

ELECTRONIC EDITION

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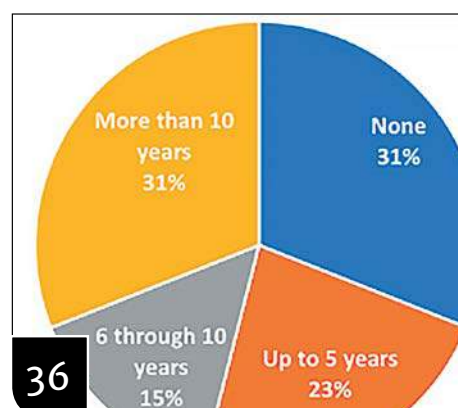
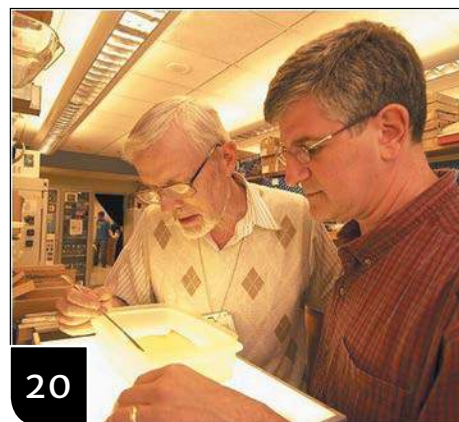
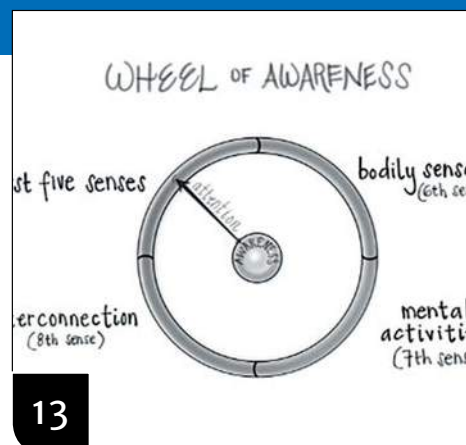
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### AMWA JOURNAL MISSION STATEMENT

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# AMWA Position Statement on Legislation That Negatively Affects the Livelihood of Freelance Medical Communicators

The American Medical Writers Association (AMWA) supports the right of self-employed medical communicators to practice as independent contractors. AMWA strongly disagrees with legislation that would either discourage companies from hiring freelance medical communicators or force independent contractors to become employees, which will diminish their autonomy and may cause harm to their business model and relationships.

Many medical communicators choose to be self-employed. This business relationship benefits both parties: companies can tap into the unique knowledge and expertise of independent contractors as needed for individual projects, and the self-employed business model affords

medical communicators a high level of autonomy and flexibility. AMWA recognizes the legitimate concerns about worker misclassification and the exploitation of workers that can result from the gig economy. Although legislation designed to protect these workers is well intentioned, if the definition of a freelance worker is written too narrowly, it will prevent those who freely choose to work as independent contractors from continuing to operate under that business model.

Although there is a need to protect exploited workers, AMWA urges legislators to ensure that the resulting laws allow those who are legitimate independent contractors by choice to continue to practice as freelance professionals.

## About AMWA

Founded in 1940, AMWA is the leading professional organization for writers, editors, and other communicators of medical information. AMWA serves as a resource for professional medical communicators, promoting excellence in medical communication and providing educational resources in support of that goal. With more than 4,000 members in the United States, Canada, and 30 other countries, AMWA members are committed to accurately and ethically making information about health and medicine clear and meaningful.

## Background Information

Medical communicators working as independent contractors (freelancers) bring their knowledge and expertise to a broad range of clients. Freelancers include working parents, people with disabilities, small business owners, those nearing retirement, and people who otherwise need or prefer the flexibility of managing their own schedules while generating income in their chosen profession.

Legislation and proposed legislation concerning independent contractors in several states could disrupt how self-employed writers and editors do business in the future. In California, AB 5 took effect on January 1, 2020, and similar legislation is being considered in New Jersey (S4204/A5936), New York (S6699A/A8721A), and other states this year.

Specific concerns about the definition of independent contractors in existing or proposed legislation include

- The stand-alone requirement that an independent contractor “performs work that is outside the usual course of the hiring entity’s business.” Many freelance medical communicators perform work that is aligned with a company’s core business, either because the independent contractor brings a unique

expertise or because the company has a transient overflow of work. These opportunities benefit both the independent contractor and the company.

- A requirement that work be performed away from the company’s place of business. Although it is reasonable to require independent contractors to maintain a separate place of business, many freelance medical communicators meet with their clients at the company’s place of business from time to time. These face-to-face meetings facilitate both the specific project and the relationship between the independent contractor and the company.
- A low cap on the number of submissions to a single company. In some instances, freelance medical communicators provide their clients with blog posts or submissions to newsletters on a weekly or more frequent basis. This type of work is common and reasonable for a freelance medical communicator.
- Vague wording that will force legislation to be clarified through litigation. A lack of clarity in the language of the law will discourage companies from hiring independent contractors under any circumstances based on the fear of being fined or sued despite genuine efforts to comply with the law.

## What You Can Do

- Call and write your state legislators about these concerns ([https://openstates.org/find\\_your\\_legislator/](https://openstates.org/find_your_legislator/)).
- Explore social media and website groups that provide information about legislation in several states.
- Consult a labor attorney in your state to better understand the specifics of the legislation in your area and how it affects your freelance business model.
- Develop talking points to explain your business model to clients and potential clients.



Melissa L. Bogen



Sherri Bowen



Lori De Milto



Ruwaida Vakil

## Seasoned Freelancers Jam in San Diego

Report by Brian Bass, MWC

*In keeping with the theme of this issue, several of our Freelance Forum contributors—[Melissa L. Bogen](#), [Sherri Bowen](#), [Lori De Milto](#), [Cathryn D. Evans](#), and [Ruwaida Vakil](#)—have provided their own unique insights into topics raised during the open session moderated by Brian Bass: “Jam Session for Seasoned Freelancers.”*

When accomplished musicians jam, their combined talent, energy, and experience make a special kind of synergy. A similar kind of magic happens when seasoned freelancers get together to discuss their thoughts, ideas, concerns, and challenges with peers of equal or greater experience. That’s exactly what happened during the “Jam Session for Seasoned Freelancers” held during the 2019 Medical Writing & Communication Conference in San Diego this past November.

### Financial Issues Topped the Bill

#### *How to Handle a Client’s Bankruptcy*

The first topic that was brought up during the free-flow, participant-driven session was a serious discussion of what to do when a client that owes you money declares bankruptcy. Fortunately, not many freelancers in the group had personally encountered this problem. There were definitely no easy answers. Taking the client to small claims court is not likely to be successful because the company already has no money, and vendors take a back seat when it comes to getting paid, behind the Internal Revenue Service and the company’s employees. Hiring an attorney might seem like a good alternative, but then the freelancer is adding costs to what they’re already owed, with no guarantee of recouping any money. Session participants also discussed the importance of identifying clients that are in financial trouble, so that outstanding balances can hopefully be caught up and accepting new work can be avoided to reduce the freelancer’s exposure should the client go bankrupt.

*This has happened only once in more than 25 years of business. The client happened to owe me \$24,000 at the point when the client decided to file Chapter 11, after which the client was not paying any vendors/subcontractors. One consultant won a “judgement” against the company in court but was never able to collect; other consultants got nothing. I managed to get \$7,000, which was a bit of a miracle. Being in receivership, the company could certainly pay some vendors, and I was determined to be one of them.*

*How did I manage to get \$7,000 when no other subcontractors got paid? Persistence pays. I was determined and remarkably persistent and patient. I sent an invoice every other week*

*by email, fax, and US post. (Yes, I sent every memo and every invoice via all 3 of these channels.) I also called every single week to check in person, with a live human being, on the status of my payment. Throughout, I was admirably courteous, kind, and understanding.*

*Finally, after months of constant reminders—always delivered with extreme courtesy and sweet-natured sympathy—I got a decision-maker on the phone and offered to take \$7,000 if the company would pay me within 21 days. She said, “You mean you will accept \$7,000 and not hold us liable for the remaining balance?” (This meant they would not have to pay \$17,000 of my contract.) I said, “Yes, if you pay the \$7,000 within 21 days, I release you from any further payments.” She immediately sent me a contract to sign agreeing to this, and I received the payment within the 21 days. By that time, it seemed like a windfall!*

*Fortunately, I had plenty of other business, so this loss was not painful. My persistence was actually a matter of principle: I was determined not let this go without receiving at least something.*

*I must add that my inner attitude happened to be very free—no anxiety, no anger. This was because I did not need the money then, and I was more or less playing a little game to see what would happen if I simply never—never—let it go until I got some kind of payment. Being relaxed, absent of anxiety and anger, and having no expectations helped immensely.*

**—Cathryn D. Evans**

### Getting Paid

The subject of getting paid for services rendered continued. Session participants discussed the problem of clients delaying payment to freelancers until they got paid from their clients. Companies that hire freelancers to do work for them on behalf of their clients (eg, medical communications companies) are a likely culprit, and payment can often be delayed for months. Ensuring that acceptable payment terms are spelled out in either the client’s statement of work or in the freelancer’s letter of engagement were recommended to avoid such problems.

*The most important factor in getting paid on time for services rendered is to ensure you have a written agreement about rate and payment terms before you start work for any individual or company. An email string in which you and the client discuss and finalize terms can suffice as a written agreement. My preference, however, is to have a written contract that spells out the rate and payment terms (among other things), signed by both parties. That strategy eliminates confusion.*

**—Melissa L. Bogen**



## Contracts

The contract should specify your rate (by project or hourly), how additional work outside the scope of a project will be compensated, reimbursable expenses (eg, for PDFs of articles or books you purchase), when you will submit an invoice, and when the invoice will be paid.

Here are some examples of wording from actual contracts that you are free to add to your own contracts:

**Rate:** [Company] shall pay [Consultant] consulting fees at the rate of [\$X] per hour. It is the expectation of [Company] that [Consultant] will devote hours as estimated per project for services performed under this Agreement.

**Additional work:** In addition, if [Consultant] is engaged by [Company] to provide additional services not outlined under this Agreement, the compensation structure and terms of payment for such fees shall be separately negotiated and agreed to in writing at that time.

**Expenses:** [Company] shall reimburse [Consultant] within 30 days of receipt of [Consultant's] invoice for all reasonable reimbursable expenses, if previously approved by [Company].

**Invoicing:** [Consultant] shall submit an invoice to [Company] within 30 days of the work completed.

**Payment:** [Company] will pay [Consultant] for services actually performed within 30 days of receipt of invoice(s) received, as instructed by the relevant Statement of Work.

Remember that contracts are negotiable. The answer to any unasked question is always “no,” so you should ask for what you want and be willing to compromise on details that are not deal breakers.

Once, a new client had in their contract the following clause: “Each invoice shall be due and payable to [Consultant] within 15 days after receipt by [Company] of payment from [Company's client].” This clause is not OK! Payment to me is for my services rendered to a company and should not be contingent upon that company receiving payment from a third party. I politely asked—and the client agreed—to change the sentence to read: “Each invoice shall be due and payable to [Consultant] within 30 days after receipt by [Company].” I did ask for 15 days, but we agreed to payment in 30 days.

—Melissa L. Bogen

## When Payment Is Late

Some invoicing services/programs (eg, Square) automatically send out reminders at time intervals you specify. For invoices I email myself, on the 31st day after sending an invoice that remains unpaid, I send a friendly request for a status report: “Can you tell me when my invoice #XYZ dated [>30 days ago] will be paid?” I then note on the invoice hard copy when I sent that reminder. When I've asked for status of an invoice, every single client has investigated and replied. Sometimes the

invoice got lost in the shuffle of emails, so I need to resend my invoice, or the check is in the process of being mailed.

—Melissa L. Bogen

## Kill Fees

Another financial discussion focused on whether and how seasoned freelancers charge kill fees. Some session participants noted that they charge a kill fee if a project is discontinued before it's finished, whereas others count on progress invoicing to ensure they're compensated for work performed. If a project is discontinued before it's even begun, it was suggested that a kill fee be charged in such circumstances as well, to reimburse the freelancer for time held aside for the project and other work that may have been turned down.

A kill fee is a fee the client agrees to pay you if the client terminates a project early and you have blocked significant time for it. Its purpose is to pay you during the time you “lose business” because of having committed a large block of time to a single client and thus having had to turn down other work. It is reasonable to ask for a kill fee when a client requires extensive time commitments. Of course, you must be sure to include this in your contract: the client has to agree to it, or you cannot collect. Determination of the amount of a kill fee is at the writer's discretion: you must determine how much other business you might be losing, should they breach the contract and end the project early. There is no “fixed” way to determine this—it depends entirely on the project, client, etc. Note that I do not include a kill fee for regulatory projects, primarily because I have always billed such projects strictly by the hour. But if a client wants you to commit to X hours a week for X months and then terminates the contract much earlier, you should include some kind of penalty in your contract. I have applied this principle only in cases in which I gave a discounted hourly rate (~25%) for a guarantee of X hours per week for X months—generally with agencies or contract research organizations (CROs). In the contract, I include a statement that, if they end up not giving me that particular volume of work (upon which the discount was based), then they must retroactively pay me my full, nondiscounted hourly rate for all the hours already billed.

—Cathryn D. Evans

## Unscrupulous Activity Abounds

### Unethical Behavior

Several topics concerning unscrupulous activity on the part of clients arose during the Jam Session. One participant warned of a growing trend in continuing medical education (CME) in which manufacturers spin off an “agency” that portrays itself as an independent CME provider. The company then hires freelancers to develop content and attempts to direct the content in unethical ways. If the freelancer refuses to become complicit in the unethical behavior (as they must do), the company might summarily fire them and cite failure to deliver as cause to withhold payment.



Another case of unscrupulous client behavior that session participants discussed was a situation in which a freelancer found his or her image and biographical information on a company's website. The company was using the freelancer to promote capability that would attract business to the company. Not only had the company not asked permission to use the freelancer's likeness and information, the freelancer also didn't even have experience working with the company. The freelancer contacted the company and ordered them to take down the information immediately, and they complied. The warning to other seasoned freelancers is to be ever vigilant about where their information appears on the Internet.

It's interesting that my chief examples of "unethical" behavior involve manuscript writing, which is perhaps why I don't do that kind of work anymore. With regulatory writing, I just report the data, and if it gets any spin, it happens after the document leaves my hands (which is why I always try to express to clients, especially in my proposals, that the final content of the documents is THEIR responsibility, including to regulatory authorities AND to the public!).

But here is one example of what I considered unethical behavior: I was asked to write a white paper or a similar type of manuscript for a company that wanted it to use it to support approval to sell a prescription cholesterol-lowering drug as an over-the-counter drug, with the argument that if people were *instructed* to see their doctor and/or get a laboratory test proving they needed such a drug, they would do it—thus bypassing the need for a doctor's prescription. The company conducted a postmarketing kind of study to prove that people would actually go and get medical evidence (from a doctor and/or laboratory test) before buying such a drug over the counter. The company recruited people in shopping malls for this "study" AND *paid* for the participants' doctor visits. In early meetings about the document, I expressed concern about the validity of this study design—yes, the study participants recruited at the mall went to their doctors, but mostly (or only??) because the company paid for the doctor visits and for the blood tests. Would a regular person go to the doctor and get a blood test, without being compensated, just because the instructions on the over-the-counter drug package "strongly suggested" they do so before starting a cholesterol-lowering medication? I kept asking but never got answers.

My questions were apparently not well received, and I was fired from the project. However, a few years later, someone involved with that project (who had since moved on to another company) contacted me about a new job—the individual specifically remembered that I had stood my ground and had admired my integrity for asking the questions that I did. This just proves that your ethics matter, and people do notice!

—Sherri Bowen

Two categories of unethical behavior come to mind here: (A) sexual misconduct and (B) hiding data and/or knowingly

"spinning" information so that it tells a biased, unbalanced, and incomplete story.

**A. Sexual misconduct.** Like most women, I have so many experiences of item A that I could write a tome on the matter. (#MeToo). There are 3 categories of "sexual misconduct": sexual discrimination, sexual harassment, and sexual assault. Sadly, I have experienced all 3 as a medical writer in the pharma/biotech industry. These are all sensitive "ethical issues," and each person must prepare to have to deal with it, even in the face of #MeToo and #TimesUp. Think about it, follow your instincts, and take the necessary precautions.

**B. Hiding or spinning data.** Sadly, I have been asked to hide or spin data many times. Mostly, such requests have come from small start-ups in which the players were so enthusiastic to get their projects funded that they sometimes fell short of complete integrity in presenting the facts. In addition, a few large pharmaceutical companies have tried to do this—and, I might add, a number of CROs as well. Generally, I explain the regulations and the laws and try to convince them that this is not the prudent way to go. Transparency is best. A few times I was "forced" to do certain things and I made sure to include a yellow-highlighted boldface note right in the text, pointing out the more appropriate perspective. I left it for them to delete, but at least I had a record of advising the client to do the right thing (in case of a future lawsuit). Generally, the medical writer in pharma/biotech is not liable for the content or even the "spin" of a report—the company is 100% liable because they provide the data and they do the final edit and make final decisions about what will/will not be included. I choose to insert such comments as a matter of principle. A few times I have had a client actually become quite angry with me for pointing things out! Nonetheless, I stick to my guns—today I won't even do it with a yellow-highlighted note inserted; I simply say this is unethical or inappropriate and let the client delete adverse events or other data they don't like, after I have submitted a correct/accurate/ethical document.

Once, a client's Associate Medical Director (AMD) who was supervising a particular drug asked my client to fire me because I wrote a long-term summary of all clinical data and uncovered a rather alarming number of deaths quite likely related to the drug; of course, I reported all of it objectively, with no spin 1 way or the other. The AMD obviously had not read the company's data and was very angry to find so many deaths. She blamed me and said from now on they would have the advertising agency write study summaries (as I said to my client, "For heaven's sake, I did not kill the patients!"). My client was quite chagrined but of course continued to use me for other therapeutic areas. Six months later, the AMD asked my client, "Do you think Cathryn would be willing to come back?" The agency had made outrageous errors and could



not handle the projects. I said, “Yes of course, I am happy to come back.” We both laughed, and I resumed working on that drug (which, by the way, never gained US Food and Drug Administration approval because of the risk of death). There are many other incidents I will not reveal here because it could violate confidentiality (ie, I don’t want to identify any person or company in particular).

My advice to other medical writers, whether freelancers or full-time employees: do NOT let yourself be intimidated into doing anything unethical with data. Don’t do it! It is bad for you, bad for your client/company, and bad for our profession. Just say no.

—Cathryn D. Evans

### Many Other Topics Were Discussed

During the 90-minute open session, a wide range of other pertinent topics were discussed, including the following items.

#### *Freelancers Being Required to Use a Client’s Email Address*

Make sure they aren’t misrepresenting your status as a freelancer; it’s too easy for companies to find out the truth, and get them to automatically pass your “company” emails through to your regular email address.

I have had to set up separate email accounts (usually through Microsoft Exchange) and thus separate email addresses for several clients. I generally dislike doing so and am not sure I really believe it when the client tells me that the email account with them is “more secure” than my personal email account. However, because they believe it is more secure, I pretend not to worry about exchanging proprietary documents or data with them via the client’s email address. (Note: My clients and I now mostly exchange sensitive documents/information via a password-protected Cloud site, primarily Box or Dropbox, or via a client’s own special document management system, such as Egnyte or Veeva Vault.)

I’ve had several negative experiences juggling multiple email addresses. The worst of these has been sending clients or vendors an email from the WRONG address (on the “From” line) by accident. With people who tend to “Reply All” (creating long email strings), it’s hard to correct or stop the chain reaction, even if you send a *mea culpa* afterward and ask for replies to be sent to the “real” email address. Another negative is remembering to check all your various email accounts for messages on a regular basis.

—Sherri Bowen

I have been asked by several clients to use their email addresses for correspondence, especially with faculty members. I am sure some reasons and situations make it easier for the client if the freelancer uses their company address. Some of the reasons may include an easier-to-remember address and consistency among members of a team. I usually don’t ask for a reason from my clients because it is straightforward to set up in my email software as well as on my phone. My inbox compiles all of my

email from multiple addresses, and I can respond using specific addresses.

—Ruwaida Vakili

#### *Being Offered a Percentage of New Business as a Fee in Lieu of More Traditional Payment for Helping a Client Win a New Account*

Do you really want their risk to be your risk, especially when a lot of the deal is beyond your control?

Clients are interesting. Every once in a while, I come across a client that offers me more business if they win the account. I am steadfast in my answer. I expect to be paid for all the services I provide. I have helped many clients win new accounts/business over the years. However, I always insist on payment for any work that I develop in addition to charging a daily or ½ day rate plus expenses to attend client pitch meetings. I always get paid and am also asked to attend or help with pitches again.

—Ruwaida Vakili

#### *Telling Clients That You Subcontract*

Being honest and transparent is always the best approach, especially if they don’t want their work subcontracted.

Subcontracting work to other freelancers is a great way to handle larger projects and expand your freelance business. Some clients are glad when you deliver high-quality work on time by bringing in other freelancers. Other clients only want you to do the work. So, we always need to ask our clients if we can use subcontractors on their projects. Whether you’ll be working on a project for a current client or a new client, mention subcontracting when you first discuss the project.

I’ve taken on quite a few large projects that I could never have completed on my own by the client’s deadline. In each case, I told the client when we were discussing the project that I’d bring in a team of freelancers—they liked this. But I also had one client that said no—they preferred I do everything, even if it took longer.

—Lori De Milto

I have addressed working with subcontractors in this column before—I couldn’t do most of my projects without subcontractor help, and my subs are invaluable to me! But I am always upfront about using subcontractors with my clients. Some of my clients have contractual language that subcontractors cannot be used (either at all or without written permission). In such cases, I either don’t use them or I get written permission when necessary. Clients sometimes ask how my subcontract billing works; this is a valid question, which I also answer honestly. The details of this could be the subject of another column, but the main thing to know is that all subcontractor hours are included in each invoice from me to the client.

—Sherri Bowen

Brian Bass is the President of Bass Global, Inc, Fort Myers, FL.

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## SWANBERG AWARD ADDRESS

*The Harold Swanberg Distinguished Service Award is named in honor of Harold Swanberg, MD, the founder of the American Medical Writers Association. The Swanberg Award is presented to an active member of AMWA who has made distinguished contributions to medical communication or rendered unusual and distinguished services to the medical profession. The Swanberg Award is presented during AMWA's Medical Writing & Communication Conference. The recipient of the 2019 Swanberg Award was David Clemow.*



## Expanding Horizons as a Medical Writer

**David B. Clemow, PhD, MWC** / Principle Clinical Research Scientist, Global Medical Affairs, Eli Lilly and Co, Indianapolis, IN

### Introduction

Thank you for awarding me the 2019 Harold Swanberg Distinguished Service Award. I am very honored.

As I begin my presentation today, please know that the content and opinions expressed are solely my own and should not be attributed to any employer or other affiliated organization.

Today I will touch on several topics briefly, but know that they could all be discussed in day-long courses too. I have learned a lot about medical communication along my career journey to date. It is these insights that I want to share with you all today. I am hopeful that today's presentation may inspire some of you to stay in the medical communication field, expand your horizons as a medical writer, and enjoy the journey along the way. Today I am going to be talking about careers, medical communications, medical writing trends, communication channels, data visualization, structured and component authoring, and competency and certification.

I am speaking about these topics from a pharmaceutical industry perspective, but I believe it is nevertheless relevant to medical writers in general. It may be beneficial to think of a medical communicator in the broad sense beyond what is traditionally considered "medical writing." Trends in medical communications are leading to the need for expanding roles and breadth of expertise for medical writers. Medical writers are communicating medical data and information via new modes of content delivery that I refer to as "channels" in this presentation. For context, 1 example would be digital video abstracts.

Data visualization is now a focus, and it is now often replacing text. Structured and component authoring are becoming a reality, and I will define these for you later in the presentation. Although the core competencies needed for a successful medical writer have not changed, new knowledge, skills, abilities, and behaviors (KSABs) may be needed, and certification for professional medical writers now exists. These topics will be discussed in the context that new opportunities are available for scientific communicators to expand their horizons as they mature in their careers.

### Career

I was asked to provide some details of my career background that led me to this stage, and I believe they make a nice segue into today's presentation topics. I earned a Bachelor of Science in Psychology at Iowa State University, but I felt that my undergraduate degree would not be useful without a postgraduate degree, so I pursued and earned a Doctor of Philosophy in Neuroscience at the University of Virginia. I wasn't sure being a laboratory scientist was what I wanted. However, I wanted to give the idea a full chance, so I completed a Postdoctoral Fellowship in Neurobiology at Duke University, which confirmed that I didn't want to work in a lab. So, I tried my hand at teaching at the University of Virginia, at a local community college, and at a few other institutions. I really enjoyed teaching, but I didn't think I wanted to do it full-time. I began to wonder, "What should I do?"

