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PRACTICAL MATTERS
The Changing Face of the Medical/Technical Editor

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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.
Preface
2017 Postconference Issue

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

This is why I chose to devote this issue of the AMWA Journal to showcasing our conference content.

First, let me thank the cadre of volunteer reporters who attended and have provided brief reports of almost every open session. These brief reports are designed to share some basic information from each session so that those who could not attend the conference might nevertheless be informed of topics and trends of interest among our colleagues in the industry. If you see something particularly interesting, please feel free to reach out to the individual presenter. If you are on the fence about whether to spend your time and money in attending the conference, perhaps this glimpse into what you’re missing may help clarify your decision!

Lori De Milto, Larry Lynam, and Marilyn Massey-Stokes lead off this issue with an expanded write-up of the open session “The Freelancer’s Guide for a Successful Social Media Journey.” Next, Cathryn D. Evans, Gail Flores, Melissa Bogen, and Ruwaida Vakil provide their insights in the Freelance Forum—expanding on content from Brian Bass’s popular “Jam Session for Seasoned Freelancers.” Brian appears again—as the recipient of the 2017 Harold Swanberg Distinguished Service Award! His acceptance speech can be found on page 34.

Additional conference coverage can be found as an online-only supplement (www.amwa.org/page/Journal), including open session reports that we couldn’t fit into the print issue, presentations by Helen Osborne, recipient of the Walter C. Alvarez Award, and Steven Woloshin, MD, MS, and Lisa M. Schwartz, MD, MS, recipients of the John P. McGovern Award, as well as information from many of our exhibitors and reproductions of our conference posters.

But that’s not all!

In addition to these themed contributions, this issue also contains a feature article reporting results of the AMWA Pacific Coast Conference Survey by Gail Flores and Sarah Prins; a contribution in Practical Matters (“The Changing Face of the Medical/Technical Editor,” by Laura Palmer and Susan Lang); several media reviews; and AMWA News . . . including a report from the Annual Business Meeting and Town Hall by Katelyn Le, the 2016-2017 Annual Financial Report by Julie Phelan, and a message From the President by Kathy Spiegel.

In closing, I would like to thank the dozens of reporters and contributors who worked together to provide you with this insight into the annual Medical Writing & Communication Conference. As you can see, if you missed it, you missed a lot! I hope to see you at the next conference in Washington, DC, later this year!

Yours in AMWA,
—Jim
The Freelance's Guide for a Successful Social Media Journey

How to Keep Up With Recent Changes, Overcome Obstacles, and Get Optimal Results

As most freelance medical writers and editors know, social media can help us build authority, engage with colleagues, connect with potential clients, and even grow our businesses. Yet using social media well, and without wasting time, is difficult. LinkedIn and Twitter, the most effective social media platforms for freelancers, both made big changes in 2017, making it even more difficult to get optimal results. This article is based on a session on social media for freelances at the American Medical Writers Association 2017 Medical Writing & Communication Conference. Presented by Lori De Milto and Larry Lynam, the session highlighted how freelances can use LinkedIn and Twitter effectively while enjoying the social media journey.

Why Take the Social Media Journey?
A key reason that De Milto uses LinkedIn is that clients expect freelancers to be there and often search for freelance help on LinkedIn. Lynam finds Twitter to be incredibly helpful for expanding his network around the globe. De Milto uses LinkedIn to network, learn, and research prospects, while also using Twitter to network and learn. LinkedIn is Lynam’s “showroom,” where he can display his experience, education, and capabilities. As a science communicator, Lynam also uses Twitter, which he calls his “lab,” to increase the size and diversity of his professional scientific and medical writing network, increase his influence, learn, and share. On Twitter, Lynam meets influential contacts and fascinating characters, explores opportunities, and shares ideas and advice. Table 1 highlights the role of Twitter in science communication.

How to Enjoy the Social Media Journey
By focusing on what’s most important on LinkedIn and Twitter, freelances can avoid feeling overwhelmed by social media and can even enjoy the journey. On LinkedIn, freelances must, at a minimum, have a client-focused profile, build connections so they’ll turn up more often on search results, and check and connect with people who view their profile. Twitter can be more challenging and a bit more intimidating in that it often appears as “untamed” and less constrained than LinkedIn. Nevertheless, Twitter can be an effective tool for communicating powerful messages quickly and frequently in small bites. Twitter is at its best when it is interactive, but users must learn to tame the Twitter noise. Table 2 highlights best practices for using LinkedIn and Twitter effectively.

Table 1. The Role of Twitter in Science Communication

<table>
<thead>
<tr>
<th>Feature</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Twitter increases the size and diversity of one’s professional network</td>
<td></td>
</tr>
<tr>
<td>55% of academics on Twitter were awarded doctorates less than 5 years ago</td>
<td></td>
</tr>
<tr>
<td>Of those following academics on Twitter:</td>
<td></td>
</tr>
<tr>
<td>– 55% are in scientific professions or degree programs, or represent a scientific institution</td>
<td></td>
</tr>
<tr>
<td>– 45% are nonscientists, often including members of the media</td>
<td></td>
</tr>
<tr>
<td>Median number of academics’ followers on Twitter:</td>
<td></td>
</tr>
<tr>
<td>– 7.3 times larger than the median size of a university department</td>
<td></td>
</tr>
<tr>
<td>During the 2011 International Congress for Conservation Biology:</td>
<td></td>
</tr>
<tr>
<td>– 176 people sent 1,731 tweets</td>
<td></td>
</tr>
<tr>
<td>– Reached 110,000 Twitter users</td>
<td></td>
</tr>
</tbody>
</table>

practices on Twitter, based on Lynam’s experiences and what he has learned from his Twitter followers and social media experts.

**Table 2. Best Practices for Twitter**

**What to Tweet to Get Noticed**
- Images and video increase the likelihood your tweet will be retweeted to a larger audience or lead to interactions with followers
- Tweets can now include up to 280 characters, but don’t feel compelled to use them just because you can
- Use hashtags to focus your tweet to specific audiences

**How to Tweet to Influence**
- Be interactive—keep the “social” in social media
- Be generous—retweet to help others expand their presence; even better, “quote-tweet” to expand the conversation or perspective
- Show gratitude—be appreciative; acknowledge when others promote your tweets
- Be respectful when you communicate—and when others are not respectful, remember that an audience is out there watching your reaction
- Be cognizant of how and how much you self-promote
- Build your reputation as the person who shares generously, and others will promote you

Lynam likens trying to use Twitter directly from that long and rapid stream of tweets entering the feed to “drinking straight from a fire hose.” Through lists that he creates, shares, or subscribes to, Lynam manages his Twitter feed and turns it into a productive communication platform. These lists allow him to organize his Twitter followers into productive small groups that he can scroll through at his convenience. This allows him to be more efficient and increase the likelihood that a relevant tweet will not be lost in the noise.

On occasion, you may find that another Twitter user has added you to a list that you do not wish to be a part of. It is very easy to remove yourself from a list without causing unnecessary drama. Simply look up the list organizer’s profile and select the option to block that person. Wait about 30 seconds and then “unblock” them. This action will break your link to the list; and even when you select “unblock,” you remain off the list, without the organizer ever realizing they were blocked. That prevents any awkward encounter or observable drama. There are 2 tools that Twitter provides—“blocking” and “muting”—that can help improve your online journey should you find yourself in the need of “pulling the brakes” at some point. We all need to use these tools on occasion, so it’s best to learn how they function before you need them.

### Changes and Best Practices on LinkedIn and Twitter

**LinkedIn**

In 2017, LinkedIn changed its interface, search features, and “rules of engagement”—how you share, engage, get found, and more. The new interface is cleaner and easier to use. Profiles look better, but only if you update your profile. Profile photos and background images are different sizes now, and if you don’t use the right size photo, part of your head is probably cut off from view.

Your LinkedIn profile is a marketing tool that needs to capture the attention of potential clients quickly and make them want to learn more about you. There is less space now to make a great first impression—only the first 201 characters of the summary (about 2 sentences) show before “See more” (only 45 characters on mobile devices).

Write a compelling, benefit-oriented headline (up to 120 characters) and a concise and engaging summary of your experience. Select the words and terms that clients will use to search for you, including “freelance” and what you do (medical writing, editing, or both). If you specialize in a certain type of work (eg, CME, sales training, or consumer health content), mention that too.

Focus your summary, especially the first 2 sentences, on how you help clients meet their needs. Briefly summarize your experience based on what is most relevant to prospective clients. One or 2 sentences is enough to cover your years and type of experience. For example, De Milto has been a freelance medical writer for 26 years. In her summary, after the client benefit-oriented introduction, she states:

> “With 26 years of experience in health journalism, storytelling, medical writing, and marketing, I bring extensive experience to any project.”

Use bulleted lists to highlight and let clients scan your profile to see your:
- Services/projects
- Areas of therapeutic expertise
- Type(s) of clients you work with (if not previously mentioned).
Make your summary interesting, conversational, and concise. Leave the details about your freelance experience and any past jobs to the Experience section of your profile and your resume. Under Experience, include details about your freelance work, focusing again on what’s most relevant to your prospective clients. Use bulleted lists to highlight achievements.

The 2017 changes made it easier to connect, engage, and share on LinkedIn. That is important because these elements, especially the number of your connections, all influence where you’ll turn up in search results. People with many connections, especially 1st-degree connections, rank highest in search results. LinkedIn minimized groups, but it is still helpful to belong to them because this gives you easy access to more connections. When inviting people to connect with you, always write a personal message. Never click “Connect,” which sends the generic invitation. Table 3 highlights best practices on LinkedIn, based on De Milto’s experiences and what she has learned from social media experts.

Table 3. Best Practices for LinkedIn

<table>
<thead>
<tr>
<th>Client-Focused Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Simple background image in the right size (1536 x 768 pixels)</td>
</tr>
<tr>
<td>• Professional photo in the right size (400 x 400 pixels)</td>
</tr>
<tr>
<td>• Compelling, benefit-oriented headline</td>
</tr>
<tr>
<td>• Concise, engaging summary (focus on first 201 characters)</td>
</tr>
<tr>
<td>• Include contact information and a call to action (eg, “Call me”)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Engagement</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Help clients find you:</td>
</tr>
<tr>
<td>– Build a large network</td>
</tr>
<tr>
<td>• Share and engage:</td>
</tr>
<tr>
<td>– Post relevant articles, photos, and updates</td>
</tr>
<tr>
<td>– Comment on and share your connections’ posts and articles</td>
</tr>
<tr>
<td>– Join groups that your clients and colleagues belong to</td>
</tr>
</tbody>
</table>

LinkedIn took away the unlimited Advanced Search feature that used to come with a free membership. Advanced Search was very helpful in developing prospect lists and researching prospects. The cheapest premium account that could help freelancers, Sales Navigator, starts at $64.99 month. If you’re actively marketing your freelance business and want to develop large prospect lists fast, you might want to invest in Sales Navigator for a few months and then cancel it.

You can, however, do good searches with a free membership if you know how LinkedIn search works and are patient. The number of free searches each month is limited, and LinkedIn doesn’t tell you how many searches you can do. It just prompts you to buy a premium account when you’re close to the limit. Plan your most important searches first, and save other searches for the next months. Do as many searches as you can in ways that do not count toward the search limit (Table 4).

Table 4. Ways to Get Around LinkedIn’s Search Limit

- Search for people by name:
  – Find prospects through professional associations, leading company lists, and online directories
- Review “People Also Viewed”:
  – Find more prospects in the same or similar companies
- Look up your connections under “Your Connections,” not the general search bar:
  – Click “My Network”
  – Click “Your Connections”
  – Enter the name in the Search Connections box
- Visit your groups and scroll through members:
  – Click on the profile

Accessing more prospects is another reason some freelances might want a premium account; however, you can do this with a free membership. Since the 2017 changes, you can easily invite 2nd-degree connections to join your network. For 3rd-degree connections, LinkedIn tries to trick you into using InMail, a feature of a premium account. Get around this by clicking the three dots on the right under the person’s background image. This will give you a menu that has a “Connect” option. Click that and send the prospect a personal invitation to connect with you.

Twitter

The 2017 Twitter changes seemed to balance the need to both improve the user experience and make Twitter more attractive to potential users. The biggest, most welcome, and most controversial change is the expansion of the number of characters that can be included in a single tweet from 140 to 280. Many have dubbed this; “280 is now the new 140.”

Other changes have boosted the size of tweets by excluding the following components from the character count limit:
- Attachments (images, gifs, and videos)
- Links
- The Twitter handle of the person you are replying to in a reply tweet.
However, if you include additional Twitter handles in a tweet, those are included in the character count.

Most people have welcomed the expanded character count, but some people have been reluctant to embrace this. As we all know, change is hard.

Other significant changes in 2017 involve the expansion of direct messages to 10,000 characters and the ability to embed links and attach gifs, images, and videos. It is also now easier to create direct messages to multiple parties that keep a conversation thread flowing between those parties. This is very useful for collaboration without interruption by observers.

Other notable changes include:
- New analytics home page to make tracking your Twitter impact more effective
- New search techniques and updated search features to make it easier to retrieve information from tweets
- Additional features, including live videos, auto-playing video, retweeting yourself, stickers, and an explore tab.

Communicating on Your Social Media Journey

It is important to remember that in social media, how you say something can be as important as what you say. When you least expect it, the journey can get bumpy; however, there are ways to prevent or lessen problems. Being respectful in what you post and when you reply is key.

Social media is a very useful communication tool, but it is an inferior form of communication. While it may feel like a conversation, it is only a volleying back and forth of perspectives. You do not have the benefit of body language or facial expressions that give important clues in a face-to-face conversation, you don’t have the voice tone or inflection that a telephone conversation provides, and you don’t even have the privacy of an email conversation, as others can chime in at any moment with their interpretation.

It is very easy to lose your perspective on social media. Sometimes you need to take a step back and not be in a hurry to drive your point. It is important to remember that we are all viewing each other from the small, selective window of what we choose to reveal. We are all evaluating each other with incomplete information, and it is a very limited body of information at best. So strive to keep your perspective by:
- Remembering you are the host of your account and treating your visitors as your guests
- Keeping posts as positive as possible, whenever possible
- Treating others with the respect you expect from them
- Providing useful content and limiting self-promotion.

It is also important to realize that just as in real life, you will get blind-sided on occasion no matter how hard you try to be respectful. When that happens,
- Remember, no one ever looks good in a social media fight; you will not be the exception.
- Search your heart; if you are defending an injustice, don’t be bullied into an inappropriate apology. Even then, remember that you still won’t look good in a social media fight—don’t feed the troll!
- Just because you are invited to a fight, it doesn’t mean you have to participate.

As freelances, De Milto and Lynam make their own social media policies. However, they emphasized that if you work for an organization, you must follow the organization’s social media policy.

Successful Social Media Journeys

Freelances have used LinkedIn and Twitter to attract clients, build their businesses, and more. De Milto and Lynam provided examples of social media success stories (available on the slides). Many resources are available to guide freelances in a successful social media journey, including finding content to post and automating the use of social media (Table 5).

Table 5. Social Media Resources and Tools

<table>
<thead>
<tr>
<th>Sample Resources for Content</th>
<th>Social Media Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>• E-newsletters:</td>
<td>• Buffer</td>
</tr>
<tr>
<td>– Smart Briefs</td>
<td>• TweetDeck</td>
</tr>
<tr>
<td>– Happify</td>
<td>• Tweet Tunnel</td>
</tr>
<tr>
<td>• Content alerts:</td>
<td>• Unfollower Stats</td>
</tr>
</tbody>
</table>
| – Talkwalker                | • Storify—Storify has announced it will shut down as of May 16, 2018; all user content will be deleted at that time.
| – Google                    | • Wakelet—A program Lynam is using to replace Storify. It gives the user expanded capabilities, and Storify users can export their Storify data to Wakelet for preservation prior to the scheduled Storify shutdown. |
| • Content aggregators:      |                   |
| – Alltop                    |                   |
| – Fark                      |                   |
| • Websites:                 |                   |
| – Medical News Today        |                   |

For a copy of the slides and handouts, email Lynam at larrylynam@gmail.com or De Milto at loriwriter@comcast.net. Readers can also visit the AMWA website at www.amwa.org/page/2017sessions.

