator. And an active voice in what eventually became the story of a treatment that has gone on to change how we look at cancer and has radically altered countless lives, not just for patients, but for their parents, their children, their spouses, their colleagues, their students. It's amazing. And it is truly one of the most epic things that ever happened to me.

It also taught me that that is how it should be. I want to make it clear that I am not some Facebook mom who thinks that Googling makes me more educated than my doctors. What I am, though, is someone who has experienced what we all have in life, and particularly over the past few months, someone who knows that the medical world is the world that we live in.

That health care is not a place or a single experience or procedure. Sickness, wellness, maintenance, chronic illness, mental health—they take place everywhere, all the time. All day long. In the absolute thick of our work and our parenting and going to school and taking care of our aging parents and financial insecurity and loneliness and love and fear and hope.

I always bristle when I hear the phrase "clinical trial subject." Because it implies that I was simply an object of study. And I was. But I was not just that. Being in that trial took effort. Being a patient takes effort. Walking around in a body every day takes effort. That is why I prefer the word "participant."

And right now, we are all participants. There is not a person in the world who doesn't know what it is like to be slingshot into a health care crisis. There isn't a single person who hasn't seen the profound inequities that we face, the challenges that are unique to the most vulnerable among us, and who has not seen and depended on in a new way the underappreciated and often invisible work of the people who truly keep this world running.

We need to be sensitive to that. We need to listen to that. We need to learn from that. We need to learn from each other. I'm so deeply honored and moved to be here with you, albeit virtually, in my bedroom. To be among people who have dedicated their careers to medical communication. I'm so impressed with you. I am so impressed with everything that you are doing to make sure that the science is translated accurately and clearly, especially right now in an age where there is so much misinformation competing for our attention. And it is a very confusing and disruptive time.

Lately, I have been studying in the field of medical humanities, and I have really been so edified to see that health care and humanities actually don't have to be in competition with each other. That we can hold the dialectic and that concepts like critical thinking and listening and simple language are essential to the process.

I know that humanities aren't as sexy as data, but they are not decorative. They are essential for our survival. I have a friend who is a researcher, and at the beginning of this, I called him, and I said, "Talk me down." And he said, "We're going to get through this. It's going to be a mess. But we're going to get through this."

I spoke to him again recently and I said, "I need a pep talk," and he told me about how over the past few months, even when spikes have been happening in different places and even when the news has been particularly grim, what he has seen have been the ways in which people have been adapting. The ways in which doctors and health care workers have been learning and the ways in which we all have been learning. We are all participating in the process of making a healthier and better world, every single one of us. And we're all learning from each other. We're learning what works. We're learning how to improve the system of communication and of care. And that

is what gives me hope in all of this. And that is not just about data. It is looking at people in context. Looking at the messiness and the imperfection of our lives. The pile of laundry I believe I have mentioned.

I hope that context gives a deep well of information and richness to diagnosis and treatment. When we see not just disease, but we see the people affected by it. When we see the circumstances. When we see—what better example than when we see preexisting conditions and we see the impact that they have on health care? Health care is not isolated. We are all our circumstances. We are all our stories. We're all patients. We're all participants. We're all people, first and foremost.

The only way through this is together. And the only way through this, as ever, is just by listening. So, thank you for listening to me today. Thank you for this award. Thank you for everything you do. I am so deeply appreciative.

Acknowledgment

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

JOHN P. McGOVERN AWARD ADDRESS

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.

Learning Curves

Lisa Sanders, MD / Associate Professor, Yale School of Medicine, New Haven, CT; Clinician Educator, Yale Internal Medicine Primary Care Residency, New Haven, CT; Yale New Haven Hospital, St. Raphael's Campus, New Haven, CT; Contributing Writer, *New York Times Magazine*, New York, NY

Thank you so much for inviting me to this, the new normal, the virtual conference. It's an incredible honor to be asked to come here, to be given this McGovern Prize, and it's made even more meaningful by the fact that it comes from my peers, the people who really know how it's done.

But to be honest, what I do in my column doesn't seem to me so very different from what I do every day in the exam room. I take the complex story of people's bodies and people's diseases and give it back to them, explain it to them, in the words and ideas that I think and hope they'll understand.

I think John McGovern understood this. He was a real giant in medicine and fully embodied that connection between medicine and the humanities. In reviewing the past winners of this award, I see some of my favorite doctors on the planet, doctors who were also writers. It means so much to be included in this extraordinary crowd.

I wanted to take a few minutes to talk a little bit about my own learning curve and how I learned to write. Real learning is never a pretty process. For this talk, I've dolled it up as much as I can, but it remains a swath cut through a field of failure. But as I tell the doctors I train in both medicine and in writing, there's nothing like failure to help you learn something really, really well. Writing is no different. It is success carved out of failure.

In putting these remarks together, I marked my route to learning the writing craft with comments that were made to me by friends or colleagues that showed me the way. These were often off-hand remarks that somehow, for some reason, resonated with me. You hear exactly the right thing at exactly the right moment and, "click," it all makes sense. Sometimes it can take a long time to understand exactly why.

Of course, we all have many of these kinds of aphorisms or little lines that we tell ourselves, but I've picked just a few to help me show you what I needed to do, what I needed to hear, in order to learn to tell my stories.

Signposting:
My Learning Curves

1. You know what it looks like.
2. Where are my stories?
3. You can see it in his eyes.
4. Watercooler stories.
5. Once more with feeling!

Like many of you, I was an English major in college. But real communication, especially communicating with people you don't know, that's different. And I had to learn it on the job. And for me, that job was at ABC's *Good Morning America*. Like most of the women at ABC, I started as a secretary and slowly worked my way up to researcher and finally to producer. My very first assignment as a producer was to create pieces with the new guy, John Stossel. This was before he took that big right turn and left ABC News to go to Fox. This was back when he was a consumer reporter. He had a job on 20/20. He also had a slot on *Good Morning America*.

Our first story was about airbags. We travelled to Washington to go to the Department of Transportation to do a story about this new device. That's how long ago this was. The big fear at the time was that these airbags would go off while you were driving. So, we did a demonstration of
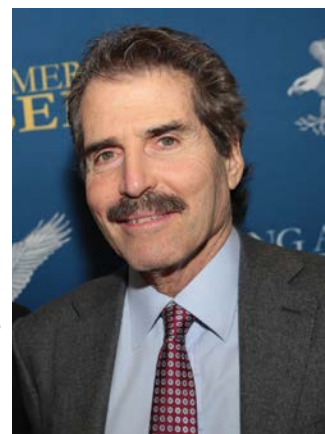
John Stossel

that. We did interviews. John did his standup. And then, at the end of the shoot, John gave me the tapes and told me to go put it together.

I'm like, I don't know how to do that. I've never done that before. He looked at me like I was some kind of moron. He said, "You've watched TV all of your life, you know how it looks, you know how it sounds." And he sent me on my way. It turned out, much to my amazement, he was right. It took me and an editor so many more hours than it should have, but we finally put together a story that looked very much like stories that you see on television. I couldn't believe it.

Most of my life, I'd been taught the things I needed to know. Suddenly John was telling me I had to figure them out. And it was terrifying, but it was also incredibly liberating. To know that, whatever it is I needed to know, I could just go learn it. Amazing.

Actually, it was also a little frightening to see that this same philosophy existed in medicine. It wasn't long that I was in medicine that I heard the phrase "see one, do one, teach one." You teach yourself; you learn by seeing it once. Fortunately, we've moved away from all that. Thank God.

If John Stossel taught me that I already knew what television looked like and sounded like, it was another correspondent, Maria Hinojosa, who introduced me to the idea that the media I made also needed to reflect who I was. I knew Maria when we were both lowly producers at the CBS Morning News in the late 1980s.

She was young and smart and far more cosmopolitan than I was. And while I was focused on mastering the art of telling the usual kind of TV news story, Maria chafed at those constraints. She wasn't interested in mastering that kind of story. She wasn't even interested in telling that kind of story. She had her own story she wanted to tell.

She was from California. Her family was from Mexico, and she knew that there were stories from her world that weren't being told. And Maria thought—and time has certainly proved her right—that these stories needed to be told.

"Where are your stories?" she asked me then. I admired her tremendously but thought that was a crazy question. The media wasn't there for us to use to tell our stories, it was for us to use to tell their stories. The stories of the old white guys, although I'm sure I didn't see it that way then. These were the stories of the news. Those stories. And Maria was not interested in telling those stories. She left CBS after a year or so to carve her own way forward, but it was those conversations we had in the hallways of CBS News that stayed with me.

Finally, I wondered, where are my stories? It took me a long time, years, really, before I really found the stories I wanted to tell. It wasn't until I left TV news and went to medical school. It was there that I found the stories I wanted to tell. I wanted

to share how very cool it was to be a physician, to hear patient stories, to help them answer the question that brought them to my office: "Doctor, what's wrong with me?" But, as I found out, I still had to learn how to tell those stories.

To learn that, I needed a coach. Atul Gawande said in an essay a couple of years ago that everyone needs a coach, and I think he's right. Or at least I needed a coach. And this was my coach: my husband, Jack Hitt. He's a writer and radio personality, and he's an extraordinary storyteller.

I learned a lot about telling stories just watching him do it. Seeing him figure out the beats and watching him adapt a story to fit his audience, their mood and interest. But I learned the most about telling my stories from his eyes.

We started off in life together as 2 journalists. Me in TV, him in print. And we would come together at the end of the day and talk about what we saw, what we did. When I went to medical school, it seemed natural to me to have the same kind of sharing. Plus, what I was seeing was so powerful, so important, so amazing, that I couldn't wait to tell him all about it, and he's a great listener.

But sometimes as I told this new kind of story, I could see he wasn't really listening. I'd start a story and somewhere along the line, I'd see that I'd lost him. It was something in his eyes. His eyes would provide immediate feedback about what worked and what didn't work—real-time, honest feedback. Way more honest than he'd ever be verbally. I could see immediately when his attention wandered, and I could see how to tweak that story to get it back.

I didn't tell him about this for years. I didn't want to ruin it. He still doesn't believe me, but it's true. And I still rely on his eyes when I have a story that I'm not sure exactly how to tell.

Not surprisingly, he's who I really write for. When I teach writing, I tell my students that they need to keep their audience in mind. That they need to have a picture of who it is they're

writing for. I used to say that the person I had in my mind, that my audience, was an 11-year-old boy. Someone who was interested, curious, but didn't know anything.

It's only recently that I realized that the real reader I was writing for is my husband, who is really an 11-year-old boy in disguise. That's him in the foreground and him age 11 on the left.

It turns out who you write for in your head is incredibly important. It helps you find the right voice, the right words, how to pitch the right ideas. And when you write for the wrong guy, when it's the wrong person in your head, well, all bets are off.

I used to write for the wrong guy. Alone at my desk, I could feel the disapproval of this old guy, this old doctor in my mind, I could feel him breathing down my back. I couldn't help it. I wanted to please this guy. I wanted to write for the approval of the doctors who told me these stories, and the doctors I saw in the hallways and in the conference rooms of the hospital. These are the folks, the doctors, the scientists who taught me. These are the people I respect and admire. But they are not my audience.

They already know this stuff. It doesn't make any sense to write for these guys. Yet it's sometimes hard to remember. Coming to med school in middle age, I had a terrible case of imposter syndrome. And because of that, I used to worry that doctors would think I didn't understand medicine if I described it in language that anyone could understand.

After 18 years of writing my column, I mostly know that even doctors appreciate clarity and simplicity. And yet, even knowing this, there are times when this old guy still haunts me.

There are 2 guys who started my career at the *New York Times Magazine*. Of course, neither one of them is there anymore. One is Paul Tough. He's a remarkable writer. A fantastic writer—writes about education—but 20 years ago, he was a new editor at the *New York Times Magazine* and had been given the job of coming up with something new for the front of the book.

I had just completed my training and taken the job on the faculty at the program where I trained at Yale when Paul called me and a bunch of other doctors. He asked one question: "What can doctors write?" Oh, I had an immediate answer. It was a story I'd been fascinated by since halfway through med school. Doctors

Paul Tough

like me, internists, we write the story every day. It's a story about a patient who comes in with a problem and asks for help in figuring out what's going on and how it can be fixed.

It's a mystery story. A detective story. The challenge of figuring out these mysteries is a big part of why we become doctors in the first place. So that was the story I pitched to Paul. He didn't believe me. And why should he? It was one of the best kept secrets in medicine. I went to med school after covering medicine for years. I thought I understood how medicine works. But I didn't know this. I didn't know that any single symptom could have any number of causes. And I didn't know that the big challenge for doctors was figuring that out. They don't tell you that.

Doctors, at least the ones I'd seen on TV, and had interviewed as a journalist, they all seemed so confident, so certain. And the science they talked about seemed so solid. I was amazed when I first saw what an uncertain practice it all was. I didn't know this. No one knew this back then. Of course, the secret is out now. It was the subtext of a show based on my column. Well, my column crossed with the work of one of my earliest heroes, Sherlock Holmes. The show was House M.D.

It's easy to see now that the story that doctors write, called an "H&P" or "history and physical," is structured a lot like an episode of *House* or vice versa. The H&P starts with the chief complaint, the lead, really. Or, if it were an episode of *House*, it would be the cold open. Something dramatic happens to the patient. Then you get a little context. What happened right before the drama? This is called the history of the presenting illness. Then you get a little backstory about the patient, him or herself.

In medicine, it's the past medical history and the physical exam. In *House*, undoubtedly one of the team would probably just break into the patient's home. And then, there's the investigation. In medicine, it's often blood testing or imaging. And finally, there's an answer. A diagnosis. To me, it was as clear as day. I sent Paul medical journals that offer these little mysteries as both education and entertainment.

Journals like *The New England Journal of Medicine, Mayo Clinic Proceedings, The Journal of the American Medical Association*—this is what doctors do for fun, I explained. It took a while for the magazine to believe me. Such a long while, that by the time it was all okayed, I had a different editor, Dan Zalewski, and he gave me the best single best piece of advice I ever got about choosing a story. He said, "Write the stories that doctors would tell each other at the water cooler." Snap. Got it. Done.

There's one more editor who lent me a line I want to share with you. Her name is Catherine Saint Louis. She was my first long-term editor at the *New York Times Magazine*. Of course, like Dan, like Paul, she's long gone. She's gone to a new medium, podcasting. So maybe, in retrospect, I shouldn't be surprised that she should suggest I read my stories out loud before I turn them in.

That was huge. Out loud, the long wandering sentences leave you gasping, quite literally, and the clunky metaphors declare themselves as soon as they leave your lips. I have to say,

after years of this practice, I don't really know what I've written until I hear it from my own lips.

Thank you for the opportunity to share these stories and to honor a few of the many people who have helped me along the way. I know that all of us have these stories, and I'm glad to be able to share a few of mine. And I want to thank you for this wonderful honor and for including my name in the roster of all of the wonderful doctor–writers you've honored in the past.

I wish I could be there. I wish we could all be there. But, we can't. At least not now. But, enjoy the rest of your conference despite all that. It won't last forever.

Thank you.

