AMWA at 75

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Conversations Between AMWA Members

Feature
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AMWA VOICES
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When you attend the AMWA conference or other conferences, what strategies do you use to get the most out of the experience?
What are the advantages of incorporating a business?

YOUR STATS REFRESHER!
Variability, Range, Interquartile Range, and Standard Deviation › Thomas M. Schindler
AMWA JOURNAL MISSION STATEMENT

The AMWA Journal expresses the interests, concerns, and expertise of members. Its purpose is to inspire, motivate, inform, and educate them. The Journal furthers dialog among all members and communicates the purposes, goals, advantages, and benefits of the American Medical Writers Association as a professional organization.
As the American Medical Writers Association celebrates its 75th anniversary, the AMWA Journal is celebrating the individuals who together form AMWA. We extended an open invitation to AMWA members to step forward and hold conversations with each other about, well, almost anything, so long as there was a connection to the theme of medical writing and editing careers or to AMWA. We wanted to hear the voices of AMWA.

A lot has changed since 1940, when a group of 6 physicians interested in medical writing came together to form the Mississippi Valley Medical Editors Association, which was renamed in 1948 to broaden the group’s appeal. Today, AMWA has thousands of members. Although AMWA remains a predominantly US-focused organization, with a strong contingent in Canada, 38 countries are represented on our current membership rolls (map, page 103). We still have physician members, of course, but we also have members who trained as pharmacists, nurses, veterinarians, biologists, epidemiologists, journalists, teachers, and many other professions. We are united by a common interest in the communication of medical information and united in furthering our training and understanding of medical communication.

What follows are edited and generally condensed transcripts of recorded conversations. The individual audio segments are all available online. I encourage you to download the audio, as the actual voices radiate personality and warmth that cannot be captured in the published text.

As you will see and hear, the participants took a variety of approaches to the wide-open assignment. Some discussed their personal medical writing histories, highlighted the services AMWA offers, pondered how medical writing has changed through the years, contemplated the business side of freelancing, or looked back at how they met each other or became involved with the organization. Some participants even paid very close attention to the initial suggested time limit of 5 minutes—and created a 5-minute conversation! (Thank you, Jim and Sue Hudson, spouses who have given much to the organization over the years.)

Within these conversations, we hear from 6 past presidents of AMWA—Max Losi, Art Gertel, Sue Hudson, Barbara Snyder, Douglas Haneline, and Brian Bass—whose tenures in office span from 1987 to 2014. We hear from people who have experience in regulatory writing, continuing medical education, hospital public relations, website design and writing, medical content marketing, and journalism. Geographically, we have participants from across the United States and from 2 other countries, Poland and China.

I hope you enjoy perusing these pages and downloading the audio. If you are interested in contributing an AMWA Voices segment of your own for a future issue, please drop me a line (JournalEditor@amwa.org).

—Victoria J. White, Editor-in-Chief, AMWA Journal
AG: I'm Art Gertel. I am now an independent regulatory consultant, and I work out of my home office in White House Station, New Jersey. I have been an AMWA member since 1979 and I have to thank Max for that. When I was applying for my first job in clinical medical writing, I was contacted by Max, who said, "Have you heard of the American Medical Writers?" Of course, I had not. And it was that year, 1979, [the conference was] being held in Kansas City. He said, if you could make your way to Kansas City, I can interview you for the job there. So that was my first encounter with Max and my first encounter with AMWA. It's been a long 35-year relationship with both Max and AMWA.

ML: That's it?

AG: Well, that was my intro.

ML: Okay, I'll jump in and introduce myself. Max Losi. I'm currently retired. I'm 75. I can remember my age because it's the same as AMWA, and I think we've aged at the same rate. But I'll go back from that very fortunate meeting with Art back in '79, which really became a very important part of my life also. I'll go back 5 years because that's when I joined AMWA and that was my first year in pharmaceutical writing. Actually, to go really far back before 1974, I was a medical student and dropped out of medical school back in the early 60s and ended up getting my doctorate in English at NYU. I thought I would do teaching as a career and I did indeed get some jobs teaching. It was going quite well, but then I left briefly to finish my dissertation and found when it was time to go back that there were no jobs anymore. It was kind of the worst time, maybe, in recent decades, for teaching. So I had to turn around and look for something else, and just the logic of it was that I had this English and writing background and the medical, so medical writing seemed to be logical.

My first job in medical writing was medical abstracting and indexing for an organization—I don't know if it still exists—called the Council for Tobacco Research in New York. Within 6 months, it became clear that that was not a good fit because we were expected to abstract not whole articles, but extract favorable comments about tobacco, and I didn't catch on too well with that. So when I left there, I ended up getting a job at Squibb and that began my pharmaceutical writing. The more I got into it, the more I felt that it was a good fit. So I stayed with it and 5 years later is when I started as a manager at Revlon Health Care, which is where I met Art. I think my success at Revlon was largely due to my hiring Art, who was just a wonderful employee and made me look good.

AG: I'm don't know if it's true, but I am blushing right now. I'll cut in here. I don't know if was true for you, Max, but I always felt like writing was effortless. I found that writing
and data analysis, and clarifying the essence of data came very naturally to me. I felt like I was hard-wired for the profession.

**ML:** Well, you were a natural. There’s no question.

**AG:** It just felt easy. When I was in graduate school, I was working at a toxicology lab, and my supervisor at the time complimented me on the reports that I wrote of the necropsies that I was performing. He said, “Would you be interested in becoming a report writer?” Compared to cutting up small animals, it seemed like a pretty good career path. And so I tried that, found that it was something that I was able to pick up quite readily, and then Max offered me the opportunity to get into the clinical side. Back in those days at Revlon Health Care, as a medical writer, you would get a box of case reports and they would arrive in your office and you would have to take them out and hand-tabulate all of the data of the case report.

I remember doing Student’s t-tests and chi-square analyses, so you did your own statistics. You basically were a chief cook and bottle washer when it came to the analysis, interpretation, and communication of the data from these clinical studies. Of course, at that time there were no PCs. So you hand-wrote your report, gave it to the typing pool who then typed it up, gave it back to you for proofreading, and it went through several iterations and you were loath to make a change because they would have to retype the page or perhaps the entire document. So the ease of editing was very limiting.

**ML:** Good old days.

**AG:** Good old days. But I was also thinking, Max, when you mentioned the few available teaching jobs. I’m wondering whether that was due to the Vietnam War and whether people were going into teaching because it was a deferment.

**ML:** It’s possible. One of the incentives for me to go to graduate school after I left medical school was because of the 2S classification. But I think there was something else going on. What had happened in the 60s was I think there was a great explosion in graduate education, and there were just so many doctoral candidates out there that by the early 70s, when the economy started to contract a little bit and colleges started to lose some of their students—I think part of it was the Baby Boom began to taper off—there just wasn’t anything available, and so I did what seemed to be logical and never really regretted that. It’s been a wonderful career in medical writing. I’m not sure I would say that it was easy for me, but really, it was fun. You know, analyzing data, the good old days when we had to analyze and compile the data from case reports and then write up the reports. When technology improved, we lost some of that but gained a lot of other things.

**AG:** I think that because we had to do so many tasks associated with the act of medical writing, it gave us a much broader perspective on data as a continuum and we knew how data were collected. We knew how they were recorded. We knew how data were analyzed and interpreted and then ultimately communicated. And I think that the specialization that has occurred since that time has narrowed the experience of medical writing as a profession. I think that, had I not had that opportunity to learn many of those associated tasks, I would not have been able to avail myself of opportunities to take a different career pathway. As you know, Max, I didn’t stick with pure medical writing. Once I left Revlon Healthcare, I moved into other parts of the machine, which included project management, publication, electronic data capture, and regulatory affairs. The skills that I learned as a fledgling medical writer, and most of those skills I say I learned from you because you were my mentor. The skill sets that you’ve provided to me included management skills, professionalism, very high standards of quality, conflict resolution, problem solving. All of those skills that are intangible but come into play as you both broaden your experiential path and also increase your responsibility in a managerial role. So, it’s the medical writing and associated skills, but it’s also the management skills that I think are very important to preparing one for career growth.

**ML:** I think you really diversified beautifully. When we left Revlon by necessity because Revlon was taken over and they just let our entire department go, we all went in different directions. I stayed narrowly focused on the work we were doing and just got more and more into NDA [new drug application] development and writing and managing the writing of clinical reports and NDAs. My track was kind of much narrower and maybe more boring. But you did so many different things with it.

**AG:** Well, it certainly wasn’t by design. I think it was by serendipity. I think that the ability to communicate effectively is
such a valuable skill, regardless of which pathway you pick. I think that the people who were making the hiring decision recognize that one doesn't necessarily have to have specific experience in that discipline in order to be effective. I was able somehow to convince people of that fact as I made each branch in my career. I had never been formally a regulatory affairs professional, but medical writers in our experience, as you know Max, were responsible for preparing the various parts of the dossiers that were submitted. We were very familiar with the requirement of regulations that applied to preparing clinical study reports, integrated summaries, and applications. So there was certainly a lot of Venn diagram overlap between medical writing requirements and regulatory affairs requirements.

The same is true with project management. Ultimately, the medical writer as the endpoint recipient of a lot of materials has to manage those data flows and has to be effective at getting people to deliver on time and with the quality expected and in the format expected. So those skills translate very readily into a formal project management role.

**ML:** I agree with you. The medical writing itself really is a kind of a managerial exercise. You've got to coordinate sources of information and people and create and implement timelines. So, I agree, I think that's a great preparation for a lot of things.

I did want to mention that the pharmaceutical industry was a great boon for many of us in medical writing because it has been, and remains, I think, one of the more successful corporate enterprises in America. The pharmaceutical industry has always been a good, solid, often secure and well-paying profession for anyone in it. And medical writing plays a significant role in pharmaceutical development and getting new drugs to the market and then promoting them afterward. So, just to put in the plug for the pharmaceutical industry, it was good to me and my family, enabled me to have and support a family in a reasonably comfortable way and was just a lot of fun at the same time.

**AG:** The role of medical writers or medical communications professionals is expanding with the move towards disclosure and transparency, as we bring in the lay public and patients as audiences that go beyond regulators and prescribers, which is all that we had back in the day. We couldn't promote, to the general public. You had to restrict your communications to the regulatory authorities and prescribing physicians. Now that audience has expanded significantly to include, certainly, marketing pieces, but also to help technology providers who determine reimbursement schemes, the posting of clinical trial data on public forums—all of these things that didn't exist 10 years ago. So these are general opportunities that expand the need for trained and experienced medical writers. So if you're looking for a career, medical writing does represent a pretty good opportunity.

And can I just put in one more plug here? I've always been on my soapbox about advocacy for the profession. And you know the professional organizations like AMWA and EMWA, the European Medical Writers Association, and ISMPP [International Society for Medical Publication Professionals] and TIPPA [The International Publication Planning Association] and like organizations rely on volunteerism and rely on people who are going to be willing to dedicate a certain portion of their waking life to the good of the profession and for their fellow professionals.

I think that people need to understand that. I think we should take a much more vocal role in communicating the value that we bring to the table. I don't think we've been particularly effective in doing [this]. So, now I put a plug in there to rise to the occasion, self-advocate, volunteer, and contribute to the profession.

**ML:** Well said. Medical writers of the world unite!

**AG:** From each according to his abilities, to each according to…

**ML:** That's right.

**AG:** I have Max to thank for so many things—a career, my AMWA involvement, and, my role model. And I mean that sincerely, and I was so glad that Max was willing to participate in this conversation.

**ML:** It's a great honor, Art, and I really appreciate it, and you are definitely one of my best hires. Thank you. Wonderful knowing you.
Founded in 1940, AMWA now has members from 38 countries. In its early years, the organization was affiliated with the Mississippi Valley Medical Society. As shown in the 1959 booklet below, the organization offered a medical editing service—1,000 words for $5.
BS: I’m Barbara Snyder and I’ve been a medical writer for 33 years, spending the first 30 years in the pharmaceutical industry and the last 3 in oncology biotechnology.

PB: And I’m Peggy Boe. I’ve been in the pharma industry for 18 years, 17 of which have been in medical writing. And that was actually my third career. I started out as an English teacher in secondary education, then went back to school to become a registered nurse. I loved nursing and worked in hospitals for many years. I’d love to hear how you got your start in medical writing, Barbara.

BS: In my case, it was purely accidental. I graduated with a BA in British literature that really didn’t qualify me to do anything in particular. So I went to a temporary agency, which placed me at a subsidiary of a large pharma company in the Midwest. I started out doing exciting things like making sure the physicians signed all the forms in black ink. Eventually the company recognized that they could use people who were dedicated to writing regulatory documents like study protocols and reports, and they hired me as their first medical writer. This was back when even people who identified themselves as medical writers couldn’t tell you what that title meant in a general sense. And most of the folks I knew in the field had stumbled into it like I did. How about you, Peggy? How did you get started as a medical writer?

PB: In 1997, I was getting a little burned out from hospital nursing, and I felt it was time for a major change; so I went to work at a large local contract research organization (or CRO) as a clinical quality assurance auditor. I guess I owe my career to that CRO, because they took me from hospital nursing and trained me on basically everything you could possibly want to know about the drug development process and what it takes to get a product to market. They also let me transfer into the relatively new medical writing department, and once I was there I knew I had found my new career. Barbara, you mentioned that you’ve spent your career working directly in the pharma and biotech industries. I have also worked at major pharmaceutical companies, but the bulk of my career was spent on the contract organization side. Two years ago I formed my own LLC and went freelance, and I absolutely love the independence of running my own business. My second favorite position in this field, though, was the time I spent as a director starting the medical writing service for a company that specialized in software and publishing regulatory submission documents.

BS: Speaking of software reminds me of how much things have changed during just my tenure as a writer. Shortly after I started, the magnetic card typewriter was introduced, which recorded text on a magnetic card (the ancestor of the floppy disk). This was great because before that we had to use Liquid Paper or Wite-Out to make corrections to documents. If the addition or deletion of words changed where pages broke, we sometimes
had to retype entire pages. The regulatory environment has changed dramatically over the past 3 decades as well. In July 1988, FDA issued the “Guideline for the Format and Content of the Clinical and Statistical Sections of an Application,” which became the bible for regulatory writers. It included outlines for not only clinical study reports but for the Integrated Summary of Effectiveness and Integrated Summary of Safety (which FDA still requires). Then in 1995 the International Conference of Harmonisation came out with the E3 guideline, which changed everything, from what we wrote to how we wrote it.

**PB:** Absolutely, and in many ways the ICH E3 Guideline made our jobs easier, starting with finally giving us a global, comprehensive structure for the clinical study reports. As the technology and software progressed, having the E3 Guideline also encouraged us to create other types of individual document templates, with standardized content. Then along came the ICH Guidelines on the Common Technical Document, meaning we were given one structure and electronic format for all global submissions, with the premise that it would make our lives incredibly easier by having the ability to submit a new marketing application to the FDA, the European Union, and Japan all on the same day! Talk about a game changer! Hmm, it takes skills to stay in the game. Barbara, can you think of some new skill sets we’ve had to acquire over the years as a medical writer, in conjunction with regulatory and technological advances?