I knew nothing about medical writing at the time. Then I heard about it briefly from a fellow post doc who had recently gotten a medical writing job, and I thought ... this is perfect! It includes what I liked about my PhD experience, and it didn't have what I didn't like. I could be immersed in the science and presentation of research results in a variety of forms (manuscripts, oral presentations, abstracts, posters) while not having to work at a lab bench or be in a job that lacked daily variety.

So, I took a job as a medical writer at a Clinical Research Organization called Pharmaceutical Research Associates, where I wrote clinical study reports and protocols. Then I took a job as a medical writer in Global Scientific Communications at Eli Lilly and Company, where I wrote regulatory documents and publication documents of all types. Next, I took a role as a manager of a medical writing group with responsibility of staff oversight and development. I had a stint outside of medical writing in Lilly's Medical Affairs organization. I took subsequent roles as an operations and technical advisor for the medical writing department with responsibility for process, technology, and innovation. This all led to my second Global Medical Affairs role, with my current title being Principle

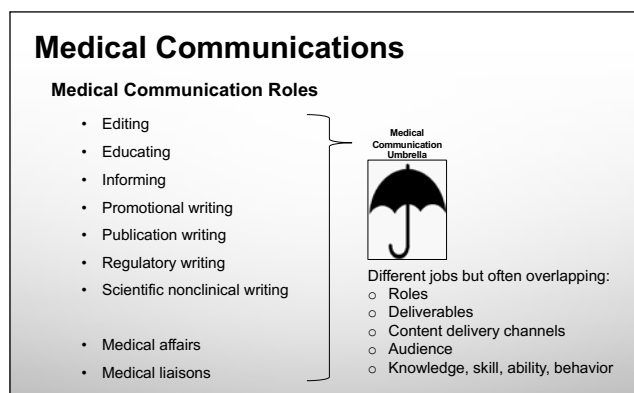
Clinical Research Scientist, Global Medical Affairs, Eli Lilly and Company.

You may be thinking, what is the connection between my career path and today's presentation? My medical affairs role had a significant overlap with a medical writing role: I authored protocols, publication documents, and medical information documents; I reviewed and approved cross-functional medical communication outputs; I added relevant KSABs and communicated clinical data and disease state information via new venues and channels (including advisory boards), promotional tactics (including print, Web, TV, and congress booths), and other promotional communications. I got the variety I was looking for and kept the scientific communications that in turn provided job satisfaction.

To bolster the day-to-day job variety and satisfaction, I have been involved in the medical writing external environment throughout my career. I have been a medical communications meeting chair, session chair, and/or topic presenter at both the American Medical Writers Association (AMWA) and the Drug Information Association (DIA). I have held leadership positions in both organizations. For example, I am currently the Medical Writing Certification Commission Chair for AMWA and am the recent past Chair of the DIA Global Medical Writing Community. Additionally, I have published several articles regarding medical communications, including on the topic of medical writer competency.

## Medical Communications

So, when thinking about medical writing careers, perhaps think about being a medical communicator in the broad sense. Think of *medical writing* as an umbrella term, in which communication equates to transmitting medical information beyond writing alone and in which medical editing or writing roles can be a subcomponent of multiple job functions that are involved in medical communication. Roles or jobs focused on medical communications content creation include medical editors, medical educators, medical information communicators, and medical writers who are promotion focused, publication focused, regulatory focused, or nonclinical focused.



Some jobs are focused more on direct-to-audience content delivery than on content creation, but a medical editor or writer can be involved in all these spaces, including delivery-focused areas like medical affairs or medical liaisons. In my medical affairs roles, I have heavily utilized my medical writing competency for editing, educating, informing, and promotional and publication writing.

Some roles may have unique competencies and KSABs, but core medical communication competency domains are relevant across roles: deliverables (manuscript compared with continuing medical education presentation); channels (scientific congress compared with television commercial); and audience (health care provider compared with patient). Thus, all these roles are generally involved in planning, creating, reviewing, and delivering medical communication content; they may just be doing it via different venues and channels. As such, moving from 1 part of the medical communication umbrella to another can be a way of maintaining career variety while expanding one's competency and skill sets, and thereby personal marketability.

## Medical Writing Trends

Pharmaceutical companies still submit content to regulatory authorities in static portable document format (PDF), which is the equivalent of e-paper. This method is extremely antiquated. For regulatory submissions, the industry is working toward providing digitized data tagged with metadata for interactive review. For publications, the industry is working toward moving from static to digital content, and by digital, I mean programmed or coded content. Digital content is not new for other industries communicating data, or even for marketing within the pharmaceutical industry, but it is new within the scientific medical communications umbrella.

Audiences do not have time to read voluminous content. On average, readers only read 20% to 28% of text-based content. Visualization is our number 1 sense for learning, bolstered significantly by interactivity. We only remember 20% of what we read but up to 80% of what we visualize and interact with; thus, as visualization significantly improves engagement, understanding, and retention, the trend is for visualization to replace text and long prose.

Component authoring, at a high level, refers to chunking content for reuse. Particularly for regulatory writing work, to handle the volume and variety of documents that contain much the same information, component-based authoring tools are now being utilized. This is not a new concept, but the standardization and technical advancement needed is finally making it a reality, and it will continue to become more robust over time.

Interactive data analysis and visualization tools such as Spotfire are now being used for clinical statistical analyses to aid data review and interpretation of study data and to enable





statisticians to deliver analyses and data outputs in new and advanced ways.

Finally, an increasing number of writers are getting certified, and certification is now being recognized by employers. Although not an absolute requirement, I would contend that to be a successful medical writer, you would need to have a working understanding of these topics with some level of expertise in elements relevant for your medical writing niche. Now I am going to provide a little more insight into each of these trends.

### Channels

As medical communicators in a time of advancing technology, our venues and content delivery channels continue to morph. For example, infographics and visual abstracts are becoming more commonplace. These new channels address data visualization needs and meet customer needs for concise summary information that provides take-home key points.

Venues such as scientific congresses are moving from paper to static e-posters and, eventually, to interactive digital posters. The future example shown here is advanced, but digitally based content for medical communications is now here and advancing in complexity and commonplaceness. Meanwhile, publications are moving in the same direction. A paper poster developed into a digital poster is another example of content moving to a digital channel. Digitization allows for inclusion of the following

- graphic design and data visualization principles,
- icons and infographics,
- video and audio,
- user interactive installations,
- computer-generated imagery (CGI),
- animation,
- augmented reality,
- virtual reality,
- gamification, and
- integration into Web and mobile applications.



In the future, medical communications will provide disclosure-ready tables and figures that can be used in component authoring across internal and even external medical communication functional groups. Through validated interactive

tools, customers will be able to customize the data visualization to meet their needs, removing back-and-forth communication, medical writer rework just to meet nuanced needs, and voluminous revalidation work.

### Data Visualization

Data visualization is moving from raster nonscalable and noneditable file formats to vector scalable and editable file formats, from static to animated and interactive tables and figures, and from content lacking data visualization principles to incorporation of visualization and graphic design principles. Data analysis and visualization tools like Tableau, Power BI, SAS VA, and Spotfire can help authoring teams with data interpretation when reviewing study data, which can aid authoring teams in figuring out what needs to be written. And, as noted already, content delivery is moving from electronic paper to digital formats.

One example is a key figure in a published manuscript reporting changes in the Psoriasis Area and Severity Index, which is a measurement of plaque psoriasis clearance. This static figure was published in the article and shows only the final portion of the data in PDF format. An animated version was published as a supplemental figure cited and housed online: <https://www.tandfonline.com/doi/suppl/10.1080/09546634.2018.1473551> (*Supplemental Figure 2; click play*). Every patient in the clinical study across 3 treatment groups is represented over time in this one animated figure. Data points are color-coded based on efficacy category reached and linked to stacked bars to aid in data summary. The animated manuscript figure is an example of data visualization. As medical publications become more digital, this figure would move from being supplemental to being embedded.

### Structured and Component Authoring

Document authoring refers to the writing of text-heavy documents. Structured and component authoring each utilize a different approach to medical writing. Structured authoring is a rules-driven writing technique to deliver simplified, focused content that increases readability and the ability to find information. Structured authoring enables component authoring.

Component authoring revolves around creating content in chunks with downstream reuse in mind. As mentioned, this is not a new concept, but standardization and improved technology is finally making it a realistic approach to authoring. It utilizes parent-child relationships and structured templates to make easy changes to documents and increases consistency across documents. Component authoring is necessary for content reuse platforms, and it enables the automation of document creation. A content platform is a software application that enables the integration of component content.

Structured and component authoring enable machine learning, artificial intelligence, and automation to aid in document development. This is particularly useful for regulatory documents, and indeed the current application is within regulatory medical writing.

A lot of the push for such ideas is related to searching for efficiency gains in a time when medical writers are continually asked to do more with less. Automation can accelerate content creation, increase consistency, and reduce resourcing effort. This requires doing work somewhat differently, but it is more about embracing innovation to allow the medical writer to focus on what is actually important, which is the writing of narrative that accurately describes their medical data and information while providing the key points.

### Competency and Certification

Competency means a person is qualified to perform a specific role, has the ability to perform that specific role successfully, and uses their KSABs to satisfactorily perform their role. A competency model defines the functions, tasks, and activities, as well as KSABs that define the profession.

When asked what is needed for a medical writer to be successful, I always respond that they have to be able to

- understand and speak the language of science,
- write a document (knowing what to include, how to include it, and where to include it to meet audience needs), and
- manage a project team that doesn't report to you and is often challenging (requiring good soft skills and people skills).

More recently, I have begun to add that one has to be able to understand the strategy behind communication plans, the different aspects of the medical communications umbrella, concepts of structured authoring, and data visualization principles.

Importantly, however, one cannot and does not need to be an expert on everything nor be an expert on all technology and tools. Take data visualization as an example. A medical writer should

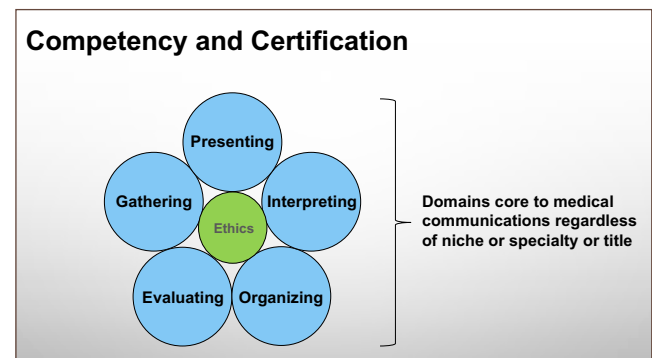
- know the best type of data display needed for the data or information being conveyed;
- understand and advocate use of data visualization and basic graphic design principles;
- hand off creation of the data visualization to a data analyst, graphic designer, or digital creator; and
- learn how to create basic low-complexity visuals such as basic infographics or visual abstracts, or, at a minimum, know who can do it for them.

Certification tests an individual's competency, which requires professional experience, and involves a formal assessment process leading to a professional designation. AMWA's Medical Writing Certification Commission (MWCC) in collabora-

tion with a testing agency, developed the Medical Writer Certified (MWC) credentialing program that is an exam-based professional certification. Professionals who hold this credential have demonstrated their understanding of medical writing core competencies through successful completion of an examination. To be eligible for the program, the medical writer must have at least 2 years' experience. The program also requires continuing education for recertification. All of this shows a medical writer's dedication to their profession and identifies a professional medical writer compared with someone just looking for a job.

Certification is awarded by a third-party standards organization. The standard is set via a defensible job analysis process that outlines the required knowledge and skills necessary, but not sufficient, to be competent. An individual's competency is measured by a standardized test.

The DIA Medical Writing Competency Model is linked to the MWC examination. Certification examination domains and the associated knowledge tested is based on the competency model, which can be a great road map to expanding horizons for beginners, for those changing their specialization area, and for those wanting to expand their development plans. The certification domains focus on gathering, interpreting, evaluating, and presenting, with the topic of ethics built into each domain. The KSABs associated with these domains are core to what all medical communicators do, regardless of their niche or specialty or job title.



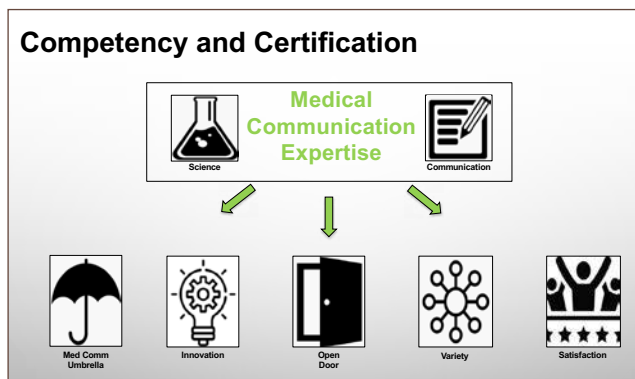
The certification examination tests a medical writer's core foundational knowledge needed for success in the workplace and shows a medical writer's breadth of knowledge. Successful certification provides a designation (credential) to use with one's name. Ongoing requirements are needed to maintain the certification, which provides robustness over time.

Certification can look good on a medical writer's resume and is now showing up in job postings under preferred qualifications.

So, I recommend that medical writers be medical communications experts in addition to being medical writing experts. Learn what is under the medical communications umbrella and embrace innovation. This can keep career doors open,



which is nice, even if you choose not to step through, and it can bring variety to career paths while keeping medical communications and medical writing a core focus, which can lead to a high level of job satisfaction.



### Summary

Working across medical communications roles brings variety to the job. There is a medical communications umbrella that is made up of medical editing, education, and information; promotional, publication, and regulatory writing; and medical affairs and medical liaison activity.

Medical writing trends include increasing digital content, data visualization replacing verbose prose, viable component-

based authoring tools, interactive data analysis and visualization tools to aid clinical study data review, and medical writing certification.

Medical content delivery channels are increasing in variety and complexity. Ensuring the integration of data visualization and graphic design principles in medical communications content is important. Structured authoring can help focus written content, and component authoring can enable efficiency through content reuse and automation. Strong medical communications competency opens doors. Certification shows professional dedication, and employers are starting to recognize it.

Embracing innovation trends is important for staying competent, competency in overall medical communications opens doors to opportunity, and medical communication expertise can expand horizons for medical writers and other medical communicators.

In closing, let me again thank AMWA for the honor of this Harold Swanberg Distinguished Service Award and for allowing me to share my thoughts with you today.

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

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## WALTER C. ALVAREZ AWARD ADDRESS

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AMWA President Ann Winter-Vann presents the Alvarez award to Daniel J. Siegel.

Photo credit: EPNAC.com

# Aware: The Science and Practice of Presence

**Daniel J. Siegel, MD<sup>1,2</sup>** / <sup>1</sup>Clinical Professor of Psychiatry, School of Medicine, University of California, Los Angeles, Los Angeles, CA; <sup>2</sup>Executive Director and Cofounder of the Mindsight Institute, Santa Monica, CA

Thank you so much to the American Medical Writers Association, to all the wonderful people in your administration, and to all of you for being here.

In this short time, we have an opportunity to talk about not only the experience of writing but also the experience of writing for professionals, for people in the clinical world, for scientists, for people in organizations, and for the public. And we're in an incredibly important moment in our experience as part of humanity, in which writers have a very important role to play in terms of how human beings come to understand themselves, the way they relate to their inner life, the way they relate to other human beings, and the way they relate to all of nature, the planet. And in many ways, that perspective of how you relate, how you communicate, how you understand, how you connect with those 3 things—the inner world, the interpersonal world, and, if you will, the intranature world—has everything to do with where we've come as a modern society.

Writers play an incredibly important role in shaping what a person (whose name I can never pronounce because I don't speak French, but it's "Pierre Teilhard de Chardin") wrote about something called the noosphere, which is the atmosphere of knowledge, of information. And this atmosphere of knowledge, the noosphere, is the way we know things, from, I believe, the Greek. So, *noesis* is the Greek term for how we know things, *gnosis* is the Greek term for how we believe things, and this noetic view of how we come to know things in culture has everything to do with what writers do.

My hope is in this very brief time together that we'll be able to talk about some things that may actually support you in your inner journey as a writer and in what you do in your interpersonal work because, after all, mostly you're writing to human beings (I don't know if your dogs are reading the writings, but it's usually to people), so that's a part of the interpersonal relationship. But what you do actually influences how human beings are a part of nature.

If you just think about what Greta Thunberg has inspired with "Fridays for the Future"—and, incidentally, today is a Friday—you know that we are at a turning point on this planet and that the way people come to understand our role in influencing the future of life on Earth is not just some intellectually interesting cultural phenomenon (which it is), but it's actually a matter of life and death.

In writing that, then we come to the inner experience you have when you're writing for human beings: for example, how what they do impacts the planet (that's the nature part). You could say, "Well, I actually am struggling with this because I'm feeling incredible amounts of something I don't even know how to articulate."

At breakfast this morning with your wonderful leaders, I was mentioning that recently I was asked to go to 2 schools that happen to be literally across the street from each other. One was a high school and one was a medical school. In both cases, the students in those schools were killing themselves (literally—jumping in front of a train or using other ways of ending their lives), and so I was asked to do an intervention independently at Stanford Medical School and at Palo Alto High School across the street from Stanford University.

On our website ([www.drdansiegel.com](http://www.drdansiegel.com)), if you go to Resources and go to the videos, you can see the video that the students made of the intervention (I have their permission to use it) talking about what's happening in modern culture, in which we have higher rates of suicide than we've ever had. And if you look at the recent reports from the Mayo Clinic and related organizations, of physicians in human medicine and also animal medicine (veterinarians), more than half have serious clinical levels of depression, anxiety, and suicide.

So, at Stanford at the medical school within the nursing department—and also within the nursing school there—we talked about what is going on that leads to this problem. And I didn't go to Stanford for medical school; I went to Harvard, the



Stanford of the East. (I shouldn't say that, but my mom graduated from Stanford, so whatever they do is their rah-rah thing.) I'll just say this: they have this same issue where they asked me to come to speak.

These are the questions I'm going to try to address in this short period of time. I have a bunch of slides that I'd love to show you, primarily because my daughter did the drawings, and she's a graduate student now in environmental science, and I'm so proud of her. We may get to a few of them that are in the book, *Aware*, but usually the shortest talk I give is about 8 hours, so this is really a challenge to give a short 20-minute talk. We're going to try to define what the mind is—what is a healthy mind, and how can we cultivate a healthy mind and a healthy world? And I'll invite you to consider that the important work you do as medical writers, whether it's for organizations on regulation or whether it's actually writing for the professional audience of physicians or scientists or translating that for public consumption, is all about these questions.

### Basic Questions:

What is the Mind?

What is a Healthy Mind?

How can we Cultivate a Healthy Mind  
and a Healthy World?

Mind Your Brain, Inc., (c) 2018

You might be shocked to find (and this is now addressing more of the “looking at what it means to be a writer”) that, for me, after I was trained in research but before I had ever written anything really, I was asked to be the training director in child and adolescent psychiatry at the University of California, Los Angeles. It was the beginning of the Decade of the Brain, 1990, and I was done with all my training—I was board-certified in this and board-certified in that—so I was finished, and now they were asking me to run the educational program. At that time, it was the largest training program for anyone working clinically with children and adolescents, so I felt really responsible because I had gone through that training.

But then when I was starting to take on that role, I realized something was missing, and if you look at this first question, that's what was missing. I was board-certified in everything you could be board-certified in, and this is about psychiatry and the psyche. *Psyche* is the Greek term for the soul, the spirit, the intellect, or the mind; it's the specialty of medicine that deals with the mind. So, you would think that a specialty focusing on

the mind would know how to say what the mind is, wouldn't you? Yes or no? Yes ... at least that's what I thought.

And I went, “Whoa, hold on! No one's said what the mind is!” So I brought 40 scientists together from all over the campus, because I had been an interdisciplinary research fellow through the National Institute of Mental Health, and I brought all of my teachers who were now my colleagues together, and it was the beginning of the Decade of the Brain, and we said, “What is the connection between the brain and the mind?” And I wrote a whole book on this 1 set of meetings we had, and the book is called *Mind*—that's it, just *Mind*.

Because this is the weird thing...the field of psychiatry does not say what the mind is, the field of psychology does not say what the mind is, the field of education that helps minds develop does not say what the mind is, and even the field of philosophy (which includes the branch of philosophy of mind) not only doesn't say what the mind is, but it also says you should never say what the mind is. These are my dear friends! I said, “Well, why shouldn't I say what the mind is?” They said, “Because it's a philosophical error.” I asked, “Well, how's that an error?” And they replied, “Because if you say what it is, you'll limit your understanding of it, because words never really do the thing.” So, then, I guess we should all just stop writing and just be quiet, silent.

Okay. So, the point of all that is when you're a writer like you are, it's important to realize that words are both limiting and liberating, and being humble about that as a writer is very important. Now, this was before I ever became a writer, but it was when I was an educator—which is similar to being a writer—and I decided that I wasn't going to do to my students what was done to me, which was only to talk about disorder and dysfunction, kind of like the whole field of medicine.

This issue of the mind is very interesting, because, of course, Hippocrates (the grandfather of modern medicine) defined the source of our joys and sorrows in a book on epilepsy called *The Sacred Disease*; what did he say—does anyone know from 2,500 years ago? Because he did offer a definition of the mind, basically. He said it just has to do with the activity of your brain. And he made the point in that book of saying ONLY the activity of your brain. So, for 2,500 years, the field of medicine has used the word “mind,” based on Hippocrates' writings anyway, as a synonym for brain activity. And then in 1890, William James, the grandfather of modern psychology, affirmed what Hippocrates had said thousands of years earlier.

If that's true, if the field of psychology and psychiatry are really the study of brain activity, why in the world would we need a separate word? We should keep things as simple as possible; let's just say it for what it is: brain activity.

Well, one reason is because we have this really amazing thing called subjective experience. And when I was a biochem-

istry major in college looking for the enzyme that lets salmon go from being hatched in fresh water to surviving in salt water, and we found the enzyme, I was so interested in that. But at night, I would work on a suicide prevention service, and I was taught as a young adolescent that the way you tune into the subjective experience of another person—their despair, their sadness, their memories, the way they are having intentions of killing themselves or not—makes the difference between whether they actually commit suicide or not. If I were on the phone with a person on the suicide prevention service and said, “You know something, I think your serotonin levels in your prefrontal cortex are probably lower than the average when you statistically calculate how many people have that serotonin level. You ...” boom, they would end their life.

Identifying the neural processes that are correlated with mental subjective experience is an exciting area of research, and a lot of my friends do it, and I think it’s awesome, but to equate neural firing patterns with subjective experience is a scientific error that has been made for thousands of years and continues to dominate a certain ... attitude—let’s just use that diplomatically—within academia.

So, when I was in medical school—I was telling this story this morning at breakfast—before I dropped out of medical school, a patient of mine had died, and my resident came to get me as a student. We went to sit by the corpse, and we were both crying with the nurse who had helped to take care of Mr Smith for all those weeks until his dying day. The attending says to me afterward, “You left rounds, why did you leave rounds”? I said, “Oh, Mr Smith died; we were taking care of him for 6 weeks, it was really sad, and we wanted to take some time and just collect ourselves as we said goodbye to him.” And this chief of oncology at Harvard Medical School says, “There’s no time for tears.” So, for the next 6 weeks of this very important rotation, my emotional life disappeared from my awareness, and I learned how to be a robot like him. I got the highest mark, he told me, in the whole rotation, which was useful for my resume and horrible for my psyche.

The socialization process of medicine is to tell you that there’s no time for tears, there’s no time to accept the feelings you have, to see that death is actually a part of life. But instead, what you do when you aren’t aware of the emotional meaning of that, the subjective experience of that process—hear the static you get? This is the static that happens in medical socialization, seriously, because in the background, you have the emotions of someone’s life. Imagine that professor saying to a young student, “There’s no time for tears.” We now know years later that, in fact, physicians who attend to the subjective experience of the patient even if they’re coming for a common cold—this is a controlled study that you can see was published

in 2011<sup>1</sup>—have patients who get over their cold a day sooner and have a more robust immune process.

It’s malpractice, you could say, to have a physician who’s not in tune with the emotional life of others, and the way we know that from neuroscience is you need to be aware of what’s happening inside of you. So when you create an entire profession—not in every program but in the vast, vast majority of them—in which a person isn’t aware of their internal world of subjective experience, including emotion and meaning, the research shows that they burn out faster and they’re more likely to be depressed, anxious, and suicidal. Whether you consider veterinarians, who now have the highest suicide rate of any profession, or physicians, who also have a very high rate—more than half of them are clinically disturbed mentally—we have a serious problem.