TRICKS AND TIPS FOR TIME MANAGEMENT

Speaker
Melissa Christianson, PhD, *Whitsell Innovations, Inc, Chapel Hill, NC*

By Jennifer L. Busch, PhD

"Imagine this: You are promised $86,400 per day for the rest of your life. You must use the money each day, or you will lose it; none of it carries over to the next day." Dr Melissa Christianson of Whitsell Innovations began her presentation with this attention-grabbing scenario. Each day contains 86,400 seconds, she informed her audience. She then offered suggestions for stewarding this nonrenewable resource.

The presentation was divided into 6 sections. Each section included a threat to time management, a challenge with which to confront each threat, and several strategies for each challenge (Tables 1 and 2). Dr Christianson encouraged the attendees to modify and personalize her strategy suggestions as needed. She concluded her talk with an admonition concerning time: "use it, don't lose it."

Table 1. Threats to Optimal Time Management and Challenges With Which to Combat Each Threat

Threat	Challenge
Inefficient use of time	Increase efficiency
Prolonged decision-making time	Start quickly and effectively
A self-reported 4-fold increase in procrastination within the past 30 years	Fight procrastination
Interruptions (They steal 90 minutes per day, and 23 minutes are needed to return to productive work after each one.)	Manage distractions
Unproductive time in meetings (Up to half of one's career is spent in meetings.)	Control your meetings
Scarcity mindset (The busier a person, the harder it is for him/her to decline a new request.)	Protect your time

Table 2. Strategies for Meeting Each Time–Management Challenge

Challenge	Strategy
Increase Efficiency	1. Keep track of project details (eg, OneNote). 2. Use organizational templates. 3. Maintain an accurate schedule of your projects.
Start Quickly and Effectively	*For starting your day…* 1. Before leaving work, plan a specific task for the beginning of the next day. 2. Work during your most productive working hours. 3. Jumpstart your day with an easy task or get a difficult task out of the way early. 4. Maintain big-, medium-, and small-picture plans of goals. *For starting a project…* 1. Plan time for getting organized. 2. Gather all needed materials before beginning. 3. Begin with easy tasks to familiarize yourself with the project. 4. Use a spreadsheet to track parts of the project.
Fight Procrastination	1. Work in small time chunks (<3 hours). 2. Enforce breaks to foster and enhance creativity. 3. Use mindless tasks as a break between projects. 4. Commit to working on an undesirable task for 5 minutes; this pledge tricks you into working longer. 5. Monitor time realistically to find time sinks. 6. Avoid procrastination pitfalls (eg, Facebook, perfecting PowerPoint slides).
Manage Distractions	1. Do one thing at a time. 2. Use a "to-do" checklist. 3. Only check emails at specific times of day. 4. Schedule known interruptions. 5. Postpone your response to nonurgent emails. 6. Use "do not disturb" digital functions when necessary.
Control Your Meetings	1. Schedule meetings with enough notice to allow for participants' preparation. 2. Provide a clear agenda. 3. Keep and disseminate accurate and detailed notes. 4. Schedule 15 minutes before and after a meeting to allow for final preparation and follow-up. 5. Follow up immediately after the meeting. 6. Communicate clearly.
Protect Your Time	1. Keep your calendar up to date; block off work time. 2. Say "no," if needed, yet offer a solution or an alternative. 3. Be clear about expectations (yours and client's) around a project. 4. Frontload your day or week.

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LOW-COST AND LOW-EFFORT WAYS TO CREATE INFOGRAPHICS AND VISUALLY APPEALING SLIDES

Speaker
Kelly Schrank, MA, ELS, *Head Bookworm, Bookworm Editing Services LLC, Canastota, NY*

By Raeesa Gupte, PhD
Many medical communicators are encountering a rising demand for visual-communication services from their clients and employers. Visual communication uses charts, graphs, and images to simplify and convey complex information or patterns in data. Infographics and slides use elements of visual communication to present concepts in a new way.

At AMWA's 2020 Medical Writing and Communication Conference, Kelly Schrank gave an introduction to and step-by-step tutorials for non–graphic designers on how to create visually appealing infographics and slides without the use of expensive software. "You need to have some patience, willingness to learn PowerPoint a little deeper or a new application, and some interest in breaking away from the words and thinking in a new way about how to present data," Schrank emphasized.

What Is an Infographic?
An infographic contains visual elements (color coding, graphics, and icons), content (time frames, statistics, and references), and knowledge (facts and deductions). It uses different colors, shapes, sizes, fonts, and icons to
- highlight main ideas,
- connect ideas or data, and
- compare and contrast information.

Color is used to accentuate important data or to separate sections of an infographic. Shapes of different sizes are used to make comparison easier. Icons may be used as bullets or for visual representation of ideas conveyed through text.

Types of Infographics
Infographics may appear in different formats:
- Images
- One- or 2-page handouts
- Rolling infographics that appear on websites and need to be scrolled through

Popular types of infographics include
- timelines,
- processes and how-to guides,
- comparisons,
- lists, and
- maps.

How to Create Infographics
An easy way to start building an infographic is to use a template. Templates make it easy to choose coordinating colors and fonts, thus ensuring style and consistency. In addition, templates can be customized by changing design elements and including the information you want to present.

Schrank shared information on applications that have templates available for infographics (Table 1). Both free and paid versions of these applications are available. However, the free versions may be watermarked or shared on the website's public domain. To protect client data and privacy, paid versions of the applications are preferred.

Table 1. Comparison of Websites Offering Infographic Templates

Site	Free Option?	Able to Export?	Public Publication?	Watermark/ Branding?	Paid Option (Individual)
https://www.canva.com/	Yes	Yes	No	No	~$10/mo
https://piktochart.com/	Yes	Yes	Yes	Yes	~$29/mo
https://www.visme.co/	Yes	Yes	Yes	Yes	~$39/mo
https://infogram.com/	Yes	No	Yes	Yes	~$19/mo
https://venngage.com/	Yes	No	Yes	Yes	~$49/mo

To avoid the constraints of commercial infographic software, Schrank relies on PowerPoint. She suggests using native PowerPoint templates available with Microsoft Office 365. Alternatively, you can download templates for free from websites like HubSpot.

Schrank provided a tutorial on how to customize infographic templates by changing shapes, colors, font sizes, and reordering or editing content. Detailed instructions can be found in the presentation handout (link in Resources).

How to Create Visually Appealing Slides
Visually appealing slides rely on the same basic elements as infographics; they
- make good use of color,
- put text into shapes or SmartArt,
- use different text size to show importance, and
- use icons to add visual interest and connect ideas.

Instead of using slides with standard bulleted lists or walls of text, thematically associated slides can be used to tell an

effective story. To accomplish this, Microsoft Office 365 provides powerful tools such as

• templates,
• Design Ideas,
• SmartArt,
• icons, and
• stock images.

Older versions of PowerPoint do not have infographic templates or the Design Ideas function and have fewer options for SmartArt, icons, and stock images. Although websites like Canva, Piktochart, and Visme also provide templates and stock images, they are harder to export and may be watermarked.

Schrank shared the following tips and tricks for creating visually appealing slides:

• Convert bulleted lists to SmartArt.
• Convert SmartArt to shapes.
• Use shapes to make your own SmartArt.
• Get inspiration from the Design Ideas function.
• Adjust icons.
• Add stock photos.

Schrank provided a step-by-step tutorial for each of the actions mentioned above. Detailed instructions can be found in the presentation handout (link in Resources).

Closing

Kelly Schrank closed the presentation with ideas for infographics and visually appealing slides by sharing some of her own work. She also suggests performing a search on Google Images to learn more about the elements of good design, discover new design ideas, and see what is currently in vogue.

Resources

Websites for stock images:
https://pixabay.com/
https://unsplash.com/
https://thenounproject.com/
https://www.pexels.com/

Presentation handout:
https://headbookworm.com/wp-content/uploads/2020/10/AMWA-2020-Low-Cost-and-Low-Effort-Infographics-and-Visually-Appealing-Slides-Handout.pdf

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A POWERFUL COMBINATION: THE VALUE OF THE WRITER–EDITOR PARTNERSHIP

Speaker
Crystal Herron, PhD, ELS, *Managing Director, Redwood Ink, San Francisco Bay Area, CA*

By Christine Holzmueller, MS

Crystal Herron's goal in this presentation was not simply to deliver information to the audience. Her goal was to ask us questions to promote self-reflection on our capabilities and careers and to consider the "value a writer–editor partnership could bring to our professional endeavors." She acknowledged basic similarities between writers and editors but pointed to different qualities and functions of each role. For one, writers are creative with words whereas editors analyze and fix text. Writers also tend to research a subject, transfer knowledge, and become deeply knowledgeable about a subject. Conversely, editors focus on examining the writing and revising the text to improve it, and they may require less knowledge of the subject matter.

Medical communicators often both write and edit content. Herron questioned this dual role, noting most people are stronger in one area. She listed some pros and cons of being a generalist (both roles) compared with being a specialist, showing career value in the latter role (Figure). If you specialize and form a partnership, Herron believes "you can harness
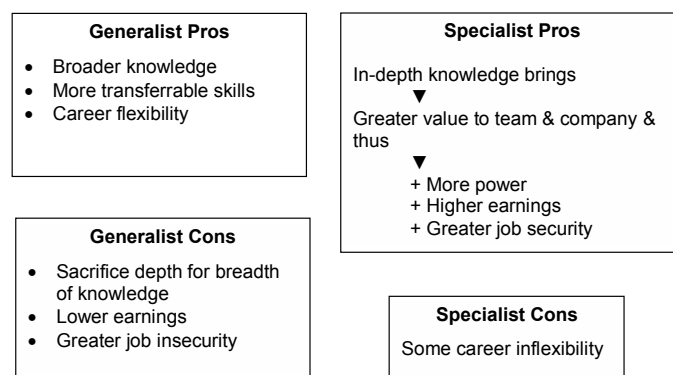
Figure. Pros and cons of generalist compared with specialist.

your strengths and focus on what you really enjoy" and let your partner complement your weak areas.

What Are Some Benefits of This Partnership?

One benefit Herron stressed related to the "curse of knowledge." The concept is that we omit information, unaware that we assume the reader knows what we know. A partner can identify these knowledge gaps in a document, find mistakes we overlook, and strengthen our writing. They can be a mentor. This person can give objective feedback and help divest our emotional attachment to our text. A partner can also save us time by taking on the refinement of documents. Importantly, a

partner can make us look good and help us achieve our career goals and advancement.

What Are Key Features of an Ideal Partnership?

Herron showed a Venn diagram of 1 skill-based and 3 relationship-based features of an *ideal* partnership:

- Complementary skills that form a larger skill set that you could not accomplish alone.
- Confidence that you can trust and rely on each other.
- Chemistry in how you relate to one another. Both must respect and value their partner and work well around decision-making, disagreements, and conflict resolution.
- Similar values. Herron described this as a core feature to figure out ahead of time rather than waiting until "something pops up and values diverge." Some questions you need to answer are: Do you have similar work ethics (deadline-driven vs value-driven) and styles (prefer to work early in the morning vs later in the day)? Do you have matching communication styles and similar risk-taking behaviors? Do you share the same goals and have a similar vision for your partnership? Is there equal commitment to the work or a clear agreement on whether one person will do more work?

How Can You Find and Establish a Successful Partnership?

To find the right partner, consider colleagues you personally worked with that meet the key features of a successful partnership. Other approaches are networking at conferences and through professional online platforms (eg, LinkedIn), soliciting interest through professional organizations (eg, AMWA website), and simply being open and ready for a chance meeting in any public space.

You can establish a partnership at work by searching within your company for a viable candidate. Another option is to contract with a consultant for a trial period to see if it works well and then hire them or someone else as an employee. If you are self-employed, you might draw up a contract agreement and establish a formal partnership.

Herron ended with several questions to deepen our consideration of the value added from a writer–editor partnership:

1. What is your vision?
2. What are your strengths and weaknesses?
3. What are your interests and professional goals?
4. What are your company's goals?

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EDITING: HARD KNOWLEDGE, SOFT SKILLS

Speaker
Loretta Bohn, ELS, *Senior Editor/Writer, RTI International, Chapel Hill, NC*
Crystal Herron, PhD, ELS, *Managing Director, Redwood Ink, San Francisco Bay Area, CA*
Erica Goodoff, ELS(D), *Senior Scientific Editor, MD Anderson Cancer Center, Houston, TX*

By Kelly Schrank, MA, ELS

This panel of diverse editors provided their personal experience and advice in 5 areas: credentials, developing judgement, editing on a team and individually, managing expectations, and professional development.

Credentials

Although Herron has a doctorate, she doesn't think you need one to be an editor in our field; instead, she thinks you need to "be a master of the language and have an interest in the science." Neither Bohn nor Goodoff have degrees in the sciences, but Bohn says that you need to be curious, and she enjoys "learning about subject matter and learning about language, as it changes all the time."

Goodoff mentioned Editor in the Life Sciences (ELS) and ELS Diplomate [ELS(D)] as credentials that she thinks are well known in our field. The ELS credential helped her, she said, because "Those letters after my name did help me get interviewed for my current job." Bohn also mentioned that the AMWA Essential Skills certificates and other Medical Writing & Communication Conference (MWCC) workshops and sessions gave her ways to talk about what she is doing and why.

Developing Judgement

The panel posed the questions, "How do you know what to do *when*—how do you develop judgement about when to just change something, when to change and query, and when to just query, and how do you just let something go?"

Goodoff defaults to "If you aren't sure, ask." It's nice if you have someone to ask, such as a colleague or a message board, or you can query the author for clarification. As she and Bohn note, "People writing science manuscripts are happy to talk about their research." Bohn also brought up that if and when you query might depend on how long you have worked with an author or team. Herron added, "It helps to know who you are working with. If it's someone who is new, you want to be a little more careful."

Queries may also need to be changed over the course of a reading; Bohn, Goodoff, and Herron noted that they often find their queries answered by the end of the manuscript. They agree you should reread your queries before returning the document to the author.

Editing on a Team and Individually

Bohn, Goodoff, and Herron were all mentored by more experienced editors earlier in their careers; these senior editors provided feedback and helped them get up to speed with their companies' ways of doing things. More broadly, Herron also found it helpful to see how these more senior editors "edited documents and to learn from that."

Bohn discussed the advantages of editing and working with a team of editors as having others who "get" what you do, who can assist when you are overbooked, and who can help when you are struggling with questions or internal clients. As someone with her own business, Herron has a network of editors she works with, whom she can ask for assistance when she has too much work.

Managing Expectations

Bohn can ask editors on her team to assist if there is not enough time to meet an internal client's deadline. Goodoff said that in her work, she has to balance time with thoroughness and prioritize certain types of documents over others (for example, grants over manuscripts). She provides authors with a time estimate for editing that bakes in the other work ahead of the new project. Bohn said that one way to manage expectations is to stay in contact with internal clients through a monthly email to ask them about upcoming work. Herron's approach is to underpromise and overdeliver, so she has a cushion if things don't go as planned but leaves clients happy if the work goes well. All mentioned the helpfulness of discussing the levels of edit with authors/clients and which level can be accommodated within their timelines. Bohn's team also provides a calculator to authors so they can estimate their projects before submitting.

Professional Development

Goodoff started off this discussion with 3 things she tries to work on. She explains, "It's always a good idea to brush up on skills, especially things that you don't see every single day but that you see often enough," like statistics. Despite having a writing and editing background, she thinks brushing up on grammar gives her the vocabulary to explain to authors why she is making certain changes to their writing. She also likes to learn Word tips and tricks, saying she "finds some new little trick every single time."