Author contact: loriwriter@comcast.net
Trends of West Coast Medical Communicators: AMWA Pacific Coast Conference Survey Results

By Gail Flores, PhD1; Sarah A. Prins, PhD2
1Encore Biomedical Communications, Encinitas, CA; 2Natera, Inc., San Carlos, CA

INTRODUCTION
The AMWA Pacific Coast Conference (PCC) is a favorite event of AMWA members throughout the organization. In its original inception, this meeting was hosted by the Northern California Chapter at the Asilomar Conference Center on the Monterey Peninsula. Over time, it has evolved into an annual conference hosted by the Northern California and Pacific Southwest Chapters in alternate years. While the conference is most commonly held at Asilomar, it has also occurred in other locations in the San Francisco Bay Area and Southern California, especially in recent years.

The PCC is one of the largest AMWA conferences outside of the annual Medical Writing and Communications Conference. Highlights of the PCC include AMWA Workshops, open sessions, keynote speakers, and—of course—plenty of networking opportunities. Though attendance is composed primarily of local members, the event regularly draws attendance from AMWA members around the country.

To learn more about member interest in regional activities and to support member engagement in chapter-level programs, western-based AMWA members were recently queried regarding professional education needs, local conference preferences, and personal work experience. In collaboration with the Northern California Chapter leaders, AMWA developed and distributed a survey to members living within the western United States. The results of the survey are reported herein.

METHODS
The survey was distributed electronically in September 2017 to any AMWA member with a residence in California, Oregon, Washington, Arizona, Nevada, or Hawaii. The survey consisted of 23 questions and was developed by AMWA staff and Northern California Chapter leaders. Demographic data were collected, and respondents were asked to identify their first- and second-choice answers in the following categories:

“Trends and hot topics in medical communication,” “Career and skills building for the mid- or advanced-career professional,” “The evolving regulatory landscape,” “Scientific publications and publication planning,” and “Essential writing and editing skills.” For each category, respondents could also select “Not Applicable” or “Other (please specify).”

RESULTS
Of 685 AMWA members to whom the survey was sent, 122 (17.8%) responded. The 3 most common work settings were freelance/self-employed (37.2%), biotechnology companies (14.9%), and pharmaceutical companies (14.9%) (Table 1). More than half of respondents had been involved in medical writing for 10 or more years, while 20.7% were new to the profession, with 0 to 2 years of experience (Table 1). With respect to types of medical writing, the 2 most common types were scientific publications (29.0%) and regulatory writing (29.0%), although several other medical writing settings were also represented (Figure 1).

Medical Communications Field-Related Questions
Respondents’ first- and second-choice answers identified the same top 4 trends and hot topics in medical communications: 1) global medical and regulatory updates that affect medical communicators, 2) writing in the digital age/how digital technologies are shaping medical writing, 3) research and publication in a global environment, and 4) health economics outcomes research (HEOR) (Figure 2).

The first-choice for skills building for mid-career professionals identified by respondents included mastering project management, team dynamics, and conflicts (23.3%), building an effective medical writing department/intrapreneurship within a large organization (21.7%), and exclusive sessions for freelancers with 10+ years of experience (19.2%) (Figure 3). Second-choice skills identified by respondents also included mastering project management, team dynamics, and conflicts...
To understand how AMWA members felt about the changing regulatory landscape, 14 options were surveyed; most respondents (first- and second-choice answers combined; 17.7%) selected “Not Applicable.” Beyond this, the most common answers were writing a clinical study report (CSR; 14.3%), industry standards for document review (10.1%), electronic Common Technical Document (8.4%), and what to do when you have to quality control (QC) a regulatory document (8.0%) (Figure 4).

Respondents reported similar first- and second-choice answers to publications-related questions (Figure 5) and demonstrated attention to the evolving role of medical writers in the environment of biomedical publications. An interest in management awareness in publications was also prominent.

<table>
<thead>
<tr>
<th>Location, n (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>San Francisco Bay Area</td>
<td>39 (32.2%)</td>
</tr>
<tr>
<td>Los Angeles or Orange County</td>
<td>31 (25.6%)</td>
</tr>
<tr>
<td>Oregon or Washington</td>
<td>24 (19.8%)</td>
</tr>
<tr>
<td>San Diego</td>
<td>17 (14.0%)</td>
</tr>
<tr>
<td>Central Coast of California</td>
<td>6 (5.0%)</td>
</tr>
<tr>
<td>Arizona</td>
<td>3 (2.5%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (1.0%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Primary Work Setting, n (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Freelance or self-employed</td>
<td>45 (37.2%)</td>
</tr>
<tr>
<td>Biotechnology company</td>
<td>18 (14.9%)</td>
</tr>
<tr>
<td>Pharmaceutical company</td>
<td>18 (14.9%)</td>
</tr>
<tr>
<td>Medical device company</td>
<td>8 (6.6%)</td>
</tr>
<tr>
<td>Hospital, clinic, or other health care facility</td>
<td>7 (5.8%)</td>
</tr>
<tr>
<td>Medical writing/communication agency</td>
<td>5 (4.1%)</td>
</tr>
<tr>
<td>University or medical school</td>
<td>3 (2.5%)</td>
</tr>
<tr>
<td>Unemployed or retired</td>
<td>3 (2.5%)</td>
</tr>
<tr>
<td>Contract research organization</td>
<td>2 (2.0%)</td>
</tr>
<tr>
<td>Government agency or contractor</td>
<td>1 (1.6%)</td>
</tr>
<tr>
<td>Medical education company</td>
<td>1 (1.6%)</td>
</tr>
<tr>
<td>Research institute</td>
<td>1 (1.6%)</td>
</tr>
<tr>
<td>Other</td>
<td>8 (6.6%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Years Involved in Medical Writing, n (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0-2 years</td>
<td>25 (20.7%)</td>
</tr>
<tr>
<td>3-5 years</td>
<td>12 (9.9%)</td>
</tr>
<tr>
<td>6-9 years</td>
<td>21 (17.4%)</td>
</tr>
<tr>
<td>10+ years</td>
<td>63 (52.1%)</td>
</tr>
</tbody>
</table>

Figure 1. Survey respondents’ primary work settings. HEOR, health economics outcomes research; PR, public relations.

Figure 2. Current trends and hot topics in medical communications. N/A, not applicable.

Figure 3. Career and skills building for the mid- or advanced-career professional. N/A, not applicable.

Table 1. Respondent Demographics and Characteristics

<table>
<thead>
<tr>
<th>Location, n (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>San Francisco Bay Area</td>
<td>39 (32.2%)</td>
</tr>
<tr>
<td>Los Angeles or Orange County</td>
<td>31 (25.6%)</td>
</tr>
<tr>
<td>Oregon or Washington</td>
<td>24 (19.8%)</td>
</tr>
<tr>
<td>San Diego</td>
<td>17 (14.0%)</td>
</tr>
<tr>
<td>Central Coast of California</td>
<td>6 (5.0%)</td>
</tr>
<tr>
<td>Arizona</td>
<td>3 (2.5%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (1.0%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Primary Work Setting, n (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Freelance or self-employed</td>
<td>45 (37.2%)</td>
</tr>
<tr>
<td>Biotechnology company</td>
<td>18 (14.9%)</td>
</tr>
<tr>
<td>Pharmaceutical company</td>
<td>18 (14.9%)</td>
</tr>
<tr>
<td>Medical device company</td>
<td>8 (6.6%)</td>
</tr>
<tr>
<td>Hospital, clinic, or other health care facility</td>
<td>7 (5.8%)</td>
</tr>
<tr>
<td>Medical writing/communication agency</td>
<td>5 (4.1%)</td>
</tr>
<tr>
<td>University or medical school</td>
<td>3 (2.5%)</td>
</tr>
<tr>
<td>Unemployed or retired</td>
<td>3 (2.5%)</td>
</tr>
<tr>
<td>Contract research organization</td>
<td>2 (2.0%)</td>
</tr>
<tr>
<td>Government agency or contractor</td>
<td>1 (1.6%)</td>
</tr>
<tr>
<td>Medical education company</td>
<td>1 (1.6%)</td>
</tr>
<tr>
<td>Research institute</td>
<td>1 (1.6%)</td>
</tr>
<tr>
<td>Other</td>
<td>8 (6.6%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Years Involved in Medical Writing, n (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0-2 years</td>
<td>25 (20.7%)</td>
</tr>
<tr>
<td>3-5 years</td>
<td>12 (9.9%)</td>
</tr>
<tr>
<td>6-9 years</td>
<td>21 (17.4%)</td>
</tr>
<tr>
<td>10+ years</td>
<td>63 (52.1%)</td>
</tr>
</tbody>
</table>
Statistical knowledge and effective QC tactics were more commonly chosen as essential skills compared with proficiency with outlining or paragraph and sentence structure (Figure 6).

**2018 PCC Conference**

Of 114 responses to the inquiry for member interest in joining the AMWA Pacific Coast Conference Program or Host Committee now or in the future, 51 (44.7%) and 47 (41.2%) said they were unable to join in 2018 or were not interested, respectively. However, 61.7% of respondents were very interested or interested in attending, with only 33.0% indicating that they would need more details before deciding. Most (>61%) respondents were equally fine with either a beachfront hotel or campus-like retreat setting for the conference location.

**DISCUSSION**

These data demonstrate that changes in the medical communications field—including regulatory updates, a global publications environment, and technology advancements—were, understandably, in alignment with AMWA member interest in project management skills and development of medical writing teams and departments. For example, a recurring theme identified by the survey was an interest in effective management skills and the relevance of processes specific to a medical writing team. As the field and scope of medical writing expands and increasingly more companies require medical writing support to fulfill their business strategies, ensuring that medical writers are properly trained on how to build effective processes for publication planning and management of scientific...
Clients Demanding Freelances NOT be Freelance

There is a disturbing trend some seasoned freelances reported encountering lately in which clients insist their freelances take a W-2, which means they are legally not freelancing for that client but are actually part of the client’s staff. Forcing a freelance to work not as a freelance has a number of concerning implications. It affects freedom and flexibility, estimating and invoicing, and relationships with and availability to other clients. Perhaps most important of all, it has the potential to adversely affect the freelance’s finances with respect to both income and taxes.

CDE: Yes, I agree that this is disturbing. In fact, 15 years ago my accountant told me to try NOT to accept W-2 wages as it might affect my status as a self-employed businessperson. He did compromise and said, “OK, as long as it is a small percentage of your income.” If you are doing most of your work under W-4/W-2 status, recognize that you are NOT self-employed or in business: you are a temporary/transient employee. That said, today our profession has changed so dramatically—perhaps especially pharma/biotech—that some of us now must make a choice between “flexibility” and “focus.”

For example, a new, inexperienced medical writer who wants to break into the pharma/biotech industry needs to say “yes” to whatever comes, and W-2 contracts might have to be accepted initially to gain experience, samples, and references. An established freelance with solid clients and a great income can say “no” to W-2 work with impunity and focus on building his/her business and not agreeing to temporary employee status. And, regardless of your status, there are times when a W-2 project just seems necessary or is simply quite appealing. In summary, if you can afford it, be flexible; just make sure you watch your tax situation.

MB: As a freelance, I am loath to agree to W-2 status with any client, but in fact I have done so for 2 clients in 20 years. I live and work primarily in New York. One client was a contract research organization (CRO) in New Jersey; the other was a medical communications company in Connecticut that is part of the New York-based Greyhealth group. Both clients told me they had to pay me this way and pitched it as an advantage to me because they would take taxes out for me.

To address Brian’s concerns about effects on freedom and flexibility, estimating and invoicing, relationships with and availability to other clients, and income and taxes, here are certain issues to consider:

• Because I work for 6 to 12 clients per year, I knew I would have no trouble confirming my nonemployee status should the need arise.
• I worked onsite only for 1 client and only sporadically; most of my work was from home at hours of my choosing.
• I set my rates with these clients, so estimates were still enough under my control. Invoicing for 1 client was a pain because they wanted me to log hours into their online system, but other (1099) clients have required me to use their time sheets as well. This aspect to invoicing using their time sheets was the most onerous; when I complained enough, they had their human resources person log my time into their system for me on a weekly basis.
• I made it clear from the outset that I had several clients and they were not retaining me, so I did not lose other jobs or clients as a result.
• My accountant handles my taxes, though I provide him with the 1099s and W-2s and clear instructions about which income came from which client so he can keep track of the tax implications.

Jam Session for Seasoned Freelances

In keeping with the theme of this issue, our Freelance Forum contributors—Cathryn D. Evans, Gail Flores, Melissa Bogen, and Ruwaida Vakil—have provided their own unique insights into topics raised during the open session moderated by Brian Bass, MWC—“Jam Session for Seasoned Freelances.”
In some instances, it may be possible to work for such a client without taking a W-2, but that may require carrying a serious amount of professional (errors and omissions) and commercial (business) liability insurance.

A number of the session attendees said they carry such insurance policies and discussed the circumstances under which they came to carry insurance, which was diverse. Other types of insurance policies that were discussed included worker’s compensation insurance, which is required by some states for certain types of businesses (eg, New Jersey requires worker’s compensation insurance for S-corporations), and long-term disability insurance.

CDE: Yes, this is another problem: some CROs and other companies/agencies want you to accept liability and carry expensive insurance. I do not do this. It is too expensive, yes, but the primary reason I will not buy such insurance or sign a contract agreeing to accept liability is that the majority of my medical writing work is for pharma/biotech and they are 100% legally responsible for the content of all and everything! They dictate direction, focus, content, and structure; they provide all the data and background material (which means the writer cannot be certain s/he has received “everything”); and finally, they absolutely make all decisions about the final outcome. I will not agree to be held liable in such circumstances; my contract wording, which was approved by my attorney, makes this quite clear (wording was published in a prior version of the AMWA Journal in case anyone wants to see it.)

MB: As an editor and a sole proprietor, I do not carry errors and omission insurance or any other insurance specifically for my work. I strike out insurance requirements in contracts, as they do not apply to the kind of work I do because I am not responsible for what happens to the work after it leaves my hands. I realize the situation is different with medical writers.

Lawyers, Guns, and Money
No discussion of insurance is complete without someone mentioning lawyers. The conversation quickly broadened to include contracts, master service agreements (MSAs), nondisclosure agreements (NDAs), confidentiality agreements (CAs), and conflict of interest (COI) clauses. The seasoned freelances in attendance were familiar with these documents and agreed that freelances should never consider contract language unchangeable. They discussed how to request changes in contract wording, the benefits and drawbacks of providing your own contracts instead of using the client's contracts, contract enforcement, and investing in hiring an attorney to help review and enforce contracts.

CDE: It is reasonable for a self-employed small businessperson to revise a contract. After all, a contract is an agreement between 2 (or more) parties—it should not be one-sided, always in favor of the client! All of us need to read the NDAs, CAs, and COI statements carefully and delete unnecessary restrictions. Be brave! You likely will not lose a client over this, especially if you speak about it honestly on the phone or in person and NOT in an email.

RV: I completely agree. It is essential to carefully read through all the contracts that you sign. I have been pleasantly surprised that there is rarely a push back when I strike out a clause in the

MB: I agree with Brian that clients usually don't realize what details are in their contracts. I often strike out clauses in contracts that don't pertain to my work as an editor. In addition, I require the “hold harmless” clause goes both ways.

Most importantly, I require that every contract specify what my rate is and when I will be paid. If the term is longer than net 30, I ask if the client's legal department can change the terms to net 30 and I have had success in getting the time shortened in the contract.

The one time I used a lawyer was to review my first contract. True confession: the lawyer was my father; he was a labor lawyer who represented employees of unions, so was familiar with how to word contracts. I never got work from that client because we tore their contract to shreds. After that, I opted not to agree to, such restriction, and attendees discussed their approaches for striking or at least revising such covenants.

As several seasoned freelances noted, restrictive covenants can be fairly easy to revise or delete because clients usually don't even realize that language is in their contracts, let alone appreciate how restrictive they are. The bottom line is that medical communications companies don't want freelances taking their business, helping others take their business, or otherwise messing with their business. As long as you make clear that such activity would be unethical (to say nothing of it being bad for business), clients are usually fine with revising the wording of their restrictive covenants.

CDE: Yes, this is another problem: some CROs and other companies/agencies want you to accept liability and carry expensive insurance. I do not do this. It is too expensive, yes, but the primary reason I will not buy such insurance or sign a contract agreeing to accept liability is that the majority of my medical writing work is for pharma/biotech and they are 100% legally responsible for the content of all and everything! They dictate direction, focus, content, and structure; they provide all the data and background material (which means the writer cannot be certain s/he has received “everything”); and finally, they absolutely make all decisions about the final outcome. I will not agree to be held liable in such circumstances; my contract wording, which was approved by my attorney, makes this quite clear (wording was published in a prior version of the AMWA Journal in case anyone wants to see it.)
contract. I always make sure I strike out any phrase that makes me indemnify the client, or holds me entirely responsible for the final work. In my 11 years of freelancing, I only had one client push back on the indemnity clause, and we agreed that I would indemnify them up to the amount that they had paid me for that year.