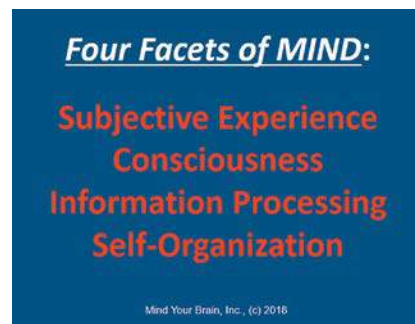
The simple thing to say from this first point of this slide is that by not saying that the mind includes subjective experience that distinguishes it from the brain, we are actually mistreating trainees in the field of medicine. It is a trav-

esty that a medical, caring profession has more than half of its people in massive amounts of suffering. Not only is that bad for the physician, but think of how bad that is for their patients.

At the Mindsight Institute, we actually offer a definition of the mind, unlike the philosophers or psychiatrists or psychologists. We actually say what we think the mind is; it’s a definition from 1992, so it’s been around a long time. Then from that definition, we offer a definition of a healthy mind. And then from that definition we ask, “How do you cultivate that healthy mind, and how is it that a healthy mind might actually make a healthier world?”

That’s why usually these talks are 8 hours long, so we’re not going to get into all that. But I do want to look at a couple of fundamental issues.

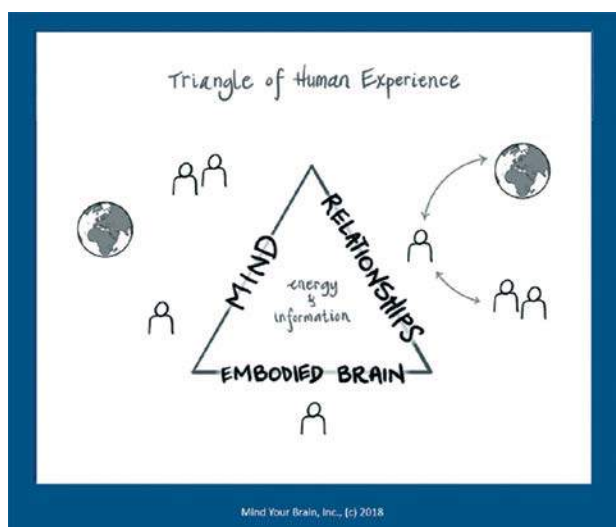
The field of interpersonal neurobiology that began in that 1992 meeting basically says that if you brought all the fields of science together—math, physics, chemistry, biology (including neuroscience and genetics), psychology, sociology, linguistics, anthropology, and everything in between—and you made one framework that built on the beautiful, hard-earned findings from the independent disciplines, what would that look like? We call that—I had to think of a name, so I named it—*interpersonal neurobiology*. If I had to do it all over again, I would absolutely not use that name, but now with the 70 textbooks under that name, no one’s going to let me change the name. And the





reason I would change the name is because it's not actually neurobiology. And since then, a new field has come out called social neuroscience. And people think they're identical, and they're not at all. Social neuroscience is a branch of neuroscience, which is a branch of biology; interpersonal neurobiology is just 2 words that indicate a framework embedding all the sciences into 1 perspective.

So, in that view, the fully embodied brain is the inner part of your life, and the relationships are your connections with other people on the planet. And one take-home message from this slide is that modern culture—including science, including medicine, including everything you write about—has had a word, *mind*, that, whether you know it or not, has been made a synonym for brain activity. And one of the products of the mind is the self, and that limited perspective of “mind equals brain activity” means the self only comes from inside your body. Let's just name that with a word: the “separate self” or the “solo self.”



You, as medical writers, have an opportunity to actually change the course of life on Earth, and here's how you can think about it and see whether this fits with what feels real to you or not. One way of understanding what's happened on Earth is that contemporary culture has equated the self with the body. That separate self may be not only from a scientific point of view, a limited view—that's a really diplomatic way of saying it. A little bit less diplomatic way of saying it is that it's a partial truth, an even less diplomatic way of saying it is that it's wrong, and an even less diplomatic way of saying it (that's probably more accurate) is that it's a lethal lie. You choose how you want to describe it.

Why is this limited perspective a lethal lie? It's a lie because it's not true and people are saying it as if it is true: “the mind is the brain” or “the self is separate.” And it's lethal because of the way human beings are treating each other across racial divides.

Racism, in America, is based on this idea that self is only this body or people who have bodies like this with the same skin color, or the same religious belief, or like that. Racism is based on this lethal lie of a separate self.

Look at climate change issues. Look at a deep analysis of the ecology of climate change on this planet, the excessive differentiation of human beings thinking they are not a fundamental part of nature, that they're separate. The key thing to do before you die, to have meaning in your life, is to get as many toys as possible. To get those toys, I need to earn a lot of money—I think I'll make a factory. Okay, I'm going to build a lot of stuff and get people to think they need to buy the stuff I build, so they can then give me the money, so I can get more toys and then give those to my kids, so then I'm going to feel like I had a meaningful life. And now I take my factory, and I don't care about the ocean around the factory or the forest around the factory—just burn it down and pollute it. Who cares, because I got a lot of toys? Does that sound familiar?

The pathway of contemporary culture with that kind of mentality is about to destroy life on Earth. As Edward O. Wilson, a professor emeritus at Harvard, says in a book called *The Meaning of Human Existence*, part of the problem is that human beings, as a species, rely primarily on 2 sensory inputs: sound for hearing and light for seeing. Wilson says that this reliance is such a sensory limitation that it gives us the illusion of separation. And years before Wilson wrote that, a separate scientist, someone you know named Albert Einstein, wrote that the problem with humanity is that we have—and these are his words—“an optical delusion of consciousness” that we're separate from the rest of nature. So, whether you call it a delusion, which is a psychotic belief, or you call it an illusion, which is an inaccurate perception, either way it's wrong.

Here's what I'm suggesting we consider: that in our work and in our lives, we challenge the error of modern living—which says that the self is separate or the mind is the brain—in a loving and gentle and supportive way, realizing this just like I did when I was in medical school (when I didn't grab my professor and say, “You aren't recognizing the mind!” Maybe I should have, but I didn't), and slowing trying to introduce new ways of thinking so that people can embrace them.

This hidden lie of a separate self is actually making individuals profoundly stressed. If you look at your own burnout, or you look at the veterinarians or physicians who have a high suicide rate, what do they describe? They describe not belonging; they describe not feeling connected; they describe feeling isolated. The problem with that is that we are a profoundly social species. So, the linguistic term *self*, like any linguistic term (you probably know this), is the surface level that has an iceberg beneath it of concepts and categories that are usually not reaching the light of consciousness.

Let me just get to one more thing; I want to make sure you have something useful, not just conceptually but for your personal life, because I was told there's a lotta, lotta stress.

Now, you're not the only ones who are being stressed. I just did an immersive weekend conference on emotional resilience teaching with Dr Elissa Epel. And you probably know Elissa's beautiful book, called *The Telomere Effect*, that she wrote with her colleague, the Nobel Prize winner Dr Elizabeth Blackburn. So, in that intensive weekend, Elissa and I dove through the science of resilience and what the participants could do—and you can look at our work and you can see what we do. But in the evening, the retreat center asked us to do a public event on climate resilience, which isn't related to what we're doing. What do you do with your emotions on this?

So, one of the things we talked about are in these slides, and this is how I'll end the short talk. Wilson has a great term that you probably know from his 1998 book *Consilience*—*consilience* is a word for when you find common discoveries across independent pursuits. When you look through a long line of reasoning, gathering all these fields of science together, you come up with 2 shared views—2 consilient findings—across all the different disciplines. Number 1 is that to have change, you need to invite consciousness to participate. When people read your writings, hopefully they are conscious of what they're reading, and so you have an opportunity in your writing to actually invite change. That's number 1: consciousness is needed for change.

## Consilient Ideas

Mind is an Emergent Phenomena of a Complex System of Energy Flow.

Sometimes that Energy has symbolic value, and is "Energy-In-Formation" known simply as **Information**.

Emergence arises from the interactions of elements of a complex system, i.e., from the flow of energy within *embodied* activity and *relational* communication

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## Two Consilient Ideas Combined

- 1. Integration is the basis of **HEALTH**
- 2. Consciousness is needed for **CHANGE**
- 1 + 2 = Integration of Consciousness

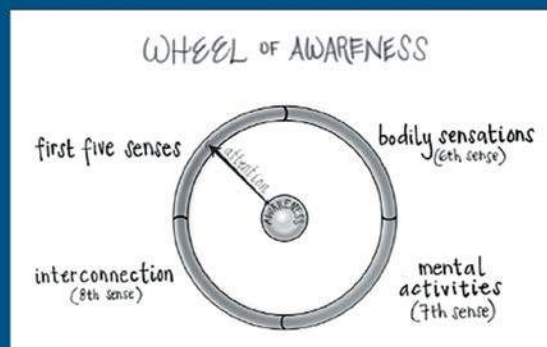
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Number 2 is when you ask the question. Now, there's a whole book called *The Developing Mind* (it's a textbook for graduate school), from which I've reviewed more than 2,000 papers to support what I'm about to tell you. But if you look at that book, it says—and this is the second consilient idea—that health emerges from a process we can call integration. Integration is simply defined as aspects of a system, whether it's your brain or your body, or your relationship with your spouse or your kids, or a society or a planet. Aspects of that system are differentiated and then linked to each other. When you balance that differentiation with the linkage—there's no name in math for that but we'll call that integration—integration looks like it is the fundamental mechanism of health at any level of system analysis.

Now, if that's true, if you combine the 2, how would you then take "consciousness is needed for change" and "integration is health" and actually in your personal life after this talk today try to integrate consciousness?

There is a table in our office; it has a glass center and an outer rim. I would bring my patients into the office back in the early 90s, and I would say, "Let's integrate consciousness and see if we can get something happening with that." They'd say, "What are you talking about?" I would say, "Well come on, come off the chair, off the couch, walk around this table. Let's place the knowing of being aware, the knowing of consciousness." For example, if I say, "good morning," how many of you know I said "good morning"? Right, raise your hands. So, you have the sound "good morning"—we'll put that on the rim of the table as a sound. But then you also have the "knowing" of it, and we'll put that "knowing" in the hub. The hub represents the knowing of consciousness, the rim represents the knowns, and a metaphoric spoke, which is the thing holding up the table, is the focus of attention.

## Integrating Consciousness



AWARE by Dr Siegel Copyright (c) 2018  
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Madeleine Welch Siegel



So, I worked with my patients to differentiate all the knowns from each other and from the knowing, and then we explored the knowing. In doing so, mild-to-moderate depression got better, anxiety got better, and trauma was helped a lot. People with life-threatening diseases could face their diseases with more equanimity. People who were burnt out at work stopped being burnt out. It was remarkable.

Then I taught my students who are therapists. They themselves found improvement with it; their clients got better. So, then I said, "Okay, well now I'll try to doing it with people who don't know me as my patients or my students—I'll try it with workshop participants." And so, I did it, and because I'm a scientist, I recorded all the results. I did the first 10,000 people, had them say what it was like, and then I had to try to find a scientific explanation.

You can find the explanation in a book from years ago called *The Mindful Therapist*. (They wouldn't let me put it in a book called *Mindsight*; they said it was too weird.) But over the course of the years, once these kinds of things became accepted, people actually stopped telling me what I could or couldn't do. So, then I put it in a book called *Mind*, and then the deepest discussion of it is in the last book, called *Aware*. (You can go to my website, for free; go to Resources.)

The bottom line of all that is that if you do this practice, which integrates consciousness, you get these 3 things that are built into the practice, fortunately, that science has shown give you positive effects in your life. You're going to strengthen your capacity to focus attention; you're going to open up your awareness as you build up that hub of the mind. So instead of your consciousness being the size of an espresso cup when life dishes you out a challenge like a tablespoon of salt to absorb, now you've cultivated and expanded your consciousness to like 100 gallons in size, so when life dishes out a tablespoon of challenge, it's diluted in that expansive consciousness.

And then you build kind intention. And here's what I want to inspire you with, which is this last slide we're going to show. This is the Three Pillar Practice. Those are usually done on separate kinds of practices, but the good fortune of the Wheel is that it has all 3 in one practice, which we can't find in any other practice. But the research that's actually been done to show the findings in this slide are in peer-reviewed journals of the highest caliber in the world; the Wheel just happens to have 3 of the 3 that are shown to be needed.

So, what does it do? Number 1, if you do Three Pillar Practice—and the Wheel hasn't been studied like this, but it has all 3 in it, so it should work—but if you do Three Pillar Practice, you will change the structure of your brain.

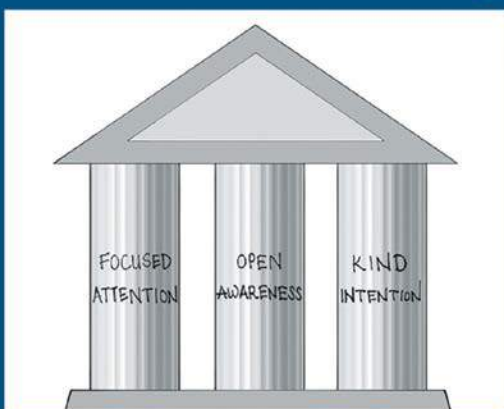
How? You will grow integrative structural changes; for those of you who like brain areas, the corpus collosum will grow, the hippocampus will grow, the prefrontal cortex will grow, and your connectome will become more interconnected. Don't worry about all that. The bottom line is that anything you're going to regulate—like attention, emotion, mood, thought, memory, morality, relationality—is all related to integration of the brain.

If you look at Smith et al,<sup>2</sup> integration of the brain is the best predictor of well-being, of any measure of well-being they could find. Integration of your brain is the best predictor of your well-being. And now I'm telling you that there's a Three Pillar Practice that science has demonstrated to integrate your brain.

If this were a pill that did this, you would take it in a heartbeat. And it doesn't even have negative side effects; you just have to do it. So that's amazing!

And then the final 5 things are physiological changes. If you told me 15 years ago that I'd be up here showing you peer-reviewed scientific journals publishing these 5 findings, I would say you're out of your mind (now that we've defined the mind, we can say you're out of it). But it turns out you're in your mind. These are from time and practices. So, if you

### Three Pillars of Mind Training



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### Three Pillar Mind Training Findings:

- 1. **Integration** of structure and function of Brain
- 2. **Reduction in stress** hormone, cortisol
- 3. Enhancement of **immune** function
- 4. Improvement in **cardiovascular** risk factors
- 5. **Reduction in inflammation** via epigenetic changes
- 6. Optimization of telomerase—Repairs and maintains ends of **chromosomes**—**Slows Aging**

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start doing Three Pillar Practice after this talk on a regular basis—just like brushing your teeth regularly will preserve your teeth—you do the Three Pillar Practice, and you will reduce stress; you will enhance immune function (these are literally blood tests to see if your immune function will be better; Richie Davidson's lab and other people have done that); you will improve your cardiovascular risk factors (lower cholesterol, lower blood pressure, and, in fact, make the heart communicate with the head in a more balanced way, which you can measure with heart rate variability coherence); and you will reduce inflammation in your body and your brain by altering the non-DNA molecules—the epigenetic regulators like histones and methyl groups—that change the configuration of part of the gene that regulates inflammation. (What you do with your mind will literally change the epigenetic controls to reduce inflammation. I'm not kidding about this.) And, if you do these practices, the research suggests you are very likely to optimize an enzyme called telomerase (this discovery earned Elizabeth Blackburn the Nobel Prize). You will optimize an enzyme that repairs and maintains the tips of your chromosomes—the ends, the telomeres.

When I sent the manuscript of *Aware* for Elissa Epel to just review it, she wrote me back, saying, “Dan, did you send it to the printer yet?” Now, as a writer you know what that feels like. And I said, “Elissa, in 2 days it's going to the printer, what's up?” She said, “You left something out.” And I said, “Oh! Oh my god, not another chapter I have to write?” She said, “No, not another chapter. Everything you said is accurate, everything is very accurate, but you left something out.” I asked, “What did I leave out?” She said, “You have to say it slows the aging process—the Three Pillar Practice.” I said, “That's audacious, how can I say it?” But this is Elizabeth Blackburn, the world's expert within aging, right? She said, “Because we've proven that; you need to say that.” So, I put it in because she told me I had to.

So, you will slow the aging process, probably by accumulation of all these things: reducing inflammation, improving cardiovascular functioning, enhancing immune function, reducing stress, and optimizing regulation because you're integrating the brain and changing the structure of your brain.

Let me ask you something. Do you care enough about yourself, as inner and inter as that may be, to start doing this on a daily basis? Do you care enough about your teeth to brush your teeth every day? Just like you know 100 years ago people didn't brush their teeth and their teeth fell out, and now you are brushing your teeth every day, if we can get you to mobilize yourself to do a practice like the Three Pillars or other ones (in the Wheel you get them all in 1 practice, so it's a useful way of doing it), the research shows are very likely to get these positive results.

The final thing I'll say is that if you integrate all of this into your life, what people have described is this—without it being a goal, without it being something that's trying to be achieved—the reports are something like this:

You know, I feel much clearer. My burnout has gone away. I'm not anxious. My depression has subsided. I feel really alive; I feel vital; I feel energized. And something else has happened: my feeling—it's just a feeling of who I am, of what my self is—is not just isolated and disconnected; it's not just in me. I'm a part of other people, I feel a part of nature, and I even feel a part of life that happened before I was born and life that will exist afterward, so I have a deeper sense of meaning and purpose in life that goes beyond the time I get to live in this body.

Now, what's the word we use for that kind of relational self? So, you don't want to get rid of the inner self, you want to sleep your body well, exercise your body. But that's a “me.” But in addition to the “me,” you're also a “we.” So, the fun way that we'll end this talk is with that: we can integrate me plus we, because in integration you don't lose the elements; you bring them both together: me plus we equals “MWe.” And when people start living in an integrated self as a me plus we equals MWe, then the world becomes more meaningful, more connecting, and together MWe can see ourselves as writers in the world, as educators to support humanity finding a more integrated way of being compassionate and kind and seeing our way through the challenges ahead.

Thank you so much for your kind attention.

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

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## JOHN P. McGOVERN AWARD ADDRESS

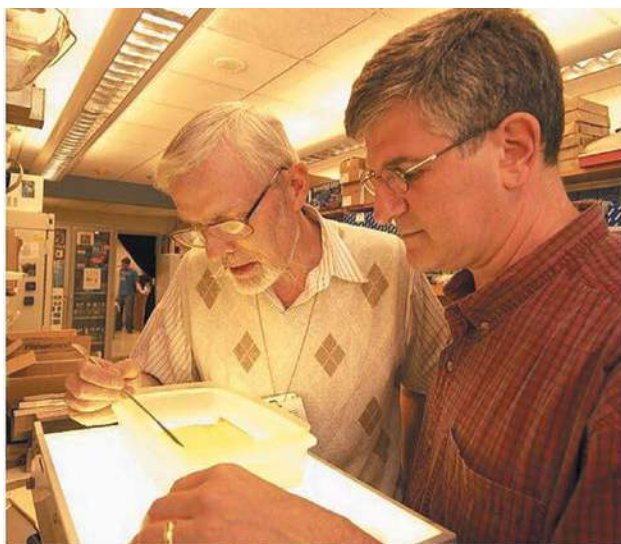
*The John P. McGovern Award is named in honor of John P. McGovern and is presented to a member or nonmember of AMWA to recognize a preeminent contribution to any of the various modes of medical communication. The McGovern Award is presented during AMWA's Medical Writing & Communication Conference.*

# Reluctant Advocacy

**Paul Offit, MD** / Maurice R. Hilleman Professor of Vaccinology, Professor of Pediatrics, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA

Thank you for this award; it's very kind. I was asked to speak about how I came into medical writing, which was reluctantly, so let me tell you how I got there.

Although trained in pediatrics professionally, I am, for the most part, a viral immunologist. I worked for 25 years trying to identify what parts of rotavirus induce protected immunity and what parts of rotavirus make you sick. In doing so, we created strains that eventually became the bovine human reassortment vaccine, RotaTeq, which was licensed for use in all children in this country in 2006 and for all children in the world in 2013. It was a team effort; the key member of the team is Dr Fred Clark, on the left. So, that's really how I saw myself—as a viral immunologist.



H Fred Clark (at left) and the rotavirus vaccine project.

What happened to me, what got me out of the lab for better or worse, happened in 1998. I was asked to be on the Advisory Committee for Immunization Practices, which is the major recommending group for vaccines in the United States. And between 1998 and 2000, there were 3 big hits to vaccines. One was that Rota Shield was removed from the market. It was the

first time a vaccine had been taken off the market because of an issue of safety in 50 years.

Second, it was discovered that there was an ethylmercury-containing preservative in vaccines called thimerosal. Basically, the public health service put a gun to the head of the pharmaceutical industry and said, "You're going to have to take this out of all vaccines as quickly as possible." It really scared people and, frankly, created antivaccine groups.

And third, Andrew Wakefield—and this is a story you know all too well—published a paper claiming that the combination measles/mumps/rubella (MMR) vaccine caused autism. On that committee, we, as voting members, were actually asked to vote on whether or not we should divide that vaccine into its 3 separate parts because that's what Andrew Wakefield thought would end the autism epidemic.

I think what struck me in all this was that I didn't see scientists standing up to address this. Certainly, the American Academy of Pediatrics stood up. They had pediatricians. They got out there and said, "You know, vaccines are good; vaccine-preventable diseases are bad. You know, we vaccinate our own children." But I didn't see anybody addressing the science.

Certainly, the epidemiology exonerated ethylmercury as a cause of the problem or exonerated the MMR vaccine, but I didn't see people saying, "Here's why it didn't make any biological sense that that would be true." I thought that was our job as scientists to do that, and I didn't think we were doing it.

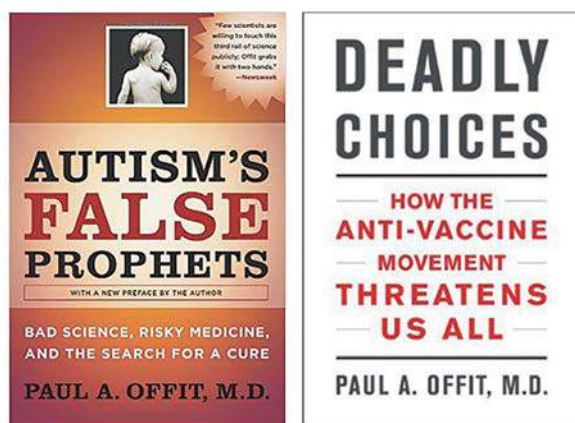
That got me interested in trying to explain science to the public. So, initially I took a somewhat safer route—I wrote a couple of books. One was called *The Cutter Incident* about a polio vaccine that was made badly in 1955 when Cutter Laboratories failed to inactivate their polio vaccine. As a consequence, about 120,000 children were inoculated with live, fully virulent polio virus. Approximately 40,000 of these children developed abortive polio, 164 developed permanent paralysis, and 10 were killed. I think it was one of the worst biological disasters to ever happen in this country's history, and it gave birth to vaccine regulation.



Photo credit: EPNAC.com

The second book that fell into the category of just trying to explain the science of vaccines was a book about Maurice Hilleman called *Vaccinated*. Dr Hilleman, who most people don't know, was actually the primary researcher for development on 9 of the 14 vaccines that we currently give children. He was diagnosed with disseminated pancreatic cancer, and he was kind enough to let me interview him for the last 6 months of his life because I didn't want to lose those stories. I thought it was a better way to explain the modern vaccines with this man's voice.

Where I think I crossed the lines was with these 2 books—*Autism's False Prophets* and *Deadly Choices*—because now I wasn't just a scientist anymore. Now, I was sort of pulling back the curtain explaining what was motivating the people who were antivaccine. Who was funding them? Did people know that Andrew Wakefield had a patent on a safer measles-containing vaccine? Did people know that he'd received hundreds of thousands of dollars to essentially launder legal claims through a medical journal? And with that, I put an X on my back. As a scientist, I was now forced more into being in the media.



Crossing the line from science to politics.

I guess for the rest of this talk, I just want to tell you about all the mistakes I've made basically being in the media, so you won't have to make the same ones. For example, I had to appear in front of Dan Burton's committee on government reform. I was on many morning and evening news shows including this news show—*CBS This Morning*. And then, I had to be interviewed by Samantha Bee on *The Daily Show*.

So, here are the challenges that I've learned. In general, scientific training is the opposite of media training, and here's some examples. I think one challenge is the scientific method. So, for example, when Andrew Wakefield wrote his paper claiming that the MMR vaccine caused autism, it basically described 12 children, 8 of whom had developed autism within a month of receiving vaccines. (By the way, anybody who's interested in doing epidemiology, you should always have

more study subjects than authors—just as a tip.) The best thing you could say about this paper is that he raised a hypothesis. As you know, the way hypotheses work in science is you create the null hypothesis. So, in this case, the null hypothesis is that MMR vaccine does not cause autism.