Herron believes it "improves your work" to put in the time for professional development. She believes that if you get certificates, you can make up for the cost by giving yourself a pay bump. To make sure she spends time on professional development, she adds it to her calendar on her historically slower days. Sometimes she just spends an extended lunch time reading up on something or squeezes in just 15 minutes of reading here and there.

Bohn liked Herron's idea of "making it bite-sized" and focusing on 1 idea and what you can read/learn in 15 minutes.

Tips:

Erica Goodoff: If you're early in your career, the ELS credential is worth it.
Loretta Bohn: Always go back and reread your queries when done editing the full document.
Crystal Herron: Keep a file of boilerplate comments: just copy and paste into comments. (Bonus from chat: use AutoCorrect to insert boilerplate comments or create macros to insert them into docs.)
Crystal Herron: Focus on one thing a month to learn/brush up on skills. (Bonus: teach it to others on a blog to learn it better.)

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COLLABORATIVE WRITING: ENSURE SUCCESS WITH AN EFFECTIVE STRATEGY

Speaker
Crystal Herron, PhD, ELS, *Managing Director, Redwood Ink, San Francisco Bay Area, CA*

By Sadie van Dyne, PhD

Collaborative writing projects often stir up a mix of emotions in the writing professionals tasked with their completion. While these collaborative projects can provide an opportunity to learn new skills, generate new ideas, and gain new perspectives, negative feelings can overwhelm those involved and hinder the writing process. However, before memories of collaborative project-induced dread could set in attendees of AMWA's 2020 Medical Writing & Communication Conference,

Crystal Herron, PhD, ELS, highlighted strategies to use in three key phases of the writing process to help rein in those overwhelming negative emotions.

The Planning Phase

Deriving all the benefits collaborative writing can offer begins in the planning stage. Herron recommended attendees use a project-management approach. This approach includes creating a feasible schedule that takes the project scope, work style of team members, and prior obligations into consideration. Team members should agree on a file naming convention that works well for everyone. Creating an organized storage structure (Figure) can also help streamline the writing process. Herron also offered this helpful organizational tip: archive older versions of files and store the most up-to-date version of a document in each version folder.
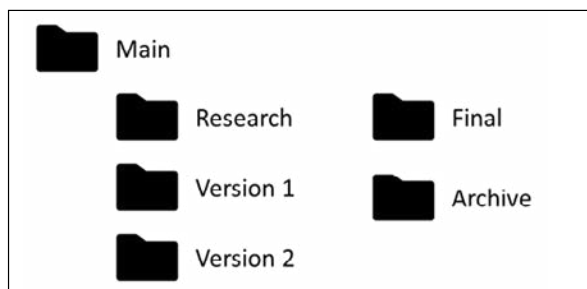
Figure. Example file structure.

Identifying a strong leader who can take on responsibility is also a necessity during the planning phase. General duties of the team leader include the following:

1. Managing deadlines
2. Updating team members
3. Scheduling and directing meetings
4. Combining drafted sections
5. Coordinating with editors
6. Proofreading
7. Submitting final product
8. Following up with client

The Writing Phase

Herron discussed three different collaborative writing methods: layering, combining, and stitching. The layering method involves the team meeting to discuss the content and overall direction of the project while one person (usually the team leader) writes the first draft. The draft is then sent to the team members, who then weave, or layer, their ideas into the existing text. This method allows for a more continuous writing style.

The combining method of writing allows for each team member to contribute written content. The team meets to discuss content and outlines major themes or sections. Each section is delegated to a team member and returned to the team leader. The leader then combines each section into a comprehensive document. This method is time-efficient and allows for each writer to use their strengths.

Finally, the stitching method takes a highly structured and focused approach. The team meets to discuss content and outlines each paragraph, including topic sentences. Team members are assigned a specific paragraph and the team leader stitches each paragraph together. The stitched document is then returned to the team to refine. While this method does require more meetings to plan specific content, the time invested up-front can ultimately help save time later.

The Editing Phase

Establishing an efficient editing process is critical in collaborative writing. Herron discussed the pros and cons of two different review styles. First, she described in-parallel editing as a process in which the team leader sends the document to each team member to review simultaneously. The leader is then responsible for incorporating revisions into one document. Incorporating and keeping track of each author's edits can be challenging for the team leader. Similarly, team members may make duplicate edits or edit an old draft. This can introduce inefficiencies, as each team member is unable to see other authors' perspectives and may not be updated about the status of the project. Overall, Herron discouraged attendees from using this method of editing.

In-series editing is a time- and effort-saving alternative. The team leader sends a draft to Author 1 to make edits. In turn, Author 1 sends the edited draft to Author 2 for review. The series continues until each author has edited the document, which is then returned to the leader. This method eliminates the possibility of duplicate edits. Furthermore, each author can see the revisions other authors suggest, making for a more efficient process.

Conclusion

Overall, Herron reminded attendees the best process to follow in collaborative writing projects is the one that works for your team. Considering the members of the team, knowing their strengths and weaknesses, and knowing each team member's professional goals can help identify the most appropriate methods to use throughout all major phases of the collaborative writing process.

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STRATEGIES FOR EFFECTIVE RISK COMMUNICATION

Speaker

Melissa Christianson, PhD, *Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC*

By Núria Waddington Negrão, PhD
Good risk communication is key for empowering patients and the public in general to make informed decisions about their health. However, since risk communication involves an interplay of complex mathematical concepts, personal beliefs, and emotions, effective risk communication can be hard to achieve. For example, if we compare some of the things that people are most afraid of, such as terrorist attacks, gun crime, and bird flu, with the things that cause the most deaths, cardiovascular disease and cancer, we see that there is a disconnect in society between perceived risk and actual risk.

In her talk, Dr. Melissa Christianson, a Medical Writer and Consultant at Whitsell Innovations, Inc., defined risk as "the probability of the occurrence of an event or outcome" and emphasized that risk communication is "the open, two-way exchange of information and opinion about risk, leading to a better understanding of the risk in question and promoting better (clinical) decisions about management" with no clear right answer.[1] "Successful risk communication points out hazards and helps navigate crises and avoid danger."

In medical communication, we typically talk about incidence, the number of new cases, prevalence, the total number of cases, absolute risk, the probability of an outcome in a population, and relative risk, a comparison of the absolute risk between 2 populations. The role of medical writers is to bring clarity in how these concepts are presented to the target audience.

Dr. Christianson identified 4 major obstacles for clear risk communication. The first is that the math involved is hard and many people, even college-educated individuals, do not have the numeracy skills to "do the basic computations that are necessary to understand risk."[2–4] This leads to general overestimation of risks and inconsistent interpretation of equivalent data.

The second obstacle to effective risk communication is that we are inconsistent in the way we assess risk.[2,5,6] Many variables influence our assessment of risk, such as the statistical measure used to present the risk, the framing of the data, mental shortcuts, emotions, and our numeracy and literacy skills.[7] The speaker gave various examples of how the way the risk is described affects the audiences' perception of the risk and consequent decision-making. People understand absolute risk better than relative risk, but presenting the relative risk leads to an overestimation of the effect and, therefore, to treatment acceptance.[3,5,8,9] Studies have shown that how we frame the data is extremely important. For example, when told that "32% of patients were dead 1 year after treatment," more patients chose to take the treatment than those told that "68% of patients were alive 1 year after treatment," even though these 2 statements represent the same risk of death.[10] The last 2 obstacles to risk communication are that doctors and scientists speak a different language than the public and that personal beliefs enter the mix as well. Dr. Christianson emphasized the need to be careful with the word "significant," which is normally interpreted as meaning "clinically significant" by the general population.

Finally, Dr. Christianson presented 6 strategies for better risk communication. **Strategy number 1** is to start basic, to not assume that your audience already understands the background information, and to clearly define the risk, the time interval, and the population. **Strategy number 2** is to make the math as easy as possible to increase the chance of the appropriate interpretation of the numbers. Best practices are to use natural frequencies (2 out of 100 people), to use a mix of numeric and verbal descriptors (low risk—10%), to present the absolute risk or combine it with the relative risk (risk of A was 10% and risk of B was 20%), to use visual aids, and to build up to multiple levels of precision. **Strategy number 3** is to be consistent when comparing between different treatments and to use the same statistical measure, population, time interval, denominator, and framing. **Strategy number 4** is to give context, be careful when presenting risk comparisons, and consider using an incremental risk format. For example, present the background risk of an outcome regardless of intervention. **Strategy number 5** is to reduce the emotion by eliminating emotive language, using balanced framing, and being open about what is known and what is not known. **Strategy number 6** is to write to the audience. Take into consideration the socioeconomic makeup, concerns, habits, and knowledge of your audience when writing and "proactively intervene if your audience will have trouble assessing or acting on the risk." In summary, Dr. Christianson advises us to "use our tools wisely" when communicating risk.

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MENTORING PROGRAMS: ONE SIZE MAY NOT FIT ALL

Speaker

Mary Burder, PhD, *Senior Medical Writer, Parexel International, Durham, NC*

By Niada Niederhauser, BS

As the demand for skilled medical writers increases, medical communication and regulatory medical writing companies are seeing the value of mentorships; however, different mentorships fit different situations. At AMWA's first virtual conference, Parexel International's Senior Medical Writer, Mary Burder, described 3 different mentoring programs and highlighted how they can benefit both employees and their companies. The 3 mentoring programs included new hire mentoring, project mentoring, and role shadowing. The benefits of mentoring and best practices for implementing mentoring relationships were also discussed.

Mentoring programs benefit both companies and employees:
- Mentees can learn new knowledge-based skills, build confidence, and advance their medical writing career.
- Companies can see improved productivity levels and increased employee retention and satisfaction and facilitate a culture of growth.
- Mentoring relationships can foster cross-cultural exchange and understanding while improving communication skills.

When implementing mentoring programs, best practices should be developed first to ensure the programs are beneficial and to clearly define the mentor/mentee responsibilities. Some practices are specific to certain mentorships, but others are applicable to all programs. The most important general best practice, according to Burder, is to define the goals of the mentorship based on the needs of the mentees before the first meeting. During the mentorship, mentees should proactively disclose their needs to their mentors to assure the appropriate knowledge and skills are conveyed. Scheduling regularly occurring meetings is a must; both mentees and mentors should commit to attending. Mentors should encourage mentees to propose job-relevant topics for their meetings. Mentors should willingly share experiences, both positive and negative, as well as be approachable and accessible outside of meetings for support and feedback. As the program continues, mentoring style should adapt to the mentees' advancing skill level and job responsibilities.

The first mentoring program discussed in Burder's presentation was the new hire program, which enables new employees to acquire specific skills and knowledge needed to excel in their job. New hire mentoring differs from onboard training, as the latter is the core information conveyed to all new employees. By contrast, new hire mentoring is focused on helping the mentee acquire the knowledge, skills, and understanding of the processes and workflows specifically relevant to the new job. Mentors should provide examples of well-written documents, which should be closely reviewed to highlight key features that make the document effective. Mentors should also incorporate hands-on training, perhaps allowing mentees to work on small parts of the mentors' projects while the mentors provide guidance and feedback. Effective new hire mentoring programs should enable mentees to become self-sufficient more quickly, boost confidence, and ensure a smooth adjustment to the new job's responsibilities.

Project mentoring, the second program presented by Burder, focuses on ensuring current employees achieve specific new levels of knowledge and skills to take on more challenging roles so that they are equipped to skillfully complete projects and meet clients' needs. Burder pointed out that line managers or team leads usually assign their employees to the project mentoring program. Mentors are responsible for guiding mentees on specific document preparation and providing feedback on performance. Effective project mentoring programs enable mentees to acquire new project/role-related skills, promote professional development, and may increase employee retention and satisfaction.

Role shadowing, the last program discussed by Burder, differs from the other mentoring programs in that mentees request the opportunity to acquire knowledge and skills needed to transition to new responsibilities or positions within the company. Role shadowing exposes mentees to new roles, projects, and complex processes while conveying how to apply certain job-related skills. It can be either observational, in which mentees observe meetings and interactions, or hands-on, which allows mentees to perform small tasks to be reviewed by mentors.

Burder closed the presentation with a summary of mentoring programs while emphasizing how their success depends on determining mentoring objectives before implementation.

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ANALYSIS OF MENTORING: FROM MARGINAL TO MAXIMAL

Speaker
Susan Morris, MEd, CPCC, ACC, *Susan Morris Coaching*

By Christina Barnes, MSN, RN, CPNP

One of the most important business relationships is the mentoring relationship. Traditionally, the mentoring relationship has been innately hierarchical, with the mentor as the expert and the mentee as the junior or apprentice. Morris classifies this type of mentoring as traditional or minimal mentoring. "Learning goes in one direction, from the mentor to the mentee," Morris says. "The mentee is dependent on the mentor." Morris advocates for moving away from this minimal model and instead adopting a mentoring relationship that opens possibilities for both the mentor and the mentee. Morris calls this mutually beneficial model of mentoring "maximal mentoring," and she encourages professionals to cultivate this type of mentoring relationship within their own network.

What is maximal mentoring? Maximal mentoring is a professional relationship between a mentor and a mentee that is mutually beneficial. The expectations of both parties are exceeded. The mentoring process is not generic, but rather is highly customized to the needs of the mentee. There is an emphasis on the mentee as a whole person; the focus goes beyond career-related needs and goals. The relationship is transformational, as both the mentor and mentee change as a result of this style of mentoring.

Traditional or minimal mentoring, in contrast, is a generic professional relationship. The mentor has a standardized way of mentoring others that is not tailored to the needs of the specific mentee. This is usually a tr ansactional relationship or exchange; the mentee needs a job, and if the mentor helps the mentee find a job, the mentor hopes for access to the mentee's network. The focus in this relationship is solely on career development. The mentee is dependent on the mentor, and the 2 are not considered to be equals.

Maximal mentoring requires mentors and mentees to move away from the mindset of traditional mentoring. In doing this, mentors and mentees can enjoy a relationship founded on equality, respect, and trust. "Learning is a two-way street" in maximal mentoring, says Morris. The mentor and mentee are equals, and there is the expectation that they will learn from each other. Both the mentor and mentee can experience personal and professional growth as a result of this relationship. Maximal mentoring can be "positive, uplifting, appealing, attractive, and fun," Morris says. The mentor and mentee can expect to have conversations about both professional and personal matters. Morris quotes a maximal mentor who describes these conversations: "I am very close with my mentee. There are few things that we don't talk about. … Our mentoring relationship helps me grow and learn as much as my mentee."

So, how do you create a maximal mentoring relationship? What is the "secret sauce?" According to Morris, there are 4 important ingredients to establishing and maintaining this valuable connection:

1. **Relationship:** In maximal mentoring, friendship comes first, and the professional relationship comes second.
2. **Connection:** It is important for the mentor and mentee to have a strong connection. They must care about each other's success, be responsive to communication, and create a safe space for each other. A firm commitment is required, with many maximal mentoring agreements and logistics outlined in a document or contract.
3. **Acceptance:** The mentor and mentee must accept each other for who they are with no judgment. There is no hidden agenda or pretending to be someone else; the "masks are off." The mentor and mentee can discover their best selves, and both are able to take risks within the privacy and safety of the relationship.
4. **Preferred traits on the part of the mentor and mentee:**
   a. Trust and mutual respect
   b. Interdependence
   c. Authenticity
   d. Vulnerability
   e. Patience

If maximal mentoring does not sound feasible, Morris suggests starting with reverse mentoring. Reverse mentoring is when a younger, inexperienced employee is paired with a senior executive who is *willing* to learn. The younger employee exposes the executive to issues important to the younger generation and addresses gaps in the executive's technology skills. This style of mentoring helps the organization retain young talented professionals while increasing representation of the younger demographic throughout the organization.