Bridges and Boundaries
Well-written contracts build bridges to new clients and new opportunities. They also help freelances set boundaries, which seasoned freelances agree every client needs. A contract that describes who does what and when, what the deliverable will look like, and every other detail down to the number of revisions, provides a safety net for both the freelance and the client.

During the session several seasoned freelances shared horror stories about clients who went off the rails, which even the best-written contract cannot prevent.

CDE: Indeed. A caveat here: I think all of us should remember to incorporate into our contracts what is NOT included in the contract fee (ie, what you will NOT do for them under the contract). This can save many headaches along the way.

RV: Unfortunately, this can happen even with the best of clients. Although I price my work on a per-project basis, my contracts always include a line about scope change and the number of revisions, including how they will be priced. I add a statement like, “This estimate includes one round of in-scope revisions. If additional revisions are needed, they will be billed at the hourly rate of X or can be renegotiated with a new fee.”

This led to a discussion about clients who went too far and got themselves fired. Firing clients is an art in itself. Seasoned freelances shared their approaches, which ranged from confrontation to ghosting. Innovative approaches to setting boundaries were discussed. Perhaps the best, and certainly the most widely applied, were rush fees and PITA (pain in the a**) fees.

CDE: I certainly agree that PITA fees are sometimes appropriate.

Although a formal vote wasn’t taken, it seemed that every seasoned freelance in attendance implements some sort of “special” fee structure for clients who are difficult to work with but have not yet elevated themselves to the stature of being fired. They’re on the cusp. As one attendee explained, it’s amazing what you can put up with when you’re being paid excessively well for it. Of course, difficult clients don’t know they’re being charged a PITA fee. They simply receive the project fee that includes the special PITA fee and either agree to the fee or not. If they don’t agree, that’s one of the more subtle approaches to firing a client that doesn’t involve confrontation but keeps them around in case you ever need them.

CDE: It is quite simple to “be too busy with another project” when a client you dislike calls; then you need not fire him/her—they just go away quietly.

GF: As Brian mentioned, firing clients is indeed an art in itself. In my 18 years of freelance medical writing, I have had to let a handful of clients go. I’ve done it a few different ways, but ultimately, I think that having an honest conversation with the client about why you don’t want to continue to work with them leads to the best outcomes. While this may be difficult, in most cases the client deserves it, and it’s likely a good exercise for the both of you. Telling them you’re too busy to work for them again could backfire if your perceived lack of availability gets passed to their colleagues at other companies, and “ghosting”—not returning their calls or emails—could make you look unprofessional. In contrast, a frank conversation about why you feel the relationship should end can help them better understand the unique needs of freelances and may benefit future freelances they hire. Such a conversation could even resolve your issues and make you reconsider working with them.

MB: I agree that some clients are a pain. Fortunately, none of my current clients are. One client had complicated time sheets that had to be completed online every week. Because I was charging them an hourly rate not a project fee, hiding a PITA fee was tricky and I was unable to add time to my invoice for all the online logging. My solution was to become “too busy” to take on more jobs from them. Eventually they stopped contacting me for work. That was a long time ago. Now I would be more upfront and explain that their system was not user-friendly and see if we could negotiate a way to offload some of the nonbillable time-logging tasks onto the client or if I could bill for my time spent updating their online time sheets.

As the session came to an end, it was apparent that attendees had much more they wanted to discuss. Those topics and more will surely take the Jam Session into new uncharted territory at the 2018 Medical Writing & Communication Conference in Washington, DC.
BY the NUMBERS

PROGRAMMING

30 Workshops with 741 Attendees

36 Open Sessions

8 Posters

8 Staff

14 Exhibiting Companies with 32 Representatives

4 General Session Award Speakers

VOLUNTEERS

12 Conference Planning Committee Members

50 Session Leaders

24 Workshop Leaders

33 Roundtable Facilitators

242 Gallons of coffee and hot tea served
**Attendees**

206 postconference survey respondents

**Satisfaction**

- **Attendee Satisfaction**: 93% of respondents Very Satisfied or Satisfied
- **Networking Opportunities**: 87% of respondents Very Satisfied or Satisfied
- **Recommend to a Friend**: 95% of respondents Very Likely or Likely
- **Planning to Attend Next Year**: 72% of respondents Very Likely or Likely

**Conference Attendance**

- 10 or more conferences: 32% first-time attendees, 17%
- 6-9 conferences: 20%
- 3-5 conferences: 20%
- 1-2 conferences: 11%

**Years in the Industry**

- 0-2 years: 18%
- 3-5 years: 14%
- 6-9 years: 18%
- 10 or more years: 50%

**Employment Areas**

- Self-employed/freelance: 30%
- Pharmaceutical company: 12%
- Medical writing/communication agency: 11%
- University or medical school: 9%
- Medical device company: 8%
- Other: 8%
- Contract research organization (CRO): 5%
- Hospital, clinic, or other health care facility: 4%
- Biotechnology company: 4%
- Government agency or contractor: 3%
- Nonprofit organization or professional society: 2%
- Research institute: 2%
- Publisher or journal office: 2%

**Geographic**

- 40 US States
- 13 Countries
READY OR NOT: THE NEW MEDICAL DEVICE REGULATIONS ARE HERE!

Speaker
Felicia R. Cochran, BS, PhD, CMPP
Associate Director of Regulatory and Scientific Affairs, CTI Clinical Trial and Consulting Services, Covington, KY

By Hazel O’Connor, PhD
The current European Medical Device Regulations (MDRs) and In Vitro Diagnostic Device Regulations (IVDRs) have replaced the former Medical Device Directives in place since the 1990s. Felicia Cochran explained the new regulations that affect the development and market authorization of MDRs and in vitro diagnostic devices.

The new regulations affect devices in the European Union (27 countries) and an additional 4 countries that together encompass the European Economic Area (EEA). The Notified Bodies (NBs) exert control over market authorization and quality systems for medical devices by performing technical and medical reviews of marketing applications and renewals. They are independent, for-profit organizations that are authorized and monitored by Competent Authorities, and, thus, the decisions issued by NBs must be very rigidly followed. Competent Authorities are responsible for market surveillance and enforcement and exist in every member state. The “CE” mark symbolizes conformation with the European standards for health, safety, and performance and is indicative of market authorization in the EEA.

Regulatory Framework Involving MDRs
The new legislation was approved on April 5, 2017. Existing directives were repealed and replaced with Regulation 2017/745 for medical devices and 2017/746 for in vitro diagnostic devices (IVDs). The distinction between a Directive and a Regulation is important; Directives have been ratified by the EU Parliament and transposed into national law by each member state, whereas Regulations have very clear and defined rules that are binding across all member states. Manufacturers of currently approved medical devices will have a transition time of 3 years, until May 26, 2020, to meet the requirements of the MDR and 5 years, until May 26, 2022, for manufacturers of IVDs. There will be no grandfathering of existing medical devices into the MDR; instead, there will be a 4-year transition period.

Examples of Key Changes Imposed by MDRs
The new regulations are essentially more conservative than their predecessors.

- In the past, most IVDs did not need to go through NBs, but this is now required of 80% to 90% IVDs.
- NBs can conduct unannounced audits.
- More frequent recertification is required.
- An “Expert Panel” may review recommendations for the CE mark.
- The EU definition of a medical device was expanded to include devices that are not necessarily therapeutic (eg, aesthetic devices such as tinted contact lenses).
- Device equivalency requirements now state that equivalence can only be established using a single CE-marked device that satisfies all the clinical, technical, and biological requirements. Differences between a device and its equivalent must be addressed with respect to safety, performance, and clinical benefit. In practice, this will limit the use of equivalence to devices for which there are available, relevant clinical data (eg, predicate devices).
- The database European Databank on Medical Devices (Eudamed) was implemented (but not yet established) under the new Regulations. It contains data on medical devices that have been collected and entered by Competent Authorities and the European Commission (not publicly accessible).
- The risk of adverse events must be to an acceptable level compared with the potential health benefits of a device, and the risk/benefit assessment must now rely on clinical evidence in addition to safety and performance requirements.

Post-market Clinical Follow-Up
Post-market clinical follow-up is required for all CE-marked devices sold in the EU over the entire spectrum of the device lifespan to ensure the device is safe and being used for its approved intended use. Clinical safety, usability, and performance are addressed to identify risks not observed in pre-market testing. The frequency of post-market clinical follow-up is correlated with risk class (eg, every 5 years for low-risk devices, every year for high-risk devices). A proactive post-market surveillance plan must be described in the Clinical Evaluation Report (CER) and include monitoring device safety and performance during its expected lifespan, determining the known risks that are acceptable in a large patient population and detecting emerging risks based on factual evidence. Periodic safety reports are also required of devices in Classes IIa, IIb, and III.

Hazel O’Connor, PhD, is an R&D Scientist at Sciteck in Asheville, North Carolina.
Author contact: hazelopeconnor@gmail.com
I HAVE THE ABSTRACT: HOW DO I MAKE IT INTO A POSTER?

Speaker
Michelle E. Stofa
Research Communications Manager, Nemours/Alfred I. duPont Hospital for Children, Wilmington, DE

By Anne Kissack

Medical research poster presentations can be considered a form of art that is well-received by audiences when they are visually appealing; well organized; consistently formatted; clearly written; and enhanced with meaningful tables, figures, or images. When an investigator is invited to present their abstract as a poster, it is important to recognize a few key elements that will draw an audience into a salient message of new knowledge and discovery.

Following meeting requirements and generally accepted formatting in structure and content are a first step in developing a poster. One must also consider formatting the text, figures, and tables in a meaningful and visually stimulating way. These components and their key elements are listed within Box 1. In this presentation, several “nuggets” from experience and wisdom were shared. Quotes that stand out in reference to the general guidelines and that can be considered universal included

- Meeting requirements—“Need to know before you go.”
- Title bar—“Avoid Discussion of…” and “Results of…”
- Text—“Open space is our friend.”
- Formatting—“If no figures … add one, or some.”

Visual aids that clearly highlight key findings come in the form of figures, tables, and photos. For these to be effective in a presentation, it is important to keep a few main points in mind. A poster should portray the most important data while not overwhelming or capitalizing on overall content. When creating posters in PowerPoint, one need not rely on default settings. An important point for figures and tables was that “the meaning should be clear without main text.” As demonstrated through examples of past works, consistency in colors across all tables and figures (even if you are simply highlighting each with a colored box) makes a more visually appealing composition. Last, while the researcher may demand to go outside these guidelines, one can still help make the best use of space within these limits.

Poster presentations come in different forms. Researchers may need to travel with a piece in hand, or some conferences may request electronic posters. Thoughtful planning must also consider ease of transportation. In particular, as security requirements continue to change for air travel, researchers may want to use mailing services or reasonably sized transportation tubes. Printed handouts can be a useful tool for dialogue and should be printed before traveling out of town. General rules of thumb for an electronic submission include: use a black background with white font; keep ratio in mind, rather than size (eg, HD television screens—16:9); and note that the upload date is usually much earlier than for a printed poster.

Helping a researcher transform their accepted abstract into an interest-drawing poster presentation can enhance their ability to disseminate key findings. The scientific community values this form of sharing and identifies it as one way to prove success. One can help a researcher put their best foot forward by developing a high-quality poster presentation that expresses the essence of their work in a well-organized and succinct manner. With the tips and tricks provided in this presentation, one can be well on their way to contributing to the impact of their clients and the scientific community receiving the message.

Anne Kissack MPH, RD is a Senior Grants Specialist at Aurora Health Care’s Aurora Research Institute in Milwaukee, Wisconsin.

Author contact: anne.kissack@aurora.org

General Guidelines to Follow
1. Meeting requirements
2. Placement of logos
3. Size
4. Printing medium

Parts of a Poster
1. Title bar
2. Abstract
3. IMRAD (Introduction, Methods, Results, and Discussion)
4. References

Formatting
1. Text: spacing, justification, size, font, layout, use of bulletss
2. Figures and tables: quantity and consistency in color, font and size
3. Legends, titles, and numbering
4. Photos: permissions, protections of human subjects, quality, and size
INTRODUCTION TO HEALTH ECONOMICS AND OUTCOMES RESEARCH (HEOR) FOR WRITERS

Speakers
Beth Lesher, PharmD, BCPS
Associate Director, Strategic Market Access, Pharmerit International, Bethesda, MD
Catherine O’Connor, BA
Senior Communications Analyst, Strategic Market Access, Pharmerit International, Bethesda, MD

By Kathleen Labonge, MBA

Health economics outcomes research (HEOR) is a growing field filled with opportunities for “smart, adaptable writers, regardless of your experience in HEOR,” said Catherine O’Connor. This session provided an overview of the field for writers and highlighted 3 areas:

• What is HEOR?
• Who uses HEOR?
• How can writers break into HEOR writing?

What Is HEOR?

HEOR focuses on the bottom line: what matters to payers (costs) and patients (quality of life and clinical outcomes) in the real world and what differentiates a product and justifies its cost, according to Beth Lesher.

Health economics analyzes the economic aspects of health and health care, focusing on the costs (inputs) and consequences (outcomes) of health care interventions. Outcomes can be subjective and difficult to measure, such as how a patient feels, or more scientific, such as an increase or decrease in blood pressure.

Outcomes research evaluates the effect of health care interventions on patient-related clinical, humanistic, and economic outcomes, going beyond the cost of the drug:

• Clinical outcomes include the treatment’s clinical effectiveness.
• Economic outcomes are related to the direct and indirect costs of the treatment.
• Humanistic outcomes are related to health-related quality of life and treatment preferences.

Types of HEOR Evidence

There are many ways for writers to help disseminate HEOR evidence, which comes from many sources (Table 1). Real-world evidence is emphasized, because randomized control trials may not represent real-life outcomes. With patient-reported outcomes, it is important to determine whether patients desire quality of life or longevity. In general, several different types of HEOR studies are necessary throughout a product’s lifecycle.

Products will not succeed unless their value is demonstrated. Writers use HEOR evidence to effectively communi-

cate the value of health care interventions to payers, health care decision makers, and patients. They must help scientists clearly communicate research findings. Opportunities to inform stakeholders (via manuscripts, posters, abstracts, dossiers, etc) exist along the entire product lifecycle (Table 2).

Who Uses HEOR?

Health care decision makers, physicians, and patients are the primary users of HEOR evidence. Pharmacy and therapeutic committee members who choose the drugs in health plan formularies are key health care decision makers. Patients use HEOR data when evaluating decisions concerning quality of life versus longevity.

Uses of HEOR Evidence

Clinical trials cannot answer many real-world questions, and physicians, patients, and payers need HEOR evidence, which has many uses (Table 3). These uses include determining whether the clinical, economic, and humanistic outcomes support the product’s value and supporting clinical guidelines and stakeholder decision-making.

How Can Writers Break into HEOR Writing/Editing?

Opportunities in HEOR exist for writers with and without a
science, medical, or economics background. Lesher’s science background initially prepared her for a career in pharmacy. While working in a clinical setting, she learned medical writing and began freelancing until beginning her current HEOR writing position with Pharmerit.

O’Connor’s liberal arts background makes her the first non-scientist hired as a writer at Pharmerit. Although she had no professional medical writing experience, her Pharmerit job application included an HPV vaccination proposal she had written as an undergraduate to demonstrate her longstanding interest in medical writing. Prior positions included editorial assistant and an internship with the National Cancer Institute. Initially, O’Connor did editing and proofreading at Pharmerit, but she now works on writing projects.

Roles for writers and editors in HEOR include working on dossiers and publications (Table 4). Both speakers offered tips for breaking into HEOR (Table 5):

- Show how your skill sets translate into HEOR work and how you can meet the client’s needs.
- Know the audience for each HEOR project.