**BS:** In a way, I think it’s the same basic skills we started with. To be a good medical writer you have to understand the therapeutic area you’re in and current regulations. Good writing skills are still a must, and time management and project management (working with others on the writing team) are perhaps even more critical than ever, particularly as more and more of our teams are virtual and more workers are remote. In addition, now there are a lot of different and ever-changing software applications that we need to be proficient with. For example, we long ago moved from using WordPerfect to Microsoft Word, and now have both IBM-compatible computers and Macs. We’ve always had to constantly learn new therapeutic indications and treatments, but I think the learning curve has become more complex with the major advances in science that we’ve seen, things like biomarkers, cytogenetics, and targeted therapy. And, while new regulatory guidelines and guidelines don’t come along all that often, it’s imperative that writers first know that they’re coming and second, know how to implement them when they arrive. And since many writers now work in a global environment, we have to make sure we have the pulse of not just the US FDA, but other regulatory agencies as well.

So, are you still happy now that you have been in medical writing for 17-plus years? And do you have any suggestions for those who are interested in becoming medical writers?

**PB:** Medical writing was a great choice for me because it allowed me to combine my writing skills with my curiosity and interest in science and medicine. Really, I don’t think the type of degree you have matters nearly as much as knowing how to capitalize on your primary skill sets and how to use those to find opportunities. For instance, one of my strong suits is my attention to detail. Anyone can say that, but in whatever job you’re doing, if you want to impress an employer, you have to find ways to demonstrate that skill and be able to give strong examples of how that skill has benefitted your work. My suggestion to someone who would like to get into medical writing is to apply for any position you might qualify for at a CRO, as CROs are more likely than pharmaceutical or biotech corporations to provide on-the-job training, and CROs generally also support transfers into other departments. So, for example, you might be hired as a clinical research monitor or to do database entry. Learn from those starting positions and leverage what you can to qualify for a medical writing position by volunteering to write protocols, informed consents, or study manuals, for starters. And don’t depend solely on the training offered by your employer. Do a fair amount of self-training and reading on your own. There are also certificate programs and even master’s programs specific to scientific and technical writing. But candidates should understand that earning those specialized certificates or degrees doesn’t guarantee entry into medical writing. The majority of experienced regulatory writers today have started in a related field, at the bottom, and worked their way up into regulatory writing.

**BS:** And don’t forget about the American Medical Writers Association. As a past president, I feel I should put in a plug for this great organization that I credit with teaching me how to be a professional in this field. AMWA has had a robust certificate program in place for years, but this year, for the first time, you can sit for an exam to become certified as a medical writer. This has been a long time coming and taken dedicated effort from a lot of extraordinary people. I can’t tell you how excited I am that AMWA has taken the lead on this!

**PB:** There have been so many great accomplishments from members of AMWA, and the certification potential may be the icing on the cake in terms of taking our field to the next level of professionalism.
CK: I’m Cyndy Kryder and I live in Phoenixville, Pennsylvania, which is actually suburban Philadelphia. And I became an AMWA member back in I believe 1993, which was about a year after I launched my freelance medical writing career. I do a variety of work. I do sales training. I do medical marketing and communications, for pharmaceutical companies, some patient education. And I do blogging about health care, the Affordable Care Act, and the changes coming in health care for another client on a regular basis.

DM: I am Donna Miceli. I joined AMWA in 1989. That was the year that I moved from the Buffalo, New York, area to Phoenixville. Prior to that, I had worked as an assistant director of public relations at a large hospital in Buffalo, so that’s where I got my interest in medicine, writing in the health care field. I was a freelance for 25-plus years. This is my 26th year in AMWA. I am pretty much retired. I am going to be 75 this year, and I just am really, really excited about this conference in particular because, clearly AMWA was born the year I was born.

CK: Well you know, Donna, I think 75 is the new 60.

DM: I hope so.

DM: I have something, Cyndy, that I was thinking about yesterday—a couple of things, actually. One of the things is that most of the friends I have in AMWA, or all of the friends, are people I’ve met after joining AMWA. You are the only person I knew beforehand, since we were neighbors and good friends and everything. I am so grateful that, through AMWA now, with both of us having memberships, that I get to see you once a year.

CK: That’s true. Well you’re really my AMWA connection. It’s hard to believe, but we met 26 years ago, actually it was 26 years in April when you and Art moved into the house behind us. If it weren’t for you, I don’t know that I would have found AMWA, because you were instrumental in getting my career off the ground, to be quite frank. I think I remember walking up to you in the driveway one day and saying, “How can I write and get paid for it?” That began it all.

One of the things I value most about AMWA is the friendships I’ve made through it. It’s wonderful to be able to see people at the annual conference once a year and, since you guys moved to Florida, you’re right, this is the only opportunity that I do get to see you anymore. We make time for each other at the conference, and always try to go out to dinner and have a coffee or something just so we can catch up.

DM: And that means a lot to me. I am so proud of what you’ve done, you know, and I kind of take great pride in it, not only in the fact that you were interested in wanting to be a writer, but that you are actually a good writer. You’ve been really successful, and
you’ve shared that success with the people in AMWA that are just coming up and learning and so on. You’ve had a different track than I’ve had. I actually came to it late. I was 50 when we moved there, and I was just going back to freelancing and deciding to do the medical stuff. I’d been doing it a couple of years, I think, before we had our conversation and had built up some fairly good clients, but you’ve just done so much more in terms of sharing and the workshops you and Brian [Bass] did. Actually, I think if I remember correctly, I think I’m the one who told Brian about you.

CK: That could be.

DM: We had just moved to Florida and he called me. I don’t know how long I’d been here, but not very long, and he called me looking for help with a job, and I was in the process of doing something. He asked if I could recommend anybody, and I recommended you. I think you had met him, but I recommended you.

CK: I remember that. That was the very first job Brian subcontracted to me. Believe it or not, I still remember the topic. It was magnetic resonance angiography. Go figure. That was a long time ago.

DM: It was a wonderful circumstance anyway.

CK: Well, and you know I think we were very fortunate. We both were members of the DVC, the Delaware Valley Chapter, and that was a very, very active chapter. Every month back then, and this was the 90s, we would have a meeting at some restaurant in Philadelphia. We always knew when it was going to be held, because it was something like the third Tuesday of the month, and sometimes there would be a speaker. Sometimes there would just be a networking opportunity. I remember one of the very first meetings I went to. There were, something like, four of us who lived out here in Chester County, and we all hopped into the car together. We carpooled down into the city, and that’s where I had the opportunity to meet “Dear Edie,” [Schwager] who was just a wonderful AMWA member and a great contributor to the organization and to our chapter. It was just a great opportunity to meet these people you read about in the AMWA Journal. “Dear Edie” had her regular column for years and years, and here she was live and in person. Those were just wonderful, wonderful experiences I’ve had over the years through my connections with AMWA.

DM: Yes, the giving back is something that AMWA is all about, because I know a lot of us, when we were starting our careers, we turned to AMWA, because we were seeking what they had to offer in terms of the networking opportunities and the educational opportunities. I think it behooves all those of us with experience, to share what we know about the profession—things we wish we had known when we were starting out. I think that’s part of what we have to do as professionals. I’m curious, Donna, how did you find AMWA? What led you to AMWA?

DM: Well, it was interesting, because I worked in hospital public relations for a few years before we got transferred. I decided to go back to freelancing and I liked the medical writing I had done. I had a friend I had worked with—another public relations director—who had moved near Boston, and she called me and she said, “Have you ever heard of the American Medical Writers Association?” I said, “No, I haven’t.” And she said, “Well, they have a conference in Boston.” She told me when it was going to be—I think that year it was in November—and she said, “I’m going to go. Why don’t you sign up and go with me?” She said, “You could stay with me.” Actually, she lived in New Hampshire. I was glad that I went, but I would never stay with someone again. You need to stay where the conference is. I decided to do it. I was kind of at loose ends, and so I actually took a train to Boston, and that’s when I joined. After that, I started only going to the ones on the East Coast, because of the finances, and then I decided, at some point, that I owed it to myself to go to the conferences wherever they were because it’s a wonderful networking place.

CK: That’s true. Two of the things you mentioned. One, the fact that always struck me about giving back. People in AMWA are not proprietary. They’re willing to give and suggest. They’re not saying, “Well I don’t want to take a chance that you’re going to steal one of my clients, so I don’t want to share anything with you.” The other thing is Edie. This is before I joined AMWA. I belong to the Women in Communications group—it’s now called the Association for Women in Communications—and they had a conference there in Philadelphia right after I moved in, or shortly after. I went to one of the sessions, and who should be there but Edie. Of course, I didn’t know who Edie was. She did basically the same sort of thing—not medical related—but the kinds of mistakes that you find in newspapers, and all those kinds of grammatical things. It was the most interesting thing I’d ever gone to. When I went to AMWA and saw her, I thought, “Oh my goodness. This lady’s not just an AMWA person. Other people know her.”

CK: That’s right. I know. It was great. It’s been fun. We’ve been colleagues together professionally, because at one point you and I have worked on some projects together, but then we’ve also been friends and neighbors, and you’re a surrogate grandmother to my 2 children, so it’s just been a fabulous experience all around.
JH: Hi, this is Jim Hudson. I’m retired and have been a tech writer and medical writer for over 50 years, working full time in companies as well as freelance, in Minnesota and here in California.

SH: I’m Sue Hudson. I’m also retired. I worked for more than 40 years in technical writing, tech writing management, and then finally in medical writing. We both live in Simi Valley, California.

SH: Jim, how did you get your start in medical writing?

JH: Well, this is some time back, before personal computers. I looked at the Sunday newspaper and saw an opening at Medtronic. They mentioned that they had a 4-day work week and 36 hours. Bingo! Off I went for a job interview. Just before I went in for the interview, I sat out in the parking lot and looked at an article in my *Scientific American*, [which] talked about hummingbirds and their rapid beat-per-minute hearts. It talked about the physiology and the anatomy. So I went in there, armed with this knowledge, and that’s how I got the job. So...

SH: Did you want to know how I got started?

JH: (Laughs) Yes, how did you get started, Sue?

SH: I was working as a tech writing manager. I had worked in the same company for 15 years and was really burned out. I quit cold turkey. I thought, “Well, I’ll take a few months off, and then I’ll find another job.” So, while I was off, your client asked if you knew anybody who had expertise in FrameMaker, which was an authoring tool that people used for writing manuals. It happened that I did; I had a lot of experience with FrameMaker. So they hired me to do some conversions of documents into FrameMaker. While I was converting, I noticed a lot of things that needed editing, and I got permission from the company to edit it. Eventually, I was working for them as an editor and a writer, all freelance. From there, I joined AMWA, and many of my AMWA friends gave me leads on other jobs. That’s how I got into medical writing.
JH: Did you ever have problems, in all your freelance experience, getting paid?

SH: Really, only once. I made it a practice to stay on top of our receivables; that's some advice we got from a friend who owned his own business. I would badger the accounts payable people, and so forth. This was a good client run by a couple of partners. One partner was responsible for paying everybody and kind of running the operations, and the other partner was responsible for getting new business. So the new business kept coming in, but eventually the person responsible for paying us stopped paying us. It got to the point where they owed us $18,000. Asking to be paid and cajoling and all that didn't help; it seems nobody [who worked for them] was getting paid at that point. It wasn't until they asked me to do another project, and I said I won't do it until you pay everything you owe, that they finally did because they needed me to do this other project.

SH: Did you ever have trouble getting paid?

JH: Yes, a PR [public relations] firm [owner] some time back refused to pay me. I had written an article on the splicing of fiber optic cables so that the signal still remained strong past the splice. He said at the trial, “I could not use Jim’s work at all.” Unfortunately for him, I had obtained a copy of the journal I was writing for through him, called *Lasers and Applications*. The article I had written was the cover article.

SH: Did you take him to court, is that what you’re saying?

JH: Yes, I did. I took him to small claims court. One of the key things about small claims court is to get a declaration of assets, so that if the person fails to pay you, should you win, you can put a lien on the goods listed in that declaration of assets. When we were in the [courthouse] parking lot, I got the VIN number [vehicle identification number] of his Porsche. I put that on the declaration of assets, so that nailed down assurances that I would get paid. After the trial, he said, “OK, I will pay you, but I hope I can do so in 3 equal payments over 3 months. My wife divorced me, and my business partner left me to [start] his own business.” He did pay me the 3 installments, so that worked.

SH: Those are some highlights from our medical writing careers. Thank you!

I joined AMWA, and many of my AMWA friends gave me leads on other jobs. That’s how I got into medical writing.
RV: Lori, can you tell us about the kind of work you do?

LD: I do what I call medical marketing communications, and that’s different from what most medical writers do. I specialize in writing for patients and the general public, and mostly I do newsletters, magazines, Web content, and other types of writing for hospitals, health systems, and medical communication agencies that work for hospitals and health systems. So it’s not the more clinical and technical work that a lot of medical writers do. I also do some medical marketing communications for professional audiences, but what I really love to do is help people learn about how to stay healthy or get healthy, and if they’re sick, how to find great health care and evaluate their options.

RV: That sounds very interesting. How did you end up in medical writing?

LD: Like most people, I just fell into it. I didn’t even know it was a field. I studied journalism at Temple University, and then I went to work for an advertising agency for a few years. Then I went back to Temple to do communications for their business school. While I was there, I got a master’s in journalism. Toward the end of my graduate program, I started thinking about what I might want to like to do. I did some freelancing really just as a way to see what else might be out there. Because I live in the Delaware Valley, which is a hub for hospitals, medical schools, pharma, and other organizations related to medicine, I started getting medical writing assignments without knowing anything at all about the field. When I decided to freelance full time, I had 2 separate marketing campaigns. I had one that was geared toward the medical writing and one that was geared toward business. But within 1.5 years, I was doing entirely medical writing.

RV: Why did you join AMWA?

LD: I’ve always known that professional associations are really important in any career. They’re the best way to make key contacts and to learn about a field. So when I fell into medical writing, I started looking for professional associations to join, and I found AMWA. But joining is only the first step. To get the most out of a professional association, you need to get involved. I’ve been volunteering for AMWA since a few months after I joined, both with the Delaware Valley Chapter and with national. In my chapter, I’ve done everything from sitting at the registration desk before a meeting, which is a great way to start volunteering, to founding and co-chairing our freelance conference, to serving as president. For national, I’ve served on the board, the annual conference committee, and the AMWA Journal Freelance Forum. I often present at the annual conference and have covered sessions for the journal.

RV: How has AMWA helped you in your career as a medical writer?
**LD:** It’s helped me in so many ways. I’ve built a very strong network and have gotten many referrals for business over the years, and they’ve always been with really good clients, which is very important. I’ve also learned a lot about medical writing and about freelancing through AMWA.

I have a wonderful group of freelancers, including Ruwaida, who I can turn to when I need advice on specific issues in freelancing or if I just want to commiserate about a bad client or bad situation. Volunteering has also enabled me to learn new skills, like meeting planning.