Morris summarizes the most important aspects of building a meaningful mentoring relationship as follows:

1. Build a **relationship** based on candor and **trust**.
2. Look for opportunities to explore **professional** goals and **personal** dreams.
3. Be open to give and receive critical feedback, sharing successes and **mistakes**.

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KNOWING WHICH BUTTON TO PUSH: COMMUNICATING THE VALUE PROPOSITION OF MEDICAL WRITING

Speaker

Robin Whitsell, *Whitsell Innovations, Inc, Chapel Hill, NC*

By Lisa English, PhD

As medical writers, it is essential to understand that everything we do communicates our value. Our emails should be free of spelling and grammatical errors and highlight our writing expertise. Our presentations should have well-prepared slides based on a solid understanding of the science involved. We need to show others that the document is safe with us and that they can put their confidence in us. Scientific knowledge and writing expertise alone aren't enough to do that. There is more.

Understanding Team Dynamics

We need to understand our teams. To own the document, we need to influence without authority, which is challenging, especially when team members may be more senior. Understanding team dynamics allows us to own any situation and shepherd the team and the document toward success.

Mastering Our Reactions

It is equally important to understand what our actions might be saying to the team. To do this, we need to be observers of our reactions. Try taking private notes during a meeting. When something uncomfortable happens, write it down. Include only observations, no judgments. After the meeting, evaluate the information critically. Understanding our feelings and how they manifest in us gives us the power to change them to improve our interpersonal effectiveness.

Seeking the Gift of Feedback

What if others seem concerned about our value? In those situations, it is vital to own the disconnect and ask to reset. When seeking feedback from an individual, compliment the person on something specific and real to create a connection and confirm commitment. If the person does not provide feedback, lead them to it, explaining the behavior that's creating the disconnect and asking to learn more. But what if the disconnect is with the team? The same basic principles hold, but it's probably best to address it at the beginning of a meeting: "Hi, it seems we're experiencing a rough patch. I'd appreciate your advice about the best way to move forward."

Putting It All Together

Let's look at a few stereotypical examples of team dynamics and how being aware of our feelings and mastering our reactions can help.

Captain Obvious. What happens when a team member says something obvious? How do we feel? How do we react? Understand both and then own the situation. Try pulling Captain Obvious more fully into the conversation. Ask him a question related to his expertise and make room for him to answer.

The Interrupter. What happens when someone consistently interrupts? Often, if the interrupter is more senior, we think we must allow the behavior, but we should not. Again, identify the feeling and reaction elicited. Then own the situation. Try practicing neutral phrases to address this situation. One example is "I promise we will get to that, Jack; please, let's complete this discussion point first."

The Combative. How does a combative team member make us feel, react? Owning this situation requires staying neutral, being succinct, and redirecting the individual. For example, one might say, "Catherine, I hear how important this is to you. Maybe we can address it in Section 11. Right now, we need to move to comments from Clarice."

Skill at Leading and Motivating a Team

Although disagreeing may make us feel combative, respectful disagreement is often necessary to get the documents right. In this situation, we need to maintain a neutral tone and remain matter-of-fact. Try posing the disparity as a question. For example, one might say, "It seems we are missing a source for the data on page 82. How should we resolve this?"

The value proposition of a medical writer is multifold. It is about scientific knowledge and writing expertise, understanding team dynamics, and understanding (and being willing to change) ourselves. It's about getting the document right, not being right; about conveying empathy, respect, and dedication; and about giving others the benefit of the doubt. As medical writers, we need to show up every day as our best selves to do our best work because that invites everyone to do the same.

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WHAT THE BEST MEDICAL WRITERS KNOW ABOUT NONCLINICAL DATA

Speaker

Beth Krause, MS, MBA, *Senior Medical Writer, RRD International, LLC, Rockville, MD*

By Stacie Marsh, MPA, CPH, GPC

Medical writers specialize in a variety of fields, such as continuing medical education, patient education, scientific publications, regulatory documents, and research-grant applications. Writers pursuing Medical Writing Certification (MWC) must at least be familiar with each of these areas, and even those not pursuing certification benefit from cross-disciplinary understanding.

Ms Krause's presentation at the AMWA's 2020 Medical Writing & Communication Conference explained the importance of nonclinical data and studies from a broad context, resonating with medical writers from all areas, including those with and without expertise in regulatory documents.

Overview of the Drug Development Process

The life cycle of drug development occurs through 4 phases, some of which can occur simultaneously. These include

- phase I (relatively small studies focused on establishing safety, and clinical pharmacology studies),
- phase II (larger studies focused on evaluating clinical efficacy),
- phase III (pivotal, large, randomized, placebo-controlled studies with clinical trials to prove clinical efficacy prior to marketing authorization), and
- phase IV (large studies to establish processes for ongoing safety and efficacy surveillance after a drug is approved and marketed).

The most important function of nonclinical data is to establish that a drug is safe to be administered to humans. These data are submitted with an Investigational New Drug application prior to initiating studies in humans. However, the data from nonclinical studies may impact the clinical development, and thus, clinical documents, throughout a drug's life cycle.

The Importance of Nonclinical Data in the Drug Development Process and Placement of Nonclinical Data in Clinical Regulatory Documents

Ms Krause set the stage for writers unfamiliar with regulatory documents by explaining the lifecycle of drug development within the framework of the "Common Technical Document" (CTD) Triangle (Figure).

Endorsed by the International Council for Harmonisation, the CTD Triangle is a standard framework for applications for approval of new medical drugs to regulatory authorities
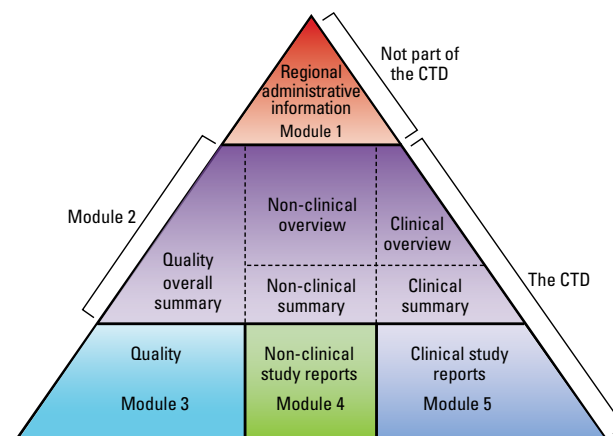

Figure. The CTD triangle. The CTD is organized into 5 modules. Module 1 is region specific, and modules 2, 3, 4, and 5 are intended to be common for all regions. CTD, Common Technical Document.

in the United States, Europe, and Japan. The CTD Framework is organized into 5 modules. Most medical writers with regulatory document expertise focus on Module 5 (Clinical Study Reports). However, the preceding module, Module 4 (Nonclinical Study Reports), includes valuable content that impacts the documents in Module 5.

> "Nonclinical data enrich the overall understanding of a drug during the development and approval process, starting well before new drugs are first tested in humans."
>
> —Beth Krause

As Ms Krause explained, the most important role of nonclinical information in regulatory documents is to provide basic safety support for a new chemical entity (drug) before it is tested in humans, including a detailed assessment of benefits and risks. Thereafter, nonclinical information is required throughout development and marketing, including the medication packaging.

Nonclinical data impact risk language, dose selection, design elements, and development. For example, nonclinical studies inform risk language in clinical documents such as informed consent forms, clinical protocols, general investigational plans, and investigator brochures. Nonclinical studies also predict potential side effects when it is too difficult or unethical to test in humans (ie, reproductive side effects).

Nonclinical data are also valuable in informing first-in-human dose selection by establishing starting doses and safety margins, as well as dosing regimens, on the basis of findings in toxicology studies. Additionally, nonclinical data inform the rest of the drug development process by determining the need for additional clinical studies, identifying potential new indications/targets, and even terminating development if the safety profile is poor.

Following an overview of the basics of the drug development process and the value of nonclinical data therein,

Ms Krause provided a detailed explanation of the role of nonclinical data within Module 4. The 3 main categories in Module 4 include

- pharmacology (how a drug works, how a drug may affect organ systems secondary to its main target, and how coadministration of drugs may affect how they work),
- pharmacokinetics (how a drug is absorbed, distributed, metabolized, and excreted from the body as well as the potential for drug interactions), and
- toxicology (how a drug may cause adverse effects, including single-dose toxicity, repeat-dose toxicity, and the potential for genotoxicity and carcinogenicity).

Ms Krause explained how to link nonclinical data in Module 4 to clinical documents with which regulatory medical writers may be more familiar (typically Module 5) by using a fictional example of a new chemical entity compared with a drug that is repositioned for a new indication.

Importance for All Medical Writers

Even medical writers who focus on other areas of medical writing, with little or no experience with regulatory documents, benefit from this presentation by its comprehensible overview of drug development and how nonclinical data fit in.

Although regulatory writing is a popular area of the medical writing profession, it is often limited to those with medical or pharmaceutical backgrounds or early-career experience and can be intimidating to those who specialize in other areas. The content in Ms Krause's presentation is particularly salient for writers without a medical or pharmaceutical background, given the myriad aspects of the drug development and approval process that require proper placement of nonclinical data.

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EXHIBITOR PRECIS

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UC San Diego EXTENSION

The Medical Writing Certificate program at the University of California San Diego (UCSD) Extension is designed to provide graduates with the foundational knowledge and skills needed to work as a medical writer in the commercial sector, government agencies, and/or academia. The certificate equips scientists, communication professionals, and others with a strong biomedical and/or life-sciences background to write specifically for scientific, education, or regulatory audiences and to fully understand the profession.

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For more information on the UCSD Extension Medical Writing program and our faculty, visit https://extension.ucsd.edu/courses-and-programs/medical-writing-courses.

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Oxford University Press is the proud publisher of the *AMA Manual of Style*, 11th edition, the must-have resource for anyone involved in medical, health, and scientific publishing. Written by an expert committee of JAMA Network editors, this latest edition addresses issues that face authors, editors, and publishers in the digital age. Extensive updates include examples of how to cite digital publications, data repositories, and social media. Full-color examples grace the chapter on data display, with newer types of graphic presentations and updated guidance on formatting tables and figures. The usage chapter has been revised to bring the manual up to date on word choice, especially in writing about individuals with diseases or conditions and from various socioeconomic, racial/ethnic, and sexual-orientation populations. In sum, the answer to nearly any issue facing a writer or editor in medicine, health care, and related disciplines can be found in this 11th edition.

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Cabells Scholarly Analytics Is a Force of Knowledge Against Predatory Publishing— An Interview With Simon Linacre

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

Because of the significance this topic poses for medical writers and editors, I am pleased to continue our planned series of articles about predatory publishing for the AMWA Journal.

INTERVIEW WITH AMWA

We welcome Simon Linacre, an expert on predatory publishing and the Director of International Marketing & Development at Cabells Scholarly Analytics (see Box). Simon had previously spent 15 years at Emerald Publishing specializing in journal acquisitions, Open Access, and business development. He holds a diploma in journalism and master's degrees in Philosophy and International Business. In 2020, he was co-opted to serve his first term as a trustee for the Committee on Publication Ethics.

AMWA: *From 2003 to 2018, you worked at Emerald Publishing, which held a unique portfolio of journals related to librarianship, as they prepared to move toward providing Open Access. How did you connect with Cabells during that period?*
Linacre: During my career at Emerald Publishing, I was the contact for citation, journal rankings, and indexing for Cabells' lists of journals related to library titles. Like other commercial publishers at that time, Emerald also faced the difficulties of trying to move from a subscription-based model to the Open Access free-to-read model. In 2015, I oversaw this launch in response to what the United Kingdom mandated for all commercial publishers. In the transition to an Open Access route, all sorts of technical issues can arise for publishers. For example, a few discovered that one of their journals had been hijacked by a predatory publisher who had copied and pasted the publisher's website using a slightly different URL. No link worked except the "pay here" button that led directly to the predator's site. Such examples highlight the tactics of predatory publishers. One must be extremely careful and remain on the lookout.

AMWA: *For background, can you describe Cabells' initial concept of creating a list that would help critically assess scholarly journals?*

Background on Cabells

For more than 40 years, Cabells Scholarly Analytics (https://noaa.cabells.com/) has achieved an exemplary reputation for analytics across 18 disciplines in more than 11,000 international journals. In 2015, Cabells began their work to vet predatory journals by establishing analytics for this group of Open Access journals. In 2017, they launched a multidisciplinary journal blacklist of an initial 4,000 predatory journals that met 60 "behavioral indicators" that identified violations related to integrity, peer review, metrics (eg, impact factor), and publication and business practices. Today, Cabells offers subscriptions to its Predatory Reports (formerly the Blacklist) with 14,000 titles and to its Journalytics (formerly the Whitelist) with 11,000 titles—soon to expand with the addition of more than 5,000 medical journal titles.

Linacre: In 1978, Management Professor David Cabell had the idea to establish a verified and verifiable list of journal information that would serve as a time-saving guide for researchers, tenure committees, and doctoral students who were searching to find the right journal to publish their scholarly business research. The first list included important factors for tenure, such as times to review, accept, and publish in a reputable journal in the management field. This original directory of recommended business journals expanded in the early 2000s to include journals from the fields of social sciences and computer sciences. This would later evolve into what was then called the Whitelist (renamed now as Journalytics), which indexed across all areas except medical, engineering, and some humanities. Within the next few months, Journalytics will add a new medical list that indexes data and analytics for more than 5,000 more journals.

AMWA: *As Open Access began to gain momentum in the early 2000s, a group of predatory publishers emerged who would exploit the Gold Open Access model with aims to collect article processing charges (APCs) at the expense of quality. Tell us about Cabells' transition in expanding the directory to add predatory journals.*

Linacre: By 2015, Cabells began their product development to vet predatory journals and create a new list using a unique set of analytics judged by an internal review team. As part of this effort, they convened a conference panel in Boston in 2017 on the subject of predatory publishing; I was part of the panel of experts that also included Jeffrey Beall (see Sidebar). It was sheer coincidence that Beall removed his list early in 2017 and Cabells launched their Whitelist and Blacklist several months later, with an initial listing of 4,000 journals.

AMWA: *The specific criteria are clearly defined in Predatory Report Criteria v1.1, with violations rated from minor to moderate or severe. Can you explain how these criteria are valuable in helping researchers and medical writers avoid predatory journals and in understanding the depth of Cabells' undertaking?*

Linacre: The initial multidisciplinary journal Blacklist (renamed now as Predatory Reports) included predatory journals that violated more than 60 criteria, called "behavioral indicators," used to ascertain the legitimacy of a publication. These metrics indicate violations in issues of integrity, website, publication and business practices, and indexing and metrics. Today, Cabells' Journalytics indexes 11,000 scholarly titles, and its Predatory Reports lists nearly 14,000 predatory journals from all academic disciplines, with medical biological sciences and medicine forming a large proportion of the total.

