



BLAZING THE TRAIL

in Dallas at AMWA's 69th Annual Conference

By Mary G. Royer, MS, ELS

AMWA's 69th Annual Conference was held in the sparkling Dallas Sheraton in the Wild West city of Dallas. Although the venue was anything but wild, it certainly was pioneering with its state of the art "Link," which provided attendees with free PC workstations, Internet access, and printing; strategically placed electronic maps and signs guiding attendees to classrooms and events; and beautifully and newly appointed rooms and facilities. Amidst its glistening skyscrapers, Dallas offered many affordable and very civilized restaurants presenting a wide array of culinary choices.

The theme of this year's conference was "Blazing the Trail." And blaze we did, beginning with our keynote speaker, fellow medical writer turned CEO of ProScribe Medical Communications, Karen Woolley, PhD. Dr Woolley gave an extraordinarily entertaining and informative presentation on the importance of taking control of our profession—blazing our own trail, as it were. She urged us to be aware of and comply with current ethical and procedural guidelines and to become pioneers of our profession by publishing research to establish our professional identity and demonstrate our value to



SESSIONS / POSTERS / EXHIBITS



ROUNDTABLES / AWARDS / ENTERTAINMENT

the research team. (Read Dr Woolley's address beginning on page 160.) This year's Alvarez speaker, Annette Flanagan, RN, MA, Managing Deputy Editor of *JAMA* (photo 2 (left), bottom row), reviewed published results of studies on authorship, editorial policies and procedures, reporting standards, and quality of published scientific information and offered invaluable suggestions regarding how we as medical communicators can contribute to this growing field of research.

In addition to presentations on blazing our professional trail, the conference featured many other offerings of interest to medical communicators of all stripes. Our McGovern speaker, David Dary (photo 3 (left), bottom row), author of the recently published book *Frontier Medicine: From the Atlantic to the Pacific, 1492-1941*, entertained us with his talk on the challenges of writing medical history and medical writing in general. The conference offered a stellar lineup of 84 workshops, 14 of which were brand new. At the same time, 38 open sessions provided registrants with timely and topical tips, tricks, and tactics from experts on topics from the globalization of medical writing to publication guidelines to navigating today's continuing medical education landscape. As always, choosing among the many offerings presented an agreeable dilemma.

Networking emerged as a salient, if unheralded, theme of this conference. Roundtables and dessert klatches provided the usual opportunities for collegial kibitzing on topics from surviving during a recession to employment opportunities in the federal government to chickens in your backyard. This year's posters were excellent and afforded attendees a means to meet and talk with presenters about research efforts in the field. Reinforcing the networking theme, the secrets and usefulness of social networking tools, including Facebook, Twitter, and LinkedIn, were shared in 2 roundtables and an open session. And in another pioneering advance, member Victoria White, MA, ELS, spearheaded a team that communicated conference highlights as they transpired to non-attendees and attendees alike through the 2009 Annual Conference Blog (<http://amwaconference.blogspot.com>).

As the rest of us learned, networked, and enjoyed the 2009 Dallas conference, the members of the 2010 conference committee took advantage of their mutual proximity and met to unfurl the sails for next year's conference in Milwaukee, where attendees will meet to seek, soar, and succeed!

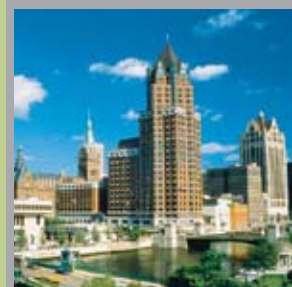
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KEYNOTE ADDRESS:

“GETTING RESPECT—TWO STEPS FORWARD AND...?”

By Karen Woolley, PhD

CEO, ProScribe Medical Communications Adjunct Professor, University of Queensland;
Adjunct Professor, University of the Sunshine Coast, Queensland, Australia

Editor's note: We originally assigned a reporter to cover the Keynote Address, but Karen Woolley's presentation was thought to be of such value that we made the decision to reprint it in full. The address is followed by a commentary written by the reporter, as well as comments from AMWA leadership.

Dr Karen Woolley is the first AMWA keynote speaker in recent memory who is one of us: a medical writer. She's internationally engaged in advancing our profession through teaching, research, and advocacy for higher educational and ethical standards. Karen strode into the conference hotel's ballroom accompanied by Aretha Franklin's song "Respect," then outlined 3 major problems facing medical writers: lack of evidence that we add value to our projects and are ethical; lack of a truly international approach to training; and isolation from other stakeholders, particularly journal editors. For each problem, she suggested actions that individual members can take, as well as actions that the profession can take. Her recommendations go far beyond denouncing ghostwriting! Karen received a long standing ovation followed by more than 20 minutes of questions, suggesting that AMWA members will be discussing her ideas for months to come. Don't miss reading about them here.

—Faith Reidenbach, ELS

Thank you so very much for inviting me to deliver this keynote address. The big question mark in the title refers to whether we are going to get more or less respect in the future. Will we take 2 steps forward and 1 step back or 2 steps forward and more again? I also want to thank Aretha Franklin for her version of “Respect,” as it provides a motivating match for the theme of this keynote. Aretha was and is a true pioneer. She was the first woman inducted into the Rock and Roll Hall of Fame and continues to impress. When you look at pioneers, you come across 4 things that are particularly relevant today.

First, pioneers take risks. Our chair, Sue Hudson, and AMWA took a risk inviting me; I think I might be the first non-US-based person in the history of AMWA to deliver the keynote address. I better not ruin it for anyone else! Second, pioneers get shot at. I may say things today that you don't like or don't agree with—that's good. We'll test some boundaries this morning and, today, you can shoot the messenger. Third, pioneers explore options. I am going to explore options that could help address 3 major challenges for our profession. And fourth, pioneers can make it easier for others. I truly hope that something comes from today that makes it easier for the next generation of medical communicators.

If we want respect for our profession, we need to continue to find and support the pioneers in our profession. We've certainly had pioneers in the past who have helped our profession earn respect. To start, I want to pay homage to a few of AMWA's pioneers (and I apologize in advance for not being able to list more). These pioneers took steps forward to advance our profession, even in rocky times.

In 1940, the pioneer was Harold Swanberg, who with 5 others (all MDs), founded the Mississippi Valley Medical Editors Association, which, as many of you know, evolved into AMWA in 1948. Harold must have known that you can't respect something if you don't know what “it” is. Harold realized that there was a body of knowledge about medical communication, and he took the step of establishing an organization to serve its needs.

In 1971, the pioneer was Eric W. Martin. He became AMWA's first non-MD President; he also pioneered the draft of the first Code of Ethics, which was approved in 1973. Ethics is certainly not a new issue for medical communicators, but it remains critical to our profession.

In 1977, the pioneer was Virginia T. Eicholtz. Virginia was not the first woman to contribute to AMWA, but she was the first woman to serve as President.

In 1978, the pioneer was Edith Schwager. Edie not only started the much-revered Dear Edie column, but by turning green at a smoke-filled AMWA meeting, she also helped AMWA take the first steps to being a nonsmoking organization. Like so many advances, this may not have been popular at the time, but it was the right thing to do.

In 1979, the pioneers were Lottie B. Applewhite and Gerald McKee, who started the AMWA core certificate program at the 1979 AMWA Annual Meeting in Kansas City. This was another important step forward in getting respect for the body of knowledge required by medical communicators.

In 2003, the pioneers were Cindy Hamilton and Mary Royer. These women are certainly not past being pioneers, but their past actions have advanced our profession. On behalf of an AMWA Taskforce, Cindy and Mary published the AMWA Position Statement on the Contributions of Medical Writers to Scientific Publications.¹ This statement has served as a benchmark for other organizations and reinforces the legitimacy and ethics of our profession.

Just as our past pioneers faced challenges affecting respect for our profession, we now face challenges affecting respect for our profession. Today, I will identify 3 major challenges and suggest ways that we, as a profession, and you, as a medical communicator, might help solve them.

The first challenge is that to some people, we may as well be peddling

snake oil. Where is the hard evidence about the value and ethics of medical communicators? The second challenge is that we are facing new frontiers. Medical communicators are appearing in all corners of the world; how can we ensure that we all offer value and ethics? The third challenge is that we can seem a little lonely. How can we reach out more effectively to those who need to hear our side of the story, such as medical journal editors and journalists? We need to overcome these 3 challenges to get more respect.