### Table 3. Uses of HEOR

<table>
<thead>
<tr>
<th>Uses of HEOR</th>
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<tbody>
<tr>
<td>• Evaluates real-world outcomes and provides evidence on what happens to a</td>
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<tr>
<td>patient in the real world (ie, outside of a controlled trial setting)</td>
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<tr>
<td>• Allows treatment comparisons that are not directly available from clinical</td>
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<tr>
<td>trial data</td>
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<tr>
<td>• Produces meaningful evidence to inform selection of appropriate cost-effective</td>
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<tr>
<td>therapy</td>
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<tr>
<td>• Supports evidence synthesis to directly or indirectly compare different</td>
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<tr>
<td>treatments’ efficacy and safety</td>
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<tr>
<td>• Informs for clinical guidelines development</td>
</tr>
<tr>
<td>• Evaluates product cost, budget impact, and cost effectiveness</td>
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<tr>
<td>• Helps illustrate product value</td>
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<tr>
<td>• Guides formulary coverage and reimbursement decisions</td>
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</tbody>
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### Table 4. Roles for Medical Writers/Editors in HEOR

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<thead>
<tr>
<th>Writing</th>
<th>Editing</th>
<th>Project Management</th>
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<tr>
<td>• Dossiers</td>
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<td>• Publications</td>
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<tr>
<td>• Value messaging</td>
<td>• Slide decks</td>
<td>• Reports</td>
</tr>
<tr>
<td>• Objection handlers</td>
<td>• Reports</td>
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</table>

### Table 5. Tips for HEOR Writers

<table>
<thead>
<tr>
<th>Freelance</th>
<th>Nontechnical Background</th>
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<tbody>
<tr>
<td><strong>Leverage Your Skill Set</strong></td>
<td><strong>Skill Assessment</strong></td>
</tr>
<tr>
<td>Manuscript writing</td>
<td>Learn or brush up on statistics!</td>
</tr>
<tr>
<td>Editing</td>
<td>Promote your Microsoft Word knowledge</td>
</tr>
<tr>
<td>Scientific background</td>
<td>Know your audience (HCDMs, HTAs, patients)</td>
</tr>
<tr>
<td>Slide decks</td>
<td>Don’t take liberal arts skills for granted!</td>
</tr>
<tr>
<td>Reports</td>
<td>• Audience analysis</td>
</tr>
<tr>
<td>Know Your Audience</td>
<td>• Big picture</td>
</tr>
<tr>
<td>Journal selection</td>
<td>• Writing mechanics</td>
</tr>
<tr>
<td>HCDMs</td>
<td>• Organizing ideas</td>
</tr>
<tr>
<td>Global</td>
<td>Provide insight into nonexpert audiences</td>
</tr>
<tr>
<td>National</td>
<td>Attend AMWA workshops</td>
</tr>
<tr>
<td>Know Your Resources</td>
<td>Focus on your “highest and best use”</td>
</tr>
<tr>
<td>ISPOR website</td>
<td>AMCP, Academy of Managed Care Pharmacy; HCDM, health care decision maker; HTA, health technology assessment; ISPOR, International Society for Pharmacoeconomics and Outcomes Research.</td>
</tr>
<tr>
<td>AMCP format</td>
<td>Kathleen Labonge is a freelance medical copyeditor and the owner of Write Point Editing Solutions in Greensboro, North Carolina.</td>
</tr>
<tr>
<td>Healtheconomics.com</td>
<td><strong>Author contact:</strong> <a href="mailto:klabonge@writepointeditingsolutions.com">klabonge@writepointeditingsolutions.com</a></td>
</tr>
</tbody>
</table>

### REALIZING THE BENEFITS OF STRUCTURED CONTENT MANAGEMENT IN A STEP-WISE FASHION

**Speakers**

- **Mitzi Allred, PhD**
  Director, Clinical Operations, Merck, North Wales, PA
- **Angela Horowitz, MPH**
  Practice Director, Structured Content Management, ArborSys Group, Lawrenceville, NJ

**By Mary Rykert-Wolf, MD**

The goal of this session was to demonstrate the capabilities and potential of the new Merck Structured Authoring Tool (MStAT).

**Merck’s Implementation of the TransCelerate Common Protocol Template (CPT)**

Per Mitzi Allred, the original TransCelerate CPT was designed to standardize the flow of protocol development. Merck decided to utilize the tech-enabled CPT to allow the creation of structure from nonstructured content. “We’re trying to elimi-
nate what we would call the copy-paste of the world,” Allred related.

As a first step, Merck made the core content uniform by standardizing for all heavy numbers in the outline. Next, Merck worked to make the tech-enabled CPT increasingly complex by adding specific content libraries and operational activities. Allred then reviewed MStat, pointing out various features and options, including outline format and table of contents, instructional text and content libraries, inclusion and exclusion criteria, and extraction capabilities. If the development timeline held, MStat was to go live with Version 5 on December 2, 2017.*

Allred then described the process through which TransCelerate CPT and Merck content outlines were merged. Updates to the common language occur monthly.

Automation Engine Behind MStat
Horowitz addressed the more technical aspects of the presentation. Utilizing MStat starts by inputting the type of trial into a request form. Based on this selection, specific content is prepopulated into a docx template, including a specified content library. This results in a customized protocol. Elements of protocol documents include content controls, binding pre-specified content (which may be pulled out later), destination controls for user-inserted library content, and presence of both mutable (editable) or immutable (untouchable) content. Variations in shading, which may later be removed, delineate mutable versus immutable text for document review. Of note, Merck stores content libraries in a central location rather than on individual laptops to make for easier updates.

Further Benefits
Allred noted that additional benefits include shortened writing time, more efficient use of reused text, and more focus on libraries and content. Reuse of text within a document offers improved consistency and reduction in errors. Understanding of content reuse is essential, as phrasing is often vetted and changes are unacceptable. Multiple opportunities for reuse must be explored. Examples given included reusing text in other documents (such as informed consent or lay-oriented documents) and the potential for language translation. The “XML bubble” was denoted as a section of text that may be extracted and inserted into other types of documents in the future.

Developing Content Models
Per Horowitz, a content model includes the structured information (or content) and how the content is created, described, managed, and used in outputs (such as a protocol). Note that MStat has limitations and may be inefficient in such areas as visibility and traceability. The general process of developing a content model involves identifying a piece of content that is variable, identifying how to reuse it, identifying information policies on how the content should be reused, and determining who should know about it. To standardize and harmonize content, first find inconsistencies. For example, in different locations within or even between documents, is “randomization” the same as “treatment assignment?” Next, look to see if it makes sense to develop a structure to carry through that content together. In addition, remember to look at the actual output document to see if the content is truly following across as anticipated. Remember to think of related instructional text.

Question and Answer
The session concluded with a brief exercise, available online, to familiarize the audience with the use of some features of MStat. A short question-and-answer session followed, during which it was noted that while MStat can help medical authors, they must still use their own judgment. Also, MStat development drew participants from multiple disciplines, including scientists, study teams, and physicians. Finally, smaller companies may incorporate CPT with less customization than larger companies.

Mary Rykert-Wolf is a physician in western New York.

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PROFESSIONAL DEVELOPMENT FOR MEDICAL WRITERS: CREATE, PROMOTE, AND MONITOR PROGRAMS AND TOOLS FOR GROWTH

Speaker
Linda Yih, BSc
Director, Medical Writing Services, PAREXEL International, Lyme, CT

By Kelly Schrank
Linda Yih works for a large international contract research organization (CRO) that employs approximately 160 medical writers and 30 managers. She believes that having a structured professional development program for medical writers can differentiate a company and is “central to employee retention in today’s work environment.”

The development program for medical writers that Yih described had 6 parts, and her presentation was broken into 6 matching sections: onboarding, development, support, development directory, promotion, and metrics.

Onboarding
For the onboarding process, the company has an “Onboarding Checklist for Line Managers,” which Yih says is good for new
managers or those who don’t onboard new employees often. It includes details like requesting access to shared drives and assigning new hire mentors. There is also onboarding training for managers to assist them in getting new medical writers onboarded.

The “Onboarding Presentation for New Hires” covers 5 topics: department overview and training (including an organizational chart), writing tools and administrative information, meetings and communications, development tools and programs, and performance management. There is a template, and it can be customized to different regions within the medical writing department.

Some best practices for new employees include providing first projects that are easy wins and/or in which they collaborate with other more experienced medical writers; having them start on days when the manager is in the office; and, if possible, having a cohort of new medical writers start and go through onboarding at the same time. Similarly, if remote teams can be brought on site for onboarding, that is often better.

**Development**

An important component of their development program is the Medical Writer Skill Standards, which include necessary skills for each level of medical writer. These standards include proficiencies required at each writing level, for consistency across a global writing team. For instance, one of the functional competencies is “Time and Project Management,” which is defined as the “ability to manage the time spent on tasks and proactively identify deficiency” and the “ability to understand all necessary steps in a project, plan steps ahead, and identify critical paths.” Functional competencies encompass document experience, some of which may be region-specific. These “hard skills” are divided into “core documents” and “non-core documents,” which are defined in the skill standards. The writer is evaluated for these types of documents by job level and given a check mark in the corresponding box.

Yih mentioned that this is an “objective, consistent way to evaluate writers,” as the documents and competencies align with job descriptions. They are evaluated based on a quality assessment, such as QC checks by managers or peer feedback, as well as how many documents of a certain type they have authored as the lead writer. This is a great tool for promotion-readiness and justification.

The Manager Skill Standards are more focused on soft skills such as decision-making, problem-solving, holding others accountable, and collaboration. They are rated as “Basic,” “Proficient,” or “Advanced” in these areas. Because the Manager Skill Standards are also used as a promotional tool, managers are expected to exhibit skills at previous levels before being considered for the next level. Yih mentioned that most managers already have documentation experience, so it’s usually the soft skills where development is needed, and the Manager Skills Standards identify areas on which to focus.

The Individual Development Plan is completed by each writer and documents what that writer wants to accomplish. It lists short-term (0 to 1 year), mid-term (1 to 3 years), and long-term (>3 years) goals for the medical writer as well as “planned actions” for how to accomplish them. It begins with a “current profile” that provides general information, document experience, other work experience and skills, and professional strengths. It’s considered a living document that is owned by the writer and can be updated if interests or business needs change. The short-term goals should match annual development goals and are reviewed on a quarterly basis.

The Writer and Manager Mentoring Programs are an essential element of the development plan. There is New Hire Mentoring for new writers as well as Project-Based Mentoring, which can be used for new writers or experienced writers. The project-based mentoring may assist a writer in learning how to write a new type of document or get the writer up to speed on a soft skill, such as project management or communications. There is mentoring for managers as well, such as New Manager Mentoring (which may focus on managing former peers) or Developmental Mentoring for Managers (where the focus may be on leading high-performing teams).

Essential in writer and manager growth is access to soft skills trainings. There are instructor-led and online training and presentations available for both writers and managers. Soft skills training for writers includes conflict management, negotiations, time management, leadership, and communications. Soft skills training for managers includes performance management, providing feedback, and fostering collaboration.

**Support**

Yih discussed the company’s “Medical Writing Handbook,” presented at last year’s AMWA conference. It is a living document and updated periodically. She described it as a “single source for information about roles, processes, and guidelines,” which contains hyperlinks on shared drives to everything needed within the medical writing department.

Similarly, the Manager’s Toolkit is a “single source” for managers with information about recruitment, on- and off-boarding, training, mentoring, and performance management.

**Development Directory**

An important component of the development program is the Development Directory, which houses links to the Development Newsletter, Medical Writing Handbook, Medical Writer Skill Standards, New Hire Onboarding Checklist, and New Hire Onboarding Presentation. This document lists the
available tools, anticipated users, description/when to use, and location on share drives. Its purpose is to provide easy access to all of the departmental development resources.

**Promotion of Tools and Programs**

The Development Newsletter is distributed quarterly and shows how the development program and its tools can “facilitate growth and careers.” It provides links to resources; introduces new development opportunities, tools, and programs as they become available; offers recommended trainings and advice for how to fit professional development into “busy work schedules”; and announces new hires, promotions, and group and individual achievements. The Development Newsletter is helpful in keeping everyone apprised of new information while also building team morale.

**Metrics**

The medical writing management team gathers metrics to measure the success of the programs and find areas for improvement. For example, management measures participation in the writer mentoring program by gathering the number of mentor/mentee pairs, the types of projects, and the time spent on activities. They have also been gathering feedback from surveys completed by mentors and mentees, which are submitted at the end of the mentoring relationship.

The company started this initiative 3 years ago, and Yih stated that some aspects of the program are very popular and that others are gaining traction.

**Lessons Learned**

1. Ensure senior management buy-in on employee development plans. Time and effort need to be invested and supported to implement long-term development plans.
2. Work closely with your HR representative to ensure your department plans align with company policies and plans.
3. Think big picture and long term; consider long-term goals planned for your team and how your development plan will support these goals.
4. When drafting guides, programs, or tools, circulate for global review so they are applicable across a global team.
5. Pilot projects within a region or small groups to see what works and what needs adjustment; feedback via focus groups is useful.

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**ZIKA—THE BITE HEARD ROUND THE WORLD**

**Speakers**

**Larry Lynam**  
Principal, The Lynam Group, LLC, Coral Springs, FL

**R Michelle Sauer, PhD, ELS, CRA**  
Director of Office of Sponsored Programs, Prairie View A&M University, Prairie View, TX

**By Rebecca Mueller, PA-C, MSc**

This open session sought to update professionals in the medical writing industry on the history, science, and current state of the public health situation surrounding the Zika virus and the mosquito vector, *Aedes aegypti.*

**The Virus**

Mosquitos, the deadliest animals in the world, are linked to 475,000 human deaths annually. Both Florida and Texas have had hot spot zones that were monitored by the Centers for Disease Control and Prevention (CDC), though most recently, Texas has been removed as a hot spot. Texas and Florida have over 80 species of mosquitos; however, only 1 has been confirmed as a transmitter of the Zika virus—*A. aegypti.*

The Zika virus is part of a unique group of viruses known as the Flaviviridae. Viruses of the flavivirus family are most often transmitted through vectors, most commonly mosquitos and ticks. Some members of the flavivirus family, including Zika, have been associated with sexual transmission and blood-borne transmission. Cross-reactivity has been a problem in diagnosing the specific flavivirus, but the cross-reactivity of the antibodies has not proven to be protective between species of virus. Zika appears to be unique in the flavivirus family in that it has proven both competent at crossing the placental barrier during pregnancy and capable of causing congenital abnormalities.

The Zika virus was first identified in 1947 in primates of Uganda. The vector for these primates was a mosquito in the Ugandan forest that was active at night and fed off primates, not humans. The virus has now jumped vectors to a human-biting mosquito, *A. aegypti*, that feeds during dawn and dusk. The first serious Zika outbreak was in Yap, a Micronesian island, in 2007. The virus has continued to spread east throughout the years, complicating the 2014 Olympics in Brazil. Climate change has allowed *A. aegypti* to live farther north, aiding the spread of the virus farther into the United States, giving rise to the title of this talk: “Zika—The Bite Heard Round the World.”

Researchers from the Chinese Academy of Science in Beijing have linked a single gene mutation, S139N, to the virus’ ability to cause microcephaly in utero and Guillain-Barré syndrome. The switch of serine to glutamine at the 139th posi-
tion in the Zika genome occurred in 2013 and makes the virus deadlier to neuron precursor cells, disrupting fetal development and causing congenital Zika syndrome. This same mutation has also been linked to Guillain-Barré complications in adult Zika infections, particularly in the elderly.

The Vector: Aedes Aegypti
There are roughly 80 species of mosquitoes throughout Florida, only one of which has been a confirmed transmitter of the Zika virus—A. aegypti. The mosquito has distinctive black and white markings and can transmit Zika, dengue fever, and chikungunya individually or can co-infect a victim with multiple viruses. There have been suspicions that a concurrent infection of Zika with another vector-born virus (dengue fever or chikungunya) could result in a worse outcome; however, recent studies have not demonstrated a link.

The Victims: Health Presentation, Diagnosis, and Congenital Zika Syndrome
Approximately 1 in 5 people infected with the Zika virus will develop symptoms, which are generally mild and last 2 to 7 days. The disease presentation includes common symptoms that include headache, fever, conjunctivitis, joint pain, diffuse itchy and blanching rash, and muscle pain (see Box). As these are very common and general symptoms of a myriad of diagnoses, it is difficult to determine a specific diagnosis without specific testing. There are no standard-of-care guidelines for practitioners at this time, further presenting a challenge when tracking the virus. As of October 2017, there have been 254 confirmed symptomatic Zika cases in the United States, 3 of which were transmitted through sexual contact and the remainder presumed through a mosquito vector while traveling in an endemic area; 554 cases have been confirmed in US territories.