**LD:** Ruwaida, can you tell us about your work?

**RV:** I have been freelancing on a full-time basis since 2007, and I specialize in educational pieces for health care professionals and pharmaceutical sales training materials. I do online articles, CME [continuing medical education] needs analyses, and all aspects of CME including slide presentations, monographs, and webinars. My therapeutic expertise in terms of the major areas I write in are immunology, oncology, and cardiovascular disease.

**LD:** That sounds very interesting and very varied. How did you end up in medical writing?

**RV:** I pretty much stumbled into the field. I had been doing some freelancing part-time for an online and in-print geriatrics journal since I was in grad school. But I discovered the field of medical education by accident. I was at a job fair. At the time, I was working at Hoffmann-La Roche as a research bench scientist, and I was looking for a position closer to home, since we had moved. I was standing in line for Bristol-Myers Squibb to look for bench research opportunities there. There was a small table for a medical education company. The HR [human resources] representative of the medical education company at the table called me over and encouraged me to give her my résumé because they were actively recruiting. I gave her my résumé, and she saw that I had some freelance medical writing experience.

The president of the company called me a day later, and I went in for an interview. The rest is pretty much history. I was hooked as soon as I went in for the interview and realized the opportunities and the growth that the field allowed for. I joined them as a project manager and worked with them for a little bit. Actually, it was there that I met Brian Bass, and he introduced me to freelance medical writing. That was my transition.

**LD:** Why do you feel medical writing is a good career choice for you?

**RV:** I get bored very easily. I cannot imagine doing the same things day in and out. I love a diversity of work, which is definitely something that medical writing allows me to have. I love science, but bench research was not enough for me. Medical writing allows me to be on the cutting edge of the latest therapeutics that are already in development. And I also love the flexibility of freelancing and working from home on my schedule.

**LD:** What advice would you give to someone starting off in medical writing?

**RV:** Joining AMWA is definitely top on the list. It not only allows you to meet your peers, but it also offers learning opportunities that are specific to the field. Once you join AMWA, the next thing that is very important to do is to clearly define what type of medical writing you would like to do. I think there are 2 major buckets in medical writing: you have regulatory medical writing and you have “other.” Those are the 2 major fields that I don’t see any crossover between. Within the “other,” you have promotional, you have CME, and lots of other varied opportunities. But those tend to crisscross. Regulatory and this “other” bucket do not go back and forth. You’re either a regulatory writer or you fall into this “other” bucket.

The next thing to do once you identify the type of writing you want to do is to network, both in person and online, especially updating your LinkedIn profile. If you want to be a medical writer, your LinkedIn profile should look like one of a medical writer.

**LD:** Tell us about your involvement with AMWA.

**RV:** I am involved both locally at the Delaware Valley Chapter and nationally as well. At DVC, I am the secretary of the chapter as well as the chair for the DVC Freelance Conference this year. Nationally, I’m the section editor for the “Freelance Forum” section of the AMWA Journal. I’m also on the webinar committee and the online education advisory committee.

**LD:** It sounds like AMWA keeps you very busy. What are some of the key benefits that you get from volunteering?

**RV:** The benefits that I get are both personal and professional. I have grown both personally and professionally by networking. It has been great for me. I have met some great people. Not only have I been able to network with them, but I have had them refer me for some great freelance writing opportunities.

**LD:** It’s wonderful to hear that. I’ve had very similar experiences with AMWA. Those of you who are newer to medical writing and AMWA, jump right in and get involved. We have plenty of opportunities for everybody.

**RV:** Absolutely. I would highly recommend it too.
AR: I’m Amy Rogers, and I am a former physician living in the north Dallas area. I left practicing medicine about 15 years ago and just over time kind of fell into the medical writing field.

BM: I’m Bliss Mishler and I just recently stopped practicing physical therapy, and I also sort of fell into medical writing when a friend of mine asked me if I would do some work for her for her medical practice. I live in Hawaii, so it’s a wonderful way for me to telecommute.

AR: Excellent. So we met at the 2014 AMWA convention in Memphis in one of the sessions. Bliss was there looking for writers coincidentally.

BM: I was also looking for other medical writers that did the kind of writing that Amy and I do, meaning not pharmaceutical specifically. I hadn’t really met anybody who is doing medical writing for hospitals and private practices and the like, and so it was wonderful when I stumbled upon Amy because of a brilliant question she asked in a session we were in together.

AR: I don’t remember that, but I think it is important to clarify that we’re probably not your typical AMWA writers because we really do content marketing, and we do things like blogging and condition papers, that hospitals or practices would put on their website so that potential patients and patients can benefit from that and understand what they are about—and, hopefully, want to make them their practitioners. So it’s a little different than most of the people you come across at AMWA.

BM: We want to make medicine more understandable and clearer to the average person, and we have a unique perspective on that, having dealt with patients, but also knowing what we know about writing, copy writing, and content marketing.

AR: We’re very convinced of the importance of increasing the voice of evidence on the Internet. There’s plenty of the voice of alternative medicine or whatever term you want to call it, and we’re very driven in the other direction. We agree very strongly on that, so it makes this very easy for us to decide clients we want to work with and who we don’t want to work with. Our ethos for what we want to do is very similar, so that’s been nice.

BM: And we’re both silly.

AR: That is true, yes.

BM: Which I think makes for working nicely together, but also there’s a little bit of that component in translating hard science, evidence-based medicine into something that’s digestible for the average person. If you inject a little less formality, even sometimes a little silliness, I think you can pass along some really important information in a way that doesn’t
feel like you’re being talked down to or that’s intimidating, which I think it can be the case for patients often.

AR: You came from physical therapy. I came from medicine. What did you feel like you needed to learn to do when you moved into medical writing?

BM: A lot. That’s a really good question. I started early in college just knowing that I needed to learn how to write at all. I come from a state that unfortunately ranks quite low in standard English scores because of the pidgin English that people grow up speaking here. My father really pushed me to do better in terms of that. I took a lot of writing courses in college, and then when I started actually writing, I just studied a lot because I was mortified at the thought of making mistakes, grammar mistakes, not having a comma, and so I’ve done an incredible amount of self-study.

BM: How did you get into medical writing?

AR: I have always loved to write, so ever since the Internet came to be, I had a blog, but it was always very self-serving. Coming from a medical background, I can do the science fairly easily, but the biggest thing for me was writing for a particular audience because when you like to write, you like to write big fancy sentences with really amazing SAT words, things like that. Well, that’s not really great, depending on the audience that you’re writing for, and so learning, “Oh, this audience is different than that audience,” and understanding how to transition the type of writing you do was a huge learning curve for me.

It took a lot of study and understanding how you do that and still make it feel like sophisticated writing. It’s not that people are not smart, it’s just that they don’t have time and they’re being bombarded with messages from so many places that it needs to be easy to digest.

BM: That’s something that I think about too, the difference between writing or business writing and copywriting. You are effectively writing a sales piece but trying to find a way to do that is more geared towards patient education and less overtly “Look how great we are” selling tactics, and that’s a little bit challenging. That seems to be the way content marketing is going, and I think that’s because people want real information. They don’t want just to be sold to.

AR: I agree, and the best way to sell yourself is to be helpful, right, so, that’s hopefully what the content we create is doing. It’s offering help to people who are looking for that information.

BM: I’ve been an AMWA member for 3 years maybe. I just found it during searches on the Web. I just decided to take a chance on it. I wasn’t sure based on the website if this was something that was just trying to sell me something or if it was an actual beneficial group, so I decided to take a leap of faith and it looked good, so I went, and boy, what a thought. It was amazing. I felt like I found my people when I went [to a conference]. That was kind of neat, to find my place in a field that I wasn’t even sure existed.

AR: It’s true. I haven’t been in AMWA quite as long. I joined at the beginning of 2014, and I was at a crossroads. I’ve been writing little bits here and there, but I didn’t know if it was going to work or not. I would get an article in a magazine, but just nothing really consistent, and so I said “I need a career, and I’m either going to be a writer or I’m going to be a college professor or I’m going to be lawyer.” And so I joined AMWA. I applied to law school, and I started teaching at the local college all at the same time. I called it my shotgun moment.

I was just putting it all out there, and whatever I hit, that’s what was meant to be, and I applied to law schools and actually got admitted with some nice scholarship money. I didn’t really enjoy teaching college very much, and then the minute I did that, it was like the faucet came on and the [writing] clients started coming, and the referrals started coming, and I just kind of hit that critical point where work just started rolling in, and that was nice. It turned into a real career at that point, and it was just about the time, at the beginning of 2014, that I joined AMWA. I signed up to go to the convention, and started trying to do some of the classes, and now here we are getting ready to go to San Antonio and we’re going to have our own session.

BM: I think both Amy and I really want to encourage people that are like us, former clinicians that are doing this, because I know there are a lot out there, and I think a lot of them don’t even know that there is a community. I think we’d really like to build more of a presence for that particular community within AMWA, whether that’s bringing in members or just bringing the members that are there out of the woodwork.

AR: Last year, I talked to so many people who were really new to the concept of medical writing and didn’t really even know where they were going to fit in. Content marketing for medicine is huge because as in everything, medicine seems to lag a little bit. They’re slow to adopt new ways, and so content marketing has taken off so strongly in so many other industries, but it’s really just an open door right now in medicine, so there are lots of opportunities.

BM: So much opportunity. There’s a lot on the Web that’s really good, but there are so many more practices out there that are just not even aware of how to do it. Our goal is to help practitioners get in there, practitioners who believe in putting good information out there, to help them do that.
KS: Hello, my name is Kara Sorrell. I am a new medical writer at Medpace Inc in Cincinnati, Ohio. I just started in the field and have been working as a medical writer for 9 months. Today, I am interviewing Kathy Wekselman, senior director of regulatory and scientific affairs at CTI Clinical Trial and Consulting Services in Cincinnati. Kathy has been working in the medical writing field for 18 years.

To begin, I think listeners might be interested in hearing a brief overview of your education and career path.

KW: I started out in the arts, actually—a degree in art history and then one in librarianship, and then I switched over to the sciences and got a nursing degree. Then I went on to get a PhD in nursing. So, I was doing an academic career path, teaching and researching, and got invited to a pharmaceutical company, Procter and Gamble pharmaceuticals here in Cincinnati, and they talked to me about coming in as a medical writer. That was 18 years ago, and I was there for 9 years. They sold themselves to another pharmaceutical company and at that point I jumped over to the CRO side, contract research organizations, and I’ve been doing that for 9 years. So now instead of being in a pharma company, my clients are pharma companies.

KS: Interesting. Well, what is your day to day like as senior director here?

KW: Well, for every single year that I’ve been a medical writer, no matter what my title was, a common theme has been that I never knew going into work what my day was going to be like. It’s pretty rare that what you have planned for a day is what you actually wind up doing. You usually wind up juggling a lot of different projects. People have questions and so you’re really ready to change on a dime and rejigger your workday.

Now, I should say that in my background before the PhD in nursing, I was a labor and delivery nurse, so that’s a fantastic preparation for medical writing work because you get super used to changing courses, the unexpected happening, emergencies—you know, needing to work really fast all of a sudden out of nowhere. Also, the whole practice of being where you are very fully, getting immersed in what you’re doing and not thinking of anything else outside of that until you come to a stopping point. And then you think about, okay, what else is going on in my work life or in the universe, for that matter?

KS: Wow, well it kind of sounds kind of like my days sometimes. I’m sure mine are much more simple compared to yours.

KW: Well, I don’t know about that. And then, of course, there is the meetings versus working time, and that’s a constant pain point I think for medical writers. I personally, and I might get pilloried for this, but I sort of really like meetings. I like working in a group and having some social time instead of just being in my office every single hour.
of every single day. That being said, you do need plenty of alone time to just focus in and quietly work.

**KS:** What kinds of skills have you had to learn on the job?

**KW:** Well, this seems obvious, but I’m going to say writing. You know, I came into medical writing with 2 bachelor’s degrees, 1 master’s degree, and a PhD. I had written a lot for publications, I had published a lot of journal articles, I had written zillions of papers in my academic career, and I fancied myself an accomplished writer. And I learned that I had a lot to learn working with more experienced people in medical writing. And particularly taking medical-writing-focused courses in AMWA, I learned so much more about writing. With regard to the therapeutic areas, there is always more to learn, and that keeps it really exciting. Whole new fields of study suddenly pop into existence, and then all of the regulatory stuff. I came in with a good working knowledge of clinical medicine and patient care. But then the whole regulatory process, what the documents are for regulatory agencies—first the US, but then all around the world—that was all brand new to me—all the jargon, all the regulations, all the documents, so I had all that to learn.

**KS:** How do you see the field changing and where do you see it going?

**KW:** It isn’t actually the question you asked, but a big concern of mine is the status of medical writing, and what do people think about it. I think it continues to have a problem with people underestimating the value of it or the capabilities of people who do it. It’s a little bit like nursing in that regard, so I’ve kind of specialized in low-status, underappreciated kinds of job titles, responsibilities. I think that’s the real challenge for medical writing—to make the field understood as much, much more than some kind of clerical or quasi-clerical field where you’re sort of taking information that smart people gave you and sticking it in a document and making it pretty. Where [instead], you’re actually leading groups, leading processes, and contributing in significant ways to how best to present clinical trial data and all other kinds of information as well.

**KS:** If a new medical writer wanted to join the management ranks, or aspired to one day, what tips would you offer them, and what opportunities would you recommend that they keep an eye out for?

**KW:** One thing is that it just depends what kind of organization you’re in and how the job progression is structured and what the history is. I know at Procter and Gamble, and this is pretty common, I think, because medical writing didn’t have a lot of status, people with the title medical writer didn’t have a lot of opportunities, or at least there wasn’t an expectation that they would rise in management or in seniority, unless it was just within medical writing, like supervising other medical writers. So I actually wound up getting out of a medical writing title after just a couple years, and I haven’t had that title ever since. What I do is medical writing, really, but I have had other titles like the one I have now—regulatory and scientific affairs.

You’d have to really look at whether keeping the title medical writer is going to put a real ceiling on your advancement. I don’t think it should be that way, but I think in many organizations it is. And I’ll say this—medical writing and nursing both: one reason I think they struggle with underappreciation is that there is just such a wide range of sophistication of practice within the field. And so, it’s a little confusing to folks outside and even within the profession, like where do you want your level of practice to be and then how do you communicate that to those around you? You know, I think a lot of it is just demonstrating what you can do, and people with eyes to see will recognize that.

**KS:** What have you found to be some of the most difficult aspects of the job for new medical writers? What gets easier with time?

**KW:** It’s an awful lot to learn all at once. I think there really are 3 threads to the job that you have to learn to weave together. So, one is the writing piece, which I put first. But, then there is the technical piece. You may be new in a field, and the information you get is gobbledygook to you, so you have a tremendous learning curve, whatever it is, if it’s osteoporosis, oncology, nutritional supplements—whatever. Then there’s the whole people management piece and the psychology piece. Anything we do in an organization and in drug development is, what do you want to say, 70% science and 30% psychology? You’re working with teams of people as various as people are, and keeping everyone moving in a good direction. It’s usually your responsibility to meet the deadlines for document completion, but yet you don’t have authority over people who have to give you pieces or complete their reviews and give you their comments, so there is just a tremendous need for people management skills and learning how to approach different people and how to make things happen.