Now I know, particularly in light of recent media and political pressure, that AMWA members have been asking AMWA: "Can we, as a profession, do anything?" "Can I, as an AMWA member, do anything?" By the end of this presentation, I want you to be able to say "yes" to both questions.

So, in broad terms, what can we do? Well, we can do some things that make no real difference at all. We can worry. And worry we do; the problem is, all that worry gets us no closer to getting more respect. We can also react, when others say something good about us and when others say something bad about us. But again, that may or may not get us more respect. What we need to do is take control. I am now going to suggest ways in which we can take control over those 3 challenges affecting our profession.

NEED FOR EVIDENCE ABOUT THE VALUE AND ETHICS OF MEDICAL COMMUNICATORS

To address our first challenge, we need to investigate the value and ethics of our profession. Where is the evidence that we provide any value? Further, where is this evidence published so that those who might criticize us can read it? Most of the information we have on our value and ethics has been published in our association newsletters and journals, which are rarely read by influential editors, journalists, regulators, or politicians. How can these people really know about our value; how do they (or in fact we) really know that we can

- Save time for authors, peer reviewers, editors, or regulators?
- Enhance the quality of documents?
- Reduce costs by doing things the right way the first time?
- Reduce the risk of important data not being published?

In addition to our need for published evidence on the value we provide, where is the evidence on our ethics? We know from the last survey of AMWA members that ethics is "by far the greatest concern" (your number-1 issue), and these issues arise on the AMWA listserve. For example, one AMWA member asked listserve users whether medical writers or editors were involved in any of the papers recently retracted for misconduct. This is a perfectly reasonable question to ask and wouldn't it be nice if our profession could point to some hard data to say that medical writers are rarely involved in papers retracted for misconduct? As it turns out, last year, before this question was posted on the listserve, we had begun to investigate this very issue!

I'd like to share some of our original research, as it demonstrates that medical communicators can investigate ethical issues and, in so doing, generate hard data that can be used to get more respect for our profession. Colleagues and I are doing our best to communicate the results of our research to audiences who may question the ethics of medical communicators. As such, we presented these data at the 2009 International Congress on Peer Review and Biomedical Publication hosted by *JAMA* and the *British Medical Journal* and attended by many of the world's most influential journal editors and keen journalists. Our project was just profiled in *Nature Medicine*² and we have been invited to submit a commentary on our results to *Lancet*.

Our research project was titled "Round Up the Usual Suspects? Involvement of Medical Writers and the Pharmaceutical Industry in Publications Retracted for Misconduct." Integrity in the litera-

ture is shot when misconduct occurs. Are the usual suspects really the most suspect? And who are the usual suspects? If you believe Mr McHenry, you believe that "...it is now fairly well known that pharmaceutical companies launder their promotional efforts through medical communication companies that ghostwrite articles and then pay 'key opinion leaders'...to affix their signatures to the fraudulent articles..."³ Despite Mr McHenry's dogmatic assertion and opinions, we thought we might conduct the largest study done to date on retracted publications, *especially those retracted for misconduct*, that involved declared medical writers or pharmaceutical industry sponsorship, and 2. investigate factors that may be associated with misconduct retractions. I think Mr McHenry and others might be shocked to find out who is and who isn't involved in retracted publications.

Our results showed that the first group, which comprised those papers that had declared medical writing and industry support (ie, probably the most suspicious papers in some quarters) actually accounted for very few retractions and none of the misconduct retractions (Figure 1). Even the second and third groups, which comprised papers where there was declared medical writing or declared industry support, accounted for very few retractions. The fourth group, where there was no declared industry funding, accounted for almost all of the retractions and the misconduct retractions. You have to ask why medical writers and the industry are guilty until proven innocent? These data should help our profession get more respect as they indicate that a paper that has declared medical writing involvement and industry support is unlikely to have to be retracted. Declaration of a medical writer on a paper should be seen as a good sign, not a bad sign.

This conclusion is supported by the odds ratio data, where we looked

at the odds of a paper being retracted for misconduct vs mistake. Mistake retractions served as the control group. The odds of being retracted for misconduct were significantly lower (less than 1.0) if medical writers or the pharmaceutical industry were involved, but were significantly higher (greater than 1.0) if the paper involved

- A single author
- A first author who had at least 1 other retraction (we now have evidence to support the concept of the serial offender)
- A first author who was affiliated with a low- or middle-income country

I think these results show that if a professional medical writer is involved in preparing a manuscript, a journal editor may be far less likely to go through the pain of having to retract a publication. So that is what we have done to investigate and promote ethics in our profession. What can you do?

You too can be a pioneer and investigate the value and ethics of our profession.

The importance of investigating and publishing research on our profession was eloquently stated by AMWA's Mary Royer and Doug Haneline in a recent issue of the *AMWA Journal*: "The solution to making our profession and our work visible is not only more effective public relations; it is a matter of establishing our identity and credibility through published research."⁴ They say that you should put your money where your mouth is, and on that note

I am delighted to be partnering with some AMWA legends, Art Gertel and Nancy Taylor, to kickstart funding for the AMWA Award for Best Published Research.

Importantly, we need medical writing publications in peer-reviewed journals listed in Medline so many other people can find them and read them—we can't keep publishing our work in newsletters only. Please know that I am not asking you to do the impossible; it is challenging, yes, but we have managed to publish our papers on medical writing issues in high-ranking journals such as *JAMA*, *Chest*, and *PLoS Medicine*. Gaining and publishing evidence on our value and ethics can be done. We need to do it more.

If you don't think you can become a pioneer right now, though, you can certainly do your bit right now by supporting the pioneers, particularly if you work on manuscripts. That means you need to be familiar with

- the AMWA Position Statement¹
- Good Publication Practice for Pharmaceutical Companies⁵
- the Uniform Requirements

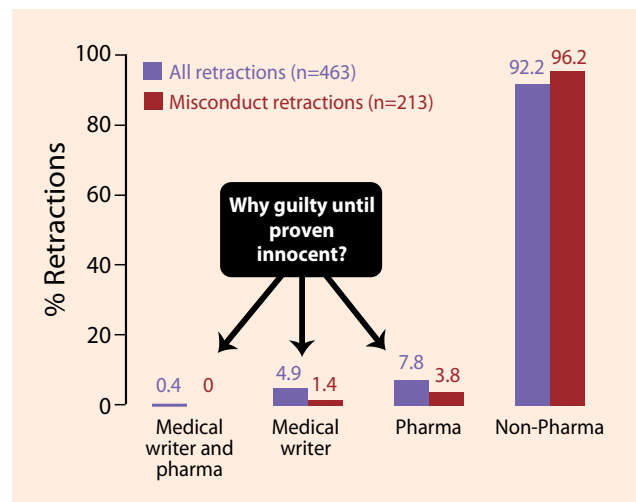


Figure 1. Percentage of retractions among 4 groups of journal articles: those with declared medical writing and industry support, those with declared medical writing support, those with declared industry support, and those with no industry support. Reprinted, with permission, from Woolley KL, Woolley MJ, Lew RA, et al., Round up the usual suspects? Involvement of medical writers and the pharmaceutical industry in retracted publications. Paper presented at the Sixth International Congress on Peer Review and Biomedical Publications; September 10-12, 2009; Vancouver, Canada. http://www.ama-assn.org/public/peer/abstracts_2009.html#113. Accessed November 11, 2009.

for Manuscripts Submitted to Biomedical Journals (www.icmje.org)

And, you simply must reject ghostwriting work—ghostwriters must be stopped—their short-term financial gain causes us long-term professional pain!

The survey recently completed by Adam Jacobs from the European Medical Writers Association (EMWA) and Cindy Hamilton, your AMWA 2008-2009 President, showed that EMWA and AMWA members are doing less ghostwriting.⁶ However, I was staggered to see that 42% of EMWA and AMWA members are still ghostwriting! This is just not good enough!! It is simply not acceptable that 42% of AMWA and EMWA members are still ghostwriting, and keep in mind that this 42% is likely to underestimate the true problem, given that these medical writers have at least recognized the importance of joining a professional association.

Lastly, when it comes to declaring your involvement and funding source, I encourage you to urge your authors to use the checklist that we recently published in *PLoS Medicine*.⁷ This checklist was designed by medical writers in Europe, North America, and the Asia/Pacific region. Importantly, the checklist is freely available, without any copyright restrictions, from *PLoS Medicine* (one of the highest ranking journals in general medicine) and on the EQUATOR network Web site (www.equator-network.org). The checklist is the only tool that gives editors “teeth” at minimal cost to them. Please get your authors to use it! If you do, we will create an international groundswell of submissions to editors that show just how ready professional medical writers and authors are to prove that they are working together ethically.