Predatory Reports is a searchable database that identifies the specific types of predatory behaviors that Cabells specialists identify and analyze among the behavioral indicators. Like Journalytics, Predatory Reports provides basic background on the journals, such as publisher, website, and geographic origin, but it uniquely provides a misconduct report about specific violations. Cabells also tracks new trends in deception or other predatory practices and welcomes researchers to alert them on any new suspect journal.

AMWA: *From your studies at university to your focus in Open Access at Emerald Publishing and your initial connection with Cabells, how did your talents and experience coalesce toward 2018 when you joined Cabells' global effort against predatory publishing?*

Linacre: At university, I developed my critical faculties, sometimes being extremely cynical and doubtful. However, today, I use this experience to identify what's legit and what's not in helping researchers navigate through this period when publisher launches are almost exclusively Open Access.

Given my positive 15-year relationship with Cabells, I reached out to them when I left Emerald Publishing. The timing was right. Cabells was a North American-focused organization with most of its customers based in the United States. However, they were looking to internationalize, creating more

The term "predatory publisher" was coined by University of Denver, Colorado, Librarian Jeffrey Beall in 2010 to describe this academic publishing model that exploited the Gold Open Access model. In 2012, he began Beall's List, which provided free lists and reports of potential or probable predatory journals and publishers; it was based on an initial set of 26 criteria that he used to define predatory behaviors (eg, deceptive business practices, lack of ethics and integrity, corruption to the scholarly literature). When Beall removed his blog in 2017, he was an expert on the explosive growth of these predatory publishers and tirelessly devoted to protecting the research community while working full-time as a librarian. He was controversial for his criticisms of the social Open Access movement and for shortcomings of his blacklist approach. Nonetheless, his blog's absence left a huge gap in scientific communication. There is only one legitimate archived Beall's List (https://beallslist.net/ accessed October 12, 2020).

business in the United Kingdom, Europe, and elsewhere. We began our product development initiatives and a thought leadership program, such as our educational blog, The Source, and educational seminars for researchers.

AMWA: *Your blog post, "Cabells' top 7 palpable points about predatory publishing practices," highlights the gravity of the issue: "Over 4,300 journals claim to publish articles in the medical field (this includes multidisciplinary journals) – that's a third of the journals in Predatory Reports." What are some of the strategies in 2021?*

Linacre: Cabells started at the other end of the spectrum in business. Until recently, the Journalytics database did not cover medical journals, although they have always been a significant part of the Predatory Reports list. Medical journals were not initially included because medical areas are huge and dynamic: they have the most journals and a rapid, high churn of journal articles. Customers had great demand for us to create a biomedical product that would list medical journals; they had many questions, especially if a particular journal was on a list. Finally, Cabells was ready to tackle the daunting field of medicine: it would necessitate its own team of experts, creation of its unique database, and its own unique set of criteria and analytics. Toward this aim, in 2018, we assembled our team of auditors to annually review all titles in Journalytics and to guide our product development in the field of medicine.

For Journalytics, publishers push their titles to Cabells for review and listing. However, we are very judicious before assigning a title to one list or the other. A common reason for a journal not to make it into Journalytics is that the journal has not been publishing long enough or is too niche. At least 1 or 2 years of citation data, robust peer review, and a minimal level of activity are needed for our team to ensure the title legiti-

mately belongs in Journalytics (https://www2.cabells.com/selection-policy2). With low citation, niche journals may never be listed on the Web of Science.

AMWA: *What about a Greylist?*
Linacre: Many of our customers have asked about this possibility. Given that most journals do fall into this in-between area, a Greylist would be larger than the combination of Journalytics and Predatory Reports. Therefore, more than 30,000 journal titles would not meet criteria for being either scholarly or predatory and would fall into this grey zone!

AMWA: *The medical area is more likely to attract predatory publishers. What global innovations are on Cabells' horizon?*
Linacre: For predatory publishers, the fields of medicine and biological sciences are the most fertile areas because they can charge higher APCs and take advantage of the publish-or-perish, high-churn culture. For Cabells, these fields are also the most difficult to characterize. Therefore, we are working on new products that use complex design technologies to bring radical changes in safeguarding scholarly publishing. For example, rather than a list analogue, a university system might red flag any author interacting with a predatory journal for research or submission.

AMWA: *Simon, thank you for sharing your perspective and expertise on Cabells' commitment. Any final points that you would like to make?*
Linacre: Compared with scholarly biomedical journals, predatory journals often include a country or origin in their title, advertise as a generic multidisciplinary field, and take advantage of the publish-or-perish culture. They especially target post-doctoral students or faculty seeking tenure. I always advise authors to do their own research and weigh each journal against a set of selection criteria, such as those from our lists. Cabells is working toward developing other products that may someday cover a portion of the costs related to producing these scholarly analytics so that they can become more widely available.

IN CLOSING

Research your research. Researchers face the need to publish their research, and increasingly, these publications will be in Open Access format, as promoted by national and international initiatives such as Plan S. Researchers must dig deep, and they have all the skills to do it.

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The Evaluation of Effectiveness, or How Do We Know Whether a Treatment Works in Real Life? Part 2

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Efficacy and Effectiveness

In our previous article (Schindler TM, Bridge H. The evaluation of efficacy, or how do we know whether a treatment works? Part 1. *AMWA J.* 2020;35(2):82-86), we described how randomized clinical trials (RCTs) determine efficacy of a treatment. Efficacy is generally understood as the ability of a drug or other intervention to reliably produce a positive effect in patients with a defined disease under controlled conditions. In other words, clinical trials are good tools to evaluate efficacy. Clinical trials provide a well-controlled framework that is characterized by the following:

- Selecting participants according to clearly defined eligibility criteria
- Randomly allocating participants to treatment groups
- Concealing study treatments to participants and study doctors (blinding)
- Clearly defining endpoint measures before study start

Provided a drug consistently demonstrates efficacy in several clinical studies and appears safe, regulators will approve it and permit its marketing for the treatment of a disease. However, once a drug is on the market, it will be used for the entire spectrum of patients and under circumstances that might not have been tested in the clinical studies. For example, the new drug will be used in patients who have several comorbidities in addition to the approved indication. The evaluation of a drug's effects under everyday conditions is called effectiveness research.

Why Does a Treatment's Effectiveness Differ From Its Efficacy?

There are many reasons why the effects of a drug in everyday clinical practice are different from those seen in clinical trials. In short, the entire societal-medical context contributes to the effectiveness of a drug or intervention. Before we look at some of the key factors, we need to remind ourselves that both "efficacy" and "effectiveness" are determined in groups of people and not individuals. While efficacy pertains to groups of participants in clinical trials, effectiveness pertains to all people with a disease who could be treated with the drug.

Issue 1: Physical Availability and Accessibility

Above all else, to be effective, a drug needs to be available to patients, at best to all patients with the disease it was developed to treat. There are national, regional, and local aspects of availability of a treatment. Approval of a drug by regulators permits its marketing and selling in a certain country. For example, a drug that is approved in the United States may not be available in Canada or Mexico.

Before the new drug reaches a patient, a number of obstacles in the supply chain need to be overcome. The first one is reimbursement, ie, the negotiation of price for the new drug with government agencies, insurance companies, and pharma wholesalers. Discussions on price may have a drastic effect on availability. If a pharmaceutical company considers the proposed price too low to ever regain its investments, it may decide not to provide the drug at all.

Regional differences in availability may arise when regional pharma wholesale companies decide on stocking of medicines. They may decide not to stock a certain drug in certain locations because they do not believe that it will be widely used there. Even if a drug is available via a wholesaler and the physician is willing to prescribe it, a patient's health insurance plan may not cover the entire cost for the new treatment. Likewise, if a patient is in hospital, she might not get the drug because the company that runs the hospital may not see its benefits and may therefore not include it in their treatment plans and offer an alternative treatment. Furthermore, health care providers may not believe in the benefits of a certain drug and may prescribe treatments that they consider to have superior therapeutic effects instead.

Issue 2: Medical Tradition

Medical doctors, ie, the prescribers of medicines, undergo many years of training, and they apply this knowledge in their clinical practice, thereby maintaining a certain medical tradition. Such traditions are tenacious, and it may take a long time before new therapeutic options are widely accepted and offered to all patients. Conversely, health care providers and hospitals may continue to offer treatments to their patients that have long been shown to be less effective because this is their established practice, offers financial advantages, or is expected by patients.

Medical practitioners follow the insights they gain in their medical practice. If they have the impression that a particular medicine works for their patients, they will continue to prescribe it. They will stick to what they believe is helpful and may not use a new drug with which they have little experience. This is particularly likely when a new drug has only been tested against placebo and not against established treatments. A new drug may not be given to a patient because the physician has not heard about it or does not believe it is superior to the drugs that she usually prescribes.

Issue 3: Treatment Adherence

In clinical trials, participants are closely monitored with regard to how and when and at which dose they take their medication. For example, study participants are reminded to take their dose at the same time every day, with or without food, to achieve the optimal effect. In normal life, things tend to be different, and patients might occasionally forget to take their medication. On days when their disease is particularly discomforting, they may be inclined to increase the dose of their medicine. If their lives are busy, patients may forget to renew their prescription in time and may therefore not take any medication for a while. Thus, although the drug is available to the patients, its effects may be smaller than those observed in the clinical studies because of limited adherence to medication plans. Furthermore, patients might be taking additional drugs to treat other conditions, and these drugs may influence the effects of the new treatment.

Real-World Data and Real-World Evidence to Determine Effectiveness

Many different factors affect the use of a drug in everyday medical practice. It is therefore very difficult to determine how effective a drug is "out there." Post-marketing (Phase 4) studies usually focus on safety rather than effectiveness. However, for many stakeholders in the health care system, it is important to know how well a drug works in the real world:

- patients taking the medicine want to know whether it works,
- payers like health insurance companies need to understand whether they are paying for an effective treatment,
- government agencies want to know how the new medicine affects public health,
- pharmaceutical companies want to understand to what extent available medicines meet patients' needs and whether there is space for additional medicines.

Recently, there has been much discussion about the usefulness of "real-world data" (RWD) and "real-world evidence" (RWE) to evaluate effectiveness of treatments and support health care decisions. RWD and RWE are generally understood to refer to data and evidence from sources other than traditional clinical trials, but it has not always been clear exactly what these categories include. Over a number of years, regulators were pressed to delineate ways to incorporate nonclassical data in their evaluations. In 2018, the US Food and Drug Administration (FDA) released the framework for the Agency's Real-World Evidence Program. There, they give the following definitions:

- RWD is "data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources."
- RWE is "the *clinical* evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD."

Real-World Data: Abundant, Promising, but Messy

Sources of RWD include registries, electronic health records, medical claims databases, mobile devices, and so on. The recent excitement about RWD and RWE has focused on the availability of apparently rich sources of data, particularly those resulting from digitization. Sources such as electronic health records from entire health systems or wearable devices that generate data on a plethora of variables at frequent intervals promise an abundance of easily collected data.

There is a growing tendency to believe that data collected in the course of routine health care, whether via the records kept by health care providers or directly from patients using apps, better reflect how treatments actually perform than data collected in the research settings of clinical trials. Large quantities of RWD can easily be collected from thousands, or even millions, of patients, and such "big data" seem to promise greater representativeness than data from the comparatively small, selected populations of patients included in clinical trials.

There are also clear practical and economic grounds for exploring RWD: vast quantities of such data can be collected and accessed quickly and cheaply by comparison with the laborious and costly collection of data in traditional clinical trials. RWD therefore holds appeal for companies keen to reduce the expense and time taken to bring treatments to market.

Easy and cost-effective access to large quantities of medical data collected from the full range of users of a treatment in real-world conditions may sound too good to be true. Sure enough, there are several major obstacles to using RWD to reach reliable conclusions regarding the effectiveness of treatments.

Obstacle 1: Data Quality

One of the factors behind the expense of running clinical trials is the quest for good data quality and the consequent rigor with which data are collected. The clinical trial protocol specifies precisely which data are to be collected for each patient, the time points at which they are to be collected, and the methods, often including the precise equipment, that are to be used. A trial is designed to answer specific scientific questions, and the data to be collected are those that are required to answer these questions. Data are recorded on a case report form designed specifically for the trial. Strict procedures are followed to ensure data are collected in accordance with Good Clinical Practice principles, and clinical trial monitors verify the data for completeness and accuracy. These methods ensure that clinical trial data are highly standardized from patient to patient and from center to center, with the same variables measured and recorded in the same way and at the same time points. These provisions make clinical trial data reliable and trustworthy.

Data from real-world sources are unlikely to share any of these qualities. Table 1 outlines the main problems with quality of RWD. These deficiencies introduce noise and bias that make it difficult to draw reliable conclusions about the effectiveness of a treatment.

Obstacle 2: Lack of Randomization

Medical research generally falls into 1 of 2 broad categories: clinical trials and observational studies (Figure 1). The key feature that separates these approaches is the presence or absence of randomization. A recent opinion piece in the *New England Journal of Medicine* insightfully contrasts the "magic of randomization" in RCTs with the "myth of real-world evidence" from observational studies. Randomization ensures that there are no systematic differences between treatment groups with regard to patients' characteristics that may affect efficacy outcomes. It is likely impossible to achieve such a balance in an observational study because the groups that are compared did not result from randomization. Whenever the treatment is a choice, whether by a doctor or the patient, groups of patients taking different treatments are likely to differ systematically, often in ways that are difficult to identify. Moreover, the reasons for the choice of a particular treatment are almost never entered into health records or databases. This

Table 1. Real-World Data: Common Problems With Data Quality

Characteristic of Data	Likely Problems With RWD
Relevance to research questions	Data are collected for purposes other than research and will not be optimal for answering the question of interest. There is a risk of allowing the available data to determine the research questions that are asked (rather than defining the question first and then looking for the data).
Reliability	Inaccuracies in the data may result from human error or faulty devices. Data collected cannot be verified by comparison with source data. Random errors and systematic bias are difficult to identify and impossible to correct.
Completeness	RWD are characterized by a high quantity of missing values, with no information as to why data are missing.
Consistency and interoperability	Variables recorded, measurement methods, and data formats and data standards usually vary greatly across patients, health care providers, devices, companies, etc. The lack of common data standards, ie, the way data are structured, stored, and summarized, makes it challenging to collate and analyze the data.

is likely to result in a biased comparison of the treatments. Indeed, there have been well-publicized cases in which observational studies and RCTs have come to opposing conclusions about particular treatments.