**KS:** Any last thoughts?

**KW:** I’m a real Pollyanna, but I say to you extremely sincerely, I love my work. I love being a medical writer. It took me a while to get there, but it’s been just a fabulous way to spend a couple decades. I certainly intend to do this for the rest of my working life. And, I think it’s a wonderful field. If you have the inclinations and interests, it’s just got tremendous opportunity, tremendous variety, tremendous reward. And, if you want a career that will make you very employable and pay you quite reasonably well, and keep you interested and motivated—lack of repetition, things always changing—I couldn’t recommend anything more highly than medical writing.
SB: Should we start with the introductions?

DG: So, Szymon, tell me about yourself.

SB: It’s pretty complicated. It may take 5 hours rather than 5 minutes. But anyway, I will try to be brief. I graduated from veterinary medicine in Poland and I’m based in Poland, currently in Warsaw. I used to work as a researcher at a medical university, where I did my PhD. Then for a couple of years, I was working in medical communication for some publishing houses. Then one day, about 5 years ago, I realized that I needed to do something on my own, and I started my small company. Initially, it was a freelancing company, but then I employed some people. Now we do medical writing, medical translations, and also medical statistics. And 3 years ago, I learned about AMWA and found out about the European sister of AMWA, EMWA, started attending the conferences and met all these wonderful people, and became a part of the medical writing community. That’s all, in brief.

DG: And this is Deb, and I came into medical writing via newspaper writing. I was a newspaper reporter for many years and covered health and medicine, and from there, I also had several jobs in managed care and other health care entities. My last job was working for a health care publisher. Fifteen years ago, I went out on my own. My business is focused in a variety of areas—consumer writing, business writing, and writing for clinicians. These days I’m doing a lot of work for business-to-business companies, explaining where they are in the health care space given health care reform today. I’ve been involved with AMWA for about 10 years.

So, I have a question about EMWA, the European Medical Writers Association. How is it different from AMWA?

SB: Oh, it’s definitely different. The first thing is that most EMWA people work for pharmaceutical companies. So, I would say that the proportion of freelancers in EMWA is like 10 percent, no more. Most of these people they work for competing pharmaceutical businesses, and this makes the relationships during conference totally different from those during AMWA meetings. The thing I like about AMWA is that there is plenty of networking during AMWA meetings and after meetings.

DG: That’s really interesting, because I know a lot of us in the US talk about joining the European organization. Do you think it’s worth us doing that or not? Particularly freelancers?

SB: I think for freelancers, it would be quite expensive because the European conferences are a little bit more costly than those in the US. But generally I think for those who are looking for a job, or for a contractor in the pharmaceutical industry, it could be a good idea to meet with some people from these big firms or businesses.
I also wanted to ask about your business model because you said you employ other writers. I tried using subcontractors a few times and didn’t have a great experience. How do you work that out?

You’re right. It’s quite challenging, especially for me, because I’m very demanding about the quality. Finding people who offer services of good quality, it’s really challenging. I used to employ some medicine students. There are some foreign students who study medicine in Poland, and some of them are native English speakers. They were very good as translators and medical writers. But, unfortunately, when they graduate, they’re no longer interested in the job. That’s really the challenge, finding people who will really help you and provide you with good quality.

So, what’s your answer? How do you find them?

Well, actually, I’m always testing some people. Some of them find me via our company website. But I’m very demanding and therefore some of them resign after 1 or 2 assignments. But still, there are some people with whom I can cooperate and who are really able to help me.

What do you think is the most challenging part of freelancing or having your own business?

Actually the problem is that you have to manage everything by yourself. If you work for a company, you just do your job. You do medical writing, statistics, whatever. Being a freelancer or owner of a small company, in turn, you have to do accounting. You have to do customer management services. You have to take care of your business travels, etc. These are challenges, but I was told once that when I started working on my own, I would never return to work for somebody, and that’s really true. That’s what I appreciate most about my business: I can work from everywhere. I can work in flexible hours. I can work from my sofa with my dog on my lap.

What do you think is the most challenging part of freelancing or having your own business?

Yeah, I do that a lot in fact, and I completely agree with you. I say I’m unemployable until I get to my downshifting phase where I can work in a winery. I could never return work in a company again, even working from home. I just couldn’t answer to somebody else.

What about time management when you’re working from home?

I have never had a problem with that. Breakfast dishes and lunch dishes sit in the sink until 6 o’clock. It’s never been a problem for me to stay very focused, and maybe that’s from working in a newspaper where there are always things going on around you when you have a deadline.
EI: I’m Evvie Ishmael, and for many years I was a high school English teacher and a volunteer writer, and I obviously had a degree in English and had a degree in writing. I decided to retire and try my hand at writing for other people. I consider myself to be more than a medical writer. I call myself a content writer.

My medical writing includes Parkinson’s disease education and advocacy material, creating presentations about caregiving for nursing supervisors, and serving on a PECORI grant committee. In other content areas, I’ve teamed with web designers, written articles about medical concerns and aging, produced educational material for a finance group, and blogged for an education company.

CB: My name is Ciranna Bird, and I’m a freelance medical writer. I have been freelancing for 2 years, and at this time I would still consider myself as starting up. Previous to this, I worked for the Department of Public Health for 9 years, and my job changed in the last 3 years, and I was responsible for digging through other humans’ fecal samples to find bacteria that cause foodborne diseases. At the time, I was a microbiology supervisor, but the material I was working with was not that enjoyable, especially during the summer and outbreak seasons. Prior to that I got a master’s degree in epidemiology, and I spent a few years working in laboratories in university settings, for pharmaceutical companies, and for the government. So I have a very strong science background.

What attracts me about medical writing is that I can reach a broader audience and convey my enthusiasm for science learning, but bring it to people who can be intimidated by the difficult concepts and bored by the aspects of science that aren’t important to them. So I’m thrilled to be a medical writer, but I also do other writing. I created a food blog, and I’m really interested in North Carolina farms and animals involved in food production.

EI: Ciranna and I have not known each other a long time. In fact, we were strangers sitting next to each other at the Delaware Valley 13th Annual Freelance Conference in King of Prussia this year. And we discovered very quickly that as much as we enjoyed each other and we talked very easily, we were very different and we came from extremely different backgrounds.

CB: Exactly. I come from a science background, and Evvie comes from a writing background. I was telling her that I was envious because writing was not in any classes that I took in my epidemiology program or biotechnology.

EI: I envied Ciranna for her scientific background. But I did feel that my teaching helped me to appreciate reaching out for an audience because each day, I had to reach out for the audience of my students.
CB: I think that’s a great skill set. Do we want to mention at all about AMWA’s past?

EI: Oh, sure. Go ahead. I think it’s interesting.

CB: So as part of the 75th anniversary committee, I learned that for the first 13 years or so, AMWA membership was only open to physicians and certain people could become a member only if they were sponsored by, at least, 2 physicians and at that time most physicians were men.

EI: Well that’s so different than now because I don’t meet a lot of physicians, but I do meet a lot of women. And I’m guessing that physicians are relieved that more people are doing medical writing because it gives them more time to focus on their patients. Just because they know medicine doesn’t mean they’re good writers or have the time to write.

CB: Exactly.

EI: I think we should talk a little bit about volunteering for AMWA because I feel like that’s the way AMWA can be meaningful to a person.

CB: I agree. I have been a member for 4 years, but only this year have I become much more aware of the services that are offered. So I joined the AMWA 75th anniversary committee, and on the local level, I became the website manager and the LinkedIn manager. That’s been tremendous because I was not very familiar with LinkedIn before I began managing the group, and now I have a lot more connections and confidence with starting conversations and see the benefit of it. How about yourself?

EI: I attend as many conferences and lunches as I can, and I have helped with the AMWA website revisions and I have edited some articles and served on some committees. I feel like, as I do those things, I’m enriched professionally, and I also meet a lot other members who are intelligent and enthusiastic and supportive.

CB: I agree. I think that one of the best parts of AMWA is the peer group. You know, there’s a lot of collaboration and there’s so much to learn.

EI: There are so many [AMWA] services, and I will honestly admit that I don’t use all of them, but my 2 favorite parts are Ginny Redish’s *Guidelines for Document Designers*, which can be downloaded from the website. I frequently turn to that as I am thinking about the best way to present my text. I also—even though maybe I’m not considered new anymore—I also refer frequently to the Toolkit for New Medical Writers. But, what about you? What services do you use?

What attracts me about medical writing is that I can reach a broader audience and convey my enthusiasm for science learning, but bring it to people who can be intimidated by the difficult concepts and bored by the aspects of science that aren’t important to them.

CB: I’m a big fan of the *AMWA Journal*. I read the print version. I like all the different sections, especially the Freelance Forum, since we are both freelancers. I also have been enjoying the webinars.

EI: I do think you hit on something with the journal. There’s something for everyone in it. It touches on a lot of different topics, at many different levels.

CB: So, this has been excellent. Shall we end it here?

EI: Yes. Should we schedule another time where we can sit next together and have breakfast.

CB: Sounds great. Thank you.
Hello, everyone! My name is Hongbo Zhu, I am a medical writer based in Shanghai, China. I work for a multi-national pharmaceutical company called Boehringer Ingelheim, or BI. I act as BI’s head of medical writing for the Asia region.

My medical writing career started in 2003, when I had just completed my postdoctoral training at the Weill Medical College of Cornell University in New York City. Around that time, I decided that I would enjoy writing even more than doing bench work. Therefore, after my postdoc fellowship, I joined a small CRO [clinical research organization] in Philadelphia as a medical writer. And since then, I worked on both the East and West coasts of the United States as a medical writer for various CROs and pharmaceutical companies. In 2013, I came back from the US to China to help set up the BI medical writing department for the Asia region.

I came to know AMWA when I was looking for a career pathway more than 12 years ago. I did some Google searches in late 2002 and early 2003 on the medical writing profession and AMWA’s website popped up. I had joined AMWA in 2003 and bought some AMWA books, studied them, before I started hunting for a medical writing job. AMWA has helped me tremendously in my career pathway. I attended many of the annual AMWA conferences and networked with many members of the organization. AMWA helps me increase my knowledge about medical writing, broadens my networking in the industry, and provides a platform for me to share what I have learned.

Over the past decade, China has quickly become one of the largest pharmaceutical markets in the world and a key player in global and regional clinical trials. To better serve the growing medical writing community in China, in late 2013, under the leadership of Ms. Xiaoling Wang, a few local medical writers established a formal organization for the growing medical writing community in China. (See related article page 126.) Our organization is called China Medical Writers Community, or CMWC. The objectives of this organization are to facilitate communication, to promote continuous professional improvement, and to create networking opportunities for all medical writers currently working in China. It is interesting to note that I currently serve as one of the 2 education coordinators under CMWC. So, after more than a decade of learning from AMWA, now I am sharing what I have learned from AMWA with new Chinese medical writers to help them grow.

At this extraordinary year of AMWA celebrating its 75th anniversary, it is a special honor of mine and of all of the CMWC members to introduce ourselves formally to you as a token of appreciation for AMWA’s leadership in promoting the medical writing profession in North America and beyond. Thank you, AMWA, for igniting the spark, thank you for leading the way, and thank you for your generosity in spreading the seeds of medical writing! 谢谢！生日快乐！
I am Ning Zheng. I am a medical writer from Beijing. I now work for Sanofi (China).

I joined AMWA in 2011 as a student when I was in the University of Chicago. My story with medical writing started when I was doing my PhD and decided that I would go look for alternative careers outside of academia. I tried to look for different opportunities and encountered medical writing. I believe that this is the profession that fits me best: I can still talk about science and data, and, in the meantime, contribute to the pharmaceutical industry, which is really where my passion is. So I did a summer internship in medical writing at Takeda Pharmaceuticals, whose headquarters is near Chicago. From there, I got to know AMWA, and I became a member.

AMWA is very useful to a student. I was amazed that there is such a big community in North America for the medical writers and soon felt at home. From AMWA, I got to know more about this profession. For example, there are various types of medical writing and various ways of working as a medical writer, like in the office or at home. I guess the most important piece to a student is the salary survey results! I felt that this is an organization that truly serves its members and provide its members with what they really need. With all information from AMWA platform, I further determined my career goal as a medical writer.

After graduation, I came back to Beijing with the family and became a medical writer in Sanofi China. Sanofi is very supportive to medical writers in Beijing. We learned a lot from our colleagues in the US and Europe. One critical [piece of] advice we got from our department head, Joan Affleck, is to receive the AMWA Essential Skills trainings. All fellow medical writers in Sanofi China are taking these courses. The courses provide hard-core knowledge on medical terminology, grammar, punctuation, as well as statistics. I have found them very useful, especially Punctuation for Clarity and Style and Sentence Structure and Patterns.

Benefiting from the American Medical Writers Association, we felt that we should form an organization for Chinese medical writers, so that medical writers in China can feel at home, too. Under the leadership of my manager, Ms. Xiaoling Wang, the China Medical Writers Community, CMWC, was founded in 2013. (See related article page 126.) CMWC had several off-line forums in Beijing and Shanghai and our appearance in DIA China. We’ve also set up an on-line communication group in WeChat, to help young medical writers grow and learn from each other. The topics of our discussion, online and offline, covered from ICH documents, such as CSRs and CTDs, to the documents for China health authority, CFDA, requirement.

This year, AMWA is celebrating its 75th anniversary. I want to express my gratitude to the service AMWA has provided to its members. Thank you for leading me through my early years exploring medical writing as a profession, thank you for the trainings and webinars you provided to young medical writers like me, and thank you for being a role model for CMWC to follow. 谢谢。
DOUGLAS HANELINE
Emeritus Professor, Ferris State University; Past President of AMWA (2012–2013), Grand Rapids, MI

BRIAN BASS

**DH:** This is Doug Haneline. I was president of AMWA in 2013. I’m a retired English professor but I continue to be a freelance medical writer and editor, which is a career I began in 1986 when I joined AMWA, and this year will be my 29th consecutive AC [annual conference].

**BB:** Hi, I’m Brian Bass. I’ve been an AMWA member since 1994, got active initially at the chapter level, and just finished serving as president of AMWA last year. Doug, when we both got involved in AMWA, who knew that there was really such a thing as medical communications? How did you get started in the business?

**DH:** I think what you said is true, Brian, that medical writing until pretty recently was one of those things that was a well-paid and very rewarding profession that was extremely obscure. I started in AMWA because I was a professor, and part of my responsibility was to teach advanced writing to nurses and pharmacists.

In the 1980s when the Internet, except for a certain few people, was the stuff of science fiction, all that information was in books or resided in associations, and I learned about the American Medical Writers Association. I went to a meeting of theirs in the Detroit area. I was invited. I met Pat Cornett, who was at that time the president, and later became president of AMWA in 1988. I thought to myself, “This is where I’m supposed to be,” and I started going to meetings, and here I still am.

But I found immediately that it had an application to my teaching career, and I used my developing competence in medical writing to propose a medical writing track for our 4-year degree in professional and technical communication. How about you, Brian?