You can do 2 things with that null hypothesis. You can reject it, which is to say that when autism follows receipt of the MMR vaccine it occurs at a level greater than would be expected by chance alone. Or you could not reject it, which is to say that when autism follows receipt of the MMR vaccine, it occurs at a level that would be expected by chance alone.

There are many studies now—there were actually 18 studies done in 7 different countries, on 3 different continents involving hundreds of thousands of children costing millions and millions of dollars showing that you're no more likely to have autism if you got the MMR vaccine than if you didn't.

I think if this paper proved anything it was that the MMR vaccine does not prevent autism. If you get the MMR vaccine, you might still develop autism because the only thing MMR does is prevent measles, mumps, and rubella infection. It doesn't prevent everything else that happens in the first few years of life.

But what you can't do is accept the null hypothesis, which is to say you can never prove never. I think that epidemiological studies aren't mathematical theorems. There aren't proofs; there are just associations of 1 event with another at a certain level of statistical power. And so, you're aware of that. When you testify in front of committees or you go on these shows, technically, you can't say MMR does not cause autism. So, what you end up doing initially—it sounds like you're waffling: "All the evidence to date doesn't support the hypothesis that MMR causes autism or that thimerosal at the level contained in vaccines causes developmental delays." It sounds like your waffling, or worse, it sounds like you're covering something up. And so, that's something you're always dealing with. You sort of have to get over that. You have to be able to realize you can say that.

For example, when I was a little boy, I used to watch the television show *Superman*—this was the one with George Reeves (before Christopher Reeves, which is probably the one you know). But in any case, Superman flew. I mean, he put his hands in front of him with this interlocking thumb grip, and he either sort of went to the left or he went to the right. His cape is flying behind him. His hair is flying. He was looking down at the city. When you're 5 years old, television does not lie! So, I went out to my backyard, put a towel around myself, and jumping from a small height using the key interlocking thumb grip, I tried to fly. (Spoiler alert—unsuccessfully!)

So, I could have tried a million times. That also wouldn't have proven that I couldn't fly. It would only have made it all the more statistically unlikely. You can't prove that there weren't



weapons of mass destruction in Iraq. You can only say that they were nowhere that you looked. You can't prove that I've never been to Juno, Alaska (even though I've never been to Juno, Alaska). You can just show a series of pictures of buildings in Juno, Alaska, with me not standing next to them.

I think the other challenge for scientists are our personalities. This is an old but true joke—how can you tell the difference between introverted scientists and extroverted scientists? When introverted scientists talk to you, they stare down at their shoes. When extroverted scientists talk to you, they stare down at *your* shoes. And that's true. We're not made for this. If you put in "scientists" in Google and then select Images, usually this is sort of what you find.



Google image search result for "scientists."

I think also our training is in many ways really the opposite of media training, as I said earlier. I mean, we're much more comfortable sharing and analyzing data in the hopes of discerning central truths about natural processes. We're generally less comfortable when we're expected to be dramatic advocates for a particular position. It's the opposite of what we're trained to do.

A good scientific paper is full of caveats. The worst thing you can do in science is go anywhere beyond the data in front of you. And let me tell you, this does not work on *The Colbert Report* or on TV. I mean, you have to be able to say things a little more definitively. Goodness knows, the other side is saying them definitively with no data. So, you have to be able to do that, and it's really against everything in your body to do that.

So, for example, I was on *The Colbert Report* here in January of 2011. And he's actually great, Stephen Colbert. He meets with you before the show, and he says, "Look I play a character. I'm going to stay in character the entire interview. Don't let my character get away with anything. I mean, if you do, it's going to be a boring show. I agree with you." As many of you know, his father was an infectious disease immunology specialist who died in a plane crash when Colbert was a little boy, when he was 10 years old. He's very sympathetic to science, as frankly

all the comedians are. I mean, take your pick—Penn and Teller, Jimmy Kimmel, and John Oliver have all been great about science because they're skeptics, so they know nonsense when they see it.

**This is an old but true joke—how can you tell the difference between introverted scientists and extroverted scientists? When introverted scientists talk to you, they stare down at their shoes. When extroverted scientists talk to you, they stare down at *your* shoes.**

They won't tell you what questions they're going to ask on the show. Emily Lazar, who is his producer, will say, "Here are the do's and don'ts of *The Colbert Report*." So, for example, watch this show—this is a don't. And Atul Gawande was a don't. The reason he was a don't was he was talking about his book, *The Checklist Manifesto*, and the don't was he kept coming back to his talking points. People don't watch *The Colbert Report* to learn how hospitals can be more efficient. They watch *The Colbert Report* to laugh at Stephen Colbert. That's the goal. Because when people joke with you, your instinct is to joke back. But again, you're not funny. Stephen Colbert's funny. You're a straight man on a comedy show. Get used to it.

I don't know if you can see that there's a little blue card in front of him. So, you're sitting there while your life is passing before your eyes for about 5 minutes before he comes over from the big seat to this little table in front of this false fireplace. Assuming you can read upside down, the first question was, "Why haven't you taken off your clothes for *Playboy*?" It was like a Jenny McCarthy sort of reference. So, I'm looking at my 2 young children sitting in the front row, anxious to hear what you're going to say, and thinking, "God don't let him ask this question."

The second time I was on *Colbert* was worse, actually. As I said earlier, I was fortunate enough to be part of a team that created the vaccine RotaTeq, and so one of the many ways people attack me is to say I'm just a pharma shill. And so he said, "So it's true you're in the pocket of industry." How do you respond to that? So, I said, "At Children's Hospital of Philadelphia, we're not in the pocket of industry. If anything, we're in the pocket of children because we do this and this and this." At which point, 300 people in the studio audience booed loudly. So, I didn't understand that. I was sort of walking out with the assistant producer, and I said, "Why did people boo like that?"



She said, “You don’t understand that when people like you, when you’re on a comedy show and you said you were in the pocket of children, it made you sound like a pedophile.” So, my daughter was there. She was 17 at the time, and my wife was with me. So, we’re taking the cab back to the train station to go back to Philly, and I said to my wife and daughter, would you ever have thought of that?

And my daughter says, “Yeah, I thought of it; that’s why I booed.”

I think the other thing is you have to be fairly thick-skinned in dealing with the media. It really surprised me, actually—I never imagined science could be so politicized and so mean, and that, I think, is something that has happened. I certainly get a lot of hate mail. I occasionally have been physically harassed and have gotten 3 legitimate death threats.

So, if you want to know, just for your knowledge—just for any of you who get death threats (and there’s actually thousands of death threats on the Internet every day)—the FBI considers it legitimate if (1) it’s a threat made by 1 person more than once and (2) it’s specific. So, it can’t be sort of “Watch your back. Hopefully, nothing will happen to you.” It has to be, “I’m going to do this. I’m going to come into your office and shoot you with a gun.” And (3) it has to be by somebody who they think could do it, meaning like a paranoid schizophrenic. At which point, they get involved. They will monitor that person to see what they’re—I’m not encouraging you now to really go into this—they’ll see whether that person bought a weapon. They’ll see whether that person is travelling to your area. They actually completely violate that person’s civil liberties. (Which is fine with you, by the way. Any notion you have of civil liberties goes out the window the minute you’re threatened.) But that certainly happened here. This just an example of that: “Wanted for genocide.” So that’s fairly typical.



“Wanted for genocide” attack ad.

So, I think it’s really important to stand up for science now more than ever. We are in an era, I think, in which scientific literacy has morphed into scientific denialism. People simply declare their own truths: vaccines cause autism, climate change is a hoax perpetrated by the Chinese, creationism and

evolution are equally valid hypotheses. We’re in a tough spot right now. Now more than ever, I think we need to stand up here. And no venue is too small.

I remember when my daughter was in the eighth grade. She was in an all-girls school in suburban Philadelphia. I was asked actually to come to speak to her class about vaccines. I thought this was going to be fun. My daughter didn’t. On the entire ride there she just kept saying, “Dad, don’t make jokes. People my age are not going to get old people’s jokes. Don’t make jokes. And don’t embarrass me in front of my friends.” Honestly, it was the most harrowing talk I’ve ever given in my life. The 19 girls seemed to be enjoying it, but one just stared grimly forward with a look on her face that said, “Don’t embarrass me.”

I think we all assume that people are challenging bad information, but it’s not really true. I don’t think a lot of people really are comfortable standing up in this arena for obvious reasons. And for me, I was fortunate enough to be funded by the National Institutes of Health for 25 years through an R01 mechanism. I mean, who was funding me? It was the public who was funding me. It was the voter who was funding me. And they can just as easily stop funding me.

Czechoslovakia was the heart of physics in the 1950s. All the great physicists came from Czechoslovakia, and then the government did not consider that important. It didn’t, and so it ended. The same thing was true of Germany in the 1930s. A lot of the Nobel Prize winners were German up until that point, and then, Adolph Hitler decided that science was not important to him. And so, then it wasn’t for that 12-year Reich. (It was about 988 years short of the 1,000-year Reich he promised.)

So again, I think we do need to stand up. And I’ll just stop right there. And thanks for your attention.

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

### ONLINE EXCLUSIVE

Please see our Online-Only Supplement ([www.amwa.org/page/Members\\_Only\\_Issues](http://www.amwa.org/page/Members_Only_Issues)), which continues our postconference coverage. I hope you find this issue’s insight into the annual Medical Writing & Communication Conference to be of value. As you can see, if you missed the conference, you missed a lot! I hope to see you at the 2020 conference in Baltimore, Maryland, where we will celebrate 80 years of AMWA!

—Jim



### INFLUENCE OF LEADERS AND SERVANT LEADERSHIP

#### Speaker

**Linda Yih, BSc**, Senior Director, Medical Writing Services, Parexel International Corporation, Newton, MA

By Shay Vasudeva, MS, MA

#### General Session Overview

This session covered the topic of the influence of leaders, what servant leadership is, and how to implement it in the work space. The speaker broke the session up into 2 components: Influence of Leaders and Servant Leadership. At the end of each section, the speaker allowed a question-and-answer session, although audience questions and participation occurred throughout. Yih closed the session by bringing both components together in a summary followed by a final question-and-answer session.

#### Influence of Leaders

When the topic of Influence of Leaders was covered, Yih discussed social influence, how leaders use influence, and the importance of awareness for leaders. Should leaders be unaware of how their leadership style and behaviors as individuals impact their employees, it can create a detrimental impact on morale, productivity, and recruitment and retention. They also miss valuable opportunities to positively influence their employees.

*Influence* was operationally defined as when a person's behaviors, opinions, and emotions are impacted by one another. Three varieties of influence were covered: compliance, identification, and internalization. These can be utilized by leaders and managers to influence and motivate their employees to achieve objectives.

As a leader, awareness of your own style and ways in which you influence others can be beneficial. Some of it can be explicit, whereas other areas can be implicit or more subtle. Examples of influence from a leader could be punctuality (eg, the leader is punctual, setting the tone for the employees), organization, respect, or assertiveness.

Four ways leaders can influence others included

1. **Focus:** What leaders are mindful of and pay attention to compared with what is ignored or receives minimal attention to is indicative of their priorities.
2. **Displays of emotion:** Employees notice when leaders stay calm and consistent in regard to their emotions, compared with mood swings or sudden shifts in emotion.
3. **Reactions to incidents and crisis:** When situations and projects do not go according to plan, employees tend to have a heightened sensitivity to the response of their leaders.
4. **Allocation of rewards:** When leaders reward certain behaviors, they are more likely to be repeated by employees. Those that are not reinforced will tend to wane.

This list serves as an awareness tool as leaders may motivate or demotivate their employees unintentionally.

*"As a leader, be aware of your behaviors and reactions: You do not have a choice on whether or not to communicate, but [you do have a choice on] how you manage what you communicate."*

—Linda Yih

This section of the session was closed out by offering time to discuss the following reflection questions:

1. In what ways have you been influenced by leadership in your organization? By peers?
2. If you are a line manager, how do your employees "see" you and react to your management and communication style?
3. How much of your leadership style influences how you manage others?

#### Servant Leadership

The first concept discussed in this second section of the session was what servant leadership is NOT. On one end of the spectrum, this includes *enabling* employees by providing assistance on a project because of an employee's complacency or lack of desire to complete the project. On the other end of the spectrum, it includes commanding employees, which can result in having employees waiting to be told what to do.

*Servant Leadership* was defined as harmonization between the leader and the employee. It is a blend and balance between the two. Leaders retain their leadership qualities when they become Servant Leaders, while also gaining a team that wants to work with them.

The 9 qualities of a Servant Leader include

1. values diverse opinions,
2. cultivates a culture of trust,
3. develops other leaders,
4. helps people with life issues,
5. encourages,
6. sells instead of tells,
7. thinks You, not ME,
8. thinks long-term, and
9. acts with humility.

This section of the session closed with several reflection questions:

1. Have you had the opportunity to work with a leader who was a positive role model or a Servant Leader? How did it affect your work and attitude?
2. Which of the Servant Leader qualities do you think will be the most difficult to implement? Which are already in place for your organization or teams?

#### Summary

The session was finalized by a summary and recap of both sections. Key take-aways on the Influence of Leaders were that it is

important to be aware of what influence is, the ways in which leaders influence their employees, and the 4 ways a leader can influence others. Key take-aways on Servant Leadership were what it is not (enabling or commanding) and what it is (leading in a way that balances the qualities of a leader and employee). The 9 characteristics of Servant Leadership were discussed, along with reflection questions that can help attendees evaluate whether elements of Servant Leadership are already present in their organization and enable implementing this leadership style with employees.

*Shay Vasudeva is the owner and founder of ShayTheCoach in Phoenix, AZ and writes on a freelance basis.*

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## Resources

### *Influence of Leaders*

1. Boundless Management. A leader's influence. Boundless.com. <http://oer2go.org/mods/en-boundless/www.boundless.com/management/textbooks/boundless-management-textbook/leadership-9/defining-leadership-68/a-leader-s-influence-340-1045/index.html>. Published May 26, 2016. Accessed January 31, 2020.
2. Friedman R. *The Best Place to Work*. New York, NY: Perigee; 2014.

### *Servant Leadership*

1. Information in this training is based on the following e-book: Prichard S. *Becoming a Servant Leader: How to Lead With Others in Mind*. 2014. <https://www.skipprichard.com/leading-with-others-in-mind/>

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## EFFECTIVE MENTORING OF MEDICAL WRITERS: PRINCIPLES AND PRACTICE

### Speakers

**Michele Vivirito**, *Medical Writing Consultant, Greater Los Angeles Area, CA*

**Vicki Foster, MSPH**, *Principal Medical Writer, Parexel International Corporation, Waltham, MA*

### By Kristen Murfin, PhD

Effective mentoring relationships are integral to professional development and growth at all career stages, and mentoring can focus on a variety of areas, such as learning technical skills, integrating into a new work environment, or developing professional goals. At the AMWA Medical Writing & Communication Conference, Michele Vivirito and Vicki Foster gave a presentation focusing on the types of mentoring and how to cultivate effective mentoring relationships. Many of the techniques discussed may be implemented regardless of the career stage or focus of the mentoring relationship.

Vivirito began the presentation with an overview of what mentoring is: a 2-way relationship focusing on professional development. There are several strategies that a mentor can use to guide the mentee and the mentoring relationship:

- Asking questions that elicit questions and solutions for the mentee to find themselves,

- Helping the mentee find the right goals (eg, SMART goals),
- Fostering accountability and gently helping the mentee find their role in fixing problems,
- Practicing crucial conversations (ie, role-playing), and
- Celebrating all successes, large and small.

Using these techniques, the mentor can assist the mentee in finding their own path through difficult situations or developing desired skills. Vivirito also discussed 3 models that can be used in discussions:

- **CMO:** Define the mentee's competency, motivation and opportunity. When these 3 come together, it is feasible to work on a strategy to achieve the desired goal or skill.
- **SBI:** Determine the situation, behavior of the mentee, and impact of the mentee's behavior.
- **SSC:** Think the situation through completely and determine what the mentee is going to stop, start, or continue doing.

Mentoring can occur in a variety of settings, such as mentoring a co-located colleague, mentoring in a professional association, or mentoring remotely. Distance mentoring offers several advantages, such as access to a global network of mentors for in-office and remote workers, flexibility for busy mentors, and time to think through questions or problems that are communicated via email. However, distance mentoring comes with a unique set of issues: geographic time differences, cultural differences, and communication problems (eg, technology issues or language barriers).

Foster highlighted key elements to a successful distance mentoring relationship. The mentor and mentee must be committed to the exchange and be accountable. She suggested having frequent meetings and sharing stories of successes and failures to cultivate trust and develop the relationship. Additionally, the mentor and mentee need to work to establish effective communication. It may be helpful to try different modes of communication to determine what will work best. Avoiding multitasking and interruptions during the meeting will improve communication as well. It is also important to choose words carefully when communication does not include body language or tone of voice. Effective distance mentoring also requires planning to schedule meetings in advance and establish the frequency and duration of meetings. Planning discussion topics in advance can provide structure to the conversation and ensure the meeting is productive. However, it is also important to allow for flexibility, such as trying to be available for impromptu meetings and allowing time for unplanned questions or topics.

Foster ended the presentation by saying that effective mentoring is productive, respectful, enjoyable, sustainable, and mutually beneficial for the mentor and mentee.

*Kristen Murfin is a medical writer at Invicro, a Konica Minolta Company, and lives in New Haven, CT.*

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### HOW TO CHECK CONSISTENCY AND ENFORCE YOUR HOUSE STYLE: USING PERFECTIT IN REGULATORY SUBMISSIONS AND PUBLICATIONS

#### Speaker

**Daniel Heuman**, CEO and Founder, Intelligent Editing, New York, NY

#### By Bridget Mazzini, RN, OCN

The value of PerfectIt in error-proofing documents has been recognized in the medical writing community. In a tools-of-the-trade survey published in *AMWA Journal*, freelance medical communicators were asked, “What is the single essential software/app that they would recommend to fellow freelancers?”<sup>1</sup> PerfectIt secured a spot in the top 3 recommendations, behind only industry giants Microsoft Office/Word and Adobe Acrobat.

Attendees of AMWA's 2019 Medical Writing & Communication Conference had the opportunity to hear Daniel Heuman, CEO and Founder of Intelligent Editing and the original developer of PerfectIt, give a step-by-step tutorial in PerfectIt basics. Heuman also gave a demonstration that spotlighted one of the software's advanced features: how to customize and enforce house style. Echoing the company's philosophy, Heuman characterized automation as the medical communicators' ally, not their replacement. PerfectIt was developed with the following credo in mind:

*“We believe that humans make the best editing decisions and that they always will. We build technology to help people edit faster and better.”*

—Intelligent Editing philosophy

#### Why Do I Write?

The speaker opened the session by taking a moment to “get existential.” Heuman asked the crowd of medical communicators to reflect on why they write. “What is your (actual) job?” Focusing on purpose not task, Heuman summarized that

The writer/editor's actual job is to make sense of

- Complexity,
- Input from multiple authors, and
- Poor writing.

In addition, the writer must

- Keep the focus on science,
- Manage stakeholders,
- Make the best impression, and
- Be consistent with organization or brand voice.

In the context of these priorities, the medical communicator has to generate flawless written communication while adhering to deadlines and budget constraints. Who couldn't use a little help with that? The detail-driven medical communicator can, of course, do it all, copy editing included. However,

enlisting automation to assist in error-proofing enables the writer to focus on content substance.

It boils down to this: Do you want to spend your finite time hunting down the rogue parenthesis in a 200-page document or do you want to devote your energy to synthesizing content that is accurate, complete, compelling, and clear (ie, content that communicates)?

#### What Is PerfectIt?

PerfectIt is a Microsoft Word add-in that has 2 primary functions: it checks for consistency in multiple categories of easy-to-overlook errors, and it allows the user to enforce house style.

Principal features include

- Microsoft Word add-in editing tool,
- checks documents for consistency,
- enforces house style,
- available in PC (PerfectIt 4) and Mac (PerfectIt Cloud), and
- includes built-in style sheets.

The speaker noted that PerfectIt is particularly useful for

- long documents in which errors in consistency may be difficult and time-consuming to uncover;
- document projects that are under intense time pressure;
- documents that contain input from a variety of authors whose voices and styles might vary; and
- complex, lengthy documents including Academy of Managed Care Pharmacy dossiers, regulatory submissions, study reports, journal publications, grant applications, evaluation reports, and package inserts.

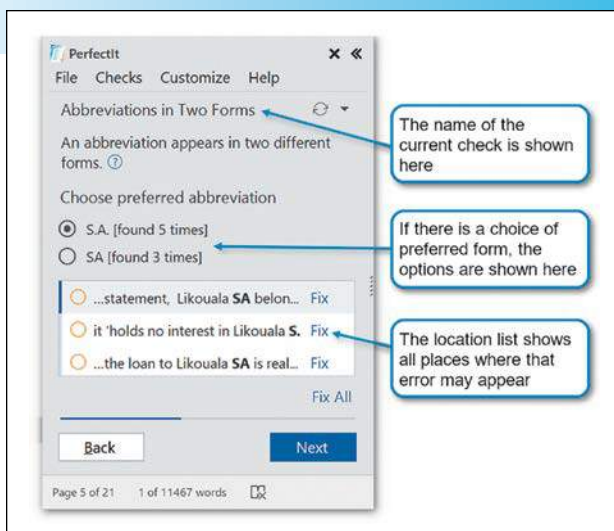
#### What Isn't PerfectIt?

Heuman discussed boundaries and limitations of the program. He mentioned

- risk of false assurances and false positives (some false positives can be decreased by using the “never find” function under style sheets),
- limited ability to check the precise American Medical Association style rules for abbreviations in tables (although many other checks of tables and abbreviations are included),
- not a substitute for grammar and spell check (although some spelling consistency issues can be proactively addressed using PerfectIt's custom styles), and
- doesn't check formatting (other than italics and some other issues).

#### How PerfectIt Works: Checking for Consistency

The speaker illustrated in a step-by-step walkthrough how to set up and run PerfectIt, demonstrating how simple and intuitive the software is and how quickly it analyzes a document and presents the writer/editor with the inconsistencies. The screen formatting makes it easy for the user to see discrepancies and swiftly reconcile them (Figure).



**Figure.** PerfectIt interface.

The software systematically reviews the entire document for consistency and style/corrections.

- Consistency
  - Hyphenation (broad based/broad-based)
  - Numbers (numerals/words)
  - Spelling (advisor/adviser)
  - Capitalization (University/university)
  - Header capitalization
  - Lists (punctuation and capitals)
- Style/Corrections
  - Common typos
  - Brackets and quotes left open
  - Comments left in text
  - Abbreviations

The abbreviation check searches for all occurrences of an abbreviation and identifies different versions (ie, N.A.T.O compared with NATO), and it makes certain the definition precedes the first occurrence only. The software also allows the user to create an abbreviation list. This feature appeared popular with attendees. One audience member stated the software was worth it for the abbreviation list alone.

### Style Sheet Editor

In part 2 of the demonstration, Heuman addressed his most frequently asked question: “How do I customize PerfectIt to create a style sheet to enforce my preferences?” Detailed video tutorials like the 1 Heuman presented at the session are located on the Intelligent Editing website. It is hard to capture in words how easily a PerfectIt style sheet can be built. A visit to the website is worthwhile to appreciate this function.

In brief, the Style Sheet Editor is a feature within PerfectIt that uses drop-down menus to present a set of questions through which the user establishes preferences for their house style guide. The user may select 1 of the built-in style sheets (eg, US spelling), taking advantage of the already built-in rules and substantially reducing the time it takes to enter preferences. The style sheet can be created in minutes and can be modified at any time. The style sheet can enforce hundreds or thousands of rules, proactively minimizing consistency errors.

The speaker made a few side notes about the Style Sheet Editor:

- Customization is not required. The basic software catches most errors of consistency. The user can take advantage of rules and preferences in the built-in style sheets.
- If you use the Style Sheet Editor in PerfectIt, then the program becomes a rule checker in addition to a consistency checker.
- You can choose “always find” to enforce find/replace preferences or “never find” to minimize false positives.
- The user can share the newly created style sheet with colleagues.

### Cost

PerfectIt software can be purchased from the Intelligent Editing website. The speaker quoted current annual pricing for individual and group licensing. It starts at \$70 for an individual license or \$49 with the 30% discount for AMWA members.

### Closing

In closing, Heuman circled back to his opening message to medical communicators: “You have enormous value.” The capacity that we as medical writers and editors have to make sense of and communicate complex information is at the core of that valuation and should be the focus of our finite time and energy. Medical writing, regulatory writing in particular, requires scrupulous attention to detail.

Although PerfectIt doesn’t hunt down all errors, the demonstration suggested that the software can save the user significant time, can be set up and run quickly, and is reasonably priced. Writers and editors who are reluctant to enlist automation in their routine may find PerfectIt a welcome solution that improves their efficiency while allowing them to stay at the helm of their document’s journey.