NEW FRONTIERS OF MEDICAL COMMUNICATION

Our second challenge relates to the new frontiers of medical communication. To address this challenge, I

put to you that we need to take a truly international approach to our expectations and our education of medical communicators. Respect for our profession cannot be piecemeal; our profession is international and we are only as strong as our weakest link. We can't have people say, “Oh yes, I respect medical communicators in this country, but not that country.” Our challenges are international, and our solutions must be international; as medical communicators, we are all in this together.



Don't say there weren't warning signs about how critical this challenge could get. Earlier here, I highlighted that retractions from low- and middle-income countries were of particular concern. The so-called worst of the worst of these countries are China, Croatia, Egypt, India, Lebanon, and South Africa. These countries not only had the highest number of retractions but also had the highest number of retractions for misconduct. The countries that should ring alarm bells are India and China, as clinical trials are surging there (almost doubling in the past 3 years). How many of you or your organizations have a risk management strategy in place to deal with the significantly higher odds of a misconduct retraction coming from these countries? You can bet that investigators in these countries will want to author papers. I want to stress that we can't punish innocent authors from these countries, but thinking that retractions from these countries will suddenly disappear is ignorant and irresponsible.

Some of you may be thinking that all this trouble over there doesn't affect you. If it doesn't now, it may in the future unless our profession acts. Market research indicates that the global medical writing market is growing; it has apparently doubled in last 5 years.⁸ Market research also indicates that about 40% of clients are outsourcing their medical writing.⁸ Quite simply, our profession is growing and it is going global. This is good news, but we have to realize that this also increases the risk that medical writers around the world may not have the value and ethics that would help our profession gain respect. We must realize that poorly trained medical writers anywhere—from Dallas to Delhi—affect all of us; they can add to or detract from respect for our profession.

So what can we as a profession do? I put to you that because our profession is working in new frontiers, we need a new certificate, and I think an organization like AMWA would be one of the best organizations to offer this new certificate. First, I want to compare the AMWA core certificate with the certificate that I propose AMWA offers, namely an international certificate. I offer this comparison not to criticize the existing core certificate; rather, I don't think the core certificate is suitable for international medical writers in terms of content, delivery, and time. And I think our profession needs a certificate that is suitable with regard to these factors. In terms of content, the core certificate requires 8 modules and ethics is not compulsory; I would make the international certificate require only 4 modules and make ethics compulsory. In terms of delivery, the core certificate offers most of its modules in person; I would make the international certificate all online. It does not matter where in the world you are, you could do the AMWA international certificate. In terms of time, the core certificate would probably take someone from India or Australia or elsewhere in the world 3 years to do and that depends on if they could do their

modules at the AMWA conference and if they could afford the travel and time costs to attend the AMWA conference for 3 years. I would make the international certificate program possible to complete in 1 year.

Why would AMWA offer an international certificate? What are the benefits for AMWA? First, if AMWA stepped into the gap in the market, it could reinforce AMWA as a leader in its field; other organizations might offer basic training, even certification in medical communication, but they don't have the history or reputation of AMWA. Second, AMWA could build this certificate for minimal cost by leveraging content from its existing modules, and the certificate could be a new source of revenue, as well as a new source of new members. Third, the certificate would help AMWA raise its profile internationally. Importantly, AMWA would not have to deliver this international certificate on its own if it did not want to. AMWA could partner with other organizations, such as the soon-to-be-formed Asia-Pacific Medical Writing Group, to offer this certificate to international members.

In addition to the international certificate, I also think our profession should start using a new tool that identifies the knowledge, skills, and behaviors we expect of a medical writer, no matter where in the world that medical writer might come from. David Clemow and I worked with medical writers in Europe, North America, and the Asia/Pacific region to develop a medical writer competency model. For the past year, the line managers at our company have piloted the use of this competency model to hire and train medical writers, and the results have been very positive indeed. You will be able to read more about this competency model when David and I publish an article on the model soon, and I will speak with AMWA about making this model, designed by medical writers for medical writers, freely available to interested AMWA members.

In the interim, though, what can

you do? I encourage you to discuss the proposal of AMWA developing an international medical writing certificate; if AMWA doesn't, then who should? There is no time to waste on this—we need to make sure that medical writers around the world have a very basic, but very clear, understanding of the value and ethics expected of medical writers. I also encourage you to be active professionals—if and when you liaise with medical writers overseas, encourage them to join AMWA and take every opportunity you can to reinforce how important ethics are to our profession. Lastly, I encourage you to trial the competency model when it becomes available to you.

THE LONESOME POSITION OF MEDICAL COMMUNICATORS

Our third challenge relates to the often lonesome position of medical communicators. To address this challenge, we need to be much more proactive and strategic in how we interact with those who need to understand the value and ethics of professional medical writers. Essentially, we have to find our rightful place—where we belong and where we are respected. Medical communicators must interact with many stakeholders if we want to take more steps forward for our profession; I will just focus on 2 groups: editors and the media.

If we really want to interact with editors in a respectful and meaningful way, we have to appreciate their concerns. In the eyes of many editors, we have a negative history. They don't necessarily know the difference between professional medical writers and ghostwriters, but they sure know that ghostwriters are bad. They don't want to embroil their journal in ghostwriting controversy and end up on the front page of *The New York Times* or *The Wall Street Journal* for all the wrong reasons. You can understand, perhaps, why some editors just want to ban all writers. There is also confusion about which organization journal editors should consult about a medical writing issue. Should they

go to AMWA, or EMWA, or the Drug Information Association (DIA), or the International Society for Medical Publication Professionals (ISMPP), or the Association of Regulatory and Clinical Scientists in Australia (ARCS), or the All India Medical Writers Association or...the list could go on. When editors need a credible, clear, and quick answer on medical writers, who is their "go to" contact?

I want to highlight to you that if we do interact with editors, in a respectful and meaningful manner, there is the possibility of gaining more respect for our profession. For example, you may have been aware that the *Clinical Journal of Oncology Nursing* previously had a policy that "banned articles written by writers as a way to avoid ghostwriting."⁹ After a few of us interacted with the editor of this journal, particularly after we had published our article about medical writers in *PLoS Medicine*⁷ (note that this was a journal that another editor had actually read), the policy was changed.¹⁰ In addition to changing the policy, the editor also kindly published correspondence from AMWA legend Art Gertel and me, which as you might guess, focused on the value and ethics of professional medical writers.^{11,12}

What about interacting with the media? First, I think it is important to highlight, as evident in a quote from *The New England Journal of Medicine*, that at least some people in the media are realizing that they must hold themselves to higher standards. Susan Dentzer wrote, "We in the news media have a responsibility to hold ourselves to higher standards...we must be more than carnival barkers; we must be... more interested in...[communicating] than carrying out our other agendas."¹³ From reading many articles in the media, you would think that there has been an agenda to get rid of medical writers. Indeed, many of these articles would have readers believe that all medical writers are bad; there never seem to be any good apples.

I appreciate that interacting with the media is not always easy or advisable, particularly when they might

corner you in a bathroom, as the journalist from *The Wall Street Journal* did to me one day in Chicago, or corner you on the telephone trying to trap you into saying that your clients force you to ghostwrite, as the journalist from the *British Medical Journal* tried to do to me last year. He was not successful—we don't ghostwrite and we never will. I gave him a simple message, but it was not the one on his agenda.

So what can you do when it comes to interacting with editors and the media? One thing you can do, and which too many medical communicators don't do, is to use the right words. Whenever you speak with an editor or the media (or anyone else for that matter), never say that you are a ghostwriter (I am assuming here that you aren't!). Instead, say that you are a professional medical writer. Explain the difference. If it helps, you can refer them to my article in *Chest*, which reinforces that professional medical writers are not the same as ghostwriters.¹⁴ We, of all people, should know how powerful words are—let's all start using the right words when we interact with others.

Also, if AMWA agrees, you could be quite proactive in your local chapter. For example:

- You could identify just 1 editor or journalist in your region.
- You could then send them a copy of AMWA's Position Statement.
- You could set up an interview with an AMWA spokesperson (someone who has strong knowledge and media training).
- You could invite the editor or journalist to attend the annual conference and have a dedicated person available to show them around—one look at the AMWA conference program and they would see how strong AMWA is on ethics and value.
- You could then build on these relationships—sending out useful press releases—fortunately, AMWA already has a very helpful publicity kit to get you on your way.