**BB:** My experience is similar to yours. I’m not as sure that I found medical communications as that medical communications found me. I had been working at an ad agency in New York City when I first graduated from college, spent about 7 or 8 years working in advertising for clients who were in the entertainment field, consumer packaged goods, and retail and then found myself freelancing for a company whose clients were in animal health pharmaceuticals.

That was quite a far afield for me, and I discovered from there that writing in the veterinary market was not the only thing that was available to a medical writer. From there I discovered diagnostics and devices on the human side and then came back into pharmaceutical writing on the human side as well. So it was an adventure for me, and I found myself in a conversation with a gentleman who was a medical illustrator long before the Internet was born. He told me about an association that he belonged to for medical illustrators, and he pondered, “Gee, I wonder if there’s an organization like that for you?”

It was a little bit harder to research than doing a quick Google search, but there I was, finding myself in medical communications, and very soon on as an AMWA member.
DH: I have a feeling. This is based on thousands of conversations with AMWA members in the hospitality room at the annual conference and in other places. I have a feeling that at least until pretty recently, relatively few people said to themselves when they were 17, “I’m not going to be a fireman or a nurse; I’m going to be a medical writer.”

Medical writing was there, and either they stumbled into it or they realized when they arrived at this certain point that it was a logical next step for them. And I think actually—if I may talk about AMWA for a second—that’s one of those valuable things about AMWA. AMWA is not dependent on your having a certain kind of degree or a certain kind of academic preparation. That would be impossible. There is of course our certificates and the certification process, which is unfolding even as we speak.

But people are drawn to AMWA for the very legitimate reason that they see that there’s a career here, but they don’t need to earn another degree in something. So I think that’s one of its main values.

BB: I think you’re right, Doug. Both you and I came into this industry from different paths, but we are the same in that we don’t have scientific or medical training that brought us into this field. And speaking for myself, the AMWA certificate program, the opportunity to network with colleagues, and things like that really gave me the understanding more broadly and deeper that I needed in order to become more successful at being a medical communicator. And so I found those experiences to really be invaluable.

DH: Yes. Now, one thing I think would be interesting for us to talk about, since we’ve both been doing this for quite a few years, is what are important changes in the landscape that we’ve seen? How is medical writing different today than it was say in 1995?

BB: Well, for me, I’ve seen a lot of changes in different areas, and that may be because I find myself working in a lot of different areas of medical communications. I’m involved in writing manuscripts. I’m involved in writing CME [continuing medical education] programs and in patient education as well. And so, if I may say that there’s been an overarching theme to the changes, it has been gladly one of transparency, of acknowledging that medical writers are involved in the process of all of this. And also just ensuring the legitimacy and the accuracy of the information that is going out is much more clearly top of mind than it used to be. It was always there, but it was not as apparent and as spoken as I think it is today.

DH: I think that’s very important, Brian. Someone once asked Harry Hopkins, Franklin Roosevelt’s assistant, to describe what his job was like, and he said, “You need to have a passion for anonymity.”

And in many ways that is still true. We are in published manuscripts, writers. We are not necessarily the author. But I think one of the most positive changes is a recognition, which you can see in, say, the guidelines for authors, where it is important now to acknowledge the contribution that writers and editors make for reasons of transparency. But that also means that, as you say, the world has taken notice of us.

I think what I’d emphasize in terms of change are changes that are engendered by technology. One is that it’s much easier to communicate with people electronically, much faster, over a much broader face of the world than it was even 20 or 25 years ago. That has meant that, in the case of drugs, for example, when you are preparing something you can say to yourself, “I’m preparing this for a truly international audience.” It might be for the American arm of a company, where the headquarters is in Tokyo, but the research facility is in Munich.

“We’re all pushing the wagon together that says, ‘We want to have better communication because we want better health outcomes.’”

BB: We are much more connected, and I must say I still serve on various AMWA committees, and I’m on one committee where—I’m here in New Jersey. We have committee members as far west as Hawaii and as far east from me as Poland. And it’s amazing that we can all come together in a single space with a united concern or a united idea and work together. We not only manage those differences but also leverage those differences for the advantages of what we do for a profession.

DH: At the end of the day, as is the case with any kind of applied writing, the test of efficacy for medical writing is, “Does it contribute to the health or the good of people who are sick, or people who want to remain healthy, who need to know more information?”

And good medical writing in that sense is directly applicable to good medicine, so even if we do not have formal medical training, even if we are not clinicians, we are nevertheless a part of a team. We’re all pushing the wagon together that says, “We want to have better communication because we want better health outcomes.”
BB: And that, to me, Doug, is really the major draw of why I love to do what I do for a living and feel so fortunate to be able to do it. I really feel, more so than any other job I could have had in my life, that I’m really making a difference, that I have an opportunity to really contribute to the greater global good to impact individuals, but also to impact the world on a bigger scale. Even in how I choose to punctuate the words I use help people understand things better and more clearly. I think that’s the one most wonderful thing about being a medical communicator.

DH: Since we were back-to-back presidents, I think it might be worthwhile for us to spend at least a little bit of time talking about what we think the greatest challenges are now for AMWA itself as an organization that is the voice of biomedical communication.

BB: I must say, being a terminal optimist as I am, I don’t see many challenges now, and I did not see many challenges last year when I was president. What I really do see for AMWA are opportunities. The organization has come so far in its 75 years, and when you think about almost the Stone Age of communications, not quite chipping on tablets, but pecking away at manual typewriters, all the way to the laptops that we have today.

There is so much opportunity for AMWA to continue its involvement and its commitment to online communications as a way of making more of what it has offered all along available more readily to more people than ever before. And I see that as the big opportunity facing us right now.

DH: I agree, and the only thing I would add to that is that, compared to when you and I joined AMWA, there are fewer people, especially who work for pharmaceutical companies, who have permanent positions with the company. There are many more people in CROs [clinical research organizations] or people who are independent contractors, or who are running their own businesses. I mention that because I noticed when I was president that we had to address more specifically the needs of people who ran their own businesses and who had to take care of their own professional development. And we needed to make sure that AMWA was valuable to them, and I think we have.

BB: I agree, and I think we have and we continue to.
As AMWA Turns 75, Arnold Melnick Turns 95: AMWA’s Longest-Serving Member, A Past President, and Key Contributor

By Lori Alexander, MTPW, ELS / Editor Emeritus, AMWA Journal

It’s hard to know how to begin the tale of Arnold Melnick, DO. Most icons excel in one arena; Arnold, however, shines in several: renowned and respected pediatrician, innovative and inspiring educator, and prolific and passionate writer. And for 57 years, he’s been an active member of AMWA.

In the AMWA community, Arnold is best known for his Melnick on Writing column in the AMWA Journal, which began in 2002. Arnold has used his column to muse on a wide variety of topics, from buzz words to the future of medical writing. He wrote his columns as he thought about things, most often prompted by a seemingly innocuous observation during his everyday activities. As a result, he was usually at least six columns ahead of the Journal schedule. An editor’s dream, really.

Arnold joined AMWA in 1958, when he was a pediatrician practicing in Philadelphia. He went to a Delaware Valley Chapter meeting and was hooked immediately. He served as a chapter volunteer and on chapter and national committees and taught at chapter events as well as the annual conference. He was recognized with an AMWA Fellowship in 1969, became president of the Delaware Valley Chapter in 1972, and served as the national president 2 years later. He was honored with the Harold Swanberg Award in 1977. Arnold also served as an associate editor for Medical Communications, the AMWA publication that ultimately became the AMWA Journal, and he served on that publication’s Editorial Board until 1980. In January 2015, 35 years later, he sat with 20 Florida chapter members at a networking brunch, delighted to be among AMWA colleagues again.

Over the years, Arnold’s drive for editorial work led him to be involved with a wide variety of professional publications. He was the founding editor and publisher of Maternal and Child Health, the official publication of the American College of Osteopathic Pediatricians (ACOP) and the American College of Osteopathic Obstetricians and Gynecologists. For 30 years (1946–1976), he was the Director of Publications/Editor of all publications for ACOP. Among his other editorial positions were Editor of the ACOP Newsletter; Executive/Senior Editor of The Pulse, another ACOP publication; and Executive Editor of the American Osteopathic Academy of Orthopedics Newsletter. In addition, he has written 14 books, more than 240 articles, and countless columns. His most recent book, It’s Me, was published earlier this year, the year he turned 95.

While Arnold was fascinated—or is it obsessed?—with writing, his “day job” was pediatrician, with a thriving practice he established in 1946. He was the founder and chair of pediatrics at two osteopathic hospitals, Parkview Hospital, Philadelphia, and Delaware Valley Hospital, Bristol, Pennsylvania. He served as Director of Medical Education at Delaware Valley Medical Center and was the first DO to be elected to full staff at Children’s Hospital of Philadelphia. He has received many prestigious appointments, including delegate to the White House Conference on Children and Youth, as well as 15 distinguished service awards from professional/medical organizations.

“It’s not how much money you make in life, or how many awards and accolades you receive. What really counts is what you do for those who come after you.”

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Growing Demand for Professional Medical Writing in China and the New China Medical Writers Community

By the China Medical Writers Community Core Committee

Over the past decade, China has been rapidly modernizing to become one of the largest pharmaceutical markets in the world and a key player in global and regional clinical trials. Many of the world’s top multinational pharmaceutical companies view China as a leading overseas market with immense growth potential; their investments in China increase every year.

The Chinese pharmaceutical market is dynamic and is becoming increasingly complex. The Chinese Health Authority, the China Food and Drug Administration (CFDA), is not a signatory to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The CFDA requires applicants to submit clinical documents beyond the ICH Common Technical Document (CTD) with the inclusion of local clinical data in order to support successful New Drug Applications (NDAs) for imported drugs. As a result, the regulatory success of international pharmaceutical companies in China is in part dependent on their ability to meet the clinical document and information requirements unique to China. In addition, as more Chinese-patient data accumulate, there is an increasing demand for the publication of primary and secondary manuscripts in international medical journals in English and in national medical journals in both English and Chinese.

A dynamic regulatory environment, an increasing demand for medical journal publications, and a need for bilingual (English and Chinese) skills in China have fostered the establishment of dedicated medical writing functions to meet these challenges. Over the past few years, more and more major global pharmaceutical companies and leading contract research organizations (CROs) have started to establish medical writing teams in China. Medical writing is a relatively new profession in China. There are few candidates available in the job market, the size of the Chinese medical writing teams in most companies is still small, and the work scope varies greatly. However, because of the increasing demand for medical writing services and the growing recognition of the need for professional medical writers by the pharmaceutical industry, medical writing as a profession is expected to experience a rapid growth period in China.

FORMATION OF THE CHINA MEDICAL WRITERS COMMUNITY

To better serve the growing medical writing community in China, in late 2013, several local medical writers proposed to establish a formal organization. The objectives of this organization are to facilitate communication, to promote continuous professional improvement, and to create networking opportunities for all medical writers working in China.

As an initiative of this endeavor, the first China medical writing forum was held in Beijing on March 21, 2014. Approximately 30 medical writers and regulatory submission document specialists from Beijing and Shanghai attended. Soon afterward, the formation of the China Medical Writers Community (CMWC) was officially announced at the 6th DIA China Annual Meeting (May 11 to May 14, 2014, Shanghai). The CMWC became the 7th community of DIA China, and it sits under the umbrella of DIA’s global medical writing community.

The CMWC has more than 100 members. Most members are medical writers who work in global pharmaceutical companies or CROs within China. The CMWC’s steering committee is composed of 9 core team members, including a chairperson, a membership coordinator, a communications coordinator, and education coordinators in Beijing and Shanghai (Table 1 and Figure 1).

CMWC ACHIEVEMENTS

From 2014 to mid-2015, the CMWC organized 4 medical writing forums (see Figure 2 for a group photo of the third CMWC forum) to foster knowledge and experience sharing among medical writers from different companies and to educate new medical writers. After each forum, feedback from all writers was collected in order to help the community gain a better understanding of writers’ needs. The CMWC plans to host 2 forums annually in Beijing and Shanghai.

The CMWC has also set up a group on WeChat (a smartphone-based social-networking program), which enables CMWC members to have spontaneous information-sharing and discussion. A dedicated community website is under construction.
Table 1: The China Medical Writers Community Core Committee Organizational Chart

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation</th>
<th>Role in the CMWC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xiaoling Wang</td>
<td>Sanofi China</td>
<td>Core member, Community chair</td>
</tr>
<tr>
<td>Haidan Wang</td>
<td>R&amp;G Pharma</td>
<td>Core member, Membership coordinator</td>
</tr>
<tr>
<td>Nan Wang</td>
<td>Bayer HealthCare</td>
<td>Core member, Communication coordinator</td>
</tr>
<tr>
<td>Rui Yang</td>
<td>PAREXEL International</td>
<td>Core member, Education coordinator (Beijing)</td>
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<tr>
<td>Hongbo Zhu</td>
<td>Boehringer Ingelheim</td>
<td>Core member, Education coordinator (Shanghai)</td>
</tr>
<tr>
<td>Julia Cooper</td>
<td>PAREXEL International</td>
<td>Core member</td>
</tr>
<tr>
<td>Karen Tye</td>
<td>Pfizer (China) R&amp;D</td>
<td>Core member</td>
</tr>
<tr>
<td>Yuko Kojima</td>
<td>Eli Lilly</td>
<td>Core member</td>
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<tr>
<td>Xing Li</td>
<td>Janssen China R&amp;D</td>
<td>Core member</td>
</tr>
</tbody>
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Figure 1. CMWC Core Committee Organizational Structure. Positions are to be held for 3 years for each term.

Figure 2. The 3rd China Medical Writers Community Meeting, 27 March 2015, Novo Nordisk China Headquarters at the World Financial Center, Beijing, China. Approximately one-third of CMWC’s members attended this forum on site (shown in this group photo) and many more joined the meeting online (not shown in this group photo).
The CMWC had a strong presence at the 7th DIA China Annual Meeting (May 24 to 27, 2015, Shanghai). At this high-impact pharmaceutical industry meeting (one of the largest meetings in the pharmaceutical industry in China, with approximately 2,000 attendees), the CMWC hosted a full-day preconference workshop and 4 sessions on medical writing:

• (Preconference workshop) Lean: Innovative approaches for authoring clinical, CMC (chemistry, manufacturing, and controls), and nonclinical regulatory documents
• Medical Writing Evolution and Expansion: From Global to China, from the Past to the Future
• Embrace the Dynamic Environmental Change: Innovations Lead to New Opportunities and Solutions
• Why is a Professional Medical Writer Needed in Boosting Scientific Publication in China?
• Regulatory Writing: CTD, ICH E3-Compliant CSR (clinical study report), and China Submission Dossier Preparation

These sessions covered a broad range of medical writing topics, including publications and regulatory writing, the role of medical writers in pharmaceutical industry, the development of good medical writers in China, and medical journals’ perspectives on medical writing. This event marked the largest-ever medical writing gathering in China and heralded the formal beginning of a connected Chinese medical writing community.