### See for yourself:

**14-day free trial:** <https://intelligentediting.com/download/choose-version/>

**PerfectIt tutorials:** <https://intelligentediting.com/videotutorials>

**Slides available at AMWA website, 2019 AMWA Medical Writing & Communication Conference Session**

**Materials, technology section:** <https://www.amwa.org/page/2019sessions>

**Product discount:** To access the discount, see AMWA Member Benefits, Affiliate Partners ([https://www.amwa.org/member\\_benefits](https://www.amwa.org/member_benefits)). Member login required.

### Reference

1. Nicosia M. Results from the 2016 Freelance Medical Communicator Tools of the Trade Survey. *AMWA J.* 2017;32(3):105-112.

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## OPEN SESSION REPORTS

### SHAREPOINT TO THE RESCUE! USING SHAREPOINT AS A TOOL TO MANAGE MEDICAL WRITING TEAMS AND CLIENT PARTNERSHIPS

#### Speaker

**Amelia Young, BS**, *Manager, Medical Writing Services, Parexel International, Billerica, MA*

#### By JP Settles, BA

A struggle for any collaborative effort is the sharing and storing of files. How do you ensure all of your stakeholders are referring to the most up-to-date database, say, or that all of your writers are working off of the most recent document? How do you avoid receiving (and sending) the dread email: “We’re having version control issues”?

Enter SharePoint. “At its most basic, SharePoint is a website you create to share information among your internal and external stakeholders,” said Amelia Young, Manager of Medical Writing Services at Parexel International Corporation. More broadly, SharePoint is a suite of software and services from Microsoft. These programs include the SharePoint Server, which an organization maintains in partnership with Microsoft; SharePoint Online, which is a Cloud-based version of the Server; and SharePoint Designer, which is a free program that helps the user to edit site content. As SharePoint is a Microsoft product, some of the features and interfaces mimic what you might be used to in the Office Suite.

Young detailed some of the reasons a team or organization might adopt a SharePoint system. First off, it can help to streamline accessing and storing of files. The churn of systems and software an organization goes through in its life cycle can mean losing track of what goes where. As files move to new locations on various servers (or somebody’s desktop or email inbox), precious time can be wasted by workers, new and old, trying to hunt down a necessary template or other document. SharePoint can ease this burden by providing a streamlined, centralized home for these important files.

“There are a number of other challenges SharePoint can help you overcome,” Young said. SharePoint can serve not only as a location to store important documents but also as a warehouse of links to the most recent versions of templates and client style guides. This method allows ease of access and insurance that you’re meeting client expectations by using the most recent files and style guides, while also helping to maintain legacy documents in the background.

Along with the ability to create links to internal documents, one can also link to external Web pages, including to things like US Food and Drug Administration guidance and LinkedIn Learning trainings, providing further streamlining of work-related information and reduction in navigation time. Another time-saving feature is collaborative authoring, which allows multiple writers to work on the same document without having to pass it back and forth through email. If that sounds frightening, though, fear not—there are alerts in place so that a

user knows when a colleague is already working within a document.

Once you’ve decided SharePoint is the solution for your organization, there is a 4-step cycle for creating and refreshing your site and its content:

1. Identify content.
2. Identify users.
3. Create SharePoint pages.
4. Periodically review content.

The first step is identifying the content you want to include, as that will inform which users will be relevant to bring on and what form the pages will take. Once you’ve identified your users, SharePoint allows you to set the level of access each will have. For example, a medical writer could be set at Full Access, making them the de facto site administrator, with the ability to edit and delete all content. At the other end of the spectrum, a user could be set as View Only, which might grant a client or freelance worker a limited ability only to see files. “There are a number of graduated access levels between these extremes,” Young said. Pages can be created either as Web part pages, which is templated, or as a blank page, which is a blank slate. Whichever method you use, you will eventually use Web parts to build your site. These Web parts include *Link*, which allows you to create internal and external hyperlinks; *List*, which displays a customizable list for doing such tasks as metrics tracking; and *Text*, through which you can develop set styles for your site. The final step in the cycle is to periodically review the site, to make sure content is still relevant and users still have the proper permissions.

Young ended the session by holding a live demonstration of how to create a SharePoint page. She recommended perusing the guide “Microsoft Office—Create a Team Site in SharePoint,” available at <https://support.office.com/en-us/article/create-a-team-site-in-sharepoint-ef10c1e7-15f3-42a3-98aa-b5972711777d>, and browsing the catalog at LinkedIn Learning for the search term *SharePoint*, as a variety of classes are available for a fee.

The slide deck that accompanied this session can be viewed at <https://www.amwa.org/page/2019sessions>.

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### AUGMENTING MEDICAL WRITING WITH ARTIFICIAL INTELLIGENCE AND NATURAL LANGUAGE GENERATION

#### Speakers

**Jeff McCrindle**, *Vice President, Sales, Yseop, Greater New York City Area, NY*



**Madhavi Gidh-Jain, PhD**, *Medical Writing Head, Sanofi, Bridgewater, NJ*

**Nishchal Sehgal, MBA**, *Senior Vice President, Life Sciences, Orion Business Innovation, Edison, NJ*

**Abie Craiu, PhD**, *Principal Regulatory Documentation Scientist, F. Hoffman-La Roche, Ltd, South San Francisco, CA*

#### By Jenni Pickett, PhD

Advances in artificial intelligence (AI) and natural language generation (NLG) have the potential to transform medical writing through automating routine content generation. NLG is programming that can turn data into language. Jeff McCrindle addressed a standing-room-only audience with an informative overview of what AI and NLG can and cannot do in today's medical writing environment and introduced a series of speakers who had piloted these technologies in their regulatory writing workflows.

#### Benefits of AI/NLG integration:

- Improves time to market for new drugs
- Reduces stress for medical writers
- Improves ability to analyze complex data
- Facilitates a single voice
- Reduces quality reviews required
- Decreases time needed to react to new requirements

AI/NLG solutions are customized for each client's individual report content standards, data sources used, data analysis methods, text style, and preferred interactive dialogue options. McCrindle compared the advent of these new technologies to the introduction of the spreadsheet. Just as the spreadsheet freed data analysts from the cumbersome repetitive work required to collect, analyze, and report data, AI/NLG will free medical writers from tedious copying, pasting, and formatting of content.

When developing an approach to bring content automation in-house, writers can use commercial off-the-shelf AI/NLG solutions from a vendor and customize them, or develop their own solutions using open-source.

#### Success at Sanofi With Clinical Study Reports Using Yseop AI

To demonstrate the technology, McCrindle presented a video from Madhavi Gidh-Jain of Sanofi. Sanofi evaluated AI/NLG as part of an overarching strategy to reduce the time from patient last visit to a completed clinical study report (CSR). The baseline time was 6.8 months, which was reduced by implementing AI/NLG.

#### Analysis of CSR content revealed that

- 55% is reused from other documents,
- 40% could be provided by NLG, and
- 5% needs to be authored.

## Natural Language Generation (NLG) Terms

**Aggregation** – merging 2 sentences in a natural way.

**Artificial Intelligence (AI) NLG** – programming that can learn and adapt when given an example.

**Commercial off-the-shelf** – programming for NLG that can be purchased and customized, avoiding the need to develop your own NLG solution.

**Rule-based NLG** – content generation that abides by user-determined rules.

In a demonstration of their AI/NLG tool Business-Oriented Bot, Gidh-Jain created a safety section of a CSR in just a few minutes using a custom AI/NLG Microsoft Word plug-in. First, with 1 click of a data table insertion tool, the entire CSR was populated with properly formatted tables including data and cross-referencing links. Second, engaging the dialogue tool generated short paragraphs summarizing the safety data in just a few seconds. Gidh-Jain emphasized, however, that “human intelligence will always be required for meaningful clinical interpretation.”

#### Orion Tackles Patient Safety Narratives

In a second case study, Nishchal Sehgal presented the development process required to create a customized Yseop tool for a client to produce the clinical summary of their patient safety narratives (PSNs). In this case, the client already had an automated content tool, but their current tool had drawbacks including long lead times, an inability to perform calculations, and an inability to use existing data outputs without modification. Through short development cycles that included daily calls and weekly meetings, a pilot tool was put in place after 3 months that was able to overcome inefficiencies in the client's current program by calculating dates, aggregating continuous adverse events, and flagging missing data. The writing process was accelerated, and the need for quality control was reduced.

#### Best practices for developing an NLG pilot included

- define clear goals for the pilot,
- standardize your data sources,
- devote resources to the connectors that integrate your data sources to your NLG tool, and
- for PSNs, keep in mind that rule-based NLG requires different rules for different therapeutic areas.

#### Automatic Content Generation at Roche

Abie Craiu explained that automatic content generation (ACG) is a part of the Faster Filing initiative at Roche aimed at reducing the critical path from database lock to filing submission from 20 weeks to 14 weeks.

#### Areas to optimize included

- outputs generation process,
- regulatory publishing process, and
- data-dependent writing, review, and approval.

Documents suitable for ACG have very similar templates, a reliable data source, and an automated transfer process.



For narratives, Roche has implemented SAS JMP clinical autonarratives software. By optimizing the output given by the data keepers using existing statistical programming software, reformatting of the data can be minimized to save effort and time.

Craiu made the point that the role of a regulatory medical writer includes much more than writing. Regulatory medical writers manage the entire writing process to deliver documents as strategy, content, and process experts. By leveraging NLG tools to reduce the mundane tasks involved in producing documents, our efforts can be focused more on these other aspects of our role.

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## REPORTING DRUG METABOLISM IN THE AGE OF PRECISION MEDICINE

### Speaker

**Teresa McNally, PhD**, Medical Writer and Consultant, Whitsell Innovations, Inc, Chapel Hill, NC

### By Chris Lee

Historically, medicine has followed a 1-size-fits-all approach. Your doctor would prescribe a medication, you would take it, then the 2 of you would discuss the benefit of the treatment and decide whether or not to switch medications based on your reactions. Under this paradigm, some people benefit from the medication, some people do not benefit from the medication, and other people have adverse reactions to the medication.

In her presentation, Dr Teresa McNally outlined the emerging paradigm for prescribing medication, known as precision medicine. Precision medicine is a concept that builds on a prescribing approach known as personalized medicine. McNally explained that doctors often assess several factors that may affect the response a patient may have to a given medication. Some of the factors that may affect one's response to a drug include

- disease subtype,
- risk profile,
- demographics,
- genetics,
- the concentration of biomarkers in the blood,
- comorbidities, especially kidney and liver disease, and
- other medications.

The goal of precision medicine is to provide only beneficial medications to each patient. Precision medicine can utilize genetic information, medical records, demographic information, biomarker analysis, and companion diagnostics, among other techniques that help identify the most beneficial treat-

ment for a disease. In this way, doctors can see an exact profile of each patient. McNally explained that many new medications are approved alongside their companion diagnostics, allowing doctors to identify and treat the specific patient population that will benefit from that medication.

To only prescribe medication to patients who will receive a benefit, doctors must understand the cause of the disease and the mechanism of action of the drug. McNally focused her presentation on the metabolism of drugs. This is often the most well-understood aspect of a drug's mechanism of action. In fact, many of the factors that affect an individual's response to a drug are the result of how those factors affect metabolism.

The most well-elucidated metabolic pathways are those of the cytochrome P450 enzymes. McNally specifically discussed the metabolism of cytochrome P450 3A4 (CYP3A4). Many common drugs are metabolized by this enzyme, including statins and selective serotonin reuptake inhibitors. Grapefruit juice also interacts with CYP3A4; in fact, grapefruit juice can inhibit CYP3A4 and reduce the rate of metabolism of these drugs. Drinking grapefruit juice while taking certain classes of medications can greatly increase their potency and cause very serious side effects. Interactions such as this underscore the need for greater understanding of the mechanisms of action and metabolic pathways of the medications we use.

Sometimes, enzyme inhibition generates positive outcomes. McNally also mentioned ritonavir. Like grapefruit juice, ritonavir is a CYP3A4 inhibitor. Some drugs are metabolized by CYP3A4 too quickly to produce the intended benefit; however, combining lopinavir with ritonavir led to a first-line treatment for human immunodeficiency virus. Likewise, ritonavir can be combined with ombitasvir and paritaprevir in a therapy that cures greater than 95% of all patients with hepatitis C types 1 and 4.

These are just a few examples of the many interactions, both genetic and environmental, that affect the effectiveness and safety of drugs. Doctors need more information to improve personalized and precision medicine. Information alone, however, isn't enough: doctors need clinical practice guidelines to make practical clinical decisions based on this information. McNally briefly touched on the Clinical Pharmacogenetics Implementation Consortium, which publishes guidelines for using genetic information to help doctors prescribe appropriate medications based on each patient's specific genetic profile.

As our understanding of the factors that influence an individual's response to medication increases, prescribing practice will continue evolving. The practice of precision medicine will grow as more clinical information becomes available and both physicians and patients increase their awareness of the effects of pharmacogenetics, drug metabolism, and other factors that impact the precision approach. Once translated into the publication of clinical practice guidelines, this will help the adoption of precision medicine approaches to treatment.

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## YOU CAN FIND A DIAMOND IN THE ROUGH: MEDICAL WRITING OPPORTUNITIES IN RARE DISEASES

### Speaker

**Christina M. Ohnsman, MD**, *Senior Clinical Development Lead, REGENXBIO Inc, Rockville, MD*

### By Lauren Stroshane, MSN, RN

During medical school, doctors in training are often advised, “When you hear hoofbeats, think horses, not zebras.” The saying is an admonishment to consider the most probable cause of a patient’s illness, not the most exotic; yet some patients do have rare diagnoses and must grapple with their identity as “zebras.” For health care communicators, working within the rare-disease space can be an opportunity to deepen their professional knowledge while helping underserved patient populations. Dr Christina Ohnsman discussed the benefits of working in rare diseases, drawing on her experience as a pediatric ophthalmologist who transitioned into medical communications and then on to clinical development, specializing in gene therapy, rare diseases, and ophthalmology.

Most patients with a rare disease have a lengthy and frustrating journey before receiving a correct diagnosis, seeing on average 8 different physicians, and receiving 2 to 3 misdiagnoses. This “diagnostic odyssey” costs patients their most valuable resource—time—as well as creating the emotional (and sometimes financial) toll of an uncertain diagnosis. Today, roughly 1 in 10 Americans is affected by a rare disease. Given that only 5% of rare illnesses have treatments available, and that the majority of these diseases are life-threatening, the need for more treatment options is tremendous.

The Orphan Drug Act of 1983 helped to address this need by providing incentives to pharmaceutical companies to develop drugs to treat rare diseases. The bill stimulated innovation in multiple fields of medicine, particularly in genetic diseases and cancer. Today, orphan drugs are big business: regulatory advantages, decreased costs of research due to smaller studies, and reduced marketing needs are all factors that make orphan drugs an attractive area for industry. The largest pipelines for new orphan drugs are in the fields of oncology and genetics, but all therapeutic areas have seen growth.

Opportunities for medical writers abound within the rare-disease space and continue to expand, including a range of possible deliverables (Table).

For those who are early in their writing career and looking to build their portfolio, reaching out and offering volunteer writing services to advocacy groups for rare diseases can be a worthwhile place to start.

Dr Ohnsman recommends the following organizations for those interested in learning more about the rare-disease space and the needs of patients:

- National Organization for Rare Disorders,
- National Institutes of Health,

**Table.** Possible Deliverables in the Rare-Disease Space

Potential Clients and Employers	Deliverables
<ul style="list-style-type: none"> <li>• Pharmaceutical and biotechnology companies</li> <li>• Government agencies</li> <li>• Advocacy groups</li> <li>• News outlets</li> <li>• Medical education companies</li> <li>• Health care insurers</li> <li>• Public relations</li> <li>• Academic research institutes</li> </ul>	<ul style="list-style-type: none"> <li>• Publications</li> <li>• Regulatory writing</li> <li>• CME materials</li> <li>• Marketing materials</li> <li>• Meeting coverage</li> <li>• Patient education</li> <li>• Advocacy materials</li> <li>• Grant writing</li> <li>• Social media presence</li> </ul>

- Office of Rare Diseases Research/National Center for Advancing Translational Sciences,
- US Food and Drug Administration,
- European Medicines Agency, and
- European Union Committee of Experts on Rare Diseases.

Additionally, EvaluatePharma’s 2019 Orphan Drug Report describes current trends in prescription sales of orphan drugs and lists key companies in the rare-disease landscape, identifying potential clients for medical communicators.

Who is a good fit to work in the rare-disease space? You must be willing to tackle a steep learning curve to become familiar with a particular disease. Medical writers must also be able to keep the focus where it belongs—on the patient—while maintaining some professional detachment in the face of illnesses that can be devastating. Creativity serves a medical communicator well in conveying complex patient stories within the constraints of regulatory requirements. If you are able to see the big picture as well as the small details, then you just might find a deeply rewarding career working with rare diseases!

*Lauren Stroshane is a freelance medical writer based in the San Francisco Bay Area.*

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## TEXT RECYCLING IN SCIENTIFIC RESEARCH WRITING: FINDINGS FROM THE TEXT RECYCLING RESEARCH PROJECT

### Speakers

**Cary Moskowitz, PhD**, *Thompson Writing Program, Duke University, Durham, NC*

**Susanne Hall, PhD**, *Hixon Writing Center, California Institute of Technology, Pasadena, CA*

### By M. Denise Daley, MD

Although using text from another source without proper citation is widely considered unacceptable, using material previously written by the same person is a more complicated issue. The latter reflects a form of self-plagiarism, also known as text recycling. In this very interesting session, Drs Moskowitz and Hall discussed the findings of the multicenter Text Recycling Research Project (funded by NSF grant SES-1737093).





### What Is Text Recycling?

As noted by Dr Moskowitz, text recycling occurs when textual material—prose, equations, or visuals—from 1 document is reused in a new document and these 3 criteria are met:

1. The material in the new document is identical to, or substantively equivalent in both form and content to, the material in the original document;
2. The material serves the same rhetorical function in both documents; and
3. At least 1 author of the new document was an author of the original document.

### Is Text Recycling Acceptable?

Although many organizations have issued statements regarding text recycling, their views on the acceptability of this practice vary widely. Furthermore, these statements are primarily based on personal beliefs, as very little research has been conducted in this field.

### What Is the Text Recycling Research Project?

The Text Recycling Research Project was initiated in 2017 to explore current beliefs and practices regarding text recycling, with the ultimate goal of establishing guidelines. It consists of 2 parts: phase I and phase II.

### What Did Phase I Find?

Now in its third year, phase I involves an examination of 3 dimensions of text recycling: beliefs and attitudes, text analysis, and legal analysis.

#### *Beliefs and Attitudes*

As discussed by Dr Hall, this dimension was first assessed by surveying 316 editors and editorial board members of academic journals in 4 disciplines: science, technology, engineering, and mathematics (STEM); quantitative social sciences; qualitative social sciences; and the humanities. These were some of the key findings:

- Approximately 84% of respondents indicated that text recycling was at least sometimes acceptable, with no substantial differences between the 4 disciplines.
- Regarding the source of recycled text, more than 95% of respondents indicated that it was acceptable to at least sometimes reuse text from a conference poster. Recycling text from grant proposals, conference papers, and grant reports was also commonly considered acceptable. Even the practice considered least appropriate—recycling text from another journal article—was deemed sometimes acceptable by more than 40% of respondents.
- Regarding the type of material, recycling Methods material was considered the most acceptable and recycling Results information was considered the least acceptable.

Interviews were also conducted with 21 editors-in-chief of academic journals. Dr Hall noted that these revealed a wide range of opinions about text recycling. For example, some edi-

tors thought that any recycling would prevent the new material from being considered original; many thought that it was acceptable to recycle unpublished text, although the editors differed in their definitions of “unpublished”; and some recommended simply rewording text when recycling was detected.

Overall, there was broad consensus that text recycling is sometimes acceptable, but there was limited consensus about when.

#### *Text Analysis*

This dimension examined the frequency of text recycling. Dr Moskowitz explained that because most scientific journal articles are multiauthored, “one’s own work” in this analysis was defined as journal articles originating from the same grant (reflecting recycling on an authorship group level). The grants encompassed 4 fields: biological sciences; engineering; mathematical and physical sciences; and social, behavioral, and economic sciences.

Preliminary findings suggested that text recycling occurred in articles from approximately 25% of grants, and this percentage was relatively consistent across fields. These results provide objective evidence that text recycling is common and, as noted by Dr Moskowitz, indicate that “it seems worthwhile to generate some clear and consistent guidelines for practice.”

#### *Legal Analysis*

This dimension involved an analysis of text recycling in the context of copyright law and contract law. Dr Moskowitz noted that on manuscript acceptance, authors typically transfer copyright to the publisher, so text recycling might be considered an infringement of copyright. However, in the United States, using material without permission from the copyright holder is permitted in “fair use” situations. Determining what constitutes fair use involves several factors, including whether the new work is transformative (ie, different in essence from the original). If a new article is accepted for publication, this suggests that the journal editor considers it transformative. Thus, text recycling would generally not violate United States copyright law.

Contracts, however, supersede copyright law. They can extend or limit what authors are permitted to do beyond copyright/fair use issues. If, for example, a contract states that reuse of text is never allowed, then all text recycling would be a violation of the contract.

### What’s Next?

The project will soon be transitioning to phase II. This phase will involve the development of guidelines, policies, and educational materials regarding text recycling on the basis of the findings of phase I and input from various stakeholders. It will be a major advance in defining the role of text recycling in academic science research writing.

### Is More Information Available?

Drs Moskowitz and Hall provided a handout about their presentation, which is available at

[https://cdn.ymaws.com/www.amwa.org/resource/resmgr/conference/2019/handouts/Text\\_Recycling.pdf](https://cdn.ymaws.com/www.amwa.org/resource/resmgr/conference/2019/handouts/Text_Recycling.pdf). To learn more about the project and sign up for email updates, check out the project's website: <https://textrecycling.org/>.

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## USING NARRATIVES TO IMPROVE HEALTH LITERACY AND COMMUNICATOR CREDIBILITY

### Speaker

**Rachel Adams, PhD, RD, LD**, *Health Communication Strategist, Rachel Adams, LLC, Dallas/Fort Worth Area, TX*

### By Ronald Zacker, MPAS, PA-C, RD

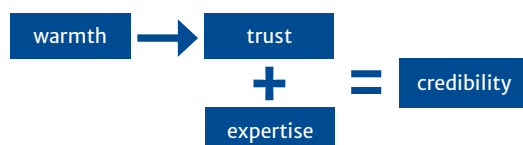
The public's trust in expert opinion is eroding. As a result, people may be even more likely to accept an argument based on emotions and beliefs rather than scientific data. Dr Rachel Adams explained how narratives can be used to rebuild trust and credibility and demonstrated how narratives enhance learning and promote healthy behaviors, particularly in disadvantaged populations. Adams defined and deconstructed the basic elements of a narrative. There is a chronology: a beginning, middle, and end. There are characters who are involved in some type of conflict. Lessons are learned, implicit or explicit messages are presented, and resolution occurs.

Narratives take advantage of the way our brain is programmed to process information. Direct experience is often stored as memory in narrative form, and new information becomes integrated with existing narratives. This default wiring is the preferred mechanism by which we learn and make sense of the world.

*People think, communicate, and make decisions through stories and narrative.*

—Dohan, et al. *Health Affairs*. 2016<sup>1</sup>

Adams provided a detailed formula to explain how narratives function (Figure). A good story engages the audience through emotion and relatability. The audience will not only identify with the characters, but more importantly, will also begin to align with and adopt the character's goals and beliefs. They picture themselves in the story. The warmth created establishes trust. And trust combined with expertise is the genesis of credibility.



**Figure.** How narratives function.

### Better Outcomes: Learning and Behavioral Change

Compared with mere facts and figures, Adams suggested that narratives offer several advantages:

- Improved comprehension due to fewer cognitive resources being required to process information.
- Better memory and recall as a result of shorter reading times and the anchoring of information to existing knowledge.
- Enhanced behavioral change as improved recall and understanding triggers situational awareness. As the audience listens to the story, they imagine themselves going through the experience. This leads to real-time decision-making and cueing of appropriate behaviors.
- Reduced controversy and less counter-arguing. The audience becomes emotionally involved with the outcome they want and expect, and the conclusion feels inevitable.
- Decreased reliance on fear. Excessive focus on fear impedes the brain's ability to process and act on information.

### Narratives for Specific Populations

Adams described how narratives are particularly helpful in certain applications. Individuals with low health literacy may find scientific data unfamiliar, overwhelming, and cold. Storytelling, on the other hand, is a natural, friendly way of sharing and teaching. Narratives also allow the message to be tailored for cultural appropriateness. Entertainment-style educational videos seem to be the most effective learning format for individuals with low health literacy.