### Zika Symptoms
- Headache
- Fever
- Conjunctivitis
- Joint pain
- Itchy rash
- Muscle pain
- Guillain-Barré syndrome

### Congenital Zika Syndrome
- Microcephaly
- Encephalitis
- Vision/hearing loss
- Arthrogryposis
- Fetal demise

The risk for developing congenital Zika syndrome is approximately 4%; this is higher than the occurrence of congenital abnormalities in the United States, which is only 3%. This is an alarming number considering the relatively high rate of occurrence and the high cost associated with its treatment (estimated $4,000,000 per child). Congenital Zika Syndrome includes microcephaly, encephalitis, vision and hearing loss, arthrogryposis, fetal demise, and possible long-term behavioral changes.

Prevention
Currently, prevention is the best approach to tackling the Zika problem in the United States, as the understanding of the disease process and treatment is still in its infancy.

In order to prevent sexual transmission, condoms, among other deterrents, are recommended for 3 weeks. There is controversy surrounding this recommendation; the challenge of recommendations to prevent sexual transmission is that it is unknown how long the virus is transmittable. Although the virus has been detected up to a year post infection, transmission risk at this time is uncertain.

There are some easy changes people can make to protect themselves from mosquitoes, including insect repellent and eliminating standing water around or near their home.

In Florida, recent measures to control the A. aegypti mosquitoes include the use of a biological pesticide containing the organism Bacillus thuringiensis (BT) to kill the larvae and a chemical pesticide, Naled, to kill the adult mosquito. The use of both of these products has raised environmental protests in the public.

There are 2 other very promising methods of decreasing the transmission of Zika through A. aegypti: (1) male mosquitoes that are infected with Wolbachia bacteria, which can only infect insects, and (2) Oxitec genetically modified male mosquitoes, both of which have been approved for release. Wolbachia is a Gram-negative parasitic bacteria, and the World Mosquito Program has found the when A. aegypti is infected with Wolbachia, it reduces the transmission of the Zika virus to other people bitten by the mosquito. When male A. aegypti infected with Wolbachia breed with infected females, the eggs remain unhatched. This somewhat lowers the A. aegypti mosquito population. However, Wolbachia will become established in the population, and when female mosquitoes have Wolbachia infections, their offspring will be born with the Wolbachia infection. Although females with Wolbachia will live, they will be unable to transmit viruses. So as a population of mosquitoes becomes more infected with Wolbachia, the transmission of dengue and Zika will be reduced.

Oxitec GMO mosquitoes are another line of defense in which sterile male mosquitoes are released, thereby contributing to a population decrease. When males are so altered, they breed and transmit the defective gene to their offspring. The defective gene means that the offspring larvae will not develop into adults. This methodology has been approved and some male mosquitoes have already been released.
The benefit to both of the *Wolbachia* and Oxitec methods is that they will decrease the *A. aegypti* mosquito population and, subsequently, the Zika virus prevalence without negatively affecting other ecosystems, though we should keep in mind that these methods involve the release of male mosquitoes and that only female mosquitoes are the ones that bite.

**In Closing**

Zika is a virus with potentially dire consequences to infected individuals and their babies while also potentiating high medical costs. Stay up to date on the numbers infected and the research by following the CDC.

Rebecca Mueller, PA-C, MSc, is a freelance medical writer at RLM Writing in Toronto, Canada.

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**MEDICAL WRITER’S GUIDE TO CLINICALTRIALS.GOV RESULT POSTINGS IN THE EVOLVING REGULATORY LANDSCAPE**

**Speaker**

Roshawn Watson, PharmD, PhD

*Associate Director, Clinical Scientist, Vertex Pharmaceuticals Incorporated, Boston, MA*

ClinicalTrials.gov is both a clinical trial registry and results database that is run by the United States (US) National Library of Medicine at the National Institutes of Health (NIH). Both publicly and privately funded clinical studies conducted in all 50 US states and around the world are included. Registration occurs at study initiation, and the registry/database summarizes information from the study protocol (eg, brief title, study design, study type, study phase, primary outcome measure information, and eligibility criteria) and recruitment information (eg, enrollment start and completion dates, eligibility location, and overall recruitment status). Study results are submitted either after the primary completion date (if partial results are submitted) or after study completion.

There are several reasons to post to ClinicalTrials.gov. Posting to ClinicalTrials.gov is a statutory mandate for sponsors and others (ie, principal investigators) responsible for certain clinical trials of US Food and Drug Administration–regulated drug, biologic, and device products. Posting to ClinicalTrials.gov also increases public awareness for a study and may assist with recruitment. Posting additionally provides an avenue to share the study results with both participants and the broader scientific community. The posting requirement is independent of decisions related to manuscript publishing. In fact, as of 2005, journals adhering to the International Committee of Medical Journal Editors guidance will not accept a manuscript of an applicable clinical study for publication unless the study was registered in a study repository such as ClinicalTrials.gov. Additional consequences for not posting to ClinicalTrials.gov include the following: responsible parties, including the grantee institution, could be held accountable for noncompliance; grant funding from Health and Human Services agencies could be withheld; substantial civil monetary penalties could be levied; and criminal proceedings could be launched.

On January 18, 2017, the Final Rule for the US Food and Drug Administration Amendments Act 801 became effective, providing much-needed clarity about which studies were required to post to ClinicalTrials.gov. It also expanded the transparency requirements of posting beyond the basic statutory requirements and necessitated that the National Institutes of Health post submitted records within specified time frames.

Medical writers are uniquely situated to facilitate ClinicalTrials.gov results postings. First, entering results is analogous to manuscript writing. Additionally, the data provider must comprehend the study design; appreciate the data analysis, nuances, and limitations; and provide thoughtful interpretation. In addition, these postings often require involvement of other team members, with whom medical writers often have already worked during the authoring of the clinical study report. Last, medical writers tend to be very detail oriented, which is required to author or oversee these postings.

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**INTERMEDIATE HEALTH ECONOMICS AND OUTCOMES RESEARCH & REAL-WORLD EVIDENCE: ELEMENTS, CONCEPTS, AND WRITING CONSTRUCTS**

**Speakers**

Patti Peeples, RPh, PhD

*Founder, CEO, and Principal Researcher of HealthEconomics.com, Ponte Vedra Beach, FL*

Tom Drake, MA

*Founder and Director of Global Outcomes Group, Reston, VA*

By Denise Galipeau, MSc

Rising health care costs are driving many organizations toward value-based decision-making methods to decide which health care interventions are worth paying for and for how much. The aims of this open session were to explain how payers determine value, what types of tools or studies are available to characterize value, and what types of medical writing opportunities there are in this fast-growing area of health economics and outcomes research (HEOR) and real-world evidence (RWE).
Tom Drake began the session with a Jeopardy-style game to introduce key HEOR and RWE terminology (Box 1). Building on these concepts, Patti Peeples introduced and discussed the function of Pharmacy and Therapeutics (P&T) committees, including how they make decisions about value in the population covered by their health plan and what kinds of information underlie these decisions. Using a case study of Sovaldi for the treatment of hepatitis C, she outlined the questions P&T committees typically ask during their review:

- What are the unmet medical needs in the management of hepatitis C, current treatment practices, and the safety and efficacy profile of Sovaldi? The phase 3 studies of Sovaldi, clinical guidelines in the treatment of hepatitis C and advanced liver disease, market research data, and claims analysis are examples of information that inform P&T committees on this topic.
- What is the prevalence of hepatitis C, particularly within the population served by the committee? Epidemiology studies, registries, and claims analysis are all useful to understand how much of the plan’s population is affected by the disease and what the estimated severity and treatment needs are.
- What are the cost drivers for treating hepatitis C? Cost of illness studies help answer this question and may include the direct medical costs (outpatient visits or visits to the hospital, diagnostic tests, and treatment) or indirect and intangible costs (reduced productivity, absenteeism from work, and reduced quality of life).
- How will adopting Sovaldi affect medical service usage? How will Sovaldi affect direct medical costs? Several types of studies help address these questions, including phase 4 observational studies, retrospective analyses of claims data, or predictive modelling studies using phase 3 data to make informed projections about health care resource utilization.
- Is Sovaldi cost effective compared with standard hepatitis C therapy? A cost-effectiveness study that determines the cost per cure would be informative. Cost utility studies, which determine the incremental cost-effectiveness ratio (ICER) of Sovaldi compared to standard treatment, answer this question by determining the cost per quality-adjusted life year gained (QALY) (see Box 1).
- Is Sovaldi affordable? A budget impact model assessment would determine the net costs of the new drug if added to the plan. For example, if 100 patients with advanced liver disease in the plan are prescribed Sovaldi, what would the total cost be for the payer (health insurance plan, Medicare/Medicaid, or a government health entity)? How does this compare to the current cost of managing these patients?

**Box 1. Terminology for Health Economics and Outcomes Research or Real-World Evidence Studies**

<table>
<thead>
<tr>
<th>Patient-reported outcomes (PROs)</th>
<th>Outcomes that are reported directly by the patient, such as health-related quality of life, functional status, well-being, symptoms, and satisfaction.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effectiveness</td>
<td>How a drug performs in a non-controlled, real-world situation.</td>
</tr>
<tr>
<td>Health care resource utilization</td>
<td>The number (or units) of medical services used (eg, medical visits, hospitalizations, lab tests, drugs).</td>
</tr>
<tr>
<td>Observational study/pragmatic study/registry/real-world study</td>
<td>Type of study that observes outcomes in a typical environment; does not mandate the type of care.</td>
</tr>
<tr>
<td>Comparative effectiveness research (CER)</td>
<td>Comparison of interventions in a real-world setting rather than a controlled clinical trial. Evaluates benefits, harms, and sometimes cost of alternate methods of care.</td>
</tr>
<tr>
<td>Dossier</td>
<td>Centerpiece of the formulary submission process. Includes a standardized set of clinical and economic evidence prepared by pharmaceutical manufacturers. Presented to health plans in response to unsolicited requests.</td>
</tr>
</tbody>
</table>

Notably, a number of international organizations have developed frameworks for assessing value and established thresholds for cost-effectiveness; for example, drugs with a cost per QALY of less than $150,000 are typically viewed as good value for health care dollars spent. However, other factors such as public health benefits, severity of the disease, and societal valuation may also be considered by the payer or the decision-making entity.

The session concluded with a discussion about the variety of developers, venues, and audiences for HEOR and RWE material (Figure). In particular, Drake highlighted dossiers (Box 1) for

**Figure.** Preparers, venues, and audiences for health economics information—opportunities for medical writers

- **Preparers**
  - Biopharma, payers, professional associations, governments, newspapers, journals, medical communications agencies, employers, academia, pharmacy benefit managers, market research groups, consulting organizations, bloggers, regulatory authorities, continuing education groups, patients
- **Venues**
  - Medical journals, dossiers for payers or health technology assessment groups, newspaper or magazine articles for lay-press, internal pharma strategy documents, sales aids for Medical Science/Health Outcome Liaisons, posters and presentations for medical meetings, white papers
- **Audiences**
  - Regulators and/or health technology assessment agencies, healthcare providers, pharma industry, healthcare professionals (Pharm D, NP, allied health), formulary decision makers, managed/ accountable care organizations, quality commissions, Medicare/Medicaid, employer, patients
payers or health technology assessment groups, such as the AMCP Dossier in the United States or Global Value Dossiers internationally, as an emerging opportunity for medical writers. Dossiers are comprehensive documents that answer all of the P&T committee’s questions in a single reference document. Preparation of a dossier typically involves a team of medical writers, health economists, a project manager, and other individuals. Manuscripts are another opportunity for medical writers, and he referenced the CHEERS guideline (Consolidated Health Economics Reporting Standards) and other applicable guidelines in the EQUATOR network for guidance on reporting HEOR and RWE studies in the literature (Box 2).

Box 2. Frequently Used Guidelines for Reporting Results of HEOR and RWE Studies

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHEERS</td>
<td>Consolidated Health Economics Reporting Standards—CHEERS: Good Reporting Practices</td>
</tr>
<tr>
<td>CONSORT</td>
<td>Consolidated Standards for Reporting Trials (parallel-group randomized controlled trials)</td>
</tr>
<tr>
<td>STROBE</td>
<td>Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for Reporting Observational Studies</td>
</tr>
<tr>
<td>PRISMA</td>
<td>Preferred Reporting Items for Systematic Reviews and Meta-Analyses: the PRISMA Statement</td>
</tr>
<tr>
<td>STARD</td>
<td>Standards for Reporting of Diagnostic Accuracy Studies</td>
</tr>
</tbody>
</table>

Note: These and other potentially relevant guidelines for other study types are available from the EQUATOR network at http://www.equator-network.org/.

Additional resources for HEOR medical writing, as compiled by Peeples and Drake, are available at www.healtheconomics.com/heor-writing-workshopwebinar-series-purchase-page/.

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GETTING DOWN TO BUSINESS: THE NUTS AND BOLTS OF STARTING (AND MAINTAINING) YOUR FREELANCE WRITING BUSINESS

Speaker
Eleanor Mayfield, ELS
ELM Communications, Pittsburgh, PA

By Marilyn Massey-Stokes, EdD, CHES, CHWC

This session targeted those new to the medical writing field (less than 3 years’ experience). According to Eleanor Mayfield, there is no one pathway to a medical writing career, as free-

1. Cover the financial basics
   - Having an additional income source or cash reserves can be particularly helpful during the startup period.
   - Examine best options for health insurance coverage. Business insurance can also be a wise investment, particularly with group rates.
   - Select a business type, such as a sole proprietorship (Schedule C) or a limited liability company (LLC). Legal and tax considerations play a role in this decision.
   - Seek advice from an accountant regarding taxes, such as income tax and self-employment tax. For information regarding business structure and taxes, check out the IRS Small Business and Self-Employed Tax Center (http://www.irs.gov/Businesses/Small-Businesses-&-Self-Employed).

2. Select freelance work that is a good fit
   - There are multiple avenues for medical writing, including regulatory writing, manuscript writing, editing, writing for patients/lay audiences, preparing presentations, and developing training programs and continuing education materials. Think about the types of writing you enjoy and your level of experience. “As a new freelance, you may have better success finding work in areas where you have a track record, particularly if the client doesn’t know you,” Mayfield stated.

3. Choose a suitable work space and equipment
   - What is your ideal work environment? Do you prefer to work with a co-located group, virtual group, or alone? Will you use a home office, rented office space, or another dedicated space?
   - There are a host of options for office equipment and supplies, such as a computer system and software, data backup system, broadband internet connection, cell phone and possibly an additional phone line, multifunction printer/copier/scanner, reference materials, and office furniture.
4. Manage the business

- Identifying potential clients is paramount and an ongoing process. Clients may be referrals from other freelances, former employers, contractor research organizations, medical communication firms, medical schools and universities, hospitals and managed care providers, health care professional societies, and medical or health care trade publications.

- Decide how to price your services—for example, via an hourly rate, project fee, per-word/per-page rate, living wage, “what the market will bear,” or a variable fee. “There is no perfect method of pricing,” said Mayfield. However, when a project fee is used, she emphasized the importance of clearly defining the scope of work and tracking hours for future reference.

- Contracts are critical and should be carefully reviewed, preferably by a knowledgeable attorney. Important aspects involve scope of the project, what the client will provide, what you will deliver, timeline, style/format, number of revisions, and price/payment terms. A valuable model is the Freelance Editorial Agreement (The Editors Association of Canada) at http://www.editors.ca/hire/standard-freelance-editorial-agreement.

- Another essential business aspect involves record keeping, which can comprise job or client folders, project files, billing, invoicing, and time tracking.

5. Engage in passive marketing

There are various passive marketing outlets that the freelance medical writer can investigate (Table). In terms of a marketing resource, “the AMWA Freelance Directory is definitely a good investment,” Mayfield stated.

6. Accomplish the task

Getting the job done requires attention to multiple details that incorporate effective planning, focus, precision, meeting deadlines, and crisis preparedness. Mayfield also pointed out that although freelancing can bring uncertainty, it is important to remember that you’re not alone.

Table. Passive Marketing Outlets

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Resources

For a copy of the rich resource list that includes selected online resources and books, visit the AMWA website at www.amwa.org/page/2017sessions. Readers can also email Mayfield at eleanor@elmcommunications.com.