Now if you or someone in your chapter doesn't take these steps, who will?

What can we, as a profession, do? I think we have to change how our profession interacts with editors and journalists. Currently, an issue breaks and, quite rightly, a whole bunch of associations or individuals respond to that issue. Not surprisingly, this can create confusion, as our profession has a splintered voice. I believe our profession needs a united voice, and I put to you that we establish an International Committee of Professional Medical Writers, modelled somewhat on the lean, but highly influential, International Committee of Medical Journal Editors (ICMJE).

This committee would allow for

- A credible response—the committee would be made up of highly respected representatives from professional medical writing associations around the world; it would not compete with our existing associations, it would complement them.
- A clear response—we could speak with a unified and international voice.
- A quick response—the committee would be the initial “go to” contact, with responses provided within 24-48 hours.

With such a committee, we could have a much simpler way of responding to an issue; further, this committee could also be used to raise issues of concern to our professional associations. If we build trust with editors and journalists, the relationship can be 2-way. If ICMJE can do all that it has without large costs, why can't we?

This keynote is drawing to a close and I promised you that by the end of this presentation you would be able to say “yes” to 2 questions. So let me summarize what we and you can do to help our profession address the 3 challenges I identified and get more respect.

1. Our first challenge is to investigate our value and our ethics.

I have suggested that as a profession, we could encourage and fund research; the AMWA Award for Best Published Research did not exist last year, but with starting funds from 3 medical writers and support from AMWA, we now have that in place.

I have suggested that you could help by

- Winning the award—why not be rewarded if you publish research on the value or ethics of medical writers?
- Knowing the rules that govern what we do and reject ghostwriting work; we simply have to get that 42% down to less than 1%.
- Using the medical writer checklist published in *PLoS Medicine*; this checklist is free and readily available.

2. Our second challenge is to address our new frontiers.

We need to take a truly international approach to our expectations and education of medical writers. I have suggested that as a profession, we could develop an international certificate and a medical writer competency model. We have the model already and I believe we can and should work toward the certificate.

I have suggested that you could help by

- Debating whether AMWA should offer an international certificate.
- Promoting ethical practices and AMWA to your international colleagues.
- Trialing the competency model; I will work with AMWA to make it available to you when it is ready. Our profession is international and our core competencies should be as well.

3. Our third challenge is to not be so lonesome.

I believe we need to interact more, and in better ways, with journal editors and the media. I have suggested that as a profession, we could establish an International Committee of

Professional Medical Writers; this might be controversial, but as we are not doing so well in our interactions right now, we need to do something different.

I have suggested that you could help by

- Using the right words—if you are a professional medical writer, you are certainly not a ghostwriter.
- Contacting your local journalist or a medical journal editor; show that you appreciate their concerns and do what you can to help raise awareness of our value and our ethics; we need more respect from journalists and editors and you could do your bit to help.

I hope I have been able to share with you what getting more respect for our profession means to me. I also hope that together, you and I and our medical communication colleagues around the world, can truly, as Aretha Franklin would say, “tcb”—an acronym (and you know how much we all love acronyms) for “taking care of

business.” Medical communication **is** our business; it is **our** profession, and we all need to take strong steps forward to ensure our profession gets the respect it deserves.

Thank you.

References

1. Hamilton CW, Royer MG. AMWA position statement on the contributions of medical writers to scientific publications. *AMWA J.* 2003; 18(1): 13-16.
2. Jones N. Analysis of retractions puts spotlight on academia. *Nature Med.* 2009;15:1101.
3. McHenry L. Biomedical research and corporate interests: a question of academic freedom. *Ethical Issues Biomed.* 2008;6:146-156.
4. Royer MG, Haneline D. AMWA awards for research in medical communication. *AMWA J.* 2009;24(3): 133-135.
5. Wager E, Field EA, Grossman L. Good publication practice for pharmaceutical companies. *Curr Med Res Opin.* 2003;19(3):149-154.
6. Jacobs A, Hamilton C. Decreased evidence of ghostwriting in a 2008 vs 2005 survey of medical writers. *The Write Stuff.* 2009;18(2):118-123.
7. Gøtzsche PC, Kassirer JP, Woolley KL, et al. What should be done to tackle ghostwriting in the medical literature? *PLoS Med.* 2009;6(2):e1000023.
8. Koreith K. CenterWatch Monthly. Demand for medical writing continues to rise. 2008;15(12):1-6.
9. Griffin-Sobel JP. The status of peer review. *Clin J Oncol Nurs.* 2005;9:669.
10. Mayer DK, Mahon SM, Eaby B. Writing for hire: advice for authors (and readers) [editorial]. *Clin J Oncol Nurs.* 2009;13(2):131-132.
11. Gertel A. Change in editorial policy will help maintain high standards. *Clin J Oncol Nurs.* 2009;13(3):261-262.
12. Woolley K. Nurses, medical writers, editors can work together ethically [letter]. *Clin J Oncol Nurs.* 2009;13(3):261-262.
13. Dentzer S. Communicating medical news—pitfalls of health care journalism. *N Engl J Med.* 2009;360(1):1-3.
14. Woolley KL. Goodbye Ghostwriters! *Chest.* 2006;130:921-923.



Karen Woolley, PhD, was the recipient of an honorary AMWA fellowship, which was presented to her by Faith Reidenbach, ELS (left), and Marianne Mallia, ELS (right), at the Sablack Dinner.

KAREN WOOLLEY HAS MY RESPECT

By Debra Gordon, MS

First, a confession: I usually skip keynote addresses. I find such talks vague and rambling, designed, by necessity, to appeal to the masses instead of focusing on a specific topic. So the main reason I was sitting in the third row of the ballroom during Karen Woolley’s keynote address in Dallas this year was because I had been asked to write a summary of the talk for the *AMWA Journal*. Then, when the decision was made to publish the address in its entirety, making my article redundant, I was asked to write an analysis/opinion piece on it.

I knew this wasn’t going to be your typical keynote address when the sounds of Aretha Franklin’s “Respect” boomed through the hall. In its wake came this lovely Australian with a pixie cut and an accent I could happily listen to all day. Then came her slides—creative, funny, and to the point. *Whoa*, I thought, *this is a woman who knows how to give a compelling talk.*

And what a talk! I hope that you’ve read her talk, so I’m not going to get into the details here. Instead, let me tell you how her talk affected me.

For most of my career, I’ve written about health and medicine for consumers. I have thousands of articles and at least a dozen books with my name on them. But I’ve also

written a few trade books for doctors under their name. In other words, I have, yes, *ghostwritten*. Not only that, but in the publishing world, ghostwriters are not only in high demand but we're actually proud of what we do. One of my closest friends commands 6 figures for every book she pens. Her e-mail signature proclaims that she is the "co-author and ghostwriter of 6 *NY Times* bestsellers."

Can you imagine a medical writer putting that on his or her sig?

All of this is a very roundabout way of saying that until Dr Woolley's talk, I really hadn't worried all that much about my own role in the ghostwriting debate. Although my work had gradually transitioned over the years from 100% consumer to about half consumer, half scientific, the few papers I'd worked on for publication in journals had, to my knowledge, acknowledged me. One even listed me as a coauthor. But I hadn't really pushed for it or made it a priority when negotiating jobs.

That has now changed. In fact, the week I returned from the AMWA conference, I received an assignment to help with a review article. The first thing I did (after trying to get more money) was ask about credit. Of course, said the project manager. No problem.

Bottom line: Dr Woolley's talk energized me. It made me really understand the ramifications of the ghostwriting issue beyond the yelling and misinformation in the media (and, occasionally, on our listserve). Why? Her research. Dr Woolley's work clearly demonstrated that medical writers are not the problem when it comes to questionable publications. Which, as she clearly pointed out, begs the question: How do we get that message out to the broader public?

One thing I loved about Dr Woolley's talk was that she didn't just throw that question out there but provided a very specific, point-by-point plan to address the problem, something I wish more speakers/experts would do. Although I know there was a lot of debate about her recommendations, I have to say (because this is opinion and I'm allowed to) that I thought they were brilliant. I support every one.

Dr Karen Woolley has provided us with the road map to respect for our profession, but she cannot singlehandedly lead us to our destination. Instead, it is up to us, the rank-and-file of AMWA, to gas up the car, choose the best routes, and avoid the roadblocks if we are to convince the broader world of our worth and contributions and address the rumors and misinformation currently cluttering this highway.