OPPORTUNITIES AND COLLABORATION IN THE FUTURE

Professional medical writers are needed in the pharmaceutical and medical communications industry because it has been recognized that it takes special skills to produce well-structured, regulation-compliant documents that present medical and scientific information accurately and succinctly. These documents also must be prepared on time and within established budgets. The CMWC was formed by Chinese medical writers with the objectives of promoting medical writing standards and improving the medical writing profession in China. Our goals are:

• to promote a standard of excellence in medical writing in China;
• to serve as a platform for sharing knowledge among medical writers working in China;
• to bridge the gap of understanding in medical writing practices between China and elsewhere.

Many CMWC members are also members of other professional associations, eg, AMWA, the European Medical Writers Association (EMWA), and DIA; many regularly attend training provided by these associations. In the years ahead, the members of CMWC look forward to more active communication with other medical writing communities and medical writers for further knowledge sharing and collaboration. Together, CMWC members can help the pharmaceutical industry bring better and safer medicine faster to patients who are in need.

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Arnold Melnick | continued from page 125

Arnold retired from his practice in 1976, but his retirement did not last long. He moved to Florida in 1980 and joined forces with a colleague to establish the Southeastern College of Osteopathic Medicine. He served as founding dean at the college as well as professor of pediatrics. The college was granted university status and merged with Nova University to form Nova Southeastern University. He became Executive Vice Chancellor and Provost of the university’s Health Professions Division, which encompassed the colleges of osteopathic medicine, pharmacy, optometry, allied health, medical sciences, and dental medicine. He later helped to establish the College of Dental Medicine at the university, the first new dental school to open in the United States in more than 20 years. Arnold received an honorary Doctor of Humane letters degree for his role in establishing the school.

Arnold brought his passion for writing to the classroom as one of the first educators to include a course in medical communication as part of the medical curriculum. The class ran 18 hours, once a week for one semester, and Arnold focused on medical writing for the first half of the semester and on medical speaking for the second half of the semester. He firmly believed that physicians should be competent in these 2 areas and considered the course an essential part of training.

Thinking about a long life of achievements, Arnold notes, “After a lifetime in medicine that included treating children and adolescents, teaching interns and residents, lecturing to nurses and graduate students, advising younger professionals, presenting postgraduate seminars, being dean of a medical school, and transferring some knowledge and experience to aspiring writers, I suddenly realized in just the last few years that much of what I did was subconscious and I only then put it into words: It’s not how much money you make in life, or how many awards and accolades you receive. What really counts is what you do for those who come after you.”

Thus is the tale of Arnold Melnick. Driven and motivated to write and teach, and still an immovable force. Louis Buttell, Arnold’s colleague and friend (and AMWA member), notes, “To me, Arnold Melnick is like the Little Engine That Could. At 95, just chugging along, speaking, writing, and advising young medical writers in his own remarkable way. Thus proving that age is no bar to talent.”

**A**

I think the opportunities are everywhere, but they are not all available all the time. They change, which is why I believe freelances who are flexible and experienced in a wide range of work are best suited to adapt and thrive regardless of the current environment. The money invested in medical communications remains relatively constant. Where that money is spent is what changes, so freelances must be prepared. When the opportunities are strong in continuing medical education, clients are likely to be pulling back on their sales forces, which means fewer opportunities in sales training. When clients are increasing their sales forces and sales training opportunities are strong, they may be making less of an investment in manuscripts. It’s the circle of life for the freelance. I recommend diversifying your portfolio of work so that you are ready for anything. Then it doesn’t matter what the deliverable du jour is; it all means opportunity to you.

—Brian Bass

I am among the many medical writer and editor specialists who have spent years preparing grant proposals. But now that obtaining grant funding through the usual channels, like the National Institutes of Health, has become more difficult than before, finding new prospects is essential. I am citing some recent, related experiences.

When I was sitting before the emergency room surgeon who had recently saved my husband’s life, I tried to think of an appropriate expression of gratitude. Because none of the usual gifts seemed worthy, I offered, gratis, proposal writing or editing for her interns. Her response was an enthusiastic, “We really need that!” I certainly don’t recommend waiting for a medical emergency to solicit work, and supplying free services won’t pay the bills. However, periodic mailings (postal, email, or social media) to physicians and institutions that seek funding or acceptance of publications could benefit the freelance who offers a one-time, no-cost service. Such an introduction could lead to continuing clients, as I am confident this experience will.

—Phyllis Minick

I have also had occasion to seek financial support for deserving public projects. After searching the Web for institutional donors and submitting proposals with some success, I discovered crowd-funding sites. One of the first such sites, Kickstarter, focuses on creative projects, such as video tapes of musicians. In the medical arena, I have found similar online sites that, for example, pay for medical procedures. For a nominal fee, the site manager handles the financial transactions and provides media hosting, social networking, and contact with contributors. Sites I have noted are www.petridish.org devoted to scientific research and www.youcaring.com, a site that seeks donations to pay for medical expenses. In my community, the website www.gofundme.com is being used to solicit a kidney donor. A creative freelance could help prepare crowd-funding presentations. Certainly, these are not routine sources of income for medical writers, but the time is right to consider some new options.

—Debra Gordon

I find that a large percentage of my business today comes from companies in the health care field, like information technology, mobile health, and revenue cycle management. They need blog posts, white papers, and webinars, and they are willing to pay very nicely for it if you’re a good writer. And they are so easy to work with!

Another area that I think will be hot is writing plain English descriptions of clinical trial outcomes for patients. In fact, I have already been approached about this. New regulations in Europe require this, and it is certain that the United States will follow. Along those lines, another opportunity is turning patient data in electronic health records into plain language. The Agency for Healthcare Research and Quality is focusing on just this, noting that educational materials delivered by electronic health records “are rarely written in a way that is understandable and actionable for patients with basic or below basic health literacy,” which includes about 77 million people.

—Debra Gordon
When you attend the AMWA conference or other conferences, what strategies do you use to get the most out of the experience?

**Give more than you take.** Helping others without expecting anything in return—or giving more than you take—is the best way to build a solid network through conferences (and all networking). Sharing information and resources and connecting people boosts credibility and builds trust.

**Set the stage for productive networking.** Review the conference brochure in advance for presenters you want to meet. Invite them to connect with you on LinkedIn, and mention that you look forward to meeting them during their session on ABC at the XYZ meeting. Follow them on Twitter. Make plans to meet up with colleagues (for a meal, a drink, or even a quick coffee break between events). If you’re new to the conference or the organization sponsoring it, look for events like the “New to AMWA and Conference Orientation Program,” where people are actively looking to make contacts.

**Participate as a presenter.** Sharing your expertise as a presenter is a great way to build your reputation and make many contacts. For the AMWA annual conference, leading a roundtable is an easy and fun way to get started. (I did this for the first time at my second annual conference.)

**Bring lots of business cards and your elevator pitch.** Be prepared to tell people—in 60 seconds or less—what you do and how your services benefit clients. Give and get business cards. Make notes on the back of each person’s business card about where you met and what you learned about the person.

**Be friendly.** Sit with different people at each session or event and start conversations with them before and after. Most people at conferences want to network, but many are more comfortable responding to others than starting conversations themselves.

**Follow up after the conference.** Meeting people at a conference is only the first step in building relationships, which takes time. Soon after you get home, send an email, an invitation to connect on LinkedIn, or a handwritten note to your new contacts. Make a list of the people you want to build strong relationships with and keep in touch with them regularly. Add these key contacts to your e-newsletter list and periodically send them relevant information and resources (giving them more than you take from the relationship).

I remember my first AMWA meeting 9 years ago. I didn’t know a soul. Now I have a blast reconnecting with friends. How?

**Leave your shyness at the door.** Yes, most of us are introverts (how else would we be able to sit alone in front of a computer all day?) Get over it. Start conversations with the person sitting next to you in a workshop; at lunch; at the cocktail party. You can always go back to your room after and lie on your bed with a cold cloth over your eyes to recover (yes, I do this).

**Bring the cards.** Give your card to people you talk to and be sure to get theirs. Write a note on the back of the card about how you met and what you talked about, then send an email when you’re in the airport on your way home.

**Dress professionally.** It does wonders for your image and, because I see so many people at conferences dressing, well, schlockily, people you meet will remember you.

**Sign up to speak.** It’s too late for this year, but consider submitting a proposal for a workshop, presentation, or breakfast roundtable next year.

**Go to your chapter dinner.** It’s a smaller venue, and everyone there is looking to interact with new people.

**Find me.** I want to meet you.

—Debra Gordon

Here are my strategies to get the most out of the national conference:

1. **Review the brochure carefully.** If there is an open session that looks very helpful but conflicts with a credit course, see if the course is offered at another time, sign up for a similar course, or perhaps take the course from home. I used this strategy when I opted to attend an EndNote open session instead of a class, and I’m so glad I did.

2. **Speak up at roundtables.** I got my first medical writing job because of questions I asked at a roundtable.

3. **Take notes on cards.** To remember people, take notes on their business cards, indicating what type of writer they may be looking for and where you met them. Follow up with LinkedIn invites later, perhaps using information from these notes.

—Cherie Dewar

continued on next page
What are the advantages of incorporating a business? Why can't I work as a sole proprietor?

While a sole proprietorship is the easiest type of business to start, this puts your personal assets at great risk, since they're not separate from your business assets. Forming an LLC (limited liability company) is an easy and cost-effective way to protect your personal assets. An LLC also presents a more professional appearance to clients, in my opinion, than a sole proprietorship. It's easy to form an LLC and generally inexpensive; the cost varies by state. Freelances don't need to incorporate, which is much more expensive and complicated (in terms of tax and legal requirements) to establish and manage than an LLC. Under an LLC, taxes are the same as for a sole proprietorship, and you can take your profits whenever you want to.

—Lori De Milto

First the fine print: I am not an accountant or a lawyer, and I do not play one on TV. My freelance business is an S-Corp, which I set up in 1989 before LLCs came into existence.

The main advantage of being a recognized, legal business entity, such as an LLC, S-Corp, or C-Corp, is clear and simple: your personal assets are protected from liability. It's not that you can't work as a sole proprietor. You can, and there are many freelances who do. But why would you put your personal assets at risk? A sole proprietorship is a functioning business, perhaps operating under your Social Security number, or perhaps under a federal ID number. But a sole proprietorship is not a recognized business entity in the eyes of the law. This means that if you were sued in connection with your professional services, all of your personal assets could be at risk, including your car, your home, your IRA—basically everything.

The risk of a freelance being sued is probably pretty small, and there are plenty of sources to obtain business liability and errors and omissions insurance. But when people are looking for someone to sue, they typically name everyone they can in the lawsuit and sort the bodies later. They ultimately look for the deepest pockets, and while your business may not have many assets beyond your computer, office furniture, and accounts receivable, your personal assets certainly make that pocket a lot deeper and therefore more appealing.

The second advantage of being a recognized, legal business entity is a marketing advantage. Being an LLC or a corporation subliminally communicates to clients and prospective clients that you are permanent and committed to the business of serving them. That's not to say a sole proprietor is not, and, for seasoned sole proprietors with a devoted client following, it doesn't matter because your clients know how permanent and committed you are. But for newer freelances in particular, creating an LLC or a corporation imparts an unspoken level of confidence and adds value to your freelance business. As an LLC or a corporation, you can also promote, as an advantage to prospective clients, that they are not required to file 1099 forms at the end of the year. LLCs and corporations are required by law to report all income for the business and its employees and to pay federal and state taxes on their behalf. This saves your clients both time and money.

—Brian Bass

The main advantage for incorporating is to protect your personal assets. The easiest and most common form for incorporating a business is an LLC. When you incorporate an LLC, you separate and protect your personal assets from potential lawsuits. All contracts that you signed with your clients are under the LLC. So the contract is between your client's company and the LLC with you as the writer for the LLC. You can be the only person in the LLC. Having an LLC also projects a more professional and permanent image to your clients. Most new freelances do not incorporate as an LLC until they decide they are doing freelancing on a permanent basis. Therefore, for many clients, an LLC represents a more committed long-term freelance.

—Ruwaida Vakil

Q: Strategies for AMWA conference | continued from previous page

1. Actively participate in all seminars, presentations, classes, etc. That is, ask a question, offer a solution to someone's problem. Essentially, be helpful and let people get to know you.

2. Stand out. For example, wear a colorful scarf or tell a funny story. I mention that I raise chickens to just about everyone I meet. People naturally have lots of questions about this pastime, so I have an opportunity to demonstrate my presentation skills in an amusing, non-work-related way.

—Melissa L. Bogen
Almost all investigations in clinical research involve groups, eg, groups of study participants or patients. Often groups are compared with regard to 1 feature (parameter) such as levels of blood sugar or cholesterol. Using the mean value of our feature of interest, we represent the central tendency of the groups (see Your Stats Refresher, AMWA Journal 2015;30(1): 31–33). The degree to which the means are a good representation of the groups will, however, depend on the variability of the data. To adequately describe the distribution of data in a group, we need both the central tendency and a measure of variability (Figure 1). This measure of variability quantifies the extent to which the individual data differ from each other in regard to a feature of interest.

There are many terms for variability, but all of them mean the same: dispersion, variability, spread, heterogeneity, all refer to the observation that individual data differ from each other. The different measures of variability introduced below describe the extent to which the individual observations are scattered or spread, ie, to what extent they differ.

Range
The simplest way to capture the variability of data is to provide the range, ie, the highest and lowest value in our data together with the mean or median. With this we get a first impression of the spread of the data. Suppose we had measured the heart rate (in beats per minute, bpm) in 7 patients. We determined the following values of 55, 60, 45, 62, 63, 110, and 56 bpm. The range of heart rates in our small sample would then be 45 to 110 bpm, and the mean is 64 bpm. Most values are around 60 bpm and close to the mean (64 bpm); the patient who had a heart rate of 110 bpm was clearly an exception. We can see in this little example that providing the range has the downside of giving us only the most extreme values in our data. If one of them is exceptionally high or low, our perception of the variability in our data will be distorted.

Sometimes the range is given as the numerical difference between the highest and the lowest value, ie, it is calculated by subtracting the lowest value from the highest value in the data set. In our little example the range in heart beats could be expressed as 65 (= 110 – 45). In doing so, the variability in several groups can be compared with each other in a simple way.

Interquartile Range
Although “interquartile” sounds technical and complicated, the concept behind this clearly defined range is straightforward: the interquartile range (IQR) is the range of the central 50% of the data. Together with the median, the interquartile

Figure 1. Central tendency and variability in a set of data. ©Thomas M. Schindler

Appreciating variability is particularly important when we investigate the effects of a treatment (drug, device, method). The gold standard is to base the assessment of efficacy on a comparison between 2 groups, one that received the treatment (active group) and one that did not (placebo or control group). Only if the 2 groups are very similar in the relevant aspects, can we conclude that the difference we observe is due to the new treatment.
range is particularly suited to provide information on the variability of data that are not normally distributed, i.e., that do not produce a symmetric bell shape when plotted.

To arrive at the interquartile range, the data first must be sorted from low to high values (or vice versa). Then the data are divided in quarters, resulting in 4 quartiles. Starting from the lowest number, the first quartile will end at the 25% mark, the second quartile will be the range of 25% to 50% of the data and its upper limit is the median (the median is the data point at which 50% of the data is higher and 50% is lower), the third quartile will extend from the median (50%) to 75% of the data and the fourth quartile will cover 75%-100% of data.