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CLINICAL TRIAL TRANSPARENCY FOR WRITERS

Speaker
Elizabeth Schiavoni, MS
Life Science Writing Solutions LLC, Buffalo, NY

By Manoj Jadhav, PhD, FCP

This presentation sought to orient medical writers on the current status and importance of clinical trial transparency. Elizabeth Schiavoni began by providing some facts about the need for transparency in clinical trials and research. She then turned to data sharing, missing data, policies related to data sharing, and how writers can contribute to improved transparency, thereby deepening the role of medical writers in this area.

Schiavoni quoted Kathy L. Hudson, PhD, former National Institutes of Health (NIH) Deputy Director for Science, Outreach, and Policy, on the importance of data sharing, especially its critical relevance to new drug discoveries, data sharing via clinical trials registration, and reporting of clinical study outcomes/results to the scientific community and the general public. She also explained the negative consequences of not publishing clinical research data (eg, loss of public trust in biomedical research). She provided succinct examples of how missing data can retard the growth of medical research and its scientific conclusions and can affect stakeholder policy design.
She also provided an example on how poorly designed clinical studies may lead to skewed data analysis, leading to biased conclusions, which eventually puts patients at risk.

Schiavoni went on to emphasize the impact of selectively publishing clinical study data, sharing that nearly half of all clinical studies performed are not published. According to a 2010 study by Song et al, researchers concluded that over 97% of studies published reported positive results, 50% reported questionable outcomes, and only 33% reported negative results, indicating the problem at large. She provided another example of a 2004 study by Chan et al, wherein researchers compared clinical study protocols with their publications, showing that more than 60% of studies had at least one primary outcome changed, omitted, or introduced. She also provided insights on www.ClinicalTrials.gov (an NIH registry for reporting clinical study protocols and results) and asserted a need for both academia and industry to improve reporting. She shared that a lack of time to write the reports was among the reasons cited for underreporting, and suggested that investigators could use expert resources such as medical writers to assist in such reporting. Schiavoni also provided a historical perspective on the Food and Drug Administration Modernization Act (FDAMA) of 1997, inclusion of studies, and exclusion from reporting (exemption to academic and mandate to industry sponsored clinical studies). Revised in 2017, FDAMA mandates sponsors to post methods before initiating trial; to post results within 30 days of drug approval; and, if the drug is already approved, to post results within 1 year of study completion. Failure to comply can fetch a penalty of $10,000 US dollars per day past the statutory deadline.

In the last section of her talk, Schiavoni spoke about how the role of the medical writer has gained importance since FDAMA. She highlighted their contribution to the whole clinical trial reporting process (eg, ensuring compliance with the Consolidated Standards of Reporting Trials [CONSORT] statement). She also provided some insights on how the NIH/National Cancer Institute can make some provision of funding for professional writers and how academic institutions can appoint publications officers who will perform duties towards ensuring compliance with current guidance, perform interim audits to check registration and reporting status, work closely with institutional review boards to ensure compliance to obtain clinical study approval, and provide other timely recommendations. She also introduced the audience to All Trial USA, a nonprofit organization that advocates trial transparency, reporting, and registration of clinical studies.

References

Manoj P Jadhav, PhD is a Translational Clinical Pharmacologist at CRC Pharma, LLC, Parsippany, New Jersey.

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COMMON CARDIOVASCULAR DISEASES:
A TUTORIAL FOR MEDICAL WRITERS

Speaker
Anne Erlich, PharmDS
Principal Medical Writer, Write Market Access, East Brunswick, NJ

By Larry Macke
Writers seeking an introductory or refresher course on basic cardiovascular concepts found what they were looking for in a brisk and entertaining presentation that speaker Anne Erlich, PharmD, introduced as the first in a 3-part series: “Body Systems Overview for Medical Writers.” The charismatic Erlich engaged the audience with questions and humor, both planned and improvised, and surprised several attendees by confessing afterward that this had been her first time presenting in public.

The frame for the presentation was the concept of homeostasis, which in this context was defined as the body’s stable internal environment as maintained by its systems working in concert (or, more generally, “health”). Markers cited by Erlich included a balanced pH of 7.0, body temperature of 98.6°F, and blood pressure within a normal range (more on this later). She noted that disturbances in homeostasis lead to morbid and perhaps mortality.

Anatomy of the Heart
Aided by a diagram and vigorous gesticulations, Erlich explained the heart’s structures and their role in circulating blood through pulmonary tissue and into the rest of the body. She also described the heart tissue layers (pericardium, epicardium, myocardium, and endocardium) and provided an overview of the Framingham Heart Study, which followed 3 generations of participants and identified high blood cholesterol, smoking, obesity, diabetes, lack of physical activity, and hypertension as the primary risk factors for heart disease.

Hypertension
Hypertension (ie, high blood pressure) describes an elevated measure of force exerted by the blood against the artery walls. The definition of “elevated,” said Erlich, has evolved over the
years and varies with patient characteristics. The American Heart Association blood pressure classifications (Table) represent general guidelines for normal, borderline, and elevated values, and the Eighth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure recommends that clinicians initiate therapy in patients who (A) are older than 60 years of age with a blood pressure of 150/90 mm Hg or higher, (B) are younger than 60 years with a blood pressure of 140/90 mm Hg or higher, or (C) have diabetes and a blood pressure of 140/90 mm Hg or higher.

### Table. American Heart Association Blood Pressure Classification

<table>
<thead>
<tr>
<th>Level</th>
<th>Systolic</th>
<th>Diastolic</th>
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<tbody>
<tr>
<td>Normal</td>
<td>&lt;120 mm Hg</td>
<td>&lt;80 mm Hg</td>
</tr>
<tr>
<td>Prehypertension</td>
<td>120-139 mm Hg</td>
<td>80-89 mm Hg</td>
</tr>
<tr>
<td>Hypertension</td>
<td>≥140 mm Hg</td>
<td>≥90 mm Hg</td>
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In discussing treatment options, Erlich listed the primary classes of blood pressure medications and their mechanisms of action.

**Coronary Heart Disease**

With a grounding in the basics of the circulatory system and hypertension, the discussion transitioned comfortably to coronary heart disease, a condition marked by the accumulation of plaque (consisting of cholesterol, fat, cellular waste, fibrin, and calcium) in the coronary arteries that causes approximately 16% of deaths in the United States, according to Erlich. Potential outcomes include ischemia (ie, insufficient blood flow to the heart muscle), angina (ie, chest pain), atherosclerosis (ie, hardening of the arteries), blood clots, stroke, and heart attack. She went on to explain that although some coronary heart disease risk factors, such as age, sex, and family history, cannot be modified, there are several factors that people can control. These include poor diet, obesity, lack of exercise, smoking, and elevated cholesterol.

**Cholesterol**

After noting that cholesterol is produced in the liver and is needed for digestion and hormone production, Erlich explained that this fatty substance circulates in the blood in 2 forms: low-density lipoprotein (LDL), or “bad” cholesterol, and high-density lipoprotein (HDL), or “good” cholesterol. Excess LDL accumulates within the arteries and narrows them, whereas HDL acts as a scavenger to sweep LDL back to the liver for recycling. This portion of the presentation included an image of test tubes containing blood collected after a fatty meal, which was disturbing enough to cause at least one audience member to opt for a vegetarian dinner that night. Erlich summarized other cholesterol-management options, particularly the statin medications.

**Arrhythmias**

The talk concluded with an overview of arrhythmias, which the American Heart Association defines as changes in the sequence of electrical impulses through the heart. These can cause the heart to beat too rapidly (tachycardia), too slowly (bradycardia), or irregularly. Erlich characterized arrhythmias as generally harmless but potentially damaging for organs that do not receive an adequate blood supply. Treatments she discussed included medications, pacemakers, and ablation.

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**ARE YOU PICKING UP WHAT I’M PUTTING DOWN? THE COMMUNICATION CONUNDRUM**

**Speaker**
Robin Whitsell  
*Founder and President, Whitsell Innovations, Inc., Chapel Hill, NC*

**By Kirby Snell**

As professional writers and editors, we depend on our excellent listening and communication skills, with our clients as well as our coworkers—but are we as good at listening and communicating as we think we are?

**Design versus User Experience**

Good communication is a challenge of design versus user experience, Robin Whitsell explained: “We think we’re going down one path, while our listener is going down another path…. It’s not as straightforward as we think it is.”

To illustrate the difference between speaker and audience perception, Whitsell replicated an uncomfortable experience from a conference she attended. She played a video of a supposed “listening exercise,” but when she asked questions about the rapid-talking video, the questions covered not only the spoken dialogue but also details of what the characters were wearing, props visible in the scene, and other visual details. What was introduced to us as “an exercise in listening” required, in reality, a different level of engagement than we were told to expect. She asked the audience to consider how they felt following this experience, recognizing that the likely perception was unfavorable.

The audience gleaned 2 lessons from this exercise: first, as listeners we should be prepared to engage with our full envi-
What Great Listeners Actually Do

Whitsell then introduced a study from the Harvard Business Review that identified 4 main qualities that define great listeners:

1. People listen better when engaged and periodically asking questions, not just listening in silence.
2. Good listeners build up the self-esteem of the person they’re listening to, allowing him or her to feel supported.
3. Good listeners are cooperative; they are trying to help, not simply win an argument.
4. Good listeners make suggestions, based on the respect already established with the speaker.

Communication Styles

The idea of communication styles also came into play. Whitsell highlighted one particularly valuable theory, the Process Communication Model developed by Dr Taibi Kahler, which presents 6 communication styles, or “perceptual languages” (see Box). While being aware of your own primary “language” is valuable, it is also important to recognize other people’s styles. “We hear people based on our communication style,” Whitsell emphasized, “not their communication style.” If you can identify the style of the people you are speaking to, you can adapt your approach to better connect with and influence them.

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<th>Box. Six Perceptual Languages</th>
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<tbody>
<tr>
<td>Thought: Talks about facts, details, logic; asks about who, what, where, and why; wants things to make sense</td>
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<tr>
<td>Opinion: Guided by values and judgment; “we ought to be doing…”; “this is what we believe in/this is our goal”</td>
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<tr>
<td>Feelings: Uses the heart as a moral compass; is perceptive and empathic; is sometimes bullied over because they’re more concerned about others</td>
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<tr>
<td>Reaction: Jumps in without much forethought; low filter; gut-based, and maybe more honest</td>
</tr>
<tr>
<td>Action: Verb-based; focused on tasks, taking charge, and getting things done</td>
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<tr>
<td>Reflection: Open and uncontrolled thought process; doesn’t speak much; likes to reflect on things</td>
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Whitsell invited the audience to put this in practice by first identifying our own primary languages and then partnering with a neighbor with the assignment of convincing each other of specific arguments (whether climate change is real, New York- vs Chicago-style pizza, our favorite books) while targeting each other’s perceptual languages. The added factor of heightened emotions around the assigned topics emphasized both the challenges and the value of meeting a colleague or conversation partner on their own territory.

Conclusion

Some final takeaways included knowing that at some point in our professional lives, all of us will likely have to convince others of something we ourselves are not excited about (e.g., when upper management has made a decision and you have to get your own team on board), being able to recognize when you need to change mediums, and remembering to check in with your listener to make sure you’re going in the right direction. The value of knowing your audience—and knowing tools that can guide that understanding, such as the Process Communication Model—has great application for medical communicators in the workplace, as well as in all areas of our professional and personal lives.

Kirby Snell is Managing Editor of the AMWA Journal and Copyediting Client Manager at J&J Editorial in Cary, North Carolina.

References


TRASH TALK: DRUG WASTE IN THE 21st CENTURY

Speaker

Ashley Khan, PharmD
Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

By Callie Rainosek

As Ashley Khan put it, “[Pharmaceutical waste] is not something you think about in your day-to-day routine.” However, thousands of metric tons of pharmaceutical waste are produced annually, which may be harming both humans and the environment.

What is Pharmaceutical Waste?

Khan defined pharmaceutical waste as “any drug product that is no longer used for its intended purpose.” Medication may be considered waste because the product is expired, discontinued, or damaged. Drug waste also includes vials, syringes, and even materials such as tubing used to administer chemotherapy treatments. Drug waste can be in solid, liquid, or gas form.
How Much Pharmaceutical Waste is Being Produced?

While working as a pharmacist in a hospital for 7 years, Khan saw just how much drug waste a single hospital can produce. But drug waste isn’t just originating in the healthcare field. A lot of drug waste arises at the source of pharmaceuticals—the manufacturing companies.

Khan estimates that large pharmaceutical companies can produce 80,000 to 100,000 metric tons of drug waste per year, per manufacturing plant. That’s approximately the weight of 50,000 cars. However, this estimate covers only solid waste. In addition, manufacturing companies produce wastewater when making drug products. Water may be used for purposes such as processing or cooling, which ultimately contaminates the water with drug waste. Khan estimates that, on average, each manufacturing plant produces 15 million cubic meters of wastewater per year—roughly equivalent to 4000 Olympic-sized swimming pools.

Where Does It All Go?

Like any other form of waste, pharmaceutical waste ends up in the environment. There are conflicting viewpoints about whether drug waste poses a serious threat to the environment, but some research suggests that it does. For instance, the disposal of inhaler propellants may be contributing to ozone layer damage. Other studies have found that the hormones in oral contraceptives may be affecting aquatic organisms, such as fish, when released as waste into the water. Additionally, drug waste could play a role in the rise of antibiotic-resistant organisms.

Drug waste can also harm humans. If drugs are accidentally ingested or purposely misused, the consequences can be fatal.

What Can Consumers Do to Reduce Pharmaceutical Waste?

There are federal regulations on how to properly dispose of, recycle, or return drugs, yet many of us are unaware of these regulations. To reduce the chance that someone may accidentally ingest or purposely misuse discarded medications, Khan said we should consider several options:

- Take the drugs to authorized collectors for disposal. These may include pharmacies, hospitals, and local law enforcement.
- Participate in a medicine take-back program. This is a good way to dispose of or recycle most public and household medications.
- If disposing of a drug at home, put the medication into a sealable plastic bag. Then, add coffee grounds, kitty litter, or any substance that makes the medication unappealing (this keeps people or animals from opening the bag and consuming the drug). Seal the bag and place it in the trash. Be sure to remove all personal information from prescription labels before recycling or discarding medication containers. Avoid flushing medications unless that method of disposal is specifically recommended by the FDA.
- Still unsure? Contact a local waste management authority to learn about medicine disposal guidelines.

What is Being Done to Reduce Pharmaceutical Waste?

There are many ongoing efforts to reduce drug waste. For instance, pharmaceutical companies are striving to recycle, recover, and reduce the sources of waste and integrating green chemistry into manufacturing processes. The public is also getting involved by participating in programs that recycle drugs and increase awareness of drug waste.

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BIOLOGICS & BIOSIMILARS: REGULATIONS, RULES OF TRIAL DESIGN, AND RISING APPROVALS

Speaker
Rochelle Mills, PhD
Medical Writer and Consultant at Whitsell Innovations, Inc., Richmond, VA

By Valerie Sjoberg, Mac

Biologics and biosimilars are gaining momentum across the global pharmaceutical market. In 2017, they were projected to account for approximately 20% of pharmaceutical sales. Costly and complex, yet highly effective, they show significant promise for the evolution of medicine.

“I like to think of biologics as the Ferraris of the drug world,” said Rochelle Mills. She focused her presentation on dispelling the mystery around biologics and biosimilars, explaining what they are, how they differ from small-molecule drugs, and current Food and Drug Administration (FDA) regulations.

Biologics

Biologics are complex molecular products composed of sugars, proteins, and/or nucleic acids or living cells and tissues. First-generation biologics are derived from humans and animals, and second-generation biologics are developed using recombinant DNA technology.

According to Mills, unlike small-molecule drugs that are chemically synthesized, most biologics are not easily charac-
Biologics are significantly larger than small-molecule drugs, and their size increases the possibility of anaphylaxis, immunogenicity, and unexpected side effects. The effects can vary between animals and humans. Mills shared a story about TNG1412, an anti-CD28 T-cell agonist developed to treat rheumatoid arthritis and leukemia. The biology had been deemed safe in cynomolgus monkeys but, when infused in human sub-
jects, induced cytokine release syndrome within all 6 subjects and resulted in multiple organ failure. (Fortunately, the subjects survived.) This reaction had not been predicted by animal models. She explained that the disconnect between preclinical studies and the clinic could be understood through retrospective investigation of cynomolgus monkey CD4+ effector memory T cells, which were found to not express CD28.

TNG1412 is now being developed by a Russian company for oncology indications at a 1,000-times lower dose—and is not generating the same side effects. “The dose determines the poison,” Mills said. “Anything is poisonous if given at a high enough dose.”