AMWA MEMBERS COMMENT ON THE KEYNOTE ADDRESS

Karen Woolley's keynote address was packed with practical tips for AMWA members. I encourage you to download the audio file and slides from the Members Only section of AMWA's Web site. While you're there, search for relevant information that dovetails with Dr Woolley's advice. For example, she encouraged us to perform research to document the value we add to medical communication; the Web site has information on AMWA's new awards on published research (www.amwa.org/default.asp?id=467) and student research (www.amwa.org/default.asp?id=468). Karen also urged AMWA members to reject ghostwriting assignments; take the time to review AMWA's recently expanded ethics section of the Web site (www.amwa.org/default.asp?id=471). Following Karen's advice will help medical communicators gain respect both for themselves and the profession.

—Cindy W. Hamilton, PharmD, ELS
2008-2009 AMWA President

By showcasing her own leadership (along with that of several peers) in conducting research on ethical practices in medical writing and publications, Dr Woolley outlined a map for getting the medical writing profession from "here" to "there." Our current situation ("here") is characterized by an underappreciation and mischaracterization of our role in the support, development, and polishing of medical and research publications. The goal for our profession ("there") is to achieve respect and recognized legitimacy in the collaborative effort that comprises modern scientific research. Not only must we demonstrate our value (ie, measurable contributions in terms of time/resource savings and improved outcomes) but we must let there be no doubt that we operate under unified, well-defined, and indisputable ethical principles. There is much work to do in this regard, especially because recent research still shows that unethical ghostwriting practices are still occurring (though at markedly decreased levels than seen in the past). Dr Woolley's mantra to those who ghostwrite medical publications, "[Your] short-term financial gain causes us long-term professional pain," is as much a call to action as it is an admonition—we must only accept and undertake work that will be conducted ethically with appropriate acknowledgment of nonauthor contributions and potential conflicts of interest. Not doing so will perpetuate a cycle of distrust, increased scrutiny, and perhaps the eventual ruin of an honorable, yet widely unrecognized, profession.

—Tom Gegeny, MS, ELS
2009-2010 AMWA President

Karen Woolley's keynote address at the 2009 annual conference raises important issues about the role of medical writers—and AMWA—in scientific communications. Dr Woolley shows us that the high road to new global respect for the value and integrity of medical communicators is paved with research, evidence, and collaboration with our brothers and sisters in related associations around the world. By working together to establish proof of our value and integrity, we can earn respect as professional medical communicators.

—Sue Hudson
2007-2008 AMWA President

OPEN SESSION SUMMARIES

▷ THE GLOBALIZATION OF MEDICAL WRITING

Moderator

Steven Casto, EdD, CMPP

Senior Publications Specialist, UCB Inc, Atlanta, GA

Speakers

Helle Gawrylewski, MA

Director, Medical Writing Early Development, and Global Alliance Manager, Johnson & Johnson Pharmaceutical Research & Development LLC, Titusville, NJ

Art Gertel

Vice President, Strategic Regulatory Consulting, Medical Writing and Quality Assurance, Beardsworth Consulting Group, Inc, Flemington, NJ

Stephen de Looze, PhD, ELS

Head of Medical Writing and Document Management for Accovion GmbH, Frankfurt, Germany

By Jennifer Maybin, MA, ELS

Tackling what is a difficult and often politically charged issue, a 3-member panel of US and international speakers who are entrenched in the global medical writing arena addressed a crowded open session on issues related to training and ethics, cooperation among organizations, and global certification. Helle Gawrylewski, MA, led off by discussing her company's development of a global training program for its allied researchers and writers at clinical research organizations in the Asian/Pacific region to handle writing and ethical issues related to medical research and publishing. Johnson & Johnson employs 162 writers, of whom 32 are contract or offshore writers, said Gawrylewski. Managing the quality and cost-effectiveness of such a large staff at more than 8 sites requires flexibility, use of strategic staff in-house, and investment in training and effective communica-

tion approaches with the offshore researchers.

Gawrylewski explained that the principles of Johnson & Johnson's training program are to encourage success and to consider international vendors as partners and as an extension of in-house staff. A challenge for researchers and writers from some countries such as India is overcoming a traditional mindset that discourages questioning one's superiors. This mindset has the potential to create ethical problems. However, said Gawrylewski, as a result of the training program, these international researchers are now evaluating, questioning, and challenging inconsistencies within the company's processes, a win-win situation for all.

She admitted that internal writers feared losing jobs to writers overseas, where fees for writing services are lower. Gawrylewski stated that saving costs was not the motivation for the move; rather the globalization process was to partner with vendors throughout the Asia/Pacific region where the company has facilities.

Stephen de Looze, PhD, ELS, spoke about the global confusion over the development of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) E3 template for clinical study reports, which was originally envisioned to be a document that would be acceptable to all regulatory authorities, including the US Food & Drug Administration. However, rather than moving toward a global template, in-fighting among organizations has led to the creation of multiple document sections that overlap in content and remain individualized for submissions to US, European, and Asian entities. Several problems are to blame, according to Dr de Looze, including the FDA's consideration of parts of the template as somewhat "optional," political differ-

ences among agencies that prevent compromise, and lack of consistent communication among organizations. He urged AMWA and the Drug Information Association (DIA) to work together to help solve the global template issue.

Springboarding from this point, Art Gertel encouraged more international unity through what he termed an "intergalactic association" of medical writers. Such an association could act as a liaison among the fractured groups of writers that consist of AMWA, DIA, JWA (Japanese Writers Association), EMWA (European Medical Writers Association), AUMWA (Australian Medical Writers Association), ISMPP (The International Society for Medical Publication Professionals), TIPPA (International Publication Planning Association), and more. Gertel's vision is that unity among writers will change the perception of who medical writers are and what medical writers do. Certification of medical writers using a global standard that verifies a level of competency could help deflect criticism about ethical issues from those outside our field, he added. But the problem is that individual organizations want to "own" such certification.

Gertel asked the rhetorical question, "How do you get people to buy into an initiative if it did not originate in their own shop?" Gawrylewski answered, "We need to get away from politicalization of issues. We all really want to improve patient care by exchanging information quickly." Although nothing was solved in this session, the problems of international medical writing were aired and a challenge was issued for worldwide medical writers to solidify as "global medical writers."

Jennifer Maybin, owner of Maybin Health Communications, is an independent medical editor and writer in Branchburg, NJ.

▷ HIGH-PERFORMANCE FREELANCING

Moderator

Debra L. Gordon, MS

Gordon Squared Inc, Williamsburg, VA

Speakers

Brian Bass

President, Bass Advertising & Marketing Inc, Robbinsville, NJ

Ann M. Volk, MA

Freelance Medical Writer, Dover, DE

By Anne McDonough, MPH, CSci

Debra Gordon, MS, started off this open session by defining “How NOT to be a High-Performing Freelancer.” Her tips included the following.

- Don’t identify your goals.
- Don’t identify your strengths and weaknesses.
- Don’t run your business like a business.
- Don’t build a professional Web site.
- Stop learning.
- Don’t diversify.
- Don’t list yourself in the AMWA Freelance Directory.
- Don’t refer work to other freelancers.
- Don’t say “no” or listen to your gut.
- Don’t take breaks or take care of yourself.

Ann Volk, MA, promised to give the secrets to doubling freelance incomes by “Building Brand You.”

The goal she that gave was “to do what you like to do for whom you want to do it” and make lots of money or have lots of time off, depending on your preferences. She advised “firing” clients that cost money and focusing on the services that are the most profitable. She recommended the book *The 4-hour Work Week: Escape the 9-5, Live Anywhere and Join the New Rich* by Timothy Ferriss.

Volk gave the following advice on effective personal branding.

- Think company, not person or product.
- Know yourself.
- Create a cohesive product line.
- Communicate your brand.
- Manage your brand.

She emphasized the most important characteristics of a personal brand:

- Professional
- Responsive
- Timely
- Reliable
- Positive
- Self-starting

In his presentation, “Own a Company, Not a Job,” Brian Bass related his personal story of epiphany: he had reached a point at which he thought he could not make any more

money, and his solution was subcontracting. He described how he overcame his fear of putting his reputation in the hands of others and his concerns about low margins and achieved “infinite income potential” and “ultimate freedom” to work when and if he wants to work.

His strategy is an emphasis on value

...to clients

- We help clients to build their businesses.
- We save clients money by consistently delivering a better quality product—on target, on time, on budget.
- We make clients look good.

...to writers

- We build and maintain solid relationships.
- We watch out for each other.
- There is more great-paying work for everyone.