Consider a sample of 16 patients whose heart rates were measured in beats per minute (bpm). The data were ordered from lowest to highest value and then the quartiles were determined. We calculate the median (66.5 bpm) and the interquartile range (60 to 74 bpm). We know that the lower and upper limits of the interquartile range describe the central 50% of the data (Figure 2), i.e., in our study 50% of patients have heart rates between 60 bpm and 74 bpm.

The interquartile range summarizes variability in a better way than the range because it disregards extreme values (i.e., 45 and 110). However, this measure still relies on only 2 values from the dataset; it does not use all of the data in the data set.

**Standard Deviation**

The idea of the standard deviation is to calculate the average distance of each data point from the mean of this data set. The standard deviation can be thought of as the average distance of the individual data from the mean. Unlike the interquartile range, this quantity has the big advantage of considering all data points and we obtain a comprehensive measure of the variability. When the individual data in a data set are clustered around the mean, the standard deviation will be small. When the individual data are spread apart, the standard deviation will be large (Figure 3).

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*The term standard deviation is actually a misnomer as there is nothing "standard" about it.*
Step 1. As a first step we calculate the mean.

Step 2. We then calculate the difference of each data point from the mean by a simple subtraction $x_i - \text{mean}$ (individual data point minus the mean). For data points that are smaller than the mean, the subtraction will result in a negative value (for example, using values from our data above, $45 - 64 = -19$).

Step 3. Before we can go on calculating the standard deviation, we must calculate a quantity known as the variance. To do so, we must square the values obtained in Step 2, add them up, then divide by the number of data points $(n)$.

**Actually, statisticians always divide by $n−1$ instead of $n$. When we divide by $n$, we obtain the variance of the sample included in our study. Generally, however, we want to use our sample to estimate the variance in the total population. Dividing by $n−1$ gives us a better estimate of the variance in the total population, although for large samples the difference is clearly negligible.”

The variance is not a very helpful quantity as it does not have the right unit. In our example of the study in heart rate (measured in beats per minute), the variance would have the unit of beats per minute squared—a unit without any medical interpretation. To get away from this problem, we have to take the square root of the variance. Thus the formula for the standard deviation is:

$$\text{standard deviation} = \sqrt{\frac{\sum(x_i - \text{mean})^2}{n}}$$

With this we have arrived at a measure that accurately describes the variability in a group. We can see from the formula that the size of the standard deviation depends on 2 factors, the average distance between the individual data points and the mean and the number of data points. The smaller the average distance, the smaller the standard deviation; also, the greater the number of data points, the smaller the standard deviation.

The standard deviation has another feature that is very useful. For sets of data that are normally distributed (bell shaped), the standard deviation always comprises a fixed proportion of the data. Within 1 standard deviation, that is from $-1$ SD to $+1$ SD from the mean there will be 68.3% of all data, within 2 standard deviations ($-2$ SD to $+2$ SD) there will be 95.4% of all data and within 3 standard deviations there will be 99.7% of all data (Figure 4).

In summary, range, interquartile range, and standard deviation are measures of variability within a set of data. Knowing the variability is important because it tells us how well the central tendency, that is, the mean or median, represents the data. While the range is the simplest way to describe variability, it has the disadvantage of providing only the extreme values. The interquartile range provides us with the variability of the central 50% of the data. It is not susceptible to extreme values but relies also on only 2 data points. The standard deviation is the most comprehensive measure to capture variability as it considers all data in our data set.

**Further reading**


Adapting Pediatric Protocol Designs From Existing Adult Data and Study Templates
Jennifer K. Strickler, BA, Medical Writer, Premier Research Group, Leander, TX
Thomas Laage, MD, MPH, Director, Regulatory Medical Writing and Product Development Consulting, Premier Research Group, Philadelphia, PA
Charlene Sanders, MD, Vice President, Global Regulatory Affairs, Compliance, & Pediatric Strategic Consulting, Premier Research Group, Philadelphia, PA

Concepts in pediatric research design are unique and require special consideration by those first venturing into the realm of conducting clinical research with children as subjects or those facing their first pediatric protocol deliverable. The objective of this presentation will be to explain the main differences between pediatric and adult study design that must be addressed when preparing clinical research protocols. We will outline the medical considerations that every pediatric protocol should include and break down protocol elements specific for children and family participation that will permit a study to succeed. The presentation will demonstrate key pediatric considerations for scientific method applied to protocol design to ensure successful and safe enrollment of children. The protocol allows the study design to be acceptable to the referring physician, investigator, legal guardian, and child. The presentation will include case studies.

Taming the Beast: Managing Complex, Multi-Author Edits
Kate Lothman, BA, Medical Editor
Amy Martin, MA, Director, Editorial Services, RTI Health Solutions, Research Triangle Park, NC

Introduction: The need to deliver a high-quality edit under constrictions of timeline and budget requires that we approach complex, multi-author documents strategically. 1) Clarify expectations: Is the initial estimate of editorial time still accurate? Are a specific template, style guide, and reference format required? 2) Identify priorities: If there is insufficient time for a thorough edit, ask the writers to identify editorial priorities. Develop a style sheet to document project-specific idiosyncracies. Keep a list of consistency searches to perform. Do an initial scan of the document to identify obvious discrepancies in writing styles (eg, different terminology for the same concept). 3) Use technology: Use a template or use Word styles to increase formatting efficiency. Consider using reference management software (eg, EndNote). Use macros and wildcards for common editorial tasks (eg, checking abbreviations; finding and replacing text). 4) Summarize the edit: Describe what was accomplished in the time available. Make a list of tasks that should be completed during subsequent drafts. Conclusions: Providing a comprehensive review of complex, multi-author documents while meeting project timelines and budgets requires that we clarify expectations with writers, identify editorial priorities, and maximize the use of technology.

S. Daniel Siepert, MA, Medical Editor
Kate Lothman, Medical Editor
Amy Martin, MA, Director, Editorial Services, RTI Health Solutions, Research Triangle Park, NC

Introduction: Is the prohibition against preposition stranding a rule up with which we do not put? It is one of a few contested rules of good writing, along with never splitting infinitives and never using which in restrictive clauses. Some style guides are relaxing their views on these rules, noting that they don’t always serve good writing. Indeed, many scholars suggest that these rules are pedantic inventions rather than accurate reflections of how English works. But what is the view among editors, tasked with enforcing proper language? Are we also relaxing these rules or perpetuating them? Do novice and experienced writers view them differently? Methods: We propose to conduct a survey of AMWA members to help answer these questions. The survey will present sample sentences, most violating one of the contested rules. Participants will rate their level of acceptance of each sentence on a numeric scale. The survey may also include direct statements of contested rules and ask participants to rate their level of agreement with the rule. Results: Results will be stratified by editors versus writers and by years of experience. Conclusion: We hope this survey will reveal attitudes regarding these contested rules among editors and writers.
Social Media and Patient Communication: Writing and Research Strategies to Increase Online Impact  
Angela Johnson, MSE, PMP, Senior PB Clinical Writer / English Department, GE Healthcare / Texas Technical University, Waukesha, WI

Patients adopt and use social media to connect and improve care, challenging modern medical communicators to bridge patient and clinical language gaps. In online communities, patients engage cognitively and emotionally with caregivers and other patients using distinctly non-clinical language that is colorful, playful, and powerful—and seeded with metaphorical narratives of injury and recovery. This poster describes software and research strategies to identify medically relevant social media and design high-impact patient language, exemplified original qualitative language research findings in over 400 cases of traumatic brain injury (concussion) communities. This poster will prepare medical communicators to analyze and implement “online” language.

Best Practices in Writing CME Needs Assessments  
Donald Harting, MA, ELS, CHCP, CME Specialist, MCM Education, Newtown, PA  
Ruwaida Vakil, MS, Principal, ProMed Write LLC, Somerset, NJ

Each year, more than 120,000 accredited continuing medical education (CME) activities are offered in the United States. Developing the needs assessments used in grant proposals to support these activities has become a specialized, niche market opportunity for skilled and savvy medical writers. Best practices for writing needs assessments are constantly changing in response to market conditions, industry needs, and technological advances. Novices who read this poster will come up to speed quickly, while veterans will have a chance to benchmark their personal practices against best practices as determined by a nationwide survey.

Human Abuse Liability (HAL) Studies: Not Your Traditional Phase I Studies  
Rona Claire Grunspan, MD, Manager of Medical Writing—Early Development Services, PRA Health Sciences, Lenexa, KS

Human Abuse Liability (HAL) studies are an essential part of drug development for central nervous system (CNS) compounds with an abuse potential. Requiring specialized settings, knowledge and can be more challenging than traditional Phase I studies. Interrupting data is not always easy especially when the drug discrimination phase alone can generate an overwhelming amount of information per subject. This poster will discuss what HAL studies are, what challenges the study team faces, and what the role of the medical writer is.

Quality of Patient Medication Information Handouts Associated With Commonly Prescribed Drugs  
Kimberly Koon, PharmD, Student, University of the Sciences, Seattle, WA

The scope of this study includes examining regularly distributed and available patient medication information (PMI) for qualities that have been shown to aid comprehension and utility for general audiences. Patient medication information is commonly used in pharmacies to inform and educate patients about medication. It is also available on the Internet. Inclusion criteria for the present study are: PMI that is pharmacy or web-based for the top 25 dispensed drugs in the United States, and PMI that is a medication guide required by the FDA for any of the top 25 dispensed drugs.¹ ² PMI is categorized according to its source/type: retail pharmacy, mail-order pharmacy, pharmacy web site, drug information web site, or FDA-approved medication guide. The study samples will be divided into 2 groups, hard-copy (paper) PMI (HC-PMI) and Internet-based PMI (IB-PMI). Hard-copy and IB-PMI will be evaluated using evaluation tools designed for this study. The evaluation tools were created for the study using writing guidelines from the Centers for Medicare and Medicaid Services and The Office of Disease Prevention and Health Promotion. The evaluation results for HC-PMI and IB-PMI will be compiled for each group as well as for the different PMI sources to allow comparisons. References: 1. IMS Institute for Healthcare Informatics. Medicine use and shifting costs of healthcare; a review of the use of medicines in the United States in 2013. www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=2684d47626745410VgnVCM10000076192ca2RCRD&vgnextchannel=736de5fda6370410VgnVCM10000076192ca2RCRD&vgnextfmt=default. Published April 7, 2014. Accessed December 7, 2014. 2. Medication guides. US Food and Drug Administration website. www.fda.gov/Drugs/DrugSafety/ucm085729.htm. Accessed November 10, 2014.

Establishing an Editorial Process: Tools for Success  
Alyssa Dallas, BA, Associate Director  
Amy Martin, MA, Director, Editorial Services, RTI Health Solutions, Research Triangle Park, NC

Introduction: Building a standard editing process should include developing tools that maximize efficiency and consis-
tency and are dynamic enough to accommodate a variety of needs and high expectations for quality.

**Style Guide**
Recommendation: Identify an existing style guide and modify to meet company-specific needs.
Benefits: Provides support for editorial decisions, increases editorial efficiency, promotes consistency within and among documents and across editors.

**Request Form**
Recommendation: Develop a request form that estimates editorial time required based on number of pages and type of deliverable; establish calculations using the literature and experience with the organization's documents.
Benefits: Quantifies and communicates standard editing times for work capacity planning and project management.

**Templates**
Recommendation: Develop deliverable-specific templates using Word styles and company branding.
Benefits: Increases formatting efficiency, results in a polished and company-distinct final product.

**Technology**
Recommendation: Use macros, wildcards, and proofreading software for common editorial tasks.
Benefits: Maximizes time available for comprehensive content review.

**Checklists**
Recommendation: Develop editorial checklists for each edit level.
Benefits: Clarifies writers' and editors' expectations, improves editorial accuracy.

**Conclusions**: Maintaining a professional editorial service for a complex organization requires a variety of tools to maximize efficiency and review quality.

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**Rational Prescribing of Antibiotics During Influenza Season**
Mary B. Sebas, CNP, Nurse Practitioner, Mayo Clinic Health Systems, Fairmont, MN

Studies show that antibiotics are overprescribed for influenza. In this poster we will discuss the following related topics: comprehensive CDC prescribing recommendations and patient education material; identifying irrational prescripting pressures and patient interventions to avoid unnecessary antibiotic use; use of pertinent, clinically useful information with repetitive messaging for long term content retention; and positive reinforcement for alternative patient education and adoption of a “wait and watch” approach to episodic viral infections.

**AMWA Salary Survey 2015—Presentation of Statistical Analyses**
Susan Bairnsfather, CEO, EPharmaTech LLC, Shreveport, LA

The salary survey conducted by AMWA, the leading professional organization for medical communicators, is internationally recognized as the largest survey of professionals considering the number of respondents and the most in-depth analysis of demographic qualities, professional characteristics, and salaries/incomes. The survey serves as the most methodical and analytical resource for setting salary ranges among employers, for negotiating salaries between employees and employers, and for negotiating fees between freelances/consultants and their clients. The 2015 salary survey will be the seventh survey conducted by AMWA. AMWA makes improvements with each survey, adding new questions to capture the interests of its membership while also retaining key questions to compare current results with those of prior surveys.

**Evolution of Expanded Access Programs: Treatment for Patients Who Have Run Out of Options**
Darryl Z. L’Heureux, PhD, Medical Writer, MedSciTech Writing, Philadelphia, PA
Amy Fesmire, MS, ELS, Manager, Medical Data Operations, Bristol-Myers Squibb, Plainsboro, NJ
Susan Dalton, Associate Director, Bristol-Myers Squibb, Plainsboro, NJ

The expanded access treatment programs at BMS bridge the gap between clinical development and regulatory approval. The evolution of these expanded access programs allows patients to receive treatment under compassionate use who have run out of treatment options and are ineligible for enrollment in a clinical trial. The clinical paradigm of expanded access is evolving at BMS where we no longer seek to collect the same magnitude of clinical data but to streamline data collection and operations to provide treatment to these patients-in-need. This session will discuss proposed modifications to model documents, templates, intake, review, and request processes that will foster increased efficiency with the goal of enabling easier access to drug treatment for patients who have run out of options. Expanded access programs bridge the treatment gap for patients and differences from clinical studies requires a re-evaluation of clinical research practices.
As we count down to AMWA’s conference this year, expect it to be spectacular! With 51 workshops, 39 open sessions, 49 distinct roundtable topics, 11 posters (see page 135 for poster abstracts), keynote speaker sessions, and ample opportunity to network, there is something for everyone. In addition, we’ll go down memory lane in grand style at the special 75th anniversary reception and dinner.

For seasoned professionals with many years of experience to new students breaking into medical communication, AMWA’s annual conference is the place to be to expand your horizons in medical communication, establish new connections, and build your network and knowledge.

TEN TIPS for you to consider to maximize your experience

1. **Come with the resolution to be at AMWA.**
   Leave work behind and come to be fully engaged to get the best out of what the conference has to offer. Discover best practices and hear about new ideas and trends that make you a stronger professional. Learn new skills or upgrade current ones. Learn from experts and be inspired. Explore and network.