Clinical Trial Design for Biosimilars and Interchangeables
The FDA has provided specific guidance on clinical trial design for biosimilars and interchangeables, including

- A crossover study design should be used to test biosimilars with a half-life shorter than 5 days, a rapid pharmacodynamic (PD) response, and a low incidence of immunogenicity.
- A parallel group study design should be used to test biosimilars with a long half-life and a higher immunogenicity that affects PD and pharmacokinetics after multiple doses.
- To determine the pharmacologic similarity between the biosimilar and reference product, a 90% confidence interval is suggested by the FDA for the ratio between the geometric means of the PD and pharmacokinetic parameters. The acceptable limit for the confidence interval of the ratio is 80% to 125%.
- For interchangeables, as stated in the BPCI Act, the sponsor must show that “the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product is not greater than the risk of using the reference product without such alteration or switch”; therefore, a switching study design is suggested by the FDA, with at least 3 switches between the test product and the reference product in the experimental arm of the study.

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<td>First biosimilar approved</td>
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<tr>
<td>Data exclusivity period for reference product</td>
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<tr>
<td>Number of biosimilars approved to date</td>
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<td>Differences in legal provisions</td>
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According to Mills, global sales for all pharmaceuticals totaled $967 billion in 2016, and, as stated earlier, biologics account for approximately 20% of drug expenditures. The hefty cost of biologics can decrease their accessibility to patients who need them. Fortunately, biosimilars are expected to help drive down these costs by $44 billion over the next decade.

Valerie Sjoberg, MAc, is a medical writer and content manager at DaVita Kidney Care in Denver, CO.

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WINNING THE WORK: GRANT WRITING BASICS

Speakers
Margaret Smith
Editor/Writer, RTI International, Research Triangle Park, NC
Loretta Bohn
Senior Editor/Writer, RTI International, Research Triangle Park, NC

By Karen Potvin Klein, MA, ELS, GPC, MWC
Crafting grant proposals that are well written, tell a story persuasively, and get submitted on time is not easy. Margaret Smith and Loretta Bohn, who jointly presented this session, gave the audience many practical tips for success. The session included material aimed at those new to the field, such as the difference between a proposal (request for funding) and a grant (the funding itself). However, the presenters also incorporated examples and comments from the more seasoned veterans in the audience.

An important point made early in the session was that persuasive writing, the core of a successful request for funding, is focused on what the funder wants to know. In any kind of proposal, it is important to assure the funder that your team knows the field, knows how to do the work, and will complete the project on time and on budget.

A core technique of persuasive writing that Smith and Bohn described was using the “six C’s.” These included being:

• Compliant—with the funder’s guidelines for applications
• Clear—in describing what you will do and how
• Credible—show your group’s expertise to best advantage (but don’t brag)
• Concise—avoid wordiness that distracts your reviewers (but be ruthless about eradicating buzz words or jargon)
• Compelling—avoid passive voice; make key points so obvious that reviewers cannot miss them
• Client-focused—show how this project will help the client/agency meet its goals

Smith and Bohn then gave an overview of the types of grant applications offered by federal funders, such as the National Institutes of Health (NIH); the Department of Justice (many people are unaware that they fund research, but they do); the Patient-Centered Outcomes Research Institute (PCORI), a newer agency funded through the Affordable Care Act; and the National Science Foundation, which supports basic science research. Smith and Bohn gave a quick orientation to these funders, such as the typical page limits and which types of applications require approval of a letter of intent before a full proposal is invited. As grant funding is a complex and ever-changing landscape, the URLs to each agency’s web pages included in the presentation are a key resource, especially for those new to the field.

Smith and Bohn then described how their team holds color-coded review meetings while a proposal is being written. For example, the Blue Team ensures that the outline of the proposal is correct and that a writer is assigned to each section; the Green Team reviews the budget. When the Pink Team gets involved, the proposal is 65% to 70% complete and includes graphics and tables. The Red Team brings the document to 85% to 90% completion, including formatting, editing, and revisions from team members. The Gold Team conducts a final review before submission, making sure the document is complete. Finally, the White Team does a visual review of the document to catch obvious errors before submission. Even for proposal writers and editors with fewer hands on deck, operationalizing color-coded reviews into their own settings may be of value.

Good organization while preparing an application is essential because deadlines are not negotiable, your team may not have much time to respond, and problems will arise at the worst times. One tool in Smith and Bohn’s arsenal is a “responsibility matrix.” This is an outline of each part of the proposal, relevant requirements and page limits, and the name of the team member assigned to that part. Parts are checked off as they are completed to ensure that every part has been addressed. In their organization, they designate one person to manage the process, so there is a “Mission Control” for each application and clear lines of communication among team members.

After the presentation there was a question-and-answer session, and the presenters both elaborated on their own experiences and facilitated discussion among audience members. This session delivered on its promise to show how tried-and-true best practices can help teams deliver winning grant proposals.

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Limited printing space demanded a random selection from among the many Open Session reports submitted. The remaining reports may be found in our online-only supplement (www.amwa.org/page/Journal).
Where Am I? A work in progress.

By Brian G. Bass, MWC

Of all the places I ever thought I might be, I never expected to be here.

I was never going to be in a field as technical as medical communications. I never imagined I would have something of value to teach others. I never thought I would be successful. As hard as it is for me to believe that I’m right here, right now, receiving AMWA’s highest honor, there are people in this audience who don’t know that someday they’re going to be here, too. And if you’re thinking to yourself that it’s impossible, I thought the same thing, if I even thought about it at all. But clearly, it’s not impossible.

When I was young, I had lots of potential. Unfortunately, it was resting potential. And boy was it resting. Perhaps hibernating is a better word.

When we’re born we have all the potential in the world. Unlimited potential. This is me at about 3 years old. Not only did I have potential, I had hair! And blonde hair at that. Unfortunately, shortly after we’re born, limitations start being placed on our potential. This is a picture of how therapists may one day say I warped my daughters’ potential. In my defense, I only wanted them to know that normal is overrated and that there’s much more to discover, much more fun to be had, if you’re not afraid to embrace your imagination.

Everyone faces limitations. Many are out of our control, but the worst limitations are the ones we place on ourselves. Those are the limitations I want you to reject.

To understand why I think it’s amazing I’m where I am today, I want to tell you where I’ve been. And I want to preface it with this: a necklace my wife gave me many years ago. It’s a double pentacle that simultaneously represents change and signifies completion. She knows me, and she knew how much meaning it would have for me. I’ve always been restless. It’s hard for me to be still, physically or mentally. I like to complete things, but I don’t like being done. This necklace is a constant reminder that every ending is a new beginning, and that I had better get started.

Once I was going to be an actor. A singer. A dancer. The theater was my passion. So much so that I ignored just about everything else. Math, science—I had the potential. But I limited myself. So much so that by high school graduation I was easily among the least likely to succeed. This was me on the right, playing an unnamed character in Fiddler on the Roof. I was about 15.

I was the first person in my family to go to college. I was paying so little attention in high school to my future, it took my father asking me when I was a junior whether I was planning to go to college or move out and get a job. With all the jobs I had had as a kid, I knew I wasn’t qualified to do much of anything that I would want to do for the rest of my life.

I’ve been working since I was about 5 years old. I always liked money. Technically, I guess that’s when I started my first company. I painted and sold rocks to my neighbors. Yes, people actually bought painted rocks. Apparently, cute little kids can get away with almost anything.

Next I sold lemonade to golfers at the golf course down the street from where I lived. I mowed lawns, and I had a newspaper route. I worked in a pet store and in department stores. I worked in factories and in food service. I really didn’t want to do any of these things for the rest of my life, but I loved performing. So college it was.
I went to college as a theater major. Near the end of my freshman year, I realized that making it as an actor really means first making it in the food service industry. I wanted none of that. So where would this journey take me next? After taking a cold, hard look at myself, the only other thing I loved to do was write. Advertising became my new passion. I was then a sophomore.

Not counting the angst-soaked poetry I wrote as a teen that was published in high school literary magazines, this is my true professional publishing debut. It’s the first ad I ever wrote. I was working at a clothing store at the mall. When the store manager mentioned he had to create an ad for the holidays, I volunteered. What did I come up with? What the well-dressed tree is wearing this year…and most people too! Clearly my punctuation skills were not fully developed. But check out my illustrative ability! That is one snappy-looking tree.

The fire was lit. I was turned on and passionate about advertising. I started taking every college course I was interested in. As interesting as that was, it led to a hodgepodge of seemingly unrelated courses. My transcript looked like a page from Where’s Waldo, with Waldo being the common thread that would support a degree. Believe me, Waldo was nowhere to be found. This was particularly a problem because at the college I attended, juniors had to apply for their majors.

Ramapo College of New Jersey was just 4 years old when I started there. It was one of only a few institutions of higher learning in America that, at the time, would grant degrees in nontraditional or interdisciplinary majors. I had spent a year taking mostly theater courses, and another year and a half taking everything from writing, marketing, and international finance to public speaking and the sciences. If I wanted to graduate at the end of 4 years, I needed to make sense of this. So where was I now? Between a rock and a hard place, that’s for sure.

I had to appear before a committee of faculty and administrators to explain why the things I had done to date and the things I would do for the next year and a half would be worthy of a degree in communications. If I was successful, they would grant my request. The room was small and stuffy, and it was the afternoon before Thanksgiving break. I remember it all too clearly. Pacing in the hallway awaiting my turn, the answer came to me.

When it was my turn to face the committee, I explained that my career was going to be as an advertising copywriter. Naturally, all my writing courses were applicable, and as it turns out, so was every other seemingly unrelated course. In advertising you have to present your ideas, which makes the acting and public speaking courses relevant. And clients will come from all industries, which makes all the other courses seem relevant. It was daring, but possibly brilliant. And this thinking, as you’ll soon see, has changed my life. And by the way, it was also successful.

It was also a very memorable day because I met the woman who would become my wife. I was energized from my very recent success, and we had a brief conversation in the hall. In all, it was the best day ever!

Breaking into advertising in New York City wasn’t easy. After college graduation, I took a job in a factory to pay for needed car repairs. I offered them an honest day’s work for an honest day’s pay, with the understanding my future was elsewhere and I would give them as much notice as possible when I needed time off for interviews. About 6 months later, I landed my first copywriting job at a New York ad agency. It was a small agency whose clients were all in the performing arts. How convenient, given my previous career aspirations. I was in heaven—the best of both worlds for me!

I was the only writer, and I got to write advertising for concert artist management companies who managed all the great classical artists of the time. My best memories were shaking hands with the great jazz pianist Eubie Blake—whose fingers I swear wrapped around my entire hand twice, meeting the violin virtuoso husband-and-wife team of Pinchas and Euginia Zukerman, and watching a young tuba prodigy play an empty 5-gallon water jug in my office. I also wrote advertising for many of the top off-Broadway theaters. Perhaps my biggest accomplishment came during the early days of cable television, when I helped to launch a new premium service called Bravo. Some of you may be familiar with it.

A good friend of mine was working at Van Heusen in Manhattan. She knew I was in advertising and asked whether I would be interested creating ads for the outlet stores around the country. Since it wasn’t a conflict of interest with my current employer, I gladly took on the freelance work—freelances should always err on the side of yes. So I freelanced in the evenings and on the weekends. This would become a pattern for me throughout my early career. Wherever I worked professionally, I always freelanced on the side.

The owner of the ad agency was a great guy. Funny, creative, energetic, but a lousy businessman. The agency grew, and then it faltered, without the owner ever really understanding why either had happened. I left for the advertising department at Macy’s Herald Square, where I nearly worked myself to death for the longest 13 months of my life. Nothing—and I mean nothing—prepared me as much as Macy’s to become a successful medical writer.
How can that be? One thing I’ve learned on this journey of mine is what I first discovered the day I defended my college degree—things that are seemingly unrelated are always related by at least one thing: the person experiencing them. The trick is learning how to tie all the loose ends together so you can learn from them. Here’s how I learned to be a successful medical writer in the advertising department at Macy’s Herald Square.

On any given day, writers in the advertising department were simultaneously working on 11 weeks of newspaper ads, 7 weeks of Sunday circulars, plus the occasional direct mail pieces. I learned endurance. Believe me, as a freelance, I rely on this every single day. Because there was no time to get anything done, there was also no time to get anything wrong. So I learned how to quickly and accurately assess what needed to be done. I learned to trust my instincts, own my decisions, and learn from my mistakes. Considering the volumes of highly technical information we have to filter as medical writers, the pace of our deadlines, and the myriad legal and regulatory guidelines we have to know, it’s easy to see how this has come in handy for me.

When my wife and I were expecting our first child and we couldn’t figure out how we found the time for that to happen, I knew it was time to leave Macy’s. Before I left the company we both performed in the Macy’s Thanksgiving Day Parade. We were square dancers around the turkey float—a float they still use at the start of the parade. Not only that, but footage from the parade was used in part of the opening for a TV sitcom the following year, so we were on TV every week!

I spent a little more time in retail advertising, but my heart wasn’t in it. I knew I had to get back to an ad agency, but how? Since college, I had interviewed with all the big agencies: BBDO, Grey, J. Walter Thompson, and others. I had great first interviews, but no one ever offered me a job. At the time, I thought that was terrible. But over the years and in hindsight I have realized they did me a great favor. I never would have been satisfied in a cubicle, being the guy who came up with “is” in “Coke is it!” That wasn’t my place. I needed to be front and center.

I answered an ad for a small ad agency whose clients were in animal health pharmaceuticals. We were both intrigued by the prospect of working together, but because I had no discernible scientific ability, I freelanced for them for a while. We quickly discovered it was a good match, and I was hired. I was thrilled to be using my creativity and my brain in scientific ways. The owner of the company was a great guy. Funny, creative, energetic, but a lousy businessman. Sound familiar?

This agency would mark the last time in my career I would work for someone else; well, not including a brief sidebar, but that’s a story for another day. Since the big ad agencies wouldn’t have me, and the small ad agency owners didn’t know how to run a business, I had no alternative. I had to do it on my own.

Of all the companies where I’ve worked for someone else, going all the way back to my newspaper route, only 2 are still in business. Fortunately, my company is one of them. Macy’s is the other, but I hear they’re struggling.

I have to thank all the bad businessmen I’ve worked for in my career. To the untrained eye those experiences might seem like train wrecks. But I learned from every one of them. I learned how not to run a business. They taught me well.

My first day in the office of my company was Monday morning, August 19, 1989. At the time it was an ad agency, just like those I knew and had worked for previously, and the company was growing. But evenings and weekends I was freelancing—yes, even freelancing on myself—as a medical writer. I was trying to figure out how to transfer my experience in veterinary medicine to human medicine. Soon that part of the business began growing, too.

I want to tell you a story about how I landed my first freelance gig with a medical communications company. I was presenting my portfolio, which comprised all the medical writing I had ever done at the time, all in veterinary medicine. So I already had one foot on a banana peel, considering I was interviewing with a medcom whose work was in human orthopedics. The person I was interviewing with saw a brochure peeking out of the back pocket of the portfolio and asked why I hadn’t showed it to him. I told him it was from a past life and I hadn’t shown it to him. I watched his movies, I read his books, his favorite samples—but not for a medical comm. The person I was interviewing with a medcom whose work was in human orthopedics. The person I was interviewing with saw a brochure peeking out of the back pocket of the portfolio and asked why I hadn’t showed it to him. I told him it was from a past life and wouldn’t be relevant to medical communications. I had forgotten the brochure was still in there. Once again, something seemingly unrelated made all the difference.

It was a brochure I had written at the ad agency in New York, for a touring production of GROUCHO, based on the life and lunacy of Groucho Marx. These types of brochures were boilerplate. A brief description of the show surrounded by quotes extolling it. But I love Groucho Marx, and I love doing things like they’ve never been done. So I chose to write the brochure in the first person, as if Groucho himself had written it. I watched his movies, I read his books, and the brochure was one of my favorite samples—but not for a freelance gig in medical communications.

I hesitantly took the brochure out of the pocket and explained what it was. I was trying to read the guy’s face as he read it. Little did I know that he loved the theatre. He put the brochure down, looked at me, and said “If you can write something like this, you can certainly write about hips and knees.”
And so the journey continues!

By the fall of 1993, I was spending more time freelancing as a medical writer than building the ad agency I had started. That’s when I realized the world didn’t need another small ad agency, but that I could make a difference as a medical writer.