Narratives can also be useful for complex social and personal issues, when reason and logic are limited. Sex education was used as an example. Additionally, Adams mentioned that narratives are well adapted for audiences resistant to learning new information, such as adolescents and skeptics.

*The plural of anecdote is not data.*

—Kernaghan K, Kuruvilla PK<sup>2</sup>

### Ethical Considerations

Adams disclosed several reasons why storytelling has a bad reputation in science. Narratives can overgeneralize, making proclamations based on small or biased samples. As described earlier in the list of benefits, narratives can be hard to counter-argue. Indeed, when a story is based on few or no actual data, it's difficult to dispute any claims. Narratives may be constructed to conceal opposing viewpoints, thereby delivering an unbalanced perspective. In these instances, teaching and informing can easily cross into the territory of persuasion and manipulation.

When considering using a narrative, Adams suggested that writers first clearly define their purpose. Do you want to facilitate controversy and discussion in the hopes of generating a greater understanding? Or would you rather reduce potential controversy through greater acceptance (persuasion)? Also, consider what level of accuracy you need to maintain. Narratives work even if the information being delivered isn't



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scientifically exact. If there are elements in your topic that require rigid accuracy, a narrative may be too relaxed to effectively convey that information.

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## PREDATORY PUBLISHING: UPDATE ON THE CURRENT ENVIRONMENT

### Speakers

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

**Donna Simcoe, MS, MS, MBA, CMPP**, Medical Publications Consultant, Simcoe Consultants, Inc, San Diego, CA

**Barbara C. Good, PhD**, Director, Scientific Publications, NSABP Foundation, Inc, Pittsburgh, PA (Note: Dr Good was unable to attend, but slides she prepared were used in the presentation.)

By Lisa Carricaburu

### What are predators up to, and what should I look for?

1. **"We do it all."** Beware of claims of broad coverage across multiple specialties, or of a large stable of journals started recently that contain no or few published articles.
2. **The issue is money.** Beware if the journal's article-processing fees are not transparent.
3. **Check credentials.** Beware of an editorial board made up of members from outside the specialty or outside the country in which the journal is published.
4. **"We make it easy for you."** Beware of a submission system that is overly simple with few questions asked.
5. **They promise the moon but give little real information.** A predatory journal may make promises of unrealistically quick peer review or provide no information about its process.
6. **Lack of indexing.** The journal is not indexed in PubMed or in the Directory of Open Access Journals.
7. **Where is it?** The journal's website notes no street address or in-country telephone number.
8. **The website is "off."** Graphics look unprofessional, English appears to have been written by a nonnative, many sections are under construction, and/or the site demonstrates web-site cloning or journal hacking.
9. **Familiarity.** The journal name sounds familiar, and the logo looks familiar but neither is authentic.

—Barbara C. Good, PhD

In the decade or so since University of Colorado Denver librarian Jeffrey Beall first began to expose the threat to scholarly publication posed by predatory publishers, awareness of the issue has grown, but so too have the number and sophistication of journal predators.

The reality that even seasoned researchers can unknowingly fall prey to unscrupulous online publishers prompted the American Medical Writers Association (AMWA) to collaborate with the European Medical Writers Association (EMWA) and the International Society for Medical Publication Professionals (ISMPP) to produce a joint position statement on predatory publishing. The 2019 statement summarizes the characteristics of predatory journals, notes the peril they create for scholars and legitimate scholarly publications, and states that deliberate submission to 1 of these journals is unethical.

"We as medical writers and editors have a responsibility to evaluate the integrity, history, practices, and reputations of these journals," Barbara C. Good, PhD, Director of Scientific Publications at NSABP Foundation in Pittsburgh and a coauthor of the position statement, noted in an email after the presentation.

Mary Kemper, BS, a medical writer at Mayfield Clinic in Cincinnati and another statement coauthor, believes predatory publishing "has given us added value as medical writers to help steer others away from these predators."

Kemper credited Beall with articulating the threat in 2008, when he first observed exploitation of the emerging gold open-access model, which shifts the pay-to-read publishing model to a pay-to-publish model. What began as an effort to foster innovation and expand worldwide access to new information sometimes was being co-opted by unscrupulous players seeking easy money.

In 2012, Beall launched a blog ([scholarlyoa.com](http://scholarlyoa.com), now available at [bealllist.net](http://bealllist.net)), which blacklisted "predatory" publishers and journals. "He spoke about this early on as an ethical issue inside the open-access social movement," Kemper said. "Beall detailed the threats that these predatory publishers posed to the scholarly literature by corrupting research communications."

Beall called out the "pseudoscience" spread by these journals, along with their fabricated editorial boards, lack of transparency about fees, insufficient or nonexistent peer review, lack of indexing on PubMed or the Directory of Open Access Journals (DOAJ), and fake or unverified impact factors.

Many applauded Beall for his efforts, but he also drew criticism. Some fellow librarians questioned whether he overstated the threat or was biased toward an established power structure in traditional publishing that favors maleness, whiteness, heterosexuality, and centrism, Kemper said.

Regardless, Beall has been profoundly influential, even since ending his blog in 2017, citing intense pressure from his employer. In 2016, DOAJ delisted 3,300 of 11,000 journals found to be questionable or inactive. In April 2019, the Federal Trade Commission won a \$50 million court judgment against Indian publisher OMICS International, whose journals appeared frequently on Beall's blacklist.

Beall continues to write articles and speak about predatory publishing. He also acted as a consultant to Cabells Scholarly Analytics, which evaluates journals based on 60 criteria and sells subscriptions to the whitelists and blacklists it maintains. Cabells estimates there are more than 12,000 active predatory journals today.

This explains why AMWA joined peer organizations beginning in January 2019 to draft a position statement on predatory publishing. “Our joint task force is committed to educating members about this issue,” said Donna Simcoe, MS, MS, MBA, CMPP, a medical publication consultant and a member of the joint position statement writing committee.

Published in the July 29, 2019, issue of the journal *Current Medical Research and Opinion* and reprinted in the *AMWA Journal*,<sup>1</sup> the statement is clear in its intent. “We encourage all authors to carry out due diligence by examining the reputation of the publications to which they submit, and send their work only to those journals that provide proper peer review and that genuinely seek to contribute to the scientific literature.”

Since its publication, the 3 organizations have provided the statement’s message to their members. AMWA, EMWA, and ISMPP also are promoting resources medical communicators can trust to help determine whether journals are reputable.

Simcoe said that university systems are also trying to help their investigators research legitimate journals. For example, Texas Tech University won a National Science Foundation grant to create online training for academics about predatory publishing, and the University of California San Diego is currently beta testing a journal evaluation checker.

Simcoe and Kemper urged care in evaluating journals. “There are new startup journals or publishers that are legitimate, but use caution and look beneath the surface,” Simcoe said.

“The ones to be most concerned about are the mega predatory journal publishers,” Kemper added. “They’re still morphing, still finding new devious pathways.”

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#### Reference

1. American Medical Writers Association; European Medical Writers Association; International Society for Medical Publication Professionals. AMWA–EMWA–ISMPP Joint Position Statement on Predatory Publishing. *AMWA J.* 2019;34(3):112-113.

## PREVIEW: Note from the AMWA Writing Committee Authors of the AMWA–EMWA–ISMPP Statement on Predatory Publishing

**Barbara C. Good, PhD<sup>1</sup>; Mary Kemper, BS<sup>2</sup>; Donna Simcoe, MS, MS, MBA, CMPP<sup>3</sup>** / <sup>1</sup>Director, Scientific Publications, NSABP Foundation, Inc, Pittsburgh, PA; <sup>2</sup>Medical Writer, Mayfield Clinic, Cincinnati, OH; <sup>3</sup>Medical Publication Consultant, Simcoe Consultants, Inc, San Diego, CA

For the last 2 years several of us have been researching the issue of predatory publishing, presenting on the topic at AMWA meetings, and collaborating with members of the European Medical Writers Association (EMWA) and the International Society for Medical Publication Professionals (ISMPP) to prepare the *AMWA–EMWA–ISMPP Joint Position Statement on Predatory Publishing*.<sup>1</sup> Because of the significance this topic poses for medical writers and editors, we are pleased to announce a series of articles about predatory publishing for the *AMWA Journal*.

Our collaborators in Europe have already published several informative papers on this topic. We believe the article by Bucceri, Hornung, and Schindler<sup>2</sup> provides an excellent description of and introduction to predatory journals, identifies some of their characteristics, and describes certain of the dangers these journals and their publishers pose for those of us involved in the publication of scientific material. Please look

for more on this article, as well as our upcoming series, in the Summer issue.

Predatory publishing has become a dangerous threat to the integrity of the medical literature, to individual researchers’ reputations, and to the actual foundations of science itself. Although we as medical writers and editors cannot influence every aspect of this phenomenon, we need to be aware that it is happening and to educate the scientists we work with about its existence and potential impact. We welcome comments about your experiences with and findings about predatory publishing.

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# Survey Says! The Business and Money of Freelance Medical Communications

Erik MacLaren, PhD / Galen Medical Writing, LLC, Denver, CO

## ABSTRACT

In 2019, the American Medical Writers Association administered the latest installment in a series of surveys conducted over the past 30 years that have collected data on the compensation received by medical communicators. The *2019 Medical Communication Compensation Survey* obtained data from 480 freelances, including 179 who work full-time, and provides an excellent source of information on the rates being charged by independent contractors in this field and factors that may be associated with differences in those rates, as well as common expenses, business structures, and practices. Full-time freelances reported median hourly rates of \$110 for writing, \$85 for editing, and \$100 for quality control. Rates were highest for freelances who had more experience in medical communications, those with advanced degrees, and those who were primarily writers. The majority of full-time freelances charged by the hour, rather than by the project, and 50% reported increased profitability of their business in 2018, whereas 12% reported decreased profitability. The *2019 Medical Communication Compensation Survey* reflects real-world data reported by working medical communicators. The results offer a unique insight into the business of freelancing and are a valuable resource for both working freelances as well as those interested in striking out on their own.

Freelance, or independent, medical writers and editors are a substantial and important segment of the medical communications workforce, as demonstrated by the demand for freelance-focused products and services produced by the American Medical Writers Association (AMWA). Seminars and symposia focusing on the business of freelance medical communications are numerous and well attended at both the annual Medical Writing & Communication Conference and at local chapter events, and resources including freelance-only message boards and job postings are popular offerings on the AMWA website. As in any business, freelance medical communicators need high-quality information on the industry to make sound career decisions, but the

decentralized nature of the work means there are few sources of reliable data on topics like the educational background of the freelance workforce, common business practices, or the remuneration rates that might be expected. As a result, many important financial aspects of freelance medical communications work are opaque, uncertain, or unknown. This can make it difficult for those considering entering the field to know what they might expect, whereas established freelances may find it challenging to determine whether they are following typical business practices or whether their fees are competitive.

AMWA's *2019 Medical Communication Compensation Survey* (the *2019 Survey*) is the latest iteration of salary surveys conducted periodically by the association since 1989<sup>1-7</sup> and is one of the most comprehensive sources of data currently available about freelancing in medical communications. An executive summary of the results published in the Fall 2019 issue of the *AMWA Journal* provided a broad overview of some factors affecting freelance income, such as years of experience and the specific type of work done.<sup>8</sup> This article delves further into select survey results for freelances, primarily those working full-time, to produce a more complete picture of the business of freelance medical communications.

## METHODS

The *2019 Survey* was created, administered, and analyzed by AMWA in conjunction with Association Research Incorporated (ARI), a third-party contractor.<sup>9</sup> Individualized links to the Internet-based survey were sent to AMWA members and non-members during the first quarter of 2019 with 2 incentives to participate: access to early results of the survey and entry into a drawing for 1 of 3 gift cards worth \$100 each.

Invitees were eligible to complete the survey if they worked for pay as a full- or part-time medical communicator in 2018. Employees were defined as those who had taxes deducted from their paycheck by an employer, and freelances were defined as those who were responsible for paying their own taxes, including respondents who considered themselves to be independent contractors, consultants, or small business owners who paid themselves a salary. To align with surveys from previous

years, full-time freelance work was defined in the *2019 Survey* as working at least 32 hours per week, including both billable and nonbillable hours.<sup>1</sup>

### Hourly Rates

The survey asked freelance respondents for the hourly rates they charged for 3 main types of work: writing, editing, and quality control (QC). To maintain consistency in the results, freelancers who charged by the project were asked to report an hourly rate using an estimate of the time “normally required to complete a freelance [writing/editing/QC] project.” The survey sample was skewed toward older, more experienced freelancers, including 47% who were 55 years old or older and 73% who had more than 10 years of experience in medical communications. So, unless otherwise noted, values are reported as medians and interquartile ranges, which are less affected by outliers or extreme values.

## RESULTS

### Education and Experience

Of 1,418 medical communicators who responded to the *2019 Survey*, 480 were freelancers (34%), including 179 full-time freelancers. The results discussed here concern data from full-time freelancers unless otherwise noted. As a group, the full-time freelance respondents were older, more experienced, and less likely to have an advanced degree than full-time employees (Table 1). The average work week included 36.5 hours of billable time and 7.8 hours of nonbillable time, including administrative tasks, billing, marketing, and similar items. The average workloads were similar for freelancers with more than 10 years of experience in medical writing (36.9 hours), those with 6 to 10 years (33.5 hours), and those with 5 or fewer years (36.9 hours).

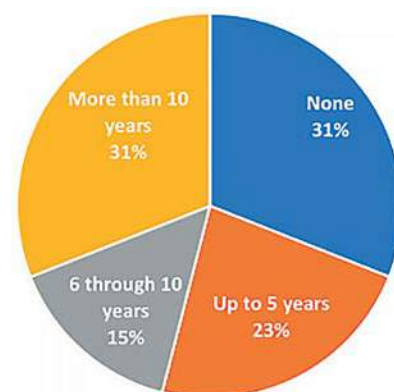
**Table 1.** Age, Experience, and Educational Background of Respondents

	Freelancers <sup>a</sup> (n = 179)	Employed (n = 903)
Age, years	52	46
Experience, years	18	11
PhD or Other Advanced Degree	38%	46%
Mostly Writing Work	71%	66%

<sup>a</sup>Full-time respondents only.

There was a broad spread in the amount of medical communications experience respondents had before starting freelance work full-time. At one end of the spectrum, 31% were employed for a decade or more as medical communicators before working as freelancers exclusively, whereas another 31% had no employment experience at all in medical communica-

tions before becoming full-time freelancers (Figure 1). Experience varied based on freelancers' educational backgrounds; a plurality of freelancers with bachelor's degrees had more than 10 years of prior experience before becoming independent (43%), whereas the majority of those with doctoral degrees (PhDs) started freelancing without any previous experience (52%).



**Figure 1.** Experience in medical communications before solely freelancing (n = 177).<sup>a</sup>  
<sup>a</sup>Full-time respondents only.

### Clients and Type of Work

To avoid the complexity of trying to categorize all clients and projects for every freelance, the *2019 Survey* asked respondents to identify the type of client and type of work that provided the highest proportion of their income in 2018, and the results for full-time freelancers are summarized in Table 2. Pharmaceutical companies (21%) and medical communications companies (19%) topped the list of clients, and more than 1 in 4 full-time freelancers identified regulatory writing as their largest source of income (26%).

### Hourly Rates

Among all freelancers, both full- and part-time, the median hourly rate for writing work was \$110, making it more lucrative than editing (\$85/hour) or QC (\$100/hour), and the rates reported by full-time freelancers were identical to these (Table 3). The rates charged by full-time freelancers varied by experience, and those with more than 10 years of experience charged \$30 to \$40 more per hour for writing projects than their less experienced colleagues, \$25 to \$30 more per hour for editing, and \$38 to \$58 more for QC work. Hourly rates also varied with education level, and freelancers with PhDs or other advanced degrees reported charging \$20 to \$40 more per hour for writing than those with bachelor's degrees; the gap was \$65/hour for QC work. Notably, rates for freelance editing were not affected by education level, with only \$5 separating rates for freelancers having PhDs from those with master's or bachelor's degrees.

Hourly writing rates for full-time freelancers were very similar between those who had an educational background in English (28 freelancers), who charged a median of \$100/hour, and those with a science background (57 freelancers), who charged \$105/hour. For editing work, the difference in median rates for English and science majors was likewise small at \$10/hour, but the gap widened considerably for QC work to a difference of \$29/hour.

Hourly rates also varied by freelancers' primary type of client and the primary type of work they do, although many

categories contained too few responses to calculate. Survey respondents whose primary types of client were biotechnology and pharmaceutical companies reported rates for writing, editing, and QC that were substantially above the overall median rates (Table 3). Rates reported by freelancers with a work role primarily in medical communications agencies were above the overall median for writing, below the overall median for QC, and equivalent to the overall median for editing.

Finally, rates charged by the 71% of respondents who were primarily writers were higher for all types of work (writing, editing, and QC) than those charged by the 21% who derived most income from editing (Table 3). In fact, editors even charged lower rates than their writing counterparts for editing work.

### Fee Structure

Among the full-time freelance respondents (n = 179), 68% reported charging by unit of time as opposed to the 22% who charged by the project. This proportion varied by age, with those under 35 years old about half as likely to charge by time (36%) as those who were from 45 to 54 years (71%) or older

**Table 2. Type of Clients and Work Responsible for the Highest Percentage of Freelance Income**

Type of Client <sup>a</sup> (n = 177)	%	Type of Work (n = 176)	%
Pharmaceutical	20.9	Regulatory writing	25.6
Medical communications	19.2	Scientific publications	15.3
Other	8.5	Continuing education	11.4
Medical education	8.5	Sales training	9.7
Biotechnology	7.9	Marketing/advertising	9.7
Medical marketing/advertising/PR	5.6	Other	9.1
Medical device	4.5	Medical news	6.3
Health care organization/provider	4.5	Medical research and grants	5.7
Medical book publisher	4.0	Education for lay audiences	4.0
Health care professional organization	3.4	Health journalism	3.4
Medical school or university	2.8		
Clinical or contract research organization	2.8		

PR, public relations.

<sup>a</sup>Only client types chosen by more than 2% of respondents are shown.

(73%). Despite the evergreen nature of the debate over how to bill, the majority of respondents have reported billing by time in the 5 most recent editions of the *Medical Communication Compensation Survey*, from a low of 55% who reported billing by time in 2004 to a high of 78% in 2011.

### Expenses and Savings

The 2019 Survey asked full-time freelance respondents about all recurring expenses for their business in 2018 to avoid

**Table 3. Hourly Rates for Writing, Editing, and QC, Correlated With Experience, Type of Client, and Primary Type of Work for Full-Time Freelancers**

Type of Work	Years of Writing Experience (n)	Hourly Rate, Median (IQR)	Type of Client (n)	Hourly Rate, Median (IQR)	Work Role (n)	Hourly Rate, Median (IQR)
Writing	Overall (160)	\$110 (90-140)	Overall (160)	\$110 (90-140)	Overall (160)	\$110 (90-140)
	<5 (23)	\$90 (60-140)	Biotechnology (14)	\$160 (96-188)	Writer (123)	\$120 (100-150)
	6-10 (21)	\$80 (60-100)	Medical communications (30)	\$120 (95-133)	Editor (24)	\$83 (68-100)
	>10 (116)	\$120 (100-149)	Pharmaceutical (37)	\$140 (113-175)		
Editing	Overall (120)	\$85 (60-124)	Overall (120)	\$85 (60-124)	Overall (120)	\$85 (60-124)
	<5 (21)	\$70 (40-95)	Biotechnology (11)	\$150 (82-165)	Writer (70)	\$103 (75-150)
	6-10 (17)	\$65 (48-83)	Medical communications (21)	\$85 (65-123)	Editor (38)	\$65 (50-75)
	>10 (82)	\$95 (70-136)	Pharmaceutical (22)	\$145 (105-175)		
QC	Overall (86)	\$100 (64-136)	Overall (86)	\$100 (64-136)	Overall (86)	\$100 (64-136)
	<5 (13)	\$50 (30-95)	Biotechnology (11)	\$150 (90-180)	Writer (59)	\$115 (80-150)
	6-10 (13)	\$80 (46-125)	Medical communications (18)	\$85 (61-125)	Editor (20)	\$65 (50-83)
	>10 (60)	\$108 (75-150)	Pharmaceutical (23)	\$135 (100-150)		

IQR, interquartile range; QC, quality control.

variations caused by large, 1-time purchases like office furniture. The most commonly selected category was professional member dues and subscriptions (94%; Table 4), although this is to be expected, as the survey was primarily distributed to dues-paying AMWA members. The other most frequent recurring expenses are likely more informative and included tax accountant (70%), office utilities (63%), education and professional development (60%), and health insurance (49%). Marketing was reported by 27% of full-time freelances as a recurring expense in 2018, including 36% of those who were younger than 35 years and 25% of those who were 55 years or older.

Separately from other recurring expenses, the survey asked whether respondents contributed to a retirement account and, if so, whether the contribution was equivalent to the limit allowed by law or less. Among full-time freelance respondents ( $n = 173$ ), 36% contributed the maximum allowable amount to a retirement fund in 2018, whereas 31% did not contribute to such an account. The proportion of freelances who contributed to retirement accounts varied by age and education level, and those least likely to contribute to retirement accounts were freelances under 35 years old (54%) and those with bachelor's degrees (54%). The proportion of freelances who contributed the maximum allowable amount was highest among those who were 55 years or older (43%) and those with more than 10 years of experience (40%).

### Business Organization and Practices

Most of the full-time freelance respondents ( $n = 174$ ) reported organizing their businesses as either sole proprietorships (41%) or limited liability companies (LLCs; 39%). There were differences in responses based on age and education. Among those who were less than 35 years old, 64% operated as sole proprietors. Most freelances with PhDs (57%) registered their businesses as LLCs, whereas 28% of those with bachelor's degrees did. A smaller number of full-time freelances reported organizing as S-corporations (16%), and 1 in 20 selected "other."

Although freelance medical communicators most often operate independently, some subcontract work to others as a way to increase their productive capacity. Subcontracting can allow freelances to cope with temporary increases in business or to complete large projects without entering long-term business relationships with others, and some freelances routinely engage subcontractors as part of their business model. About 4 in 10 full-time freelances hired subcontractors regularly or occasionally (Figure 2), and more of those with more than 10 years of experience reported working with subcontractors regularly or some of the time (47%) than those with 5 years of experience or less (31%).

### Professional Outlook

To gauge the economic outlook of the field, the 2019 Survey asked freelances about the profitability of their businesses in 2018 compared with 2017: more profitable, less profitable, or about the same. Half of full-time freelances reported greater

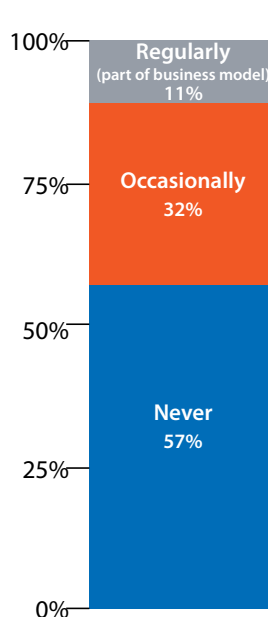
**Table 4.** Recurring Business Expenses ( $n = 174$ )<sup>a</sup>

Expense	Reporting (%)
Professional member dues and subscriptions	93.7
Tax accountant	70.1
Office utilities	62.6
Education and professional development	60.3
Health insurance	48.9
Unreimbursed business travel	33.9
Errors and omissions/general liability insurance	31.0
Marketing	27.0
Office space	25.3
Life insurance	23.6
Licensing fees	23.6
IT support	23.0
Lawyer/legal advice	19.5
Disability insurance	17.8
Other	8.6
Administrative help	7.5

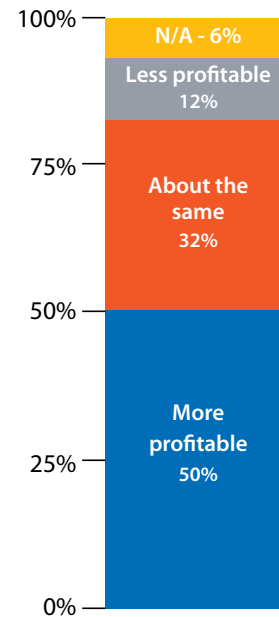
IT, information technology.

<sup>a</sup>Respondents could select all answers that applied.

profits from their businesses in 2018 than 2017—4 times as many who reported decreased profitability (Figure 3). A greater proportion of freelances with PhDs reported their businesses to be more profitable in 2018 (61%) than those with master's degrees (48%) or bachelor's degrees (44%). Of 69 freelances who worked more than 40 hours per week, 16% reported decreased profitability, compared with 9% of those who worked less (100 freelances).



**Figure 2.** Frequency of subcontracting by full-time freelancers ( $n = 175$ ).



**Figure 3.** Profitability ( $n = 169$ ). N/A, not applicable.



## DISCUSSION

The data from AMWA's *2019 Medical Communication Compensation Survey* provide unique insights into the field of freelance medical communications and represent a valuable resource for both new and experienced independent medical communicators.