2. **Be an active conference participant.**
   For some it means stepping out of your comfort zone. The central theme at any AMWA gathering is learning from each other, and everyone (new and old) has some wisdom to share. Go ahead and introduce yourself, ask questions (and more questions), and join the discussions.

3. **Take time to read the conference brochure thoroughly, and seek offerings that build you professionally.**
   Don’t go for something you already know; choose something that stretches and challenges you.

Many thanks to the 2015 Annual Committee members who worked tirelessly to put this program together for you:

- Noelle Demas, MS, 2015 Conference Administrator, Panorama MedWriters Group Inc, San Diego, CA
- Christina Bennett, inVentiv Medical Communications, Harlingen, TX
- Tara Ann Cartwright, PhD; Morrisville, NC
- Adi Ferrara, MS, ELS; HIV Vaccine Trials Network, Seattle, WA
- Jennifer Houser, CCRP, RAC; Seattle Genetics Inc, Bothell, WA
- Larry Lynam; The Lynam Group, Coral Springs, FL
- Joanne Rosenberg, MS, ELS; Jazz Pharmaceuticals, Highland Park, NJ
- Rene Michelle Sauer, PhD, ELS, CRA; International Medical Relief, Cypress, TX
- Kent Steinriede, MS; Parexel International, Bala Cynwyd, PA
- Jenilyn Virrey, PhD, CMPP; Amgen Inc, Thousand Oaks, CA
- Wendy Wippel, Medtronic Inc, Memphis, TN
- Becky Phillips, Conference Program Manager, AMWA, Bethesda, MD
Stay for the entire conference.
You never know what you might miss by arriving late or leaving early. For those new to the AMWA experience, Wednesday’s “New to AMWA and Conference Orientation Program” is a must.

Stay at the conference designated hotel.
Staying at the designated hotel, the Grand Hyatt San Antonio, means you are at the central hub which makes it easier to more effectively widen your network.

Come with an open mind to see how you can contribute to AMWA.
The local and national events AMWA puts together, as well as the many educational offerings and products AMWA provides its members, are all made possible because of dedicated volunteers. Volunteer and be part of the effort in bringing quality offerings to AMWA’s members. Don’t forget to stop by the AMWA booth in the exhibit hall where you can chat with staff and leaders about everything AMWA.

Set a goal to discover new resources that you can use in your professional work.
With so many workshops, open sessions, roundtables, and networking opportunities, this is not hard to do. The challenge will be how to keep your list manageable.

Pack your business cards.
Networking is a 2-way street. Remember acquaintances and be remembered with a simple exchange of cards.

Come to meet new people or reconnect with old friends.
AMWA’s annual gathering gives you the perfect opportunity to network with peers and colleagues (and let’s not forget the vendors) who can help you in your career. This may even be an opportunity to find a mentor or become one. Being around like-minded people is always inspirational and energizing. For those new to AMWA, the conference may be an information overload, so don’t hesitate to ask someone to help you navigate through it.

See you all at AMWA’s 75th anniversary celebration in San Antonio!
Time: Late April. Place: Bethesda, Maryland, and the Spring AMWA Board of Directors meeting. But first, the Board gathers for a day of strategic planning, designed to shape a vision for AMWA and determine its mission and goals for the next 3 to 5 years. Lori Alexander, the current AMWA secretary and the upcoming president-elect, is the volunteer leader for this process, working closely with our Executive Director Susan Krug and our consultants, Becky Choi and Anne Aden.

The group discussed AMWA using the SOAR model. It encompasses Strengths—What do we do well that we can we build on? Opportunities—What are our stakeholders asking for? Aspirations—What do we care most deeply about? And Results—How do we know we are succeeding? AMWA’s welcoming and diverse community and its broad range of high-quality educational offerings were among the most frequently noted benefits of AMWA membership.

After that meeting, Lori recruited volunteers to conduct a total of 45 structured phone interviews with additional AMWA stakeholders, including nonmembers. If you conducted an interview, or participated in one, we are very grateful that you took the time to give us your candid assessments.

Time: Mid-June. Place: Washington, DC, convention center.

I’m at the AMWA exhibitor’s booth during the DIA annual conference. With me are Susan Krug, Kim Grimm, and Rachel Spassiani from the AMWA office. A steady stream of people stops by to chat. Some were employers; some were medical communicators, with varying degrees of experience (and many already AMWA members); and some were curious about what AMWA offers. All had consistent (and consistently good) questions: “Where can I find medical writers?” “Where can I find medical writers who understand X [a specific area]?” “How can I learn more about the field?” “How can I demonstrate my skills?” “What’s AMWA all about?” For those wondering how to find medical writers, we showed them our online job posting and the Freelance Directory. For those in the profession who wanted to improve their skills, we showed them our self-study modules and a list of recent and upcoming webinars, and we previewed events at the upcoming annual conference. For those who wanted to demonstrate their skills—to impress potential clients or to document their own professional growth—we told them about the Medical Writer Certified (MWC) designation and our inaugural examination to be held at the annual conference in San Antonio.

For the last question—“What’s AMWA all about?”—the answer was, “It’s all of these things and more.” Professional, engaging, high-quality resources for medical communicators—that’s the heart of all we do.

Then we asked some questions ourselves. “If you’re a medical writer, are you an AMWA member?” “If not, is there a specific reason?” “If you’re a member but haven’t been active, why not?” “Are our educational programs and services, like the webinars and certification, valuable to you?” “How else could AMWA bolster the profession and those in it?” We listened carefully to those answers. That’s my segue to the next report from the road.

Time: Mid-July. Place: Bethesda, Maryland. I’m back again in the nation’s capital, along with Susan, Kim, and Shari Rager (AMWA’s deputy director), to meet with AMWA’s officers and Executive Committee. In addition to our quarterly meeting, we are continuing our strategic planning process, reviewing the findings from our April session and the phone interviews thereafter.

We got great information from both exercises, which made us realize that hearing from still more members would be even better. Our initial follow-up step is to reassess the field in a brief survey of our members. It’s been 2 years since we conducted a needs assessment for medical communica-
Professional, engaging, high-quality resources for medical communicators—that’s the heart of all we do.

tors, and AMWA has made many changes since. Now is a good time to reopen that discussion, so you can weigh in where AMWA should be headed. The survey will open soon after I submit this column; by the time you read this sentence, the results will be collated for reporting at the annual conference in San Antonio.

So what’s next? How will all this strategizing lead to new activities? And what does it all mean to AMWA members? Right now, I don’t have the answers to those good questions. The process will continue under Lori’s leadership and that of our next president, Steve Palmer. But the most important thing for you to consider now is how well this thoughtful, thorough process will engage our members and other stakeholders in the medical writing community, and how that dialogue will shape the AMWA of the future. Be a part of that process—I can’t wait to see where it takes us.

Update on Certification Opportunities to Earn Medical Writing Certification Credential

By Marianne Mallia, ELS / Certification Commission Chair

The Medical Writing Certification Examination has officially launched, and the first exam will happen September 30, 2015, in San Antonio (the day before the main programming of the annual conference begins). If you missed the deadline for registering for the first exam, you can register for the next exam, which will be given at the DIA Medical & Scientific Communications Annual Forum at the Gaylord Palms Resort & Convention Center in Kissimmee, Florida, in March (exam date to be determined; deadline to register: December 15, 2015). All of the information you need to prepare and apply for the exam can be found on the Commission website at amwa.org/mwc.

If you haven’t looked at the annotated example questions, take a few minutes to sample the exam. However, don’t be overly concerned if you can’t answer every question. The exam includes some questions on specific areas of medical writing (for example, writing journal articles, writing for general readerships, and regulatory writing), in keeping with the breadth of medical writing as a field. However, it contains relatively few questions on any individual area, and many of the questions apply to multiple areas. If you are working as a medical writer, you should have much of the basic knowledge required for the exam even though you may not have experience in every area of medical writing. To gain background in areas where you lack experience, you can study material in the listed resources.

You may also want to read answers to some frequently asked questions (FAQs) about the exam, which have recently been posted on the site. One question frequently asked is how the exam differs from other exams, such as those offered by ISMPP, BELS, and RAPS. To explain, we recently added the following answer to the website:

Each of these exams has a different focus and purpose. The MWC was developed because of the need for a certification exam focused on core competencies of professional medical writers with a broad range of medical writing backgrounds and specialties. The knowledge, skills, and abilities tested through the MWC are specific to medical writing and supported by data gathered through a job analysis survey of more than 1,000 professional medical writers. A small amount of overlap may exist among the exams, but the MWC is not, for example, meant to compete with any other exam. Medical writers with expertise in the subject matter covered by the other exams (for instance, publication planning, editing, or regulatory affairs) may also want to certify in those areas.

Next Steps – The commission is now finalizing materials for recertification, including a Recertification Handbook, which explains the procedures for recertification and provides guidance on qualifying activities.
Opening the book with a personal account of his father’s enrollment in a clinical trial after a cancer diagnosis, Robert L. Klitzman, MD, drives home the importance of institutional review boards (IRBs). In *The Ethics Police?: The Struggle to Make Human Research Safe*, Klitzman confronts the sometimes shadowy role of these important organizations, ostensibly tasked with protecting the integrity and rights of human subjects and patients. As Klitzman broadly asks: Whose rights are IRBs designed to protect—study participants or the organizations that sponsor the research? The outcomes of IRB activity are codified in endless consent forms, but how those forms come to be and how they are evaluated is the story that Klitzman relates.

As the clinical trials process is becoming more global, the repercussions of IRB activity can be wide-ranging. Even so, in many instances, IRB certification is an afterthought. Klitzman’s findings reaffirm the often marginal role of what should be a central consideration in human subjects research.

The text is full of primary research and ethnographic first-hand interviews. For example, Klitzman notes that those appointed to IRBs are oftentimes themselves unaware of the review process and of the impact of their role. He describes the experience of one IRB member who spent nearly a decade serving on IRBs before fully appreciating the complexity of the process and the responsibilities involved. Klitzman finds that individuals are often “volunteered” to serve on IRBs, with little or no background in ethics.

Inasmuch as we are all students of our craft, this book is a unique resource that the reader can refer to again and again. Though sometimes academic in tone, the book has relevance across many different disciplines. The first reading simply brings to light the breadth of the subject: from the views of medical and legal experts, to patients’ rights, to organizational momentum, to epidemiologic impact. A second reading allows for a deeper understanding, not just of IRB complexities and variations, but also of issues that most readers may not have considered, such as whether research participants who are minors should be paid. A third reading, followed by a period of extended mulling, can help uncover some of the implications of Klitzman’s findings.

The takeaway message is a bit startling: The opportunity to improve clinical outcomes and research with human participants lies not only in the development of better technologies, but also in the process by which they are tested. *The Ethics Police?* is a text worthy of careful study.

—Arushi Sinha, PhD

*Arushi is president of Big Think Media Inc in San Francisco, California.*
The prolific Oliver Sacks wrote 13 books, many of which are based on his observations as a neurologist (The Man Who Mistook His Wife for a Hat, An Anthropologist on Mars). Among these admired works is Sacks’s most personal, Uncle Tungsten—a seamless interweaving of childhood memoir, family saga, and chemical history—published in 2002. Ending at Sacks’s post–World War II adolescence, Uncle Tungsten begged, if not demanded, a follow-up. To which Sacks has answered with his autobiography, On the Move. Sacks recalls: “When I was at boarding school, sent away during the war as a little boy, I had a sense of imprisonment and powerlessness, and I longed for movement and power…”

And move he does. If Uncle Tungsten is a unified tapestry, On the Move is a saltatory collage, a jumping travelogue of Sacks’s itinerant adulthood. Drawing on his extensive journals and letters, Sacks recounts his life in snapshot-like paragraphs, beginning at the age of 18. Bouncing between his native England and America (particularly New York and California), Sacks first realized movement and power in motorcycling and competitive weight lifting (who knew?) during the late 1950s. But contrast these early pursuits with Sacks’s careful existence as a gay man—a position informed, no doubt, by the era’s disgust for homosexuality. “I wish you had never been born,” his mother told him in 1951 after learning of his sexual orientation. It was a destructive blow, which Sacks later rationalized and forgave. Yet the rebuke seems to have influenced his lifelong diffidence in romance and his solitary—but certainly not friendless—existence. In fact, we learn that Sacks’s only relationship approaching a domestic commitment (until recently) was that with a stray cat at his home on City Island in the 1990s.

Notably, Sacks’s clinical practice remains in the background of On the Move, despite the fact that neurology has been the fodder for much of his published writing. Perhaps for political reasons (mostly hinted at) or his admitted bungling in the laboratory, Sacks was relegated to serve at the margins of medical care—that is, in long-term homes for intractable cases. There he was given the independence to observe the afflicted and write thoughtfully of them. Sacks especially empathized with their confinement:

I hated to see the way in which the patients were treated, sometimes locked in seclusion rooms or starved or restrained…it reminded me of the way I had been treated as a child when I was sent away to a boarding school where I (and other boys) were frequently punished by a capricious and sadistic headmaster.

Despite Sacks’s keen sensitivity toward his patients, On the Move clarifies that Sacks was, foremost, not a neurologist but a writer. In fact, writing was the one constancy in Sacks’s restless life. Of its necessity, he confesses,

It seems to me that I discover my thoughts through the act of writing, in the act of writing. Occasionally, a piece comes out perfectly, but more often my writings need extensive pruning and editing, because I may express the same thought in many different ways.

A record of flashing Polaroids, On the Move is unlike Sacks’s previous works, which are known for their granular observations and careful pacing. But Sacks, who was in his 80s as he wrote this, must have been feeling life’s end acutely. He had metastatic cancer at the time and died in August, not long after the book was published. Nevertheless, Sacks had reported in On the Move that more books were forthcoming. We half expect one of these to detail his journey through death. Sacks, the faithful chronicler, will somehow send back a description of his fantastical trip to the beyond, as his mind or spirit—or whatever he calls his sentient life force—splits permanently from his corporeal brain.

—Barbara J. Martin, MD

Formerly a practicing neurologist, Barbara is a freelance writer in Lancaster, Pennsylvania, and the author of Elixir: The American Tragedy of a Deadly Drug.
Plain Language Association International
September 17–20, 2015
Dublin, Ireland
www.plainlanguagenetwork.org/

National Association of Science Writers
October 9–13, 2015
Cambridge, MA
http://nasw.org

New Horizons in Science
October 11–12, 2015
Cambridge, MA
http://casw.org/

Regulatory Affairs Professionals Society
October 24–28, 2015
Baltimore, MD
www.raps.org/convergence/

DIA Annual Canadian Meeting
October 27–28, 2015
Ottawa, Canada
www.diaglobal.org

American Public Health Association
October 31–November 4, 2015
Chicago, IL
www.apha.org

Health Literacy Annual Research Conference
November 2–3, 2015
Bethesda, MD
www.bumc.bu.edu/healthliteracyconference/

European Medical Writers Association
November 5–7, 2015
The Hague, Netherlands
www.emwa.org

Association of American Medical Colleges
Annual Meeting
November 6–10, 2015
Baltimore, MD
www.aamc.org

Alliance for Continuing Education in the Health Professions
January 13–16, 2016
National Harbor, MD
www.acehp.org

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