An obstacle to using RWD to evaluate effectiveness is that these data originate in routine health care contexts in which patients are not randomized to treatments. Although such data have long been used by regulators to evaluate the safety of treatments, using them to arrive at unbiased evaluations of effectiveness is challenging and requires sophisticated considerations on methodology. In recent years, statisticians have worked on developing new study designs and complex analysis methods, including so-called "causal inference" and machine-learning methods, to help overcome some of the limitations of analyzing observational data. The FDA has committed (in its RWE framework document) to evaluating "the potential role of observational studies in contributing to evidence of drug product effectiveness" and has supported a series of workshops that included discussion of methods for assessing and minimizing bias in observational studies.
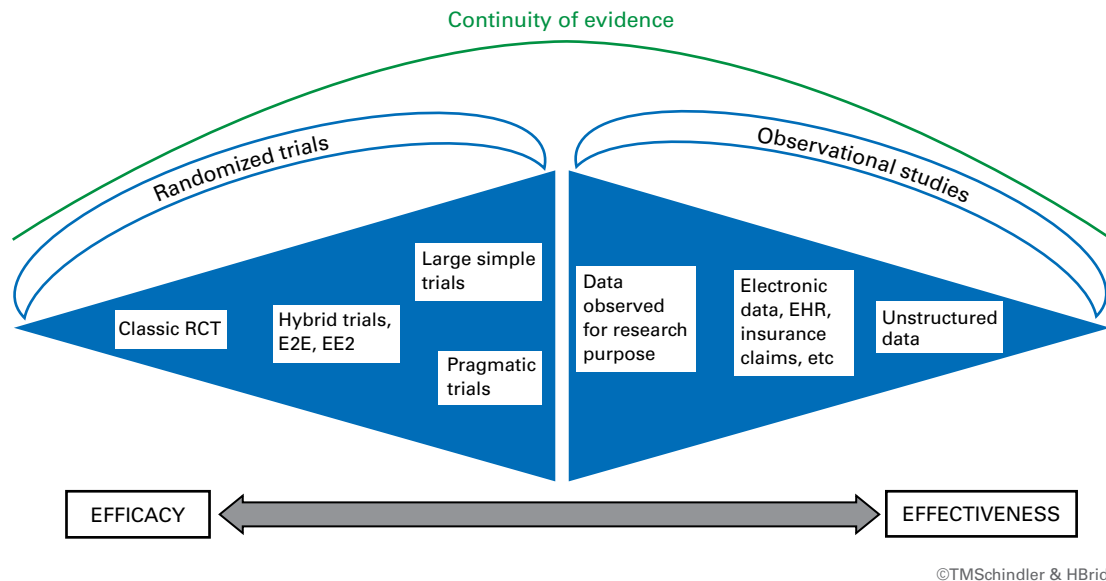
Figure 1. Idealized theoretical framework for the generation of evidence for efficacy and effectiveness. Hybrid trials are studies that combine efficacy and effectiveness assessments. E2E, efficacy-to-effectiveness trial (sequential assessment); EE2, efficacy-and-effectiveness-too trial (simultaneous assessment); EHR, electronic health records.

Obstacle 3: The Need for Rigorous Research Methodology

No amount of data can, in itself, help us evaluate treatments. Data only become evidence once they are used within a methodological framework or research study to answer specific questions, such as "Is treatment X effective in patients with heart failure?" or "How much more effective is treatment A than treatment B at extending survival in patients with advanced non-small cell lung cancer?" For RWD to provide evidence of effectiveness, they need to be analyzed using an appropriate research methodology. This includes the definition of data formats for datasets, the availability of a comprehensive study protocol, and detailed analysis plans to ensure reproducibility of results. If data are derived from novel data sources such as wearables, these data need to accurately reflect the clinical outcome that is being investigated.

Combining Clinical Trials and Real-World Data for Insight into Effectiveness

Observational studies are not the only way of using RWD to tackle the question of effectiveness. A promising alternative approach advocated in the FDA framework document as a way of generating RWE is to make clinical trials more "real life." This can be done by simplifying the trial design to become a "large, simple trial" or by otherwise incorporating pragmatic elements in the design so that patients' treatment within the trial closely resembles routine clinical practice (Figure 1). Alternatively, hybrid designs can be used whereby health data that are routinely collected are used in the trial, together

with data specified by the trial protocol (for example, efficacy-to-effectiveness or efficacy-and-effectiveness-too trials). Combining clinical trial methodology, notably randomization, with the collection and evaluation of RWD has the benefit of enabling a more unbiased evaluation of treatment effects in settings that are close to real-world clinical practice.

Particularly in rare diseases, it is often impossible to conduct RCTs because of the low number of patients available. Recruiting a sufficient number of patients into a study may take too long to yield useful results. In these instances, single-arm open-label studies may be conducted and the results compared with external controls, ie, RWD collected outside of the study. The control data could come from registries, medical records, scientific literature, or expanded access programs. A recent example of such an approach is the approval of avelumab in metastatic Merkel cell carcinoma. The drug was approved in 2017 based on a single-arm open-label study that compared the study outcomes with historical controls retrieved from electronic health records. In 2019, approval of palbociclib for HR+, HER2- advanced breast cancer in men, a label extension, was based on post-marketing reports and electronic health records.

Responses to the coronavirus disease 2019 (COVID-19) pandemic provide a further, highly topical example of how randomized trials that incorporate real-world elements can generate reliable evidence of effectiveness to guide clinical decision-making about treatments. At the time of writing, a number of large, simple trials to evaluate various potential

treatments for COVID-19 are ongoing. For example, the global Solidarity trial, initiated by the World Health Organization, had recruited over 12,000 patients by October 2, 2020, with 116 countries having joined or expressed an interest in joining the trial. In the United Kingdom, the RECOVERY trial is being conducted at all major hospitals and had enrolled over 20,000 patients by December 2020. These trials have simple protocols and heavily streamlined procedures. The aim is to maximize recruitment and minimize the burden of participation on health care staff. The RECOVERY trial, for example, has minimal eligibility criteria, simple and quick informed consent and randomization processes, and minimal data collection requirements, with follow-up information to be recorded at a single time point. Within 3 months of trial initiation, results were released showing the effectiveness of dexamethasone for reducing mortality in patients on mechanical ventilation or supplemental oxygen. The trial has also shown hydroxychloroquine, lopinavir and ritonavir, and azithromycin to be ineffective at reducing mortality from COVID-19.

These examples show the potential of combining RCTs with RWD to produce robust evidence of effectiveness that can inform decision-making about treatments. They also indicate that the use of RWD, while informative as a supplement to RCTs in certain contexts, is unlikely to replace traditional RCTs. Until a treatment is widely used in clinical practice, there are no RWD relating to its use. Consequently, data to support first-time marketing approvals for new drugs have to come from RCTs. The context of a clinical trial also allows close monitoring of patients, which is essential for their safety with drugs that have not yet received marketing authorization. As the examples given show, the situation is very different when a new drug is to be compared with a widely used drug or when well-established drugs are to be evaluated as potential treatments for a new disease.

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Leadership Behind the Scenes: A Backstage Approach to Effective Medical Writing

Katie Bates, PhD; Dwyn DeSilver, BS; Cathi Harmon, BS / Whitsell Innovations, Inc, Chapel Hill, NC

As medical writers, you've undoubtedly experienced the need for leadership in your writing projects. Have you been conflicted as to how to best establish leadership despite having no clear authority over team members? How can we motivate teams to accomplish medical writing goals and help deliver quality documents? How can we do this in a proactive, efficient, and streamlined way? Behind the scenes, we steer discussions, coordinate reviews, manage timelines, facilitate consensus, and harmonize global teams, all while writing the document at hand. Leadership is an integral part of our medical writing lives.

Imagine the following scenario: Debbie sits at her desk, a partially finished document on her monitor. Fingers on her keyboard, she hesitates, but not for loss for words. She knows how to write the report but faces a quandary that affects all medical writers: she is missing some team comments yet is tasked with meeting the timelines. The last conference call did not resolve as much as hoped and left her with no clear direction. Additionally, the data have been updated again. In this familiar scenario, leadership and efficiency are needed, and sometimes the best option is … YOU.

In this article, we offer solutions to several scenarios like Debbie's that are applicable to contract, in-house, and freelance medical writers alike. We share experiences from seasoned medical writers compiled through informal surveys and discussions with our peers and collectively provide real world ideas on how to lead without authority, exercise diplomacy to your advantage, and provide insight on time management and personal efficiency. We provide guidance on how you can implement these strategies and takeaways into your everyday practice, including being able to identify project-, team-, and time-management solutions that will help

you grow as a medical writer and exercise positive and effective influence within your medical writing projects.

Leading Without Authority

Leading without authority takes courage to establish yourself as a knowledgeable leader, not only from a writing standpoint but also in understanding all aspects of developing and completing medical writing projects. This approach also takes work in understanding disease states, indications, document-management processes, standard operating procedures, and templates, as well as the guidance and regulations that drive our industry. Last, leading without authority requires empathy in order to put yourself in your team members' shoes and understand what is driving their decisions, all while being committed to the quality and realistic management of the document.

Scenario 1

Debbie just sent out the third version of "Draft 1" for team review. She receives an email that the team has changed directions (again). Debbie is asked to abandon the third draft, return to the first draft (with some content from the third draft), and provide a new fourth draft in the next 2 to 3 days. What action should she take?

Although frustrated, Debbie knows the document is connected to a corporate goal. She also realizes it's a good time to take a quick break to relax and do something she enjoys. Returning to her desk, she checks her availability and contacts her supervisor about this unanticipated draft.

Asking for support may be her best option, rather than taking everything on herself. Debbie can

- Put a meeting on the calendar with the authoring team to discuss any questions she may have regarding this new direction.

- Check to ensure she understands the agreement for the number of drafts and the timelines.
- Recommend writing that can be done by a team member or another medical writer.
- Ask for more writing time, when appropriate, or a reduction in team review times.

> To be successful in leading without authority, as the medical writer, you need to be prepared, be kind but firm, and know your stuff.

Scenario 2
Debbie is excited that a project is finally going through approval. She unexpectedly receives an email from team management questioning the document's accuracy and expressing surprise at the 1 day approval turnaround. What good options does she have?

This individual reviewed the document a week before; however, Debbie knows the document must be approved by this individual. Although taken aback at this turn, Debbie understands this person reviews many items per day, manages 6 people, and attends numerous meetings. Does she remember last week?

Debbie realizes that clarifying the issue is the best option. Debbie can
- Take a step back to consider her approach to the situation rather than sending a premature email.
- Use empathic, fact-based language, such as:
  – "Your statistician was an integral part in reviewing and confirming the data analysis in the document; her input has been invaluable."
  – "My apologies; it was my understanding that you had previously reviewed the document and the approval step is typically only a formal step to approve the document in the system."
- Include in her response that she is available by phone to discuss further, if needed.
- Inform the entire team that document approval may be delayed and provide a revised timeline if appropriate.

To be successful in leading without authority, as the medical writer, you need to be prepared, be kind but firm, and know your stuff. Understand what is potentially driving the behavior (eg, corporate goals, being caught out of the loop) but stay committed to the quality and realistic management of the document. Use empathic language to soften the defensive nature of a person, as this approach would allow your audience to remain open to the facts you are presenting. It's not about being right or wrong. It's about building a successful relationship and demonstrating your value to the team.

Team Diplomacy
Team diplomacy involves seeking to gain the perspective of your team members and navigating conflicting opinions in such a way that everyone is pleased with the outcome. Being a diplomatic leader requires building trust and gaining respect, being willing to listen, communicating rather than dictating, and using questions to solicit ideas.

Scenario 3
Debbie is waiting on comments from the last team member. Time is running out, and she suspects that the response may come later than expected. What good options does she have?

Although not ideal, if the team member is not a primary reviewer, it may be possible to proceed without those comments. Knowing her team member's role is critical to this option. During the kick-off meeting or initial interactions with the team, Debbie should clarify the hierarchy and roles within the team.

If this team member's comments are essential, it may be necessary for Debbie to accommodate late comments. It is important that Debbie be mindful of work/life balance, however, while ensuring the document moves forward.

She could
- Call the reviewer to better understand when the comments will arrive. This not only ensures the reviewer is aware of the importance of their input but also will help Debbie to plan accordingly.
- Send another email but carbon copy someone that the team member is accountable to or respects.
- Draft the email and include language regarding the updates that only requires confirmation from the reviewer. This is frequently more straightforward than asking for revised text directly.
- Reiterate timelines and the urgent need for their response in addition to the consequences of a missed deadline.
- Be persistent; ask more than once.

Scenario 4

Debbie is not getting the answers she needs at comment resolution meetings. There is significant dissent among team members, with no resolution in sight. Furthermore, the team frequently reverses their decisions after the meetings. Is there hope?

To try to resolve this issue, Debbie could

- Ensure that the project stakeholders attend the comment-resolution meetings to address unresolved issues. This requires that Debbie understands the team dynamic.
- Break down multiple comments to an overarching comment or question to help focus the team to a more concise discussion.
- Ask the question, "Does the team agree?" as a means to prevent unnecessary discussion.
- Take the discussion offline with the key team members. Occasionally, it may be helpful to request that key team members discuss internally with one individual assigned to inform Debbie of any decisions.
- Be sensitive to cultural differences. Some team members may not directly contradict a team member in a meeting but may share information more readily with Debbie privately.

Credibility is built on effective communication with your team. Whether you need to "tease out" comments from a reviewer or obtain team consensus, thinking creatively about how to best communicate and build rapport with individual team members while maintaining your boundaries is necessary to ensure your effectiveness.

Personal Efficiency

Time management and personal efficiency are on everyone's mind, with buzz words like "productivity hacks" all over the internet. In our world, carving out these efficiencies is essential for our medical writing work, because time translates into money. This can take the form of targeted best practices for document management to understand and capitalize on personal preferences, work habits, and discipline.

Scenario 5

Debbie receives unconsolidated review comments from the team, at different times and in different formats, and some are past the deadline. What is the most efficient approach for Debbie to deal with this?

Debbie can

- Understand the make-up of the team and their individual level of contribution to the progress of the document.
- Triage incoming comments by complexity and priority—work on those requiring follow-up first, which allows

progress while simpler comments are reconciled and incorporated.
- Keep a master document. As comments are triaged, incorporate revisions likely to be essential, and make notes of those that need team confirmation.
- Mark text or comments to be discussed with the team with an easily searchable symbol (eg, $$).
- Leave global changes until the end, keeping an ongoing list of global changes within the document to make after other comments are reconciled.
- Send relevant sections of the document (with specific questions and instructions) to targeted reviewers for quick and critical input.
- Maintain version control—this is essential. Devise a naming convention that captures the chronology and source of comments.
- Communicate! One set of consolidated comments for each draft is typically expected.
- Proactively assess the effect on timelines and anticipate delays.

Scenario 6

Debbie contemplates how to proceed given missing review comments for her clinical study report and an unexpected data update. Other project timelines have now overlapped because of delays. Does she have too many balls in the air?

Debbie must

- Get organized with a spreadsheet across all projects—this is worth the time investment.
- Reel in the chaos by prioritizing what she can do and identifying where she might need help.
- Delegate! It is essential, however, to provide appropriate training to anyone helping out, with thorough instructions and realistic expectations.
- Parse out blocks of time to work uninterruptedly on one task—darting back and forth is less efficient. Specific goals for these blocks of time is helpful.
- Eliminate distractions—Debbie can respond to urgent emails at designated times, then turn off her email and phone.
- Capitalize on when she works best and stick to it—this is important.
- Remind contributors of the consequences of continued delays for critical path issues.
- Ask for a summary of changes for data updates to help focus revisions.
- Take advantage of collective insight through AMWA online resources and the Engage forum. She is not alone!

Leadership qualities such as being proactive and confident can make a world of difference in how you approach challenging tasks and situations. This can translate into time savings and efficiency in all aspects of a medical writing project. From knowing how to anticipate when you need help to interacting with difficult team members who are unable to review in a timely manner, confidence can ultimately help you get the job done.