...to himself

- I receive income when I write and income when others write.
- Work gets done while I’m away.
- I’m building an asset.

Anne McDonough is a freelance clinical research consultant based in London, England, and provides monitoring, project management, clinical scientist, medical writing, and training services.

Annual Conference Snapshots

Left: Cindy Hamilton passes the gavel to Thomas Gegeny.

Right: Sue Hudson introduces (left to right): Tom Gegeny, President; Melanie Ross, President-Elect; Mary Royer, Secretary; Judi Pepin, Treasurer; and Barbara Snyder, Annual Conference Coordinator.



▷ JUSTIFYING OUR PROFESSION: HOW TO DO RESEARCH ON MEDICAL WRITING AND GET IT PUBLISHED

Moderator

Nancy D. Taylor, PhD, ELS

Freelance Medical Writer, Greenville, SC

Speakers

Karen Woolley, PhD

CEO, ProScribe Medical Communications; Adjunct Professor, University of Queensland and University of the Sunshine Coast, Australia

Annette Flanagin, RN, MA

Managing Deputy Editor, Journal of the American Medical Association (JAMA); Director, Editorial Operations, JAMA and Archives Journals; Congress Coordinator, International Congress on Peer Review and Biomedical Publications; Coauthor and Committee Member, AMA Manual of Style, Chicago, IL

By Shannon Omisore, MA

Karen Woolley, PhD, discussed the importance of medical writers conducting research and how to move from acknowledgment to authorship. Her work has addressed the outcomes that occur when medical writers conduct research. (See *Dr Woolley's Keynote Address, which begins on page 160.*)

The first step for beginning a research project is to put together a research team. According to Dr Woolley, when recruiting people for a research team, consider quantity and quality. The quality of their research is just as important as their ability to work on the project after hours. The next step is for the team to decide authorship, establish a consensus, and write it down.

The team can then develop a budget for the project; expenses can include fees for advertising, hiring a statistician, and preparing slides.

The concept for the project should be important. She offered the following tips for generating research ideas.

- Go to conferences.

- Read lots of literature.
- Use a whiteboard for putting down your ideas.
- Let your mind drift occasionally.
- Look at ideas and prioritize them.

Dr Woolley addressed the concern medical writers have about lacking time for research. “The way we find time and still have lives is that we divide and conquer,” she said. She urged attendees to decide on a topic, divide it into manageable chunks, and get each member of the research team to work on one chunk. To ensure accuracy, an independent statistician should review the data before the team reviews it. Dr Woolley also suggested that medical writers get valuable feedback on their research project before submitting the manuscript to a journal.

Throughout her presentation, Dr Woolley stressed the importance of medical writers conducting research on their profession. “Busy professional medical writers can and should do research,” she said. She suggested that attendees refer to Tom Lang’s recently published article that addresses several aspects of conducting research on the profession.¹

Annette Flanagin, RN, MA, discussed how to get research on research, editing, and writing published. Each journal has specific publication instructions for authors. For example, *JAMA* requires that papers have a detailed methods section. According to Flanagin, the methods section is the most important part of the research paper; the authors should describe what they did. The text should not repeat information from the tables and figures.

Details that belong in the Methods section include

- Setting and date(s) of study
- Criteria and selection of the sample
- Confounding characteristics
- Measures of validation
- Methods of verification
- Types of statistical analyses

The results section should be short and not repeat information from the

Methods section. The discussion section should focus on what the study means and its importance.

Flanagin offered general tips for getting published. For example, the title of the paper should be concise, but not overly general. The tables and figures should contain accurate, consistent data. She recommended that medical writers avoid “eye candy”—graphs and pie charts with simple yes and no answers. She also emphasized the importance of having a statistician look at the research before submitting it for publication.

Flanagin suggested the article “Decreased evidence of ghostwriting in a 2008 vs 2005 survey of medical writers” as an example of a quality research article.² She, too, recommended Lang’s recent article in the *AMWA Journal*.¹

Flanagin noted that the decision of where to publish is important. Flanagin suggested that when selecting a journal, medical writers should consider the following.

- Audience
- Circulation
- Prestige
- Turnaround time
- Acceptance rate
- Demonstrated interest in subject

She urged attendees to not give up if their manuscript is rejected. Common reasons for rejection are the manuscript was poorly written, too long, included too many tables and figures, and was the right subject for the wrong journal.

Resources

1. Lang, T. Just who are we and what are we doing, anyway? Needed research in medical writing. *AMWA J.* 2009; 24(3):106-12.
2. Jacobs A, Hamilton CW. Decreased evidence of ghostwriting in a 2008 vs 2005 survey of medical writers. *The Write Stuff.* 2009;(18)2:118-23.

Shannon Omisore is a writer-editor for the Centers for Disease Control and Prevention (CDC) in Atlanta, GA.

▷ NAVIGATING TODAY'S CME LANDSCAPE

Moderator

Mary E. King, PhD, DABCC

Principal, King Medical Communications LLC, Boulder, CO

Speakers

Tara E. Hun-Dorris, MMC, ELS

President, THD Editorial Inc, Raleigh, NC

Johanna Lackner-Marx, MPH, MSW

President, InQuill Medical Communications LLC, Soquel, CA

By **Lori Buffum, MA**

What is continuing medical education (CME) and how does CME accreditation shape writing? Mary King, PhD, DABCC, began by defining CME as any activity that assists physicians in carrying out their professional responsibilities. CME helps professionals stay current, meet requirements for licensure, and qualify for Board certification by studying methods of diagnosis, treatment, or management of health conditions. Today, the format of CME ranges widely from papers to slide shows to live symposia to interactive online multimedia presentations.

Dr King noted that the Accreditation Council for Continuing Medical Education (ACCME) is the primary agency setting standards for CME providers and content. Its mission is to set high standards of quality, promote competence, and strive to improve medical care of patients. The accreditation process ensures that each CME activity identifies gaps in knowledge, provides content to fill the gaps, and assesses the results to determine how the education led to improving or changing the practice of medicine.

In her discussion of the controversial “commercial support,” Dr King emphasized 4 of the 6 standards “essential to the current environment demanding programs free of interference.” These standards included

- Independence from any control over content

- Full disclosure to resolve any personal conflicts of interest
- No advertising, trade names, or branding incorporated into educational materials
- Content and format without bias toward or promotion of any one view

Giving you a leading edge—learn how physicians learn best.

Johanna Lackner-Marx, MPH, MSW, talked about the paradigm shift in CME that is providing opportunities for communicators. With the brief presentation of a case study demonstrating several instances of medical malpractice involving one patient's hip replacement, Ms Marx dramatically illustrated the critical need for a new kind of CME—education that bridges a competency gap between current performance and the gold standard of care. She mentioned 3 landmark reports from the Institute of Medicine (IOM) that have led to new mandates in medical education. The first report, “To Err is Human,” blamed the lack of high-quality health care for thousands of unnecessary deaths due to medical error. The second report, “Health Professions Education, the Bridge to Quality,” called for sweeping changes in education. And the critical third report, “Crossing the Quality Chasm—A New Health System for the 21st Century,” outlines the paradigm shift, mandating new ways of teaching and learning.

Marx explained the 4 mandates:

- Move from knowledge-based to behavior-based education by motivating adult learners to satisfy a need and master a skill.
- Format CME to accommodate all learning styles: VARK (visual, auditory, reading, kinesthetic).
- Emphasize active formats over passive formats to allow for maximum interaction with content.
- Employ active teaching methods to engage with the content before, during, and after the CME event.

Pearls and pitfalls of creating effective CME content. Tara Hun-Dorris, MCC, ELS, provided very practical advice for

creators of CME content. Starting with the preliminaries—the needs assessment and learning objectives—writers can play a crucial role in helping to identify and delineate the gaps in knowledge. From reviews of the literature, to discussions, to analysis of current practice, identifying the need for a specific CME activity is a vital first step. Hun-Dorris gave as an example a change in guidelines that may impact a physician's practice. In keeping with the mission of CME to “improve care of the patient,” any activity should be designed to reinforce or enhance core performance.

Learning objectives should be prepared before the content and should be a well-defined number of actionable items. The ACCME (www.accme.org) is a great resource for preparing CME materials, right down to word choice for learning objectives. As discussed previously, formats are wide ranging and available on multiple platforms, so writers once again can play a crucial role by being familiar with the myriad technologies being employed for CME materials, from monographs to case studies to interactive online tutorials. Post-tests can also take many forms—another area where writers and instructional designers can contribute to the success of the activity.