The median hourly rates for the *2019 Survey* were similar to the 2015 results for writing (\$105), but the rate for editing was \$20 higher than in the 2015 survey.<sup>1</sup> Although it is tempting to speculate about the reasons for these changes over time, results from the 2015 and 2019 compensation surveys represent data from independent convenience samples and cannot be directly compared. The *2019 Survey* was the first to ask respondents about rates for QC work separately from writing or editing, so there are no comparable historical results.

Although it is not possible to make direct comparisons between these results and those from previous iterations of the survey, the consistency of results, including hourly rates and the proportion of freelancers who charge by unit of time rather than by project, lend credibility to the broad trends observed. A contemporaneous survey of freelance medical writers published last year included 175 respondents and found similar hourly rates being charged, including 39% of respondents who charged from \$51 to \$100 per hour and 37% who charged from \$101 to \$150 per hour.<sup>10</sup>

As might be expected, more experienced freelancers reported higher rates on average than those who were less experienced. The results also indicate that it is possible to be a successful freelance without any previous experience as a medical communicator, although it is more common for those with advanced degrees than those with a bachelor's degree. Full-time freelancers with English backgrounds reported charging similar rates for writing and editing as those with science backgrounds, but the gap for QC work was \$29 per hour. This could be due to the greater focus on technical details in QC work, whereas writing and editing require more balanced technical and language skills.

One major unexpected result was the finding that freelancers who primarily wrote charged more for all services than those who primarily edited, including for editing services. Writing and editing are not easily interchangeable skills, and it seems reasonable to expect that freelance editors would be able to demand relatively higher rates than writers for editing tasks. The discrepancy may indicate that freelancers tend to charge a similar rate for their time regardless of the specific task involved; after all, an hour is an hour, whether it is spent writing or editing. Because remuneration for writers is higher than for editors among both employed medical communicators and freelancers,<sup>8</sup> this may indicate that freelancers who primarily write start negotiating fees with clients from a higher base, regardless of the specific project in question.

In another intriguing result, only 27% of full-time freelancers reported marketing as a regular expense. This may indicate the importance of cost-free modes of marketing, such as social media sites like LinkedIn and Twitter, for driving business

relative to more traditional, paid forms of marketing like a company website or business cards. Additionally, the proportion of freelancers who identified marketing as a recurring expense was correlated with age, falling from 36% of those younger than 35 years to 25% among those who were 55 years or older. This may suggest that personal networks and word-of-mouth recommendations produce substantial business opportunities for well-established freelancers and negate some of the need to spend money on marketing efforts.

There are several important limitations to this survey that must be kept in mind when considering the results. First, although interesting trends and correlations have been explored and discussed in this article, the information produced by the survey is purely descriptive. This is due to the nature of the survey, which used a convenience sample of medical communicators, and it is unclear whether the results are representative of freelancers as a whole. Statistical comparisons between these results and previous versions of the salary survey are also not appropriate because of possible differences in both the respondent pools, as well as in the wording of questions and their presentation in the surveys.

## CONCLUSIONS

The freelance model continues to be a popular and enduring work model for medical communicators, and these data add to a growing body of evidence pertaining to key parts of the business, including hourly rates, business practices, and common types of clients. Regardless of its limitations, the *2019 Medical Communication Compensation Survey* is a valuable resource for freelancers at all career stages, as well as for those considering starting a freelance business, providing a snapshot of the field and perhaps indicating areas they could consider for a specialization.

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<https://customer.sspnet.org/ssp/AM20/Home>

### Survey Says continued from previous page

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# Communicating Real-World Evidence for Regulatory Purposes: The RIGOR Checklist

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## Introduction

Real-world evidence (RWE) is evidence derived from real-world data (RWD) collected in the course of clinical practice (such as in electronic health records [EHRs] and claims databases), generally outside of the strict confines of traditional clinical trials. RWE and RWD are increasingly being used to support regulatory decision-making, which led us to explore how best to communicate the design and results of RWE studies in regulatory documents, presentations, and publications. This article is not intended as a descriptive formula, but rather endeavors to propose a framework (the Relevance, Integrity, Generalizability, Organization, and Reliability and Validation [RIGOR] Checklist) to demonstrate whether RWD are fit for purpose. Throughout the article, we highlight various uses of RWE in regulatory decision-making, including case studies and resources for further reading. The article focuses primarily on the regulatory framework in the United States.

RWE has been used for many years to support commercialization, safety signal detection, clinical trial feasibility assessments, and the understanding of the natural history of diseases. In fact, as early as 1998, a historical control comparator from a registry was used to support approval of Refludan.<sup>1</sup>

## RWE Emphasis—Why Now?

So, what has spiked the current interest in RWE as acceptable evidence for regulatory decision-making? We believe it is a combination of demand and supply, but like the chicken and the egg, it is difficult to tell which came first.

1. Increasing public demand for radical innovation in drug development led to the 21st Century Cures Act passed by Congress in December 2016<sup>2</sup> that required the US Food and Drug Administration (FDA) to develop a plan for using RWE for various purposes. In December 2018, the FDA issued a framework<sup>3</sup> that outlined its plans and is expected to issue specific guidance in 2021. The European Medicines Agency and Health Canada also issued RWE reports.<sup>4,5</sup> These initiatives have created a ripe environment for industry and academia to invest in RWE projects that support regulatory

decision-making and are particularly appealing in oncology, in which the pace of drug development and the limited number of patients in subpopulations make classical randomized clinical trials impractical.

2. The supply of data at an unprecedented scale was made possible by rapid technological advances such as digitization of patient health records, devices that capture passive and active patient-reported outcomes, and genetic profiling and next-generation sequencing, as well as our ability to house and manage big and deep data. In addition, evolving analytical methods and advances in artificial intelligence, blockchain, and natural data processing (and others too numerous to list) make it increasingly feasible to draw meaningful conclusions from RWD, which often lack the traditional structure and rigor of clinical trial data.

However, critical questions remain and are mainly related to appropriate standards for quality and reliability of data and how data are deemed fit for use to meet the rigor and substantial evidence standards needed to satisfy regulators.

The FDA has issued some procedural<sup>6,7</sup> but no comprehensive guidance on these topics. The most relevant existing guidance remains “Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data” (2013).<sup>8</sup> For devices, a useful guide is “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices” (2017).<sup>9</sup>

## Substantial Evidence of Effectiveness

In December 2019, the FDA issued an update to the 1998 guidance titled “Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products.”<sup>10</sup> The update is titled “FDA Guidance for Industry: Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products.”<sup>11</sup>

In the preamble, the FDA emphasizes that although its evidentiary standard for effectiveness has not changed since 1998, the evolution of drug development and science requires

flexibility in the amount and type of evidence (including RWE) needed to meet these evidentiary standards. These pertain primarily to serious diseases with no treatment option, rare diseases, and treatments targeting subsets of diseases in which patient numbers are relatively small.

Because of this added flexibility, when writing about RWE, the writer must understand the substantial evidence required to support the approval of the product and the company's strategy, so that the writer can frame the data in the context of those expectations and address any gaps. The rationale must be presented for using RWE and for why other types of studies are not feasible or preferred.

### Reporting of RWE Studies

RWE studies should be reported according to standard regulations and guidances and be consistent with how audiences are accustomed to receiving information from traditional clinical investigations. There are a few areas, however, that deserve special attention, primarily the objectives, the design methodology, and the demonstration that data are fit for purpose, for which we propose our RIGOR Checklist (Table 1).

### Study Objectives

Considering the FDA's RWE framework, RWE study objectives can range from establishing a historical control or synthetic comparator groups; expanding indications into new populations, disease stages, or adding new efficacy claims; data to support accelerated to full approval indications; and postmarketing commitments or response to safety signals. Regulators specifically call out the potential to use RWE to expand indications to the extremes of disease and patient characteristics, which are often excluded from traditional trials.<sup>3,5</sup>

RWD sources vary tremendously in their quality and fitness for purpose. For example, some sources suffer significant missingness, others are richer in administrative than clinical details, and others are specific to their geographic location. Therefore, it is important to include in the objectives statement not only the desired research question (population, products, comparators, etc) but also the type of data sources used to conduct the investigation. Furthermore, RWD sources vary in the duration of data accumulation, which may affect the relevance of clinical practice at the time of data capture. It is therefore important to include the time and duration of look-back.

The FDA requires that sponsors clearly indicate if RWE is used as part of a package to support regulatory decision-making but does not necessarily require sponsors to indicate if it is used to establish outcome assessments, assess feasibility, or generate hypotheses.<sup>6</sup>

### RWE Study Design

What does the FDA consider RWE? Under the FDA's RWE Program, data derived from EHRs, claims and billing data, product and disease registries, patient-generated data, and wearables and devices can support many types of study

**Table 1. The RIGOR Checklist**

<b>Relevance</b>	<ul style="list-style-type: none"> <li>• Types of patients</li> <li>• Intervention of interest</li> <li>• Duration of follow-up</li> <li>• Dose and dose schedule</li> <li>• Outcomes of interest</li> </ul>
<b>Integrity</b>	<ul style="list-style-type: none"> <li>• Informed consent</li> <li>• Confidentiality</li> <li>• Controlled access</li> <li>• Correct data</li> <li>• Transparency</li> </ul>
<b>Generalizability</b>	<ul style="list-style-type: none"> <li>• Geographic location</li> <li>• Health system specifics</li> <li>• Timing of research</li> <li>• Impact of limitations on generalizability</li> </ul>
<b>Organization</b>	<ul style="list-style-type: none"> <li>• Provenance</li> <li>• Completeness</li> <li>• Granularity</li> <li>• Scalability</li> <li>• Traceability</li> </ul>
<b>Reliability and Validation</b>	<ul style="list-style-type: none"> <li>• Identifying bias</li> <li>• Misclassification</li> <li>• Selection bias</li> <li>• Confounders</li> <li>• Managing confounders</li> <li>• Sensitivity analyses</li> <li>• Validation</li> </ul>

*RIGOR, Relevance, Integrity, Generalizability, Organization, and Reliability and Validation.*

designs to develop RWE, including some randomized trials (eg, large simple trials, pragmatic clinical trials), observational studies (prospective or retrospective), and hybrid designs.<sup>3</sup> Table 2 summarizes some common RWE designs.<sup>3,12</sup>

The FDA is commissioning duplication demonstration projects to test whether results from randomized controlled trials can be duplicated in RWE studies and vice versa.<sup>13</sup> The goal is to understand for what types of clinical questions RWD analyses can be conducted with confidence and with which designs and analysis methods.

This work has shown that avoidable design issues, such as immortal person time or overadjusting for causal intermediates, are common and can result in inconsistencies in results. The ultimate advice is that time spent scrutinizing for potential flaws, biases, and confounders at the design stage is key to selection of the appropriate methodology to establish causality.



**Table 2.** Common Examples of RWE Study Designs

<b>Pragmatic Trials</b>	Simple, large, randomized trials often used to generate data in populations with broader inclusion/exclusion criteria. Randomization helps minimize confounders and channeling bias.
<b>External Comparator or Synthetic Control Arm</b>	Used to provide a comparator arm to a single-arm clinical trial when lack of equipoise precludes the conduct of a randomized trial. They can be based on registries, chart reviews, or disease history studies. They can be designed as historic or cotemporary controls.
<b>Observational Studies</b>	Studies in which the investigator observes study participants without manipulation or intervention. They include cohort studies, case control studies, and cross-functional studies.
<b>Registry Studies</b>	Observational studies used to research long-term trends in a specific population, such as patients with a particular disease or exposure to a certain treatment.
<b>DCTs</b>	Virtual real-world studies in which data are collected at home or at the point of care using digital tools (eg, wearables and mobile devices).
<b>New User-Design Studies</b>	Designed to identify a population of patients who start treatment with the medication under study and excludes prevalent users. Allows for active comparator or non-user comparator arm.

DCT, decentralized clinical trial.

An RWE study should be designed to resemble an experiment. A prospectively defined protocol and analysis plan, as well as appropriate governance procedures and a predefined data access and review plan, must be in place before conducting any analysis. A rationale for the RWE study design must be put forth. The FDA strongly recommends that sponsors discuss their plans to use RWE and their potential designs with the agency early and use presubmission processes to ensure alignment with the FDA.<sup>9</sup>

Other important design considerations include the discussion of feasibility assessments and how the treatment effect is estimated. The writer must describe how confounders will be identified and controlled for. In the absence of randomization, other methods must be used to validate the statistical assumptions from RWD. Because of the retrospective nature of some designs, statistical assumptions may require testing to ensure their validity and validation methods are clearly described.

## Data Sources

Industry and academic investments have recently led to the structuring and curation of large data sets that could potentially be used for generation of RWE. The writer should attempt to become familiar with some of these databases and their advantages and limitations. Health care providers enter routine clinical and laboratory data into a variety of EHR databases. These are helpful in collecting medical history and clinical outcome data, but because many health care professionals are neither adequately trained nor have the time to collect detailed data, EHRs are often imprecise, incorrect, or incomplete. Claims databases are set up by pharmacists or health insurers for billing and administrative purposes. The FDA's Sentinel Initiative is an example of claims data used for safety surveillance. Claims databases can help estimate exposure to treatment, treatment patterns, the economic burden of diseases, disease prevalence, and proxies for effectiveness and comparative effectiveness. Limitations include lack of generalizability, prescribing not necessarily translating to use, and containing limited clinical information.

A number of academic, private-public collaborations and industry initiatives are rapidly evolving and have led to the development of networked databases, novel research technology platforms, and collaborations to optimize the use of RWD to generate RWE. The writer should familiarize himself or herself with the specific source, network, and platforms used to conduct the RWE study.

## Are Data Fit for Purpose: Our Proposed RIGOR Checklist

A key consideration in whether RWD and RWE are "regulatory grade" is the demonstration that data are "fit for purpose." As this is an evolving field, several researchers have presented their opinions on what criteria would make data "fit for purpose." We offer this checklist (Table 1) specifically for the medical writing community to provide a streamlined and memorable structure to organize these criteria. Our checklist includes criteria described in various FDA guidances and industry presentations.<sup>8,9,14</sup>

## Relevance

The writer must address why the data are applicable for the research question at hand. Do they include an adequate number of patients with the appropriate disease severity and stage? Are patients receiving the dose and dose schedule to be studied? Are patients followed for the duration necessary to collect the outcome of interest? Is the outcome of interest collected consistently and reliably? Does the data source include data from appropriate resources (eg, hospitalization data, prescription drug data)? Is the intervention of interest used as monotherapy or in combination with other treatments? Is switching an issue? Is the outcome of interest serious enough that patients will visit the health care professional to report it? If looking at a safety outcome, is the appropriate risk window

represented? These and many other elements help provide a compelling rationale for why the database was selected in the first place.

### **Integrity**

Good clinical practice mandates that appropriate informed consent be instituted. In large aggregated databases, it is often difficult to ascertain if the use of the data for a particular purpose was authorized by patients, but one must endeavor to find out. It is also important to describe the measures instituted to protect confidentiality of patient records and identifiable patient information. One must be able to describe who has access to the data during the course of the analysis and whether a data review plan is in place to control appropriate access to data and results. Transparency is another important element to ensure data integrity. Are appropriate processes in place for record-keeping, and are human-read audit trails accessible to inspectors? Is the study protocol registered, and are there publication plans? The writer is referred to the joint report of the International Society for Pharmacoeconomics and Outcomes Research and the International Society for Pharmacoepidemiology for more information on this topic.<sup>15</sup>

### **Generalizability**

For the data to be fit for purpose, it must be generalizable to the intended population of use. One must consider whether clinical practice at the time and geographic location where data were collected are consistent with current practice and have not changed during the look-back period. For studies conducted in a database of a particular health care system, one must consider if there are center- or system-specific practices that differ from clinical practice at large. Do coverage policies or step-up rules preclude or institute the use of certain interventions over others?

### **Organization**

The structure of the database and the processes of data provenance should be described. How are the data organized, stored, and archived? How are data integrated at the provider level and moved to clinical data sets and then to analysis data sets? How are data exchanged between various provider systems and vendors? How are data aggregated? Another important issue is the difficulty in interoperability among different databases. This is particularly relevant for studies outside of small populations in which longitudinal data are collected. How are these matters managed, and to what extent do they represent a challenge?

How complete are the records? If missing data are an issue, one must describe the direction and extent of missing data and how to adjust for it. EHRs are often unstructured and inconsistent in format, resulting in missing data. Claims databases often include patients who opt in and out depending on changes in employment or living location. How is continuity of coverage tracked and accounted for? How granular are the

data? How is the lack of linkage between prescribing and dispensing managed, and does it matter?

These are the types of questions a writer must ask. They do not all have to be addressed, but it is important to ask the right questions at the protocol development stage and at the report development stage to avoid any surprises by health authority reviewers.

### **Reliability and Validation**

In the absence of randomization, one must consider biases in identifying causal inferences, including confounding, misclassification, and selection bias. The writer must describe all potential biases, including measured and unmeasured confounders, as well as the methods implemented to manage confounding, such as restriction, high-dimensional propensity score adjustment, inverse probability of treatment weighting, and multiple variable modeling. This topic is well-described in a paper by Nørgaard et al.<sup>16</sup>

One should also describe the prespecified sensitivity analyses that test the robustness of the findings. These analyses demonstrate the effect of unmeasured confounders and other sources of bias and provide evidence of potential residual confounders or how significant their effect would have to be to materially change the results.

According to FDA guidance, investigators should ensure that the medical outcomes of interest are validated, which involves establishing a clinically appropriate outcome definition and determining the positive predictive value of that definition. If the outcome has previously been validated, the writer should cite the specific literature references. The validated algorithm should be described in detail, including the population, the database, its performance characteristics, and the time frame during which the validation was performed. For studies lacking prior validation, an appropriate justification of the outcome definition used should be included.<sup>8</sup>

### **Use Cases**

Several approvals have been granted by regulatory authorities on the basis of data packages that include an RWE component. Some examples are presented in Table 3.

**About the Authors:** Mary Rofael, MD, is a drug development and regulatory communications expert. She is experienced in the critical assessment of data packages and has helped guide presentations for more than 145 FDA Advisory Committee Meetings. Aaron Csicseri, PharmD, is a clinically trained pharmacist experienced in scientific strategy and communication of clinical data to health authority audiences.

**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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**Table 3.** Use Cases of RWE in Regulatory Decision-Making

Drug	Indication	FDA Action	Comments
<b>Ibrance (palbociclib)</b>	HR+ or HER2– metastatic breast cancer in men	Label expansion	EHRs and postmarketing reports
<b>Blincyto (blinatumomab)</b>	B-cell precursor of acute lymphoblastic leukemia	Label expansion	RWE comparator compared with single-arm trial
<b>Bavencio (avelumab)</b>	First-line mMCC	First approval	Historic control compared with single-arm trial
<b>Xpovio (selinexor)</b>	Relapsed/refractory multiple myeloma	Accelerated approval	Retrospective observational study using EHR (Although approved, an advisory committee had voted 8 to 5 against recommending approval. The FDA briefing document had identified shortcomings in the RWE comparator arm, including lack of alignment with the FDA on the design, analyses not being prespecified, selection bias, misclassification, confounding, missing data, and immortal time bias.)
<b>Lutathera (lutetium Lu 177 dotatate)</b>	Gastroenteropancreatic neuroendocrine tumors	Approval	Open-label, expanded-access protocol
<b>Transaortic Valve Replacement</b>	Patients with aortic stenosis	First approval with no clinical studies	Retrospective assessment of records from 600 patients (off-label use)

FDA, US Food and Drug Administration; HER2–, human epidermal growth factor receptor–2–negative; HR+, hormone receptor–positive; mMCC, metastatic Merkel cell carcinoma; RWE, real-world evidence.

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FROM THE PRESIDENT

## Appreciating the Value in AMWA

Ann Winter-Vann, PhD / 2019–2020 AMWA President



**M**erriam-Webster's Dictionary defines *value* (*v*) as “to consider or rate highly”; synonyms include *appreciate*, *treasure*, and *cherish*. As a noun, value is defined as “relative worth, utility, or importance.”

The word *value* aptly describes my relationship with the American Medical Writers Association (AMWA). Not only does AMWA value all of its members, but I have found value in what I have received through the organization. Now, I recognize that is not a surprising sentiment coming from the AMWA President, but it was not obvious to me as a new member. I had never joined a professional organization before, and I did not really understand what I was meant to gain through membership—but I knew that I was supposed to take this step as I transitioned into my new career.

As many of us do, I started by attending in-person events and a chapter conference. In doing so, I was able to connect with AMWA members who had a range of different career paths, and some of those connections have led to wonderful personal relationships and professional opportunities. AMWA also presented an opportunity to step outside my comfort zone through volunteering, which has allowed me to hone my presentation skills, expand my professional network, and grow as a leader. Although I started with my chapter, many volunteer opportunities exist at the national level. Volunteer roles are available to all members, and AMWA is looking for the next generation of leaders. Will it include you?

AMWA has many online learning opportunities that did not exist when I first joined. For example, the AMWA webinar series has new topics each month, with recordings of previous webinars available on demand. The value is even better this year, as AMWA celebrates its 80th anniversary in 2020 by offering webinars for only \$20 to members. Better yet, one recorded webinar each month is available free to members. And that's just for starters: a whole catalog of online learning is available on our website, ranging from the snack-sized FIT series to multipart courses that provide a deeper understanding of a topic.

As always, AMWA's Medical Writing & Communication Conference provides the best value in professional development. This year's conference will be held October 11 to 14 in Baltimore, Maryland, and the program is shaping up to be better than ever. I'm thrilled to announce that this year's McGovern Award winner is Lisa Sanders, MD. Dr Sanders' trajectory from Emmy Award-winning journalist to physician and the way in which she has

integrated these professions is both amazing and inspiring, and I can't wait to hear her address in October.

As I write this column, it is mid-January, and the AMWA Board of Directors has just approved the “AMWA Position Statement on Legislation That Negatively Affects the Livelihood of Freelance Medical Communicators.” AMWA hopes to add the strength of its voice to the conversation so that legislators become aware of our members' concerns. The statement, along with background information, is available on page 3 of this issue and on AMWA's website at [https://www.amwa.org/page/Position\\_Statement](https://www.amwa.org/page/Position_Statement). I encourage you to share the position statement and background information with your clients and with freelancers in your network. You are also welcome to share the position statement with your state legislators, if and when similar legislation is proposed in your state.

AMWA took this step to support its members who are currently self-employed, but in doing so, it also supports the right of all medical communicators who may choose the freelance business model at some point in their careers. In addition, AMWA aims to educate employers and those who work as independent contractors about the value of freelance medical communicators. AMWA is an educational organization and, as such, we do not have the capacity or resources to engage in political lobbying or litigation. However, we agree that this type of legislation is damaging to the freelance community. AMWA values all of its members and believes that they should be free to work in their own legitimate freelance businesses if they so choose.

Speaking of value, one of the topics of interest that was identified at the 2019 Executives Forum was measuring and communicating the value of medical writing. This topic was independently identified by 3 separate discussion groups and was selected as one of the top 3 areas that AMWA should support. As a first step, AMWA kicked off the 2020 webinar series with a presentation entitled “[Metrics: Proving Our Value](#).” Although the live presentation was in January, the recording is available on demand in AMWA Online Learning ([www.amwa.org/online\\_learning](http://www.amwa.org/online_learning)).

How does AMWA provide value to you? That answer will differ for each of us, as we all have different needs and interests. Much of the benefit in an AMWA membership is related to your willingness to take advantage of all that AMWA offers; there truly is something for all of our members. The value is yours to discover.



# Annual Business Meeting

Held annually in conjunction with the AMWA Medical Writing & Communication Conference, the Annual Business Meeting provides members with an opportunity to hear reports from the President, Treasurer, and President-Elect and to witness the election of officers. AMWA 2018-2019 President Cyndy L. Kryder, MS, MWC, welcomed attendees to the meeting and kicked off the presentation in 1 of her final official roles as president.

## Treasurer's Report

AMWA Treasurer, Julie Phelan, MD, MBA, presented a financial report for the period of July 1, 2018, to June 30, 2019. Overall revenue was at 99% of the anticipated amount for the year, and total expenses were under budget by 7% for the year. The overall net income for the fiscal year was \$270,152 compared with a budgeted \$84,900; this includes net investment income of \$74,377. Net income from operations was \$195,775 compared with a budgeted \$89,900. AMWA had \$1,708,611 in the short-term and long-term reserve funds as of June 30. AMWA Endowment funds totaled \$193,498, and McGovern funds totaled \$158,885.

Phelan stated that the regularly scheduled, annual, independent financial audit of these numbers was underway. A financial report for the 2018-2019 fiscal year will be published in an upcoming issue of the *AMWA Journal*. Phelan also mentioned that it had been a pleasure serving as AMWA's treasurer this past year and thanked the Budget and Finance Committee for their efforts.