Conclusion

Being a medical writer is a wonderfully rewarding career and always keeps you on your toes. Every team and project are different, not to mention the constant change that goes with writing drug and device documents. Asserting behind-the-scenes leadership is often critical to the successful conclusion of a writing project, which in turn builds your team's confidence in you as a writer and valued team member. Being able to communicate effectively and diplomatically is essential in developing successful relationships with your teams. Although this profession can be demanding at times, developing strategies that make you more efficient is key. In the end, sometimes the best option is how you personally approach each challenge. Sometimes the best option is you!

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Journey From Veterinary Medicine to Medical Writing

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B eing a veterinarian and medical writer is a unique, if somewhat unexpected, combination of professional skills. I say *unexpected* because many people view veterinarians as being only in private practice, treating everything from dogs to pot-bellied pigs.

The overwhelming majority of veterinarians are in private practice,[1] so it's not surprising that "veterinarian" and "writer" uncommonly appear in the same sentence.

When I was veterinary school, nontraditional career paths for veterinarians beyond academia or the public sector were not widely discussed. I didn't learn about medical writing until several months after I earned my veterinary degree.

Fast forward to today, with 8 years of medical writing and 4 years of freelance medical writing under my belt. Although my path to and within medical writing has been circuitous, I am fortunate that I have been able to combine my veterinary training and love of writing into a rewarding career.

What I've learned about myself and the medical writing profession can help other veterinarians who are contemplating making the professional leap into medical writing.

My Lessons Learned

1. Think Outside of the Clinical Box

My year of clinical rotations made it clear that the private practice world wasn't for me. I knew that I did not want to deal with the daily grind of constant client-facing and other rigors of clinical veterinary medicine.

If you know that private practice isn't for you, don't force it. Doing so could leave you feeling like a frustrated square peg in a round hole, increasing your risk of career resentment. Remember that your veterinary degree opens many more doors beyond those of private practice.

If you enjoy practicing but don't want to do it full-time, consider medical writing as a part-time pursuit. As veterinarians, we know that pet owners are hungry for credible and accurate pet care information. Medical writing offers an excellent opportunity to translate our veterinary training into practical and beneficial information for pet owners.

2. Be Ready for Misunderstandings

When I explain to people what I do, I occasionally receive a response along the lines of, "So, why aren't you a *real* vet?"

That question used to sting a little bit. Why did people equate my realness as a veterinarian with whether I worked in private practice? Eventually, I learned that I didn't need to defend my veterinary degree or my decision to use it to pursue an alternative career path.

As you transition into medical writing, don't be surprised if you get questioned in the same way. Use the opportunity to educate people on the versatility of a veterinary degree beyond private practice.

3. Assess Your Transferrable Skills

At first glance, it might not seem like your years of veterinary training would prepare you for a medical writing career. Take a closer look.

Many skills can transfer from veterinary medicine to medical writing, including attention to detail, critical thinking, scientific and medical expertise, and strong written communication skills.

With some more introspection, you can probably come up with more skills. Write them down, and you'll realize that you're more prepared than you thought you were to become a medical writer.

4. Do Your Research on Medical Writing

During my clinical rotations, I enjoyed writing the patient discharge summaries and medical notes on patient cases. More than once, a clinician would compliment my writing.

After attending a career symposium that featured Emma Hitt Nichols, PhD, ELS, as a panelist, I decided that medical writing was the way to go for me. I joined AMWA and browsed through old editions of the *AMWA Journal* to learn more about the profession. I also attended local AMWA chapter meetings and conducted informational interviews with medical writers. If you decide that you want to become a medical writer, research the profession and determine which area of medical writing appeals most to you. The more research that you do, the more comfortable you'll feel about making the transition into medical writing.

5. Consider Human or Veterinary Medical Writing

My first medical writing positions were at medical communication agencies that focused on human oncology and hematology. Although I understood the science and medical terminology, writing for human academic and pharmaceutical audiences did not suit me well.

When I began freelancing, I realized that veterinary writing was the better fit. Over time, my freelance medical writing niche became clear: pet owner education. Although I do some human health journalism writing, my passion lies in educating pet owners.

As veterinarians, we recognize the many overlaps between human and veterinary medicine and can switch between the two with relative ease. Thus, human or veterinary medical writing are equally reasonable career options.

If you choose human medical writing, be prepared to explain why, as a veterinarian, you're qualified to write on human medical topics. A potential client or employer might need a little extra convincing that you can translate your veterinary knowledge to human health.

6. Talk to Other Veterinarians Who Are Medical Writers

Being the only veterinarian at medical communication agencies was a "fish out of water" experience for me.

Once I started connecting with other veterinary medical writers on LinkedIn and through AMWA, I realized that I wasn't the only veterinarian in the medical writing world.

Veterinary medical writers understand your professional background and can help you navigate your transition into medical writing.

7. Get Involved in AMWA

AMWA is the best organization for medical communicators at all experience levels. Being active in the organization pays dividends when it comes to learning about employment and freelancing opportunities and moving forward in the profession.

Get involved in your local chapter by serving on the chapter Board or assisting with other volunteer activities. Once you've found your footing at the local level, consider being active on the national level as well.

In addition to being active, search the AMWA directory for members who are veterinarians and send an introductory email. We're more than happy to connect with you and help you along your medical writing journey.

8. Recognize the Uniqueness That You Bring to Medical Writing

Veterinarians bring a unique perspective to medical writing. Not only do we understand the interconnectedness of human and veterinary medicine, but we also recognize the need for collaboration between human and veterinary medical experts to address public health challenges and combat infectious disease.

This perspective adds a richness to medical writing by expanding the breadth and scope of medical communication. Veterinary medical writers are aptly positioned to apply their veterinary training and knowledge to their writing, whether it is in human or veterinary health.

Final Thoughts

The journey from veterinary medicine to medical writing may not be straightforward, but it can certainly be rewarding. The medical writing profession offers an opportunity for veterinarians to use their veterinary expertise to benefit both human and veterinary medical communication.

Your veterinary degree opens up many professional possibilities outside of private practice. If medical writing interests you, explore and pursue the medical writing niche that suits you best and continue finding ways to hone your craft and grow as a writer. Connect with other veterinary medical writers and recognize the value and uniqueness that you bring to the medical writing table.

Even if you traded your stethoscope for a pen, you are still a real veterinarian.

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Metaphorically Speaking

Laurie Endicott Thomas, MA, ELS / Madison, NJ

In a previous installment of this series (Vol. 26, No. 4), I urged writers and editors to consider whether each of the subject-verb and subject-verb-object relationships expressed in their sentences is literally true. In medical writing, we deal mainly with facts. Thus, most of what we write should be literally true. However, it is sometimes acceptable and even necessary for medical writers to use figurative language, such as metaphors and metonyms, that don't express literal truth. Scientists use metaphor and analogy to make sense of the world and to express their ideas to others. For this reason, scientists often use metaphors in their writing.

Literal or Figurative Language

The word *literal* comes from the Latin word *literalis*, which means "of or belonging to letters and writing." It came to mean "according to the exact meaning of the word" (eg, the word's dictionary definition). In contrast, the word *figurative* refers to figures of speech. A figure of speech is any deviation from literal meanings or common usage. This could mean using some deviation from ordinary grammar or word order, or it could mean using a word to mean something other than its customary meaning. Shakespeare often used figurative language to express intense emotion:

> But soft, what light through yonder window breaks?
> It is the east, and Juliet is the sun.
> Arise, fair sun, and kill the envious moon,
> Who is already sick and pale with grief
> That thou, her maid, art far more fair than she.
>
> —William Shakespeare, Romeo and Juliet, Act 2, Scene 2

To understand such a poetic passage, it is helpful to create a paraphrase, which is a restatement of the meaning of a text or passage in different words. Here's how Romeo's speech would sound if stripped of its figurative language:

> I see Juliet through her window. She is more beautiful than her cousin Rosaline, who should be jealous of her.

This paraphrase captures the literal meaning of Romeo's speech but fails to express the intensity of his infatuation. Romeo had previously been smitten with Juliet's cousin, Rosaline: "The all-seeing sun / ne'er saw her match since first the world begun." But now, he is saying that Juliet *is* the sun.

Metaphor

A metaphor is a figure of speech in which a word or phrase (eg, the sun) is applied to an object or action to which it is not literally applicable (eg, Juliet). The word *metaphor* comes from the Greek for *to transfer*. In a metaphor, some attributes are being transferred from a figure (also called a vehicle) to a ground (also called a tenor). In one of Romeo's metaphors, the sun is the figure and Juliet is the ground. In another, he calls upon the sun to kill the moon. That command contains 3 figures (sun, kill, and moon) and 3 grounds (Juliet, displace, Rosaline).

Many scientific terms started as metaphors. For example, Robert Hooke used the word *cell*, which literally meant a small room, to refer to the microscopic structural units he saw in plant tissue. The so-called cells in plant and animal tissue are not literally rooms, just as Juliet is not literally the sun. Nevertheless, the word *cell* came to be the official name for the smallest structural and functional units of all living things.

Extended Metaphor

Once Romeo has established that Juliet is, metaphorically speaking, the sun, he can use the moon as a metaphor for some lesser woman. Thus, he is using an *extended metaphor*, which is a metaphor that sets up several subsidiary subjects or comparisons.

Mixed Metaphor

A *mixed metaphor* (sometimes playfully called a mixaphor) is one that leaps from one identification to a second identi-

fication that is inconsistent with the first. Merriam-Webster's dictionary offers this one:

> If we want to get ahead, we'll have to iron out the remaining bottlenecks.

You use an iron to smooth out wrinkles, not to remove bottlenecks.

Mixed metaphors can be confusing. Sometimes, they are used for comical effect. Avoid them unless you are a professional comedian.

Dead Metaphor

The expression *dead metaphor* is itself metaphorical because a metaphor is never literally alive. A dead metaphor is a metaphor that has lost its metaphoric force through common usage. In other words, it is no longer a figure of speech. Many technical terms, such as the word *cell*, started as metaphor only to become standard terminology. Once the biologists' definition of the word *cell* was added to the dictionary, the use of the word *cell* to refer to the smallest structural and functional unit of an organism stopped being a figure of speech.

A metaphor is *merely* dead if the term's new meaning has become widely accepted. A metaphor is *really most sincerely* dead if its original meaning has been forgotten. For example, a mainstay was originally the rope or wire that held the ship's mainmast in position. Today, few people know the terms for nautical rigging. However, they commonly use the word *mainstay* to mean something on which someone or something depends (eg, rice is the mainstay of the diet in much of Asia).

Metonym

Metaphors are often confused with metonyms. A metaphor creates a new link between 2 concepts from separate conceptual domains (eg, Juliet belongs to the domain of humanity and the sun belongs to the domain of astronomy). In contrast, a *metonym* relies on an existing conceptual link. For example, people in the United Kingdom, Canada, and other Commonwealth realms often use the word *crown* to refer to the monarch (who occasionally wears a crown) or to the national government in general.

Simile

A metaphor is an implied comparison, often made by using a linking verb to connect ground with figure (eg, Juliet is the sun) or by simply referring to the figure in a way that suggests the ground, such as by using the phrase "the elephant in the room" to refer to an obvious problem. In contrast, a *simile* is an explicit comparison of 2 unlike things, typically by using words such as *as*, *like*, or *than*. However, not all comparisons are similes. Similes take the grammatical form of a literal comparison

but express something that is not a statement of fact:

> My love is like a red, red rose.
>
> —Robert Burns

Clichés

Some metaphors and other figures of speech are so overused that they become clichés. A *cliché* is an overused phrase or opinion that betrays a lack of original thought. Examples include "crystal clear" and "cool as a cucumber." Some clichés are metaphors, and some are not.

- She dangled a carrot in front of his nose. (metaphor)
- The explanation was as clear as mud. (simile)

Figurative Language in Medical Writing

There are no unbreakable rules for using figurative language in medical writing. On the one hand, medical writers are mainly concerned with conveying facts and truth as opposed to expressing emotion artistically. Thus, medical writers should be cautious about using figurative language, especially when their audience includes poor readers or non-native speakers of the writer's language or if the text is going to be translated. On the other hand, a large proportion of the technical vocabulary used in medical writing consists of dead metaphors, such as the word *cell*, as well as metaphors that are not quite dead yet.

There are several good reasons for using figurative language in medical writing. One is to help your readers understand some complicated system or relationship. To do that, you may draw an analogy to something that they already understand or that you can at least explain. For example, many of the terms used for talking about how cells communicate with each other came originally from radio (eg, signal, amplification, gain, feedback). These terms were originally metaphors but lost their metaphorical force through common usage among cell biologists.

Another reason for using figurative language is convenience. For example, evolutionary biologists often talk about the evolutionary strategies of bacteria, plants, and lower animals. This use of the term *strategy* is a dead metaphor. It is a metaphor because the "strategies" in question do not represent anything that an organism is consciously choosing to do. *Evolutionary strategy* is a dead metaphor because the dictionary already tells us that the word *strategy* can mean an adaptation or set of adaptations that contribute to evolutionary success. Among microbiologists, the word *strategy* is a shorthand for that concept.

Shorthand is itself a dead metaphor. *Shorthand* originally meant a method of rapid writing that involved abbreviations and symbols. Thus, a *shorthand* came to mean a short and simple way of expressing or referring to something. Some

members of a lay audience may not understand that an evolutionary strategy is not something that the organisms are planning to do. So, depending on your intended audience, you may have to avoid using a shorthand or at least explain what the shorthand means.

Metonyms can also be used in medical writing, albeit cautiously. For example, the word *practice* is often used as a metonym to refer to a type of business in which a medical practitioner or group of practitioners provide care to patients. So, you might use the term "the practice" when you want to refer to such a business as a business or when you don't want to specify a particular part of the business. For example, you could encourage patients to "contact the practice" without specifying which person or even which office to contact. Your goal should be clarity. If the patients can contact any member of the staff, you can urge them to contact the practice.

In general, you may wish to avoid unnecessary use of figurative language in a technical report, such as a clinical study protocol—especially if it is going to be translated. However, there is considerably more room for literary inventiveness in an opinion piece. In such pieces, authors may wish to express their own emotions and to evoke emotions in the audience, especially to underscore the importance and urgency of their message. In that situation, the writer may use figurative language for rhetorical effect.

Learn More

Metaphors, similes, and metonyms are not the only forms of figurative language. The Silva Rhetoricae Web site (http://rhetoric.byu.edu/), maintained by Dr Gideon Burton of Brigham Young University, provides an extensive list of figures of speech, all of which are named, defined, and categorized. Many of these rhetorical figures have Greek or Latin names because they have been recognized since classical times to be valuable in persuasion.

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Making History: An Interview With Katrina Burton, AMWA's New President-Elect

JoAnna Pendergrass, DVM / Freelance Medical Writer, Sandy Springs, GA

The year 2020 was one that we will not soon forget. A global pandemic brought the world to its knees, social unrest reached a boiling point, and divisive politics made us weary.

And yet, there were countless bright spots amid the chaos. One of those bright spots occurred right here within AMWA, with Katrina Burton, BS, elected to serve as AMWA's next President-Elect. She is the first Black person to hold this position in the organization.

The announcement of her election filled me with excitement. Being asked to interview Burton for the *Journal* was like icing on the cake.

As a Black woman, I felt honored to be tasked with interviewing Burton to learn more about her life, medical writing career, and goals for AMWA.