Hun-Dorris also talked about the importance of copyright and permission issues when working with faculty on preparing to publish a CME activity. Considerations must include budgeting for permissions, obtaining legal advice, documenting sources, and being prepared to omit materials that cannot be adequately referenced. Her presentation concluded with a humorous slide show of “faculty types” and tips for working with them, her favorite being “Dr McDreamy” who, unfortunately, is rarely to be found except on TV.

Lori Buffum is the Web site writer/editor for the Texas Heart Institute (www.texasheart.org) at St. Luke's Episcopal Hospital in Houston, TX.

▷ NO MEDICAL DEGREE, NO PROBLEM! SUCCEEDING AS A MEDICAL WRITER WITHOUT A SCIENCE BACKGROUND

Speaker

Scott Kober, CCMEP

Manager, Medical Services, Institute for Continuing Healthcare Education, Philadelphia, PA

By Nick Sidorovich, MSED

Medical writers who do not have degrees in science or medicine may feel that they are at a disadvantage in getting hired for freelance jobs or permanent positions. Scott Kober, CCMEP, gave hope to these writers and outlined a plan of action for them.

Learn the Language of Medicine

Medical writers need to know the language that potential employers speak. Terms such as statistical significance, *P* value, and double-blind randomized trial are among those that writers need to be familiar with, Kober said.

He recommended reading the "Users' Guides to the Medical Literature" series of articles that were written by the Evidence-Based Medicine Working Group and originally published in *JAMA*. The articles can be accessed online at www.cche.net/usersguides/main.asp. Medical writers should also own medical reference books, such as *Dorland's Illustrated Medical Dictionary* and the *AMA Manual of Style*, and read various medical journals.

Get Some Education

Most companies posting job opportunities on the AMWA Web site often ask for applicants with a degree in the life sciences and a minimum of 5 years' experience. But the good news is, according to Kober, "They don't always mean it!" Writers without a science degree can make themselves attractive to employers by getting other kinds of education.

Medical writers can increase their

knowledge through AMWA's educational program and through biomedical writing programs at schools such as University of the Sciences in Philadelphia (USP) and the University of Chicago. USP offers degree, certificate and online learning, while the Chicago certificate program offers courses onsite over 1-3 days. Kober added that industry-specific organizations such as the Drug Information Association (www.diahome.org) and the Alliance for CME (www.acme-assn.org) provide training for writing about biomedical products and physician continuing medical education, respectively.

Develop Unique Skills

Medical writers should specialize in a few areas of medicine, eg, oncology, cardiology, rheumatology. "A doctor isn't expected to be an expert in every branch of medicine; neither should you," said Kober. He also recommended learning software programs such as PowerPoint for slide presentations, InDesign for publication layouts, and/or Dreamweaver or Fireworks for Web design.

Never Turn Down an Opportunity

One caveat that Kober offered is that, without having a science degree, it will be easier to get a full-time position with a company but more difficult to get clients as a freelance.

Any writing job, however, could be the one to get the writer's foot in the door and the recognition as a medical writer. In addition to reviewing the Jobs Online on the AMWA Web site (www.amwa.org), he suggested checking out job listings on these other Web sites:

- Council of Science Editors (www.councilofscienceeditors.org)
- Editorial Freelancers Association (www.the-efa.org)
- The Freelance Mailing List (www.comteck.com/~tanuki/links/jobs.html)

Develop a Sales Pitch

"Always be ready to answer the questions: What makes me better than everyone else? Why should anyone hire

me?" Kober recommended. Create a writing portfolio that can be shown to people to demonstrate writing abilities. "Ask colleagues in power to serve as your references if they believe in you," he added.

Market Writing Skills as a Commodity

The Internet is the main marketing tool in use these days and medical writers can build a network of colleagues using Web sites such as LinkedIn, Facebook, and the AMWA site. Participating in online discussion forums and message boards is useful because, he said, "An educated post that is seen by the right [people] can impress them and they might contact you if you are creating work that aligns with their needs." Other marketing advice included posting your résumé on Internet job sites, creating a professional Web site to post writing samples and provide information about your writing services, and handing out business cards to anyone you meet who may be able to help.

Minimize Feeling Overwhelmed

Kober said that no matter how well prepared the writer thinks he or she is, there will always be moments when the writer will question "What did I get myself into?" The answer lies in developing time management skills. "If a deadline is unreasonable, turn down the job," he said. "Learn to say no" and avoid the risk of doing substandard work that damages a reputation.

Writers who conduct interviews can avoid becoming overwhelmed by having supplies they need on hand, such as a tape recorder, extra batteries, and reference materials.

The Money Ain't Bad

Kober, who began his writing career as a journalist, offered a perspective on the relative merits of medical writing versus other forms of professional writing. He pointed out that the average experienced journalist's salary is between \$40,000 and \$50,000, and a search of job Web site **Simplyhired.com** revealed that salaries for copy writers and technical writers average \$47,000 and \$52,000, respectively.

Kober then quoted AMWA's 2007 Salary Survey as reporting that the average experienced medical writer's salary is between \$80,000 and \$100,000, a fact that should provide ample motivation for writers without a medical degree to pursue additional training according to Kober's suggestions.

Nick Sidorovich is the owner of Rolling Hill Health, a health communications and medical writing company in Chatham, NJ, and teaches screenwriting at Fairleigh Dickinson University in Madison, NJ.

PREVENTING ILLNESS AND INJURY: WHAT'S NEW

Moderator

Kathleen Loudon, ELS

Owner, Loudon Health Communications, Gurnee, IL

Speakers

Sandra Bond Chapman, PhD

Chief Director, Center for BrainHealth, Professor of Behavioral and Brain Sciences, University of Texas at Dallas, Dallas, TX

Riva L. Rahl, MD

Preventive Medicine Physician, Cooper Clinic; Medical Director, Cooper Wellness Program, Dallas, TX

Shelli Stephens-Stidham, MPA

Director, Injury Prevention Center of Greater Dallas, Dallas, TX

By **Ann Tennier, ELS**

Riva Rahl, MD, a preventive medicine physician, began the session by breaking up strategies for preventing illness into the ABCs: aspirin, blood pressure, cholesterol, diabetes and vitamin D deficiency, exercise. For example, new guidelines for aspirin use are evidence based; a daily dose of 81 mg is recommended for men starting at age 45 to prevent heart attack and for women starting at age 55 to prevent stroke. Dr Rahl also elaborated on the difficulties presented by vitamin D deficiency, including chronic pain, depression, and susceptibility

to seasonal flu, rheumatoid arthritis, various cancers, and multiple sclerosis. She described the current discrepancy between daily 1,000 units of D3 that are recommended by medical experts and the 200 units that are recommended by the USDA food and nutrition service guidelines. New USDA guidelines are expected in May 2010, and higher recommended levels are anticipated, she said.

For exercise, Dr Rahl recommended an accumulation of at least 150 minutes of aerobic exercise weekly, but more is better. She stated that this exercise can be accomplished in 10-minute increments throughout the week or even as a 150-minute end-of-week "cram" session. She also recommended 2 strength training sessions per week.

Sandra Bond Chapman, MD, began her presentation by asking participants what age they would choose for their brains. Participants mostly suggested ages 25 and 35. Dr Chapman noted that it is common to hear people say they like to be age 60 but would like the mind of a 20-year-old. She proceeded by showing how conventional wisdom about the brain has been proved incorrect over the last several years. For example, the brain actually gets better over time. Although time of processing slows during the aging process, the depth of the brain's ability to make sense of information increases. She, too, described an ABC approach, with the following needed for brain health: awareness (attending to cognitive warnings and signs of slippage), brain health physical (to assess strategic attention, abstract and integrated reasoning, and mental flexibility), and conditioning. She noted that completing Sudoku and other puzzles has not been proved to enhance brain capacity, whereas keeping engaged with life has.

Shelli Stephens-Sidham, MPA, described how injury prevention is often associated with disastrous events such as terrorist attacks and tornadoes. However, data show, for example, that more deaths occurred from all manner of preventable injury in the same time period in a given location than deaths occurring from a catastrophic event

that ends up covered for weeks in the newspapers.

For instance, Stephens-Sidham's organization is working to reframe the perception so that people do not continue to take traffic deaths for granted but, rather, to think about them with the same gravity as deaths from the war in Iraq. Her group has initiatives underway to improve car seat and seat belt use in neighborhoods with high rates of nonuse, as well as to increase the number of smoke alarms in homes in areas that have frequent residential fires.