## Slate of Officers Announcement

In accordance with the AMWA bylaws, the Nominating Committee presented the slate of officers for 2019-2020 to the Board of Directors at its meeting in April. The Board approved the slate, and the membership was notified of this slate 60 days before this meeting (*AMWA J.* 2019;34[3]:141-142). AMWA's bylaws contain a provision for additional nominations to be made in writing. No additional nominations were received. The bylaws state that a nominee who is unopposed for any office shall be elected automatically. Therefore, the nominees as presented were elected as AMWA officers for 2019-2020 (sidebar), led by Ann Winter-Vann, who, as President-Elect, automatically assumed the office of President. Additional officers include the President-Elect, Secretary, Treasurer, Immediate Past President, and the Executive Director (ex-officio).

## Passing of the Gavel

In a symbolic gesture, Kryder handed over the gavel to Ann Winter-Vann, PhD, to mark her transition into the official role



Photo: EPNAC.com

Ann Winter-Vann (left) presenting Cyndy L. Kryder with a commemorative gavel in appreciation of her year of service as AMWA President.

of AMWA President for 2019-2020. In 1 of her first tasks as President, Winter-Vann thanked outgoing president Kryder for her service and support for AMWA, presenting her with a commemorative gavel in appreciation of her dedication to AMWA.

## Introduction of 2018-2019 Board of Directors

Winter-Vann next reported that the new AMWA Board of Directors is composed of the officers, 9 At-Large Directors, and the Chair of the Chapter Advisory Council (CAC). The new At-Large Directors and CAC Chair were previously approved by the outgoing Board (sidebar).

## Inaugural Address

Winter-Vann gave her inaugural address, which included a review of accomplishments over the past year and exciting goals for the year ahead. You can read the full address in our previous issue (*AMWA J.* 2019;34[4]:191-192). Winter-Vann accepted a motion to conclude the Business Meeting and ended the event by saying that she is looking forward to expanding opportunities to support members as well as celebrating AMWA's 80th anniversary in the coming year.

## 2019-2020 AMWA Board of Directors

Photo on page 12

- President: Ann Winter-Vann, PhD
- President-Elect: Gail Flores, PhD
- Secretary: Katrina R. Burton, BS
- Treasurer: Julie Phelan, MD, MBA
- Immediate Past President: Cyndy L. Kryder, MS, MWC
- Director at Large: Brian Bass, MWC
- Director at Large: Loretta Bohn, BA, ELS
- Director at Large: Noelle H. Demas, MSTC
- Director at Large: Sarah Dobney, MPH
- Director at Large: Elise Eller, PhD
- Director at Large: Melory Johnson, VN
- Director at Large: R. Michelle Sauer Gehring, PhD, ELS, CRA
- Director at Large: Laura Sheppard, MBA, MA
- Director at Large: Shawn Watson, PharmD, PhD
- Chapter Advisory Council Chair: Kimberly Korwek, PhD
- Executive Director: Susan Krug, MS, CAE (ex-officio)



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## Preface

# 2019 Postconference Issue: Online-Only Supplement

**Jim Cozzarin, ELS, MWC / AMWA Journal Editor**



Welcome to the 2019 postconference issue!

Each year ~900 members, nonmembers, presenters, volunteers, awardees, exhibitors, and staff take time from their busy lives to come together for the AMWA Medical Writing & Communication Conference. This 4-day meeting is the flagship event of the year for AMWA members and provides an opportunity to attend open sessions and for-credit workshops, listen to presentations from our esteemed award winners, meet and greet exhibitors, view posters, and network with hundreds of colleagues. Yet, most of our members are unable to attend and therefore miss out on this amazing wealth of information and opportunity.

This exclusive online-only supplement continues our postconference coverage, including a [Letter](#) from past AMWA president Phyllis Minick, a report by Debra Erickson about [San Diego Zoo Kids](#) (a special presenter at the conference), and information from several of our [exhibitors](#).

I hope you find this insight into the annual Medical Writing & Communication Conference to be of value. As you can see, if you missed it, you missed a lot! I hope to see you at the [next conference](#) in Baltimore, Maryland, where we will celebrate 80 years of AMWA!

Yours in AMWA,  
—Jim





## LETTER TO THE EDITOR

### A Day in the Life of the 2019 AMWA Medical Writing & Communication Conference

**Phyllis Minick** / Past AMWA President, 1994–1995

Have you ever felt transported to a former life? That is what the AMWA staff did for me by arranging my visit to the 2019 Medical Writing & Communication Conference. As a long-ago AMWA President, I was eager to attend the annual conference (AC) in my hometown of San Diego, California, but obligations at home limited my registration to Friday afternoon's programs. Even so, the experience was so great that I wanted to share some details.

My first contacts—Susan Krug, AMWA Executive Director; Katie Bergmann, AMWA Marketing & Communications Coordinator; and Melissa Kauffman, AMWA Program Coordinator—provided absolutely perfect interactions. Susan urged me to attend, Katie made the preliminary arrangements, and Melissa followed up—even walking me to the door of the first Education Session I attended. All kindnesses and courtesies were at utmost levels of helpfulness.

During my day at the AC, I had a most pleasurable afternoon and evening of sharing successes (and some failures) with other professionals and a swath of AMWA up-and-comers.

Of the 3 sessions I chose, the first was “How to Check Consistency and Enforce Your House Style: Using PerfectIt in Submissions and Publication.” Speaker Dan Euman, CEO and Founder, was a delight: articulate, informative, and funny. He explained and demonstrated his system superbly. I found this “spell check” of style eminently worth owning. At the end of his audience-participation period, I asked Mr Euman if some embarrassing error had caused him to invent this program. In doing so, I couldn't help sharing my own such error—not correcting a misspelled name of a country where the author lived (I thought he should be able to spell the name of his own country)—for which I got fired. The large audience and I thoroughly enjoyed this Education Session packed into just 1 hour.

In my second session, “Med Write Talks II,” Research Scientist R. Michelle Sauer, PhD, provided fine background information in a TED Talk-type format. With a detail-filled presentation of her own experiences, Dr Sauer evoked good interaction among the full house of participants. While there, I bumped into a former fellow AMWA chapter member in time to reminisce—the kind of opportunity for business and personal exchanges that underlies the successes so many of us gain from our AMWA experience.

The third and last of my Education Sessions was “By the Hour or By the Project.” The leader, Eleanor Mayfield, ELS, of

ELM Communications, spoke briefly of her own freelance practice, then joined the audience at the midfloor microphone. There, she guided an exceptional interactive dialog with many participants of the very-well-attended session. Long-time freelancers freely offered advice and answered questions. Even after the session's time was up, the discussion continued, as many attendees remained in the room, then gathered in small groups outside.

There, some just starting in their new profession of medical writer/editor described woes from attempting to combine their existing skills with the new ones required in their new positions. They now needed to write contracts with clients and balance the timing of long- and short-range jobs, billing, interviewing, record-keeping, and, especially, earning enough money for self-support. To a young woman who'd begun a therapy gym but sought a medical writing career, I recalled my own start-up.

As a sport scuba diver, I wrote medical advice for several magazines read by divers and travelers, then supplemented my articles with photos from an underwater photographer who needed text to publish! Combining skills for a specialized audience can build your portfolio and provide unique opportunities. Checking <https://writersdigestshop.com/> for teaching and publishing opportunities helps.

In this Education Session, I and others gave the following advice: Find time to write several fill-in-the-blanks contracts adaptable to varied work situations so you're prepared without stopping to invent that paperwork at the last minute. Have a legal “hold-harmless clause” ready to include in product contracts. Devise a sliding scale of charges by the hour, week, or job. Develop a file of clients with notes on individual requirements. Schedule your time IN WRITING with slots for new solicitations and old client follow-up. I couldn't help saying to those gathered around us: “All of you are smart, educated, skilled, and energetic. HAVE FAITH IN YOURSELF!”

My AC day ended with dinner shared by AMWA friends and former Presidents. Later, inside my handsome AMWA tote bag, I found an unexpected gift—the 1995 Annual Conference Program with my own presidential message and photograph on the first page! AMWA Executive Director, Susan Krug, located and sent me this remarkable token of transport to my former AMWA life. Thank you, beyond my best words of appreciation.

~Phyllis

# San Diego Zoo Kids: Bringing Healing, Happiness, and Hope to Ill Children and Their Families

**Debra Erickson** / Marketing Director – Communications and Interpretation,  
San Diego Zoo Global, San Diego, CA



It all started with a brief email from a nurse on a cancer ward in Northern California. She wrote a thank you note to the San Diego Zoo, explaining how the zoo's "Panda Cam" provided distraction, comfort, and joy to her patients experiencing prolonged treatment. She summarized the effects of the live, 24-hour-a-day camera in this way: "My patients that watch Panda Cam have less pain, take less pain medication, and those are my patients that sleep through the night." When her email was posted on social media, it received comments from more than 150 individuals who had also experienced the healing properties of the Panda Cam. In fact, unbeknown to us, health care workers around the world had already coined the phrase "Panda Therapy."

Many of our wildlife care specialists and educators had also experienced for themselves the power of animals in helping ill children through their visits to Rady Children's Hospital-San Diego for more than 60 years. Thus, we realized through our discussions with caregivers that sick kids could benefit from the healing properties of animals every day. There is a deep-rooted connection between humans and animals; those who have pets understand the pure joy that animals bring us. We are in awe of animals—and there's growing evidence that having a connection with animals actually helps individuals heal and be healthier. Several studies over the years have also shown that pet-assisted therapy has a positive impact on pain levels of pediatric patients.

With this background, the idea behind *San Diego Zoo Kids* was to provide a closed-circuit, kid-friendly, noncommercial television channel for children's hospitals, which could bring animals to children and their families who are unable to spend time with their pet or visit a zoo or aquarium in person.

After talking with hospital staff, our team learned that many facilities do not have the resources, staff time, or expertise to create and provide animal programming for their patients. They were thrilled to learn of San Diego Zoo Global's interest in expanding its digital programming and expressed interest in this service.



*San Diego Zoo Kids* would give children the opportunity to see animals 24 hours a day, 7 days a week. The channel would include videos of animals at the San Diego Zoo and San Diego Zoo Safari Park, conservation fieldwork, live animal cameras, keeper and scientist interviews, and content from partner zoos and aquariums. These videos would provide entertaining and enjoyable stories for children and their parents—and provide these families with hope.

Because we couldn't bring the actual zoo into the hospital, *San Diego Zoo Kids* would do the next best thing: create a connection—a way for patients to virtually leave their beds and experience the world of animals and zoos. When kids are able to do that, they relax, they sleep better, they're distracted from their troubles, and they can heal. And that's what everyone wants—for kids to heal, be happy, and return home.

It took us more than a year to research and figure out the technology needed to bring children's hospitals the program. The toughest part was finding a donor who had the vision to see the potential of the program. We shared the concept with T. Denny Sanford, a noted philanthropist who had funded Sanford Children's Hospital as well as research on stem cells, type 1 diabetes, and breast cancer, and he saw the potential. He funded a pilot program and chose the facilities to receive the channel, including Rady Children's Hospital, Sanford Children's Hospital, the Children's Hospital Los Angeles, and the Children's Hospital of Colorado. The channel debuted with just over 3 hours of content, but even then, it was an immediate hit with the children and hospital staff. In fact, Chuck

Day, the Executive Director of the Ronald McDonald House in San Diego, heard such great things about the channel that he asked us to install it at his facility.

Mr Sanford was so impressed by the results of the pilot program that he funded the broadcast portion of the program for 5 years and gave the San Diego Zoo Global team a challenge: work with local communities, zoos, and aquariums, along with our donors, to raise the funds to cover the cost of the equipment.





And he gave us an audacious goal: bring the channel to 300 children's hospitals and Ronald McDonald Houses within 5 years.

After the pilot program, it took 9 months to recruit the next children's hospital, Primary Children's Hospital in Salt Lake City. We quickly learned that you can't cold call a children's hospital; you need to work within the local community or within the children's hospital network for an introduction to someone on the hospital staff who had the interest in providing the service to hospital patients. Primary Children's and their partner Ronald McDonald House have played a pivotal role in the success of the program. They have given freely of their time, participating in all 3 of the channel's evaluations.

The second evaluation pursued questions focused on children, parents, and caregivers describing the "human experience" specific to phenomena provided by *San Diego Zoo Kids*. The study involved 3 children's hospitals and 1 Ronald McDonald House. One hundred hospitalized children, more than 100 parents of hospitalized children, and almost 90 hospital and Ronald McDonald House caregivers participated in the study. Our analysis of the data resulted in 7 key findings:

1. *San Diego Zoo Kids* makes children feel happy.
2. *San Diego Zoo Kids* effectively provides a zoo visit for children who cannot visit a zoo.
3. *San Diego Zoo Kids* helps children learn about animals and reinforces a conservation ethic.
4. *San Diego Zoo Kids* successfully distracts children from their reason for being in the hospital.
5. *San Diego Zoo Kids* prompts animal-related discourse between parent and child in the hospital setting.
6. *San Diego Zoo Kids* provides a shared experience that clinicians integrate into a child's care.
7. *San Diego Zoo Kids* helps parents cope and persevere in stressful times.

The following is just one of the exchanges of a patient and parent with the evaluator:

**Child:** I get to watch it with my mom. She cried a lot, but when we watch it together, I get to see her smile.

**Parent:** Our leukemia is back for the 3rd time in the last year and a half. Each time it is more and more aggressive and through it all my son stays positive and the zoo channel helps us. He is more mature than I am about it all, and he always says when we watch the zoo channel is the only time I am not crying and that's when I am the happiest. It's because he loves animals. . . . The zoo channel helps us stay positive, and we watch it at the Ronald McDonald House and at the hospital and it makes a big difference in our lives. Our favorite segment is about the elephants and cancer research, because it gives us hope! This has been one of the brightest stars in our world these days. We are blessed to have it and pray the best for those who made it possible.

We have received unsolicited testimonies from hundreds of caregivers and parents on the healing properties of the channel. One mother, Jennifer, shared the story of her daughter Zoe's experience with the channel:

Zoe has stage four neuroblastoma, which unfortunately requires quite a bit of treatment. Her journey began with chemotherapy at Nemours Children's Hospital, and two back-to-back bone marrow transplants that required her to be in the hospital for a month each time. While in the hospital, Zoe discovered *San Diego Zoo Kids*. She is an animal lover and was so intrigued by the snippets of what she saw on the channel. *San Diego Zoo Kids* was an extremely important part of Zoe's journey, because she spent so much time hospitalized—she couldn't go anywhere for weeks and months at a time. To see her light up and find some happiness when she was watching the channel was so comforting. And if you ask Zoe what the favorite part of her journey was, she would say "*San Diego Zoo Kids*!" This channel meant so much to Zoe. It was something that brightened her day and made her feel that she was at the zoo when she couldn't visit.

Zoe told her mom, "We have to go to San Diego Zoo. We absolutely have got to go there." Her mom vowed that when they got through this journey, they would do everything they could possibly do to get there. Happily, Zoe went into remission. When she was feeling better, her dream came true—the whole family visited the San Diego Zoo to celebrate.

Thanks to the support of so many facilities, and a grant from the Institute of Museum and Library Services that covers the cost of the equipment and installation, we achieved that aggressive goal that Mr Sanford set: *San Diego Zoo Kids* is now seen at 306 facilities in 44 states and 12 countries because it brings healing and happiness, and most importantly, hope, to ill patients and their families.



➤ If you would like to bring the healing properties of *San Diego Zoo Kids* to your children's hospital or Ronald McDonald House, at no cost, please contact San Diego Zoo Global Marketing Director Debra Erickson at [derickson@sandiegozoo.org](mailto:derickson@sandiegozoo.org).





**PREMIUM EXHIBITORS** had the opportunity to submit company/service information in brief.

## **AMA Manual of Style: A Guide for Authors and Editors, 11th Edition**

The *AMA Manual of Style* is a well-respected, comprehensive reference for medical writers, editors, and publishers. First appearing in 1962 as an internal document for the staff of *JAMA* and the Archives medical specialty journals, the style-book has grown over the past 5 decades to become a source widely used by publishers, academics, companies, freelance writers and editors, and other organizations.

Written by the editorial staff at the JAMA Network and published by Oxford University Press, the 11th edition has been thoroughly revised, updated, and expanded. For an author, editor, or publisher working in scholarly publishing, the 23 chapters in this volume answer questions that arise in daily work as well as those that occur infrequently. There is guidance on citing sources; data displays (graphical and tabular); grammar, punctuation, plurals, and capitalization; correct and preferred usage; abbreviations; nomenclature (from genetics to organisms to oncology); copyright, licensing, and permissions; authorship; common ethical concerns; editorial policies; units of measure; numbers, study design and types, and statistics; equations; and electronic editing and proofreading. The book concludes with a list of other resources that may be helpful to authors and editors.

An online version is fully searchable, with interlinking, and glossaries in several chapters with definitions of usage, statistics, and publishing terms. The manual's website offers additional content, including quizzes for educational or training purposes, regular updates, an interactive units of measure conversion calculator, and links to social media features.

For additional information or questions, visit [www.amamanualofstyle.com](http://www.amamanualofstyle.com) or email [stylemanual@jamanetwork.org](mailto:stylemanual@jamanetwork.org).

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## **Aroga Biosciences, Inc.**

Aroga Biosciences is a boutique consulting group that provides regulatory writing services for biotech and pharmaceutical



projects. We are a team of scientists with extensive regulatory and medical writing experience in a broad range of therapeutic areas. Our writers have in-depth experience with regulatory and publishing standards, so we can ensure each document is submission ready. Our scientific backgrounds allow us to understand content at a fundamental level, which aids us in conveying messaging appropriately for its intended audience.

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## **Beacon Hill Pharma**

Beacon Hill Pharma partners with Pharmaceutical, Biotech, Medical Device, Diagnostics, Clinical Research Outsourcing, and other corporations delivering the most qualified resourcing solutions in the market today. Whether start-ups or the Fortune 500, within the public or private sector, Beacon Hill Pharma matches world-class talent with exceptional opportunities. Some of the key functional skill sets include Medical Writing, Regulatory Affairs, Clinical Development, Clinical Operations, and many more.

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## **doDOC**

doDOC is a Boston-based company that has turned the tables for medical and scientific documentation. The doDOC editor enables teams to reduce more than 70% of the time spent writing and reviewing documents. This translates into significant cost savings, reduction of manual processes and risks derived from those practices, increasing individual and team productivity, and contributing to higher document quality.

doDOC changes the authoring and review paradigm through real-time collaboration, enabling multiple people to work on a document simultaneously. Word Online, Google Docs, and other consumer editors fall short when it comes to the functionalities needed to author complex documents, forcing medical and scientific writers to resort to offline solutions. This makes collaboration impossible, generating multiple confusing and disconnected versions, lack of formatting standards, and absolutely no control.





## EXHIBITORS

The doDOC editor offers a single source of truth and information, providing content consistency, intelligent version control and compliance automation across teams authoring, sharing, reviewing, and approving content. This change of paradigm reduces the time spent on the production of all types of documentation, ensuring full control over projects and the automatic production of perfectly designed and formatted documents, customized to follow company's templates as well as journal requirements. doDOC registers every single action, providing a comprehensive audit trail (what information changed, when, where and by whom), producing automatic project reports and productivity assessments based on actual work.

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### EUBIO

#### eu (good) + bio (life)

Eubio is a team of physicians, scientists, writers, and designers who are ever amazed by science and the workings of the world around us.

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Eubio has collaborated with both US and global clients to create, design, and implement impactful strategic communications. Since its inception in 2012, Eubio has joyfully supported pharmaceutical, biotech, and medical device industries; health care systems; nonprofit groups; and renowned academic institutions.

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- We are a community of unique personalities
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We value the genuine **JOY** that comes with doing the work we love. **GRACE** and the sincere appreciation we feel toward each other and our clients embodies our everyday interactions, as does the **INTEGRITY** that binds us together and sustains the trust of those we serve.

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better. We believe **LIFE** is good, and our mission is to share scientific information that inspires us all to live our most healthful lives.

Interested in working with or learning more about Eubio? Connect with us at [amwa@eubio.com](mailto:amwa@eubio.com) | [eubio.com](http://eubio.com)

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### PerfectIt

#### Quality Control for Medical Writing Is Easier with PerfectIt

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PerfectIt is inexpensive, so it's affordable for both major companies and freelancers. Among freelancers, PerfectIt has been rated by AMWA members in their top 3 most essential software programs, beaten only by industry giants Microsoft Office and Adobe Acrobat (Nicosia, M. Results from the 2016 Freelance Medical Communicator Tools of the Trade Survey. *AMWA J.* 2017;32(3):105-112). Among major enterprises, 5 of the top 10 largest pharmaceutical companies in the world use PerfectIt in their medical writing department.

PerfectIt is free to try. Download the 14-day free trial from [intelligentediting.com](http://intelligentediting.com).

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### Trilogy Writing & Consulting

At Trilogy, medical writing is our passion. As specialists in clinical regulatory documentation, we provide a service that is more than just writing. Our writers are integral parts of our clients' teams: proactively planning, coordinating, and writing their clinical documents to meet timelines, with a readability that reduces the time for review and approval. We have been helping pharmaceutical compa-



nies and clinical research organizations of all sizes, worldwide, to streamline their documentation processes for over 18 years—either as support on a one-off document or the entire clinical development program.

We provide our clients with a constructive advice on their projects: we guide our clients' teams through the writing process and ask them the right questions in order to produce documents that communicate effectively. Our writers are trained to understand that our job is not to produce a data dump: it is to think about the data available and work with the team to pull out the messages and present them as clearly as

possible, so that a reviewer can quickly find the information they are looking for and easily understand the story to be told. Our approach to writing clinical documentation ideally results in a minimum of clarifying questions from reviewers, speeding the process of review, and ultimately leading to faster approval.

Trilogy currently has more than 50 medical writing staff who are located in Trilogy's 3 offices: Frankfurt in Germany, Cambridge in the UK, and Durham, North Carolina, in the US.

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**2020  
AMWA**

**Medical Writing &  
Communication  
Conference**

OCTOBER 11-14, 2020  
BALTIMORE, MD

*Trends and Opportunities for Medical Communicators*

# Share the Vision—Come Celebrate in Baltimore

**Elise Eller, PhD** / Chair, AMWA Annual Conference Program Committee

**Save the date!** The 2020 Medical Writing & Communication Conference will be held October 11-14, 2020, in Baltimore, Maryland. Not only will we be at a fabulous location in Baltimore's beautiful Inner Harbor, we will also be celebrating AMWA's 80th anniversary ... and we have a lot to celebrate!

AMWA's Medical Writing & Communication Conference focuses on trends and opportunities in medical communications. It is the go-to event for our profession, the place where we find our people, our space for networking, and our place for professional development. The 2020 Annual Conference Program Committee has been working diligently to develop a conference program that will appeal to the diverse needs of our members and other medical communicators. For example, education sessions and AMWA workshops will address professional focus areas such as regulatory writing, scientific publications, health communication, promotional writing, and grantsmanship; core knowledge; career development; and more. Highlighted in the program are trend-setting topics, such as artificial intelligence, data visualization, structured authoring, and patient engagement. With institutions such as Johns Hopkins University, the National Institutes of Health, and the US Food and Drug Administration in the area, we are also taking advantage of local expertise.

The 2020 conference will be a blend of new and established traditions. At the core of the conference are more than 35 AMWA workshops, many of which are new and designed to meet the evolving needs of medical communicators. Back by popular demand are a speed networking session and the popular Med Write Talks. New for this year are a panel

discussion on the state of the industry; a bioethics session with Ruth Faden, founder and former director of the Johns Hopkins Berman Institute of Bioethics; an 80th anniversary reception; and other exciting features.

You may have noticed that, instead of our usual Wednesday through Saturday schedule, this year's conference will be held on Sunday through Wednesday. Sunday is a preconference day, with workshops and special sessions. Monday through Wednesday are packed with education sessions, AMWA workshops, roundtable discussions, posters, panel discussions, and networking opportunities. I hope this schedule allows you to take time to sightsee either the weekend before or after the conference. The area is home to the National Aquarium, the Maryland Science Center, and historic ships in the Inner Harbor. You can take a harbor cruise or water taxi to see the city from the water. If you're a history buff, Fort McHenry, site of the Battle of Baltimore that inspired Francis Scott Key to pen "The Star-Spangled Banner," is at Baltimore's Locust Point. I, personally, am looking forward to being in Charm City again. It's been over 20 years since I visited Baltimore's Inner Harbor, and I'm excited to see it again.

The field of medical communication is changing rapidly, creating both challenges and opportunities. As we celebrate AMWA's 80th anniversary, we also look to the future. Learn what's new at the 2020 Medical Writing & Communication Conference, and share the vision.

Stay tuned for registration information, and I hope to see you in Baltimore!