I sat down with Burton—via Zoom, of course—prepared for an interview that ended up feeling more like a conversation between friends.

Growing Up in Texas

Burton was born in Houston, Texas, and grew up on the city's north side. Like many of us, her original career aspirations didn't include medical writing.

"I always had an interest in the medical field, especially the skin," she said. Her older sister battled a severe case of eczema, inspiring Burton to want to become a dermatologist. Without Google as an aid, she spent time at the school library and took advantage of her family's home encyclopedia collection to learn about dermatology.

Even with dreams of becoming a medical doctor, Burton loved writing. She enjoyed reading and writing fiction and family stories. "I was always told that I had a vivid imagination and that I should become a writer," she said.

After graduating from Booker T. Washington High School, a historically Black high school in Houston, Burton attended Texas A&M University in College Station, Texas. Initially entering college as a pre-med major, she switched to journalism, earning a Bachelor of Science in Journalism and a minor in Marketing.

While at Texas A&M, she served as a backup writer for *The Battalion*, the college newspaper.

Career Beginnings

"My journey is a very interesting story," Burton explained as she described her first few jobs after college.

Burton decided to stay in the Houston area after graduation. Although she loved writing, she discovered that writing for the local newsletter wasn't exactly lucrative. She took a job opportunity in retail instead while she pondered her next steps.

At a local retail clothing store, she began as an assistant manager and was promoted to manager. Burton weaved her love of writing in with her managerial responsibilities by creating a store newsletter. This newsletter caught the attention of the retail company's national office, and Burton was asked to expand the newsletter to the store's local region.

Knowing that writing was her true passion and retail would not be part of her long-term career plans, she started looking for opportunities that combined both her management and writing skills.

In addition to working in retail, Burton also explored her interest in graphic design and layout, still managing to weave writing into her work, landing several positions with well-known companies over the years.

Becoming a Medical Writer

Edging ever closer to medical writing, Burton worked as the Marketing Manager at Gulf Coast Regional Blood Center for 4 years. In her position, she worked with her team to recruit talent to appear in television commercials and marketing

materials in support of various projects, such as incentive programs and marketing initiatives. "This is where I honed my skills with project development," she said.

She spoke with pride about leading the launch of the Center's African American Commits for Life Program (now the Diversity Program), aiming to increase the number of Black blood donors. Within the first 6 months of the program, blood donations from Black blood donors increased by 25%.

As a part of her position, Burton wrote extensively for the blood bank and worked with philanthropic organizations on strategic initiatives. Working at the Center brought her back into the medical field, creating the beginnings of her medical writing career.

Burton then began working at The University of Texas MD Anderson Cancer Center in Houston, where she has been for 13 years.

Getting Involved in AMWA

In 2010, early in her medical writing career, Burton's director advised her to seek out science writing organizations to join. A Google search listed AMWA as the first search result.

She joined AMWA shortly before the Annual Conference that year. The conference, in her words, was "love at first sight." It was an exhausting yet exhilarating experience for Burton, connecting her with others who were passionate about medical writing. Since then, she has attended every AMWA Medical Writing & Communication Conference, participating as a roundtable facilitator (2012, 2013) and open session speaker (2013, 2017, 2019).

Burton's involvement in AMWA could fill an entire page. As a bonafide lover of volunteering, she first held numerous roles in the Southwest Chapter. To name just a few, she served as the chapter's Publicity Coordinator, President and Immediate Past

> " When you're in a place where you can do good and share important stories, your job doesn't feel like a job. Rather, it feels like a calling. "

Personal experiences spurred her decision to work at MD Anderson. Her father passed away from prostate cancer, and other family members have had a range of cancers and health issues.

At MD Anderson, she first served as an external communications specialist, then senior communications specialist. For 7 years, she covered cancer prevention, worked with local and national reporters, and wrote about groundbreaking cancer research and clinical trials.

Currently, she serves as a Program Manager in the Public Relations Office, managing the communications and media relations for MD Anderson's Children's Cancer Hospital. In this role, she continues to write and work with media to share pediatric patients' experiences, essential research, and important patient programs.

Burton's work varies from day to day, and she loves it. "I don't just write stories and work with media: I also build relationships with researchers, clinicians, and other colleagues," she said. "I truly enjoy getting to know patients and their families, and I am honored when they share a glimpse of their cancer journey with me. Seeing the patients do well and achieve success in life gives me so much joy."

She has continued to pursue her passion for learning about the health care industry and sharing that information with others. "When you're in a place where you can do good and share important stories, your job doesn't feel like a job. Rather, it feels like a calling," Burton remarked.

President, Chapter Delegate to AMWA's Board of Directors, and the Chapter Advisory Council (CAC) Representative.

After being instrumental in the most recent restructuring of AMWA's National Board, Burton was invited to become active on the national level, serving as the first Chair of the CAC. When she was elected AMWA National Secretary, she was Chair of the Constitution and Bylaws Committee. Now, as President-Elect, she is the Chair of the Nomination Committee.

In 2020, Burton earned the distinction of being named a 2020 AMWA Fellow, a designation bestowed upon members who have achieved an exceptional level of service to the organization over time.

To add to her extensive list of AMWA activities, Burton also actively volunteers in her local community, serving on several boards and councils. She works with local schools to inspire a love of communication in young children. "This work helps build a diverse group of future communicators and allows me to do my part to ensure that the field of communications continues to thrive with different voices," she said.

Tackling Misinformation

Burton believes that health and science misinformation is the biggest challenge in medical communication. This is not a new problem, of course, but medical communicators are uniquely positioned to take on this challenge.

To do so, Burton encourages all medical communicators to be proactive in writing accurate, fact-based information and

being credible sources of medical information. AMWA, she believes, can be the driving force in countering misinformation and teaching medical communicators how to be part of that driving force.

Serving as President-Elect

Since joining AMWA, Burton has been continually inspired by the organization's leaders with whom she has worked. She takes her commitment to AMWA, and her new role as President-Elect, seriously. "It is an honor and privilege to be elected as President-Elect of an organization that is doing essential, critical, and amazing work to promote excellence in the medical communication field," she said.

As President-Elect, Burton aims to grow AMWA's membership, expand AMWA Online Learning, and encourage membership among medical writers who specialize in public relations and marketing.

She also aspires to increase the ethnic diversity of AMWA's membership. To Burton, though, diversity in medical communication is about more than just ethnicity. It is also about a diversity of writing specialties, employment status, and medical topics (cancer, dental care, etc.).

"An organization is strenghened by its diversity," she said. "Diversity allows the opportunity to be educated on different perspectives, ideas, and values that can be crucial to organizational growth."

Becoming the First Black Female President-Elect

Burton considers being AMWA's first Black female President-Elect an accomplishment for her personally and for AMWA.

At first, though, she did not even realize that she was the first. Nevertheless, she recognizes the significance of this moment in AMWA's history. She plans to use her platform to encourage more minority medical writers to join AMWA, get involved, and pursue leadership positions within the organization.

Closing Thoughts

As we closed out our interview, I asked Burton to provide some words of wisdom for medical communicators who are starting their careers.

"Take advantage of AMWA's educational resources and tools, attend the AMWA Medical Writing & Communication Conferences, volunteer in your local AMWA chapter, and be intentional about building your expertise to align with your career trajectory." She also recommended taking advantage of AMWA's many networking opportunities that can promote collaborations and long-lasting friendships.

I am thrilled to see Burton serve as AMWA's President-Elect. While holding AMWA close to her heart, there is no doubt that she will continue to serve the organization well and push the medical communication field forward.

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

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2020 Annual Business Meeting for AMWA Members

November 9, 2020, 12:30 PM 1:00 PM, Eastern Time

Katrina Burton, BS / 2019–2020 AMWA Secretary

AMWA President Ann Winter-Vann, PhD, called the meeting to order and provided a report about the accomplishments of the organization over the past year. She acknowledged that the initiatives required many resources. She expressed gratitude to the 2019-2020 Board of Directors (BOD) and committee and task force member volunteers who devoted their time and energy to lead AMWA during a challenging year.

Dr Winter-Vann also recognized and thanked Jim Cozzarin, ELS, MWC, for his 4-year service as Editor-in-Chief of *AMWA Journal*. A search committee is currently in place to help find the next Editor-in-Chief.

Julie Phelan, MD, MBA, presented a financial report for the period of July 1, 2019, to June 30, 2020.

Dr Winter-Vann announced that in accordance with the AMWA bylaws, the nominating committee presented the following slate of officers for 2020-2021 to the AMWA BOD:

- President-Elect: Katrina Burton, BS
- Secretary: R. Michelle Sauer Gehring, PhD
- Treasurer: Julie Phelan, MD, MBA

The AMWA BOD approved the slate, and the membership was notified of this slate 60 days before the annual meeting. The AMWA bylaws contain a provision for additional nominations to be made in writing, and no additional nominations were received. Nominees who are unopposed are elected automatically at the annual business meeting.

Dr Winter-Vann declared the slate to be the elected officers for 2020-2021, led by Gail V. Flores, who as President-Elect automatically assumes the office of President.

Dr Winter-Vann passed the gavel to Dr Flores, who thanked the former for her leadership and expressed appreciation for having her at the helm navigating the organization through this challenging year.

Dr Flores shared highlights from her inaugural address and introduced the 2020-2021 AMWA BOD:

Officers:
- Immediate Past President: Ann Winter-Vann, PhD
- President: Gail V. Flores, PhD
- President-Elect: Katrina Burton, BS
- Secretary: R. Michelle Sauer Gehring PhD
- Treasurer: Julie Phelan, MD, MBA
- Executive Director: Susan Krug, MS, CAE

CAC Chair:
- Kim Korwek, PhD

At-Large Directors:
- Brian Bass, MWC
- Loretta Bohn, BA, ELS
- Sarah Dobney, MPH
- Elise Eller, PhD
- Jennifer Minarcik, MS
- Lynne Munno, MA, MS
- Laura Sheppard, MBA, MA
- Shawn Watson, PharmD, PhD, BCPS

The meeting was adjourned at 12:55 PM, Eastern Time.

2020-2021 OFFICERS

| Ann Winter-Vann | Gail V. Flores | Katrina Burton | R. Michelle Sauer Gehring | Julie Phelan | Susan Krug |

AMWA Annual Financial Report, 2019-2020

Julie Phelan, MD, MBA / 2019-2020 AMWA Treasurer

It has been a pleasure serving as Treasurer for the American Medical Writers Association (AMWA) over the past year, and I am pleased to provide this financial report for the 2019-2020 fiscal year, which ended June 30, 2020.

I begin this report acknowledging that during the last 2 quarters of the fiscal year, the COVID-19 pandemic caused severe disruption to everyday life and a recession. The leadership of AMWA quickly put a plan in place to minimize the impact of the pandemic. AMWA staff successfully converted to a remote work environment, and expenses were curtailed. Meetings and travel plans were cancelled, and vacant staff positions were put on hold.

The success of the 2019 annual conference in San Diego, popularity of live webinars, increase in membership, and careful management of expenses helped to sustain AMWA through this uncertain time. The full financial effects of the COVID-19 pandemic may not be experienced until next year.

Financial Performance

AMWA's net income for the 2019-2020 fiscal year was $448,106, with significant investment gains contributing to the results.

Revenues

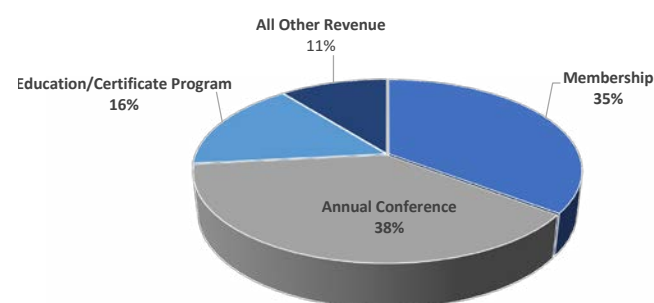Overall, revenues exceeded budget expectations by 6%, largely because of the success of the annual conference. Membership income, annual conference income, and education and certificate program income continue to be AMWA's major sources of revenue, providing 89% of AMWA's program revenue. Net investment income of $115,074 accounted for 5% of AMWA's total revenue (Figure 1).

Expenses

AMWA invests in programs, products, and services that bring value to members and the medical writing community. Overall, expenses were under budget by 10% for the fiscal year. Total program expenses for the fiscal year were $1,762,592, with 31% of the expenses going to produce the annual conference, 25% of expenses being used to fund member services and benefits, and 17% of expenses funding the education program including the certificate program and online education (Figure 2).

Reserves

Reserves are the accumulation of funds over time that enable an organization to withstand an emergency or to invest in new mission-related initiates. Unrestricted reserves of 6 to 12 months of annual operating expenses represent a standard target for not-for-profit organizations. With budgeted annual operating expenses of $1,615,950 for the fiscal year from July 1, 2020, to June 30, 2021, the target for AMWA's reserves ranges
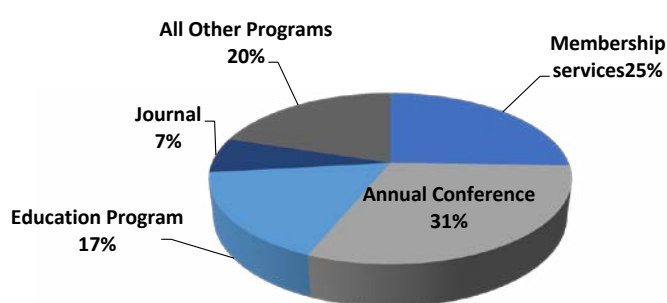

Figure 1. Sources of program revenue for the fiscal year that ended June 30, 2020.

Figure 2. Sources of major program expenses for the fiscal year that ended June 30, 2020.

from $800,000 to $1,600,000. AMWA's unrestricted short- and long-term investment reserve level of $1,800,000 on June 30, 2020, was within this targeted range.

AMWA's restricted Endowment and McGovern funds totaled $205,200 and $169,000, respectively.

Financial Position

An organization's financial position is reflected in its asset and liability holdings. AMWA is well positioned to pay its obligations and plan for the future. Total assets were $3,160,138 as of June 30, 2020, and the organization's liabilities totaled $561,680.

Financial Statement Audit Results

Abercrombie and Associates, AMWA's independent auditors, expressed an unqualified opinion regarding their audit of the financial statements for the fiscal year that ended June 30, 2020. An unqualified opinion states that the financial statements present fairly, in all material respects, an entity's financial position, results of operations, and cash flows in conformity with generally accepted accounting principles. AMWA continues to be in a secure financial position as it continues expanding member benefits and resources into the next fiscal year. The full audit report is available to AMWA members upon request.

Acknowledgment

Thanks to Calibre CPA Group, PLLC, for providing the financial data and the members of the 2019-2020 Budget and Finance Committee for their review of reports and budgets: June Baldwin, Adriana Caballero, Alice Pappas, Leena Patel, Whitney Smalley-Freed and Christine Wogan, Ann Winter-Vann (2019-20 AMWA President), Gail V. Flores (AMWA President-Elect), and Susan Krug (AMWA Executive Director).

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Ann Winter-Vann

Tax-deductible donations help AMWA fulfill its mission to promote excellence in medical communication and provide education and resources in support of that goal.

❯ To make a donation, please visit www.amwa.org/donations

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- And many more

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www.amwa.org/conference