ABCs for Preventing Illness

Aspirin
Blood pressure
Cholesterol
Diabetes, Vitamin D deficiency
Exercise

ABCs for Brain Health

Awareness
Brain health physical
Conditioning

Ann Tennier is a senior editorial assistant at the Medical College of Wisconsin, Milwaukee, WI.

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▷ GPP2, CONSORT, AND YOU

Moderator

Kim Pepitone, CMPP

Director of Credentialing and Professional Development, International Society for Medical Publication Professionals, Spring Hill, FL

Speakers

Thomas A. Lang, MA

Principal, Tom Lang Communications and Training, Davis, CA

Yvonne Yarker, PhD, CMPP

Senior Vice President, Medical Communications, Scientific Connexions, Yardley, PA

By Anne McDonough, MPH, CSci

Kim Pepitone opened the session by asking a question many medical writers probably have: There are so many publication guidelines—how do medical writers implement them in their daily practice?

Tom Lang, MA, who reported that he has served on a number of committees that have developed these guidelines, endeavored to answer that question in his presentation “CONSORTing with a QUOROM of MOOSEs.” Lang began with a short history of publishing milestones from the first printing press to the present. He noted that the problems of poor reporting in scientific research are long-standing, widespread, potentially serious, and largely unknown. He then reviewed the most commonly used reporting guidelines:

- CONSORT for reporting of randomized controlled trials (note: a new CONSORT statement for abstracts was published last year)
 - QUOROM for meta-analysis of randomized controlled trials
 - STROBE for reporting of observational studies
 - MOOSE for meta-analysis of observational studies
 - TREND for reporting of non-randomized studies
 - PRISMA for systematic reviews
- Many more guidelines are avail-

able for other research designs and for specific therapeutic areas, and a comprehensive list can be found on the EQUATOR network Web site (www.equator-network.org). Lang ended his presentation with ideas for reporting standards that are still needed:

- Biomedical images—subject details, image acquisition details, characteristics of the image, and overall meaning of the image
- Laboratory procedures—eg, for centrifugation, the centrifuge manufacturer, rotor type, duration, and g force

Yvonne Yarker, PhD, CMPP, served on the committee that developed the revised Good Publication Practice (GPP2) and started her presentation with her good news that the *British Medical Journal* recently accepted GPP2 for publication and it should shortly be available on the journal's Web site (www.bmj.com). The new version will also soon be available on the GPP Web site (www.gpp-guidelines.org). GPP2 is an update of the original guidelines for publication and presentation of results of trials sponsored by pharmaceutical companies, which were published in 2003 and addressed primarily publication bias, redundant publication of data, and the relationship between sponsors and investigators.¹ There were several rationales for updating the guidelines:

- Publication of new guidelines and reports from other organizations
- Changes in the regulatory environment
- Increased media coverage of the issues
- Need for expanded scope, particularly in the areas of authorship, reimbursement, the role of medical writers, and publication planning
- Inclusion of medical device and biotech companies

Dr Yarker then discussed the most important new recommendations in GPP2:

- Incorporate GPP requirements into a written agreement between the sponsor and author with descrip-

tions of roles and responsibilities for each.

- Form a publication steering committee within the company to oversee publications.
- Provide full access to sponsor data for authors and other contributors.
- Do not pay (including honoraria) for authorship of articles or presentations.
- Generate publication plans.
- Comply with the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for authorship, available at www.icmje.org (guidance is given for when journal criteria deviate from these requirements).
- Use the acknowledgments section for clear and concise descriptions of the roles of each author or contributor, including the medical writer.
- Include the clinical trial identifier and state whether it is the primary publication or presentation of the trial results (definitions of primary and secondary publication/presentation are provided).
- Comply with established reporting standards, such as those reviewed by Lang.
- Provide clear methodology for systematic and comprehensive review articles and meta-analyses.
- Maintain documentation of how a publication or presentation is initiated, conducted, and finalized (recommendations for items to archive are included).

She concluded that if GPP2 is followed, then integrity, completeness, transparency, accountability, and responsibility will be demonstrated.

The take-home message from both presentations was well summarized by Lang in the question-and-answer period: “Transparency is the solution... It's the cover-up that gets you.”

Anne McDonough is a freelance clinical research consultant based in London, England, and provides monitoring, project management, clinical scientist, medical writing, and training services.

References

1. Wager E, Field EA, Grossman L. Good publication practice for pharmaceutical companies. *Curr Med Res Opin.* 2003;19(3):149-154.

⇒ WHEN BAD THINGS HAPPEN AT GOOD PLACES—PR DISASTERS AND HOW TO RESPOND

Moderator

Lois J. Baker, MS

Senior Health Editor, State University of New York at Buffalo, Buffalo, NY

Speakers

Melanie Fridl Ross, MSJ, ELS

University of Florida Health Science Center News & Communications, Gainesville, FL

Barbara R. Snyder, MA

Director, Scientific Writing & Editing, The Procter & Gamble Co, Mason, OH

By Barbara Cerf-Ducastel, PhD

“To err is human, to air is humane” was the alternate title of this session: a lighter tone for a very serious topic. As Lois Baker, MS, explained, the focus of the session was to present what public relations (PR) staff should and can do when adverse events occur at their institution. She presented a case that took place at the Philadelphia VA Medical Center. A surgeon mistakenly implanted radioactive seeds in the healthy bladder of a patient instead of in the cancerous prostate. With the regulators’ consent, the surgeon rewrote the protocol to match the number of seeds actually implanted in the correct organ. However, he committed several similar mistakes on other patients later, some of which were not reported. This example, she said, shows how a “no comment” strategy can have negative consequences.

By contrast, Baker introduced 2 speakers who agreed to comment on adverse events at their respective institutions and to present how crises may be handled in a positive way.

According to Melanie Fridl Ross, MSJ, ELS, a crisis is an “event that

occurs suddenly and unexpectedly and requires a quick response.” Depending on the way the crisis is handled, it can have a negative impact on an institution or it can preserve and even enhance the institution’s reputation. Ross stated the 2 main rules of good crisis communication:

- Have a plan
- Tell the truth and tell it fast

She presented the following case that occurred at her institution. A healthy 3-year-old boy, whose growth curve was slightly below average, came to the University of Florida with his parents to receive a growth hormone deficiency test. A series of mistakes including the delivery by the pharmacy of 2 bottles of arginine instead of 1 and the injection of the contents of the 2 bottles by the nurse resulted in the boy receiving more than 10 times the required dose. He died the following day from a brain edema related to the overdose.

From the PR perspective, the situation was complicated, involving privacy issues with the family. However, when the family agreed to a press conference, 2 weeks after the tragedy, the medical director of the clinic gave his apologies to the boy’s family and presented new measures taken to prevent such mistakes in the future, including the creation of a medication committee and a change to the medical school curriculum.

Ross indicated that reacting quickly and efficiently is crucial. She suggested that preparation in advance should involve

- Knowing where management stands on basic issues before a crisis occurs
- Discussing crisis plans and exposing managers to hypothetical situations to test reactions
- Preparing for a press conference
- Anticipating possible questions from the media
- Avoiding the “no comment” reaction
- Avoiding jargon
- Using all means of communication
- Learning from experience

Barbara Snyder, MA, discussed the story that most remember: the melamine found in pet food. She described the PR side of handling the crisis. Three days after the first report of acute renal failure in cats, Procter & Gamble decided on a major food recall. However, it took a whole series of tests and several weeks to finally identify the definite cause: melamine, which was used to artificially increase the protein content of wheat gluten and, when combined with cyanuric acid, precipitated in the kidneys, resulting in fatal renal failure.

Snyder noted that the positive actions taken by Procter & Gamble during that event included

- A prompt response to the crisis, initiating a recall
- A close collaboration with the US Food and Drug Administration and veterinarians to identify the cause of the malfunction

In contrast with Ross’s example, this story illustrates how the media can play both positive and negative roles in such events from the PR standpoint. The heightened level of attention from the media helped Procter & Gamble communicate fast and efficiently; however, it also created a pressure that pushed researchers to make fast and false assumptions.

Concluding remarks from Ross triggered by questions from the audience included more emphasis on early communication, even if the actual cause of the crisis is unknown. It is better to respond that the subject is under investigation than to not respond at all, she said.

Barbara Cerf-Ducastel is a research scientist at San Diego State University, San Diego, CA, and a medical writer specializing in life sciences.