I became an AMWA member on January 1, 1994. It was very kind of Jim Yuen, then president of AMWA, to come into the headquarters office to sign my membership certificate on New Year’s Day. I never imagined that someday, this membership certificate would be joined by one recognizing me as an AMWA Fellow, a beautiful plaque commemorating my AMWA presidency in 2013 to 2014, and my achievement of MWC certification. To fully appreciate the gravity of that last one, the MWC, you need to understand that I registered “barely breathing” on the last standardized test I had taken, the SAT, back in my powerhouse high school days.

When I began focusing solely on medical communications, this was my inspiration. I was going to do medical communications like it’s never been done. I was speaking to someone who was a medical illustrator. He told me about an organization he belonged to, the Association of Medical Illustrators, and proposed there might be a similar organization for medical writers. The Internet was in its infancy, so it took more than a few mouse clicks at the time to find AMWA.

Before I found AMWA, though, I came upon an ad for a creative competition, which is quite common in the advertising field. The Medical Marketing Association was having a competition for the best medical advertising of the year, and this was the theme of the competition. The theme was “Heavy Medical” (you know, like heavy metal music). I had to buy the tee shirt. On the back was the Heavy Medical Credo—“I swear I’ll do it like it’s never been done.” The image on the front is a caduceus and the snakes have a serious attitude. And “In Awe” was emblazoned across the staff. It communicated a commitment to excellence with a take-no-prisoners attitude that inspired me to kick medical communication butt.

This was my other, and perhaps more important, inspiration. This hung on the wall facing my desk, precisely at eye level when I was seated. I saw it every day. I couldn’t not see it, and I couldn’t forget it. It’s a quote from Shakespeare, from his play Measure for Measure: “Our doubts are traitors, and make us lose the good we oft might win by fearing to attempt.” Life is scary. Business is scary. We all feel that we have so much to lose. But nothing is lost by a bad moment that isn’t regained twofold by the opportunity to learn and grow or reinvent ourselves thanks to the experience.

Seemingly unrelated things become completely related and relevant when you look at them the right way—like my college transcript or my GROUCHO brochure. The worst things can become the best things—like big ad agencies who wouldn’t hire me, and small business owners who taught me how not to run a business. Endings, and beginnings.

I remember driving to my first AWMA meeting in January 1994. Until just recently, I was a member of the Delaware Valley Chapter—shout out to my DVC peeps! Now I’m a member of the Florida Chapter—shout out to my Florida peeps!

The first AMWA meeting I ever attended was a chapter meeting held on a Saturday in Ambler, Pennsylvania. I was honestly so scared. Although I had already been a professional writer for 15 years, and a medical writer for 9 years, I knew I would be out of my league. I almost turned around, which would have been the biggest mistake of my life—fearing to attempt.

Sure enough, the people in attendance at my first AMWA meeting had more letters after their names than I have in my name. But it turns out I had nothing to be worried about. These were the most welcoming and interesting people I had ever met. I knew I had found my home. This is where I’d been headed and didn’t know it. I’m sure many if not most of you had the same first experience.

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The Walter C. Alvarez Award is named in honor of Walter C. Alvarez, MD, a pioneer in the field of medical communication. The award is presented to either a member or nonmember of AMWA to honor excellence in communicating health care developments and concepts to the public. The Alvarez Award is presented during AMWA’s Medical Writing & Communication Conference. The 2017 recipient is Helen Osborne, MEd OTR/L. You can read about her acceptance speech in our Online-Only Supplement.

The John P. McGovern Award is named in honor of John P. McGovern and is presented to a member or nonmember of AMWA to recognize a preeminent contribution to any of the various modes of medical communication. The McGovern Award is presented during AMWA’s Medical Writing & Communication Conference. The 2017 recipients are Steven Woloshin, MD, MS, and Lisa M. Schwartz, MD, MS. You can read their acceptance speech in our Online-Only Supplement.
The Changing Face of the Medical/Technical Editor

By Laura Palmer,1 Susan Lang2
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Adapted from a presentation at the 2017 Society of Technical Communication Summit

As a group, editors rarely make the news, but on June 29, 2017, employees from The New York Times walked out to protest potential cuts to the editorial copy desk. As reported in The Washington Post, editors are the safety nets, the meticulous proofreaders who catch everything from spelling mistakes to major factual errors.1

As individuals who develop and teach editing classes, we were delighted to see editors recognized for the significant contributions they make to the work of others. Yet, we also paused for a moment on the Post’s short summary of editorial tasks: Editors are apparently like anglers; they catch things such as spelling, grammar, and, of course, factual errors.

Anyone who has ever taken the Medical Writer Certified (MWC®) examination knows that what goes into editing extends far beyond this “catch of the day” model. The core competencies for the MWC designation—gathering, evaluating, organizing, interpreting, and presenting—situate a writer/editor as an individual who performs multiple complex tasks.

However, the tasks performed by editors are moving beyond words. As such, what competencies are critical for today’s editors of medical communication? While an entry-level editor still must have a firm foundation in grammar and usage, punctuation, sentence structure, and visual elements, including tables and graphs, the range of publication venues and audiences mandates a skill set beyond the traditional.

The new, expanded toolbox for editors may include, but is not limited to
1. Understanding the features of the platforms critical to publications management and delivery—including the repurposing of content from print-based to electronic environments. This means that editors need to be conversant in what the publication of information involves for such venues as print-based journals, trade publications, websites, and social media.
2. Understanding the best medium for a particular venue and audience based on content consumption practices. Some readers will engage deeply with information and desire a print copy. Others will seek an immersive experience or want “snackable” content—content that is easy to access, easy to understand, and leveraged for mobile use and sharing.
3. Understanding the rhetorical requirements of each genre. In short, who are the likely audiences of each? What are the purposes for publishing information in each genre? And what do the answers to each question mean in terms of type of information included, organizational structure of information for inclusion in each medium, and stylistic/usage conventions for each?

Audiences and multichannel platforms (genres) are now moving targets for an editor. Complicating matters is the flow of information; it is no longer possible to assume medical information will only move between subject matter experts. Medical information also flows in print and digital spaces, from expert to layperson via the medical writer/editor as an intermediary. As an example, organizations such as the Centers for Disease Control and Prevention (CDC) have an extensive podcast library that covers a wide range of medical-related topics.2 They also produce a “For Kids” series and provide radio-ready public service announcements. In addition, there are currently 2115 videos available on the CDC’s YouTube streaming health channel in both English and Spanish. From an editing perspective, the proliferation of genres (channels) moves traditional print-based medical editors into a new role—a role for which they may not be prepared.
Yet, this new role for medical/technical editors is one that lacks a foundational definition. In 2002, Jean Weber discussed the differences between substantive editing (occasionally known as developmental, or comprehensive editing) and copyediting; she noted that a primary difference was that in substantive editing, "Decisions require judgment...and therefore should be negotiable with the writer."3 Yet, in 2017, we may be at a point at which editing requires a negotiation of sorts with the reader and the technology to provide information on demand and in the desired format. Thus, one might be tempted to label today’s editors as content strategists, as per Kristina Halvorson’s definition, because in many cases, they are called on to plan for the creation, delivery, and governance of useful, usable content in addition to editing.4

Perhaps an even greater challenge for preparing editors comes from Rahel Bailie and her more granular definition of content strategy. Bailie contends, "Content strategy deals with the planning aspects of managing content throughout its lifecycle, and includes aligning content to business goals, analysis, and modeling, and influences the development, production, presentation, evaluation, measurement, and sunsetting of content, including governance. What content strategy is not is the implementation side. The actual content development, management, and delivery are the tactical outcomes of the strategy that need to be carried out for the strategy to be effective."5 Are today’s medical editors content strategists, content implementers, or a combination of both? Moreover, where do we find such coverage in traditional courses, whether they are taught in university settings or via professional continuing education?

Like Brian Brooks and James Pinson in *The Art of Editing in the Age of Convergence*, we acknowledge that new media and media convergences—digitally interconnected and evolving communication ecosystems—have upended the technical editing profession.6 However, what technical editing might be and what its role seems to be require some degree of discussion. Not surprisingly, what editors should know and why they should acquire those skills is not always clear, even to those who teach technical editing or to those who hire editors.

In 2017, Bill Swallow wrote that technical editing was due to make a comeback, given the need for a technical editor to bridge “content silos” and to work within content management systems.7 While Swallow’s argument certainly resonates, it also generated counterargument and additional suggestions. For some, Swallow’s more expansive definition of a technical editor was contentious and would potentially undercut the role of the technical editor. For example, Geoff Hart, in reply to Swallow’s article, frames technical editors as working with correctness, completeness, and clarity and as ensuring that text is appropriate for the audience.8 Hart sees the role of the technical editor as working beyond the level of systems and tools, but still situated primarily with words. Chris Despopulous brought to the table the idea that a traditional technical editor was at odds with the more agile-based development practices used in many workplaces.9 Yet others noted that subject matter experts were doing more of the writing formerly completed by specialized technical writers and editors. If that is the case, creating an expanded toolkit for technical editors makes increasing sense.

Technical editors will always be more than catch-of-the-day anglers. To succeed in a world of media convergences, in which complex content such as medical information must be disseminated across channels to multiple and diverse audiences, the basic competencies of technical editors—correctness, completeness, and clarity—will expand. As such, job descriptions for technical editors will also change (eg, the media with which a technical editor will work extends beyond print).

To help prepare students for these changes, we’ve developed a technical editing class that, while covering standard grammar and usage issues, also moves students into areas we deem critical for future success. In this class, students investigate the use of both Word and Acrobat for editing. They learn that both programs have powerful features such as accessibility checkers (ie, a tool that generates a report of issues that could make content difficult for individuals with disabilities to understand—an important tool for compliance with Section 508 of the Rehabilitation Act10). The students learn to work with
the basics of audio by developing short podcasts and, from this experience, are able to understand how to provide editorial guidance for an audio-based author. Students also review instructional videos on YouTube and provide suggestions on how to improve both the production values and the content. Nevertheless, despite our best efforts, it is not possible to cover all of the new areas in editing in one semester. The course only scratches the surface of the competencies that will be required for newly hired editors.

While the definition of technical editing in all of its varieties will undoubtedly continue to morph, we’ve reached a critical nexus in terms of what education a technical editor will need to ensure a lengthy career. As noted in our recent article in the journal Technical Communication, it’s time to revise the content of classes, such as those traditionally known as “technical editing” classes. Although these revisions would ideally be part of a close collaboration between industry and academia, the differential rate of change in those two areas makes more than local collaborations difficult. Consequently, practicing editors will be leading the charge to change the profession because of the changing nature of their position descriptions. What does seem clear is that delivering content across channels and in a variety of media formats to multiple audiences will be the future of industry and academia, the differential rate of change in those two areas makes more than local collaborations difficult. Consequently, practicing editors will be leading the charge to change the profession because of the changing nature of their position descriptions. What does seem clear is that delivering content across channels and in a variety of media formats to multiple audiences will be the future of editing. Increasing the knowledge base of aspiring editors seems a necessary first step toward a re-envisioning of the profession.

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Paul Zoll MD: The Pioneer Whose Discoveries Prevent Sudden Death
Stafford Cohen, MD
Salem, NH, Free People Publishing, 2014; Paperback, 216 pages, $19.95

The author had a front-row seat on the life and work of Dr Paul Zoll for more than 4 decades, in various settings, until Dr Zoll’s death in 1999 at the age of 87. Beginning in 1957, first as colleagues, then as office mates at Beth Israel Hospital in Boston, the two physicians ultimately became friends.

Thus, no one is better qualified than Stafford I. Cohen, MD, to write the first full-length biography of the man who, he writes, “became my teacher and the mentor who directed me on a career path to cardiology.”

Paul Zoll MD: The Pioneer Whose Discoveries Prevent Sudden Death is a celebration of the life of Dr Zoll and his contributions to medical and surgical practices as we know them now: epoch-making breakthroughs in cardiac care, exemplified by his innovative design and deployment of closed-chest pacemakers and defibrillators, implantable pacemakers and heart monitors for detecting and correcting arrhythmia.

Although Dr Cohen’s original objective was to produce an academic work on Dr Zoll—“an addition to the body of medical history”—it is heartwarming (pun intended) that he later saw fit to rejig his labor of love to try and render it engaging for those he describes in the resulting book as “curious and involved laypersons.”

Zealously, Dr Cohen made the book fascinating by including a good many heart-thumping moments, moments that combine elements of the most visceral of human experiences: love and war. Yes, Dr Zoll suffered greatly from unrequited love.

Although Dr Zoll saw action as a commissioned officer in the US Army Medical Corps during World War II, there would come even more battles with medical colleagues, both near (Canada) and far (Europe). According to the many accounts that the author hunted down and curated for his book, there was no love lost between Dr Zoll and his embattled colleagues, even up until the very end.

Though sometimes effusive, Dr Cohen’s evaluation of Dr Zoll is as objective as can be. But the narrative could have been better crafted for the intended audience; it’s clunky in places, so “curious and involved laypersons” may have some difficulty staying engaged with it.

The book’s glossary, however, deserves special praise, as do the endnotes, which are an indication of the extraordinary amount of time and effort the author must have spent on the book project. In them, Dr Cohen pays exhaustive attention to Dr Zoll’s predecessors and contemporaries, justifying his primary objective for the book as a medical history.

Dr Cohen’s book could have been a great and gripping story; it is the stuff humanity’s favorite stories are made of. For those of us involved in professional communications, however, the easily avoidable grammatical gaffes (eg, “Forward” instead of “Foreword,” differing font types and sizes) that abound in the book may prove distracting. Nevertheless, it’s a narrative that inspires gratitude and appreciation for unsung heroes like Dr Zoll, who stride through life with quiet candor and conviction, driven by a sense of mission—as Dr Cohen makes clear in his book—to make a difference in the world.

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Juggling on a High Wire: The Art of Work–Life Balance When You’re Self-Employed (A Dr. Freelance® Advisor Guide)
Laura Poole
Phoenix, AZ: More Cowbell Books, LLC, 2015; Paperback and digital formats, 98 pages, $11.75

Individuals often experience difficulty in navigating the high demands of both professional and personal responsibilities. Maintaining a balance between our personal and professional lives is not only important for personal health and relationships but also improves work efficiency and productivity. The key to creating a workable life balance is not about constructing a barrier between your professional and personal lives but about learning how to incorporate and integrate the two concepts.

In Juggling on a High Wire, Laura Poole argues that the key to creating a workable life balance is deciding when to say...
Poole inspires her readers to envision a balanced life and encourages their commitment to creating it by offering basic task management tips and concepts. She also reminds her readers that their dreams, goals, and aspirations can all fit into their balanced lives and not be tossed aside.

The various chapters focus on working from home, balancing family and other commitments, work emergency preparedness, and coping with being under- and overworked. Vignettes from other experienced freelancers provide readers with invaluable tips of the trade and words of wisdom to help navigate the world of freelancing. This informative book is intended for all freelances. Beginning freelances can learn practical approaches to crafting a work-life balance, while seasoned freelances can be subtly reminded to actively practice these approaches.

The idea of work-life balance is subjective and based on our personal values, ideals, and circumstances. Pursuing a sustainable work-life equilibrium is crucial to an individual’s personal and professional success, health, happiness, and productivity. Although there is no set formula for obtaining a balanced life, it is achievable. It is a constantly evolving journey, not a destination. We must treasure and embrace the journey.

**Reviewer:** Tara Ann Cartwright, PhD
*Tara Ann is a medical writer and editor in Research Triangle Park, NC.*

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**The Gene: An Intimate History**

Siddhartha Mukherjee, MD


Siddhartha Mukherjee, MD, begins his third book, *The Gene: An Intimate History*, as personally as possible, with his own family’s history of debilitating mental illnesses. The author’s weighty relationship to the material builds important trust with wide audiences, each carrying varying relationships with their own genetic inheritance.

*The Gene* impressively covers the gene’s journey from archaic abstraction to malleable experimental material in 2015. Sticking to a journalistic style evoking human interest, Dr Mukherjee wraps the seminal thought and laboratory experiments of an introductory genetics textbook around the lives and cultural contexts of their authors.

As audience understanding builds so does the number of elements in flow diagrams spaced throughout the book. The final diagram on page 410 links genes to RNAs, proteins, organisms, and environments through regulatory and influencing relationships. This accessibly presented scientific knowledge equips the reader to reflect on social, technological, and ethical questions continually presented by the text explicitly and implicitly:

- Can an intelligent machine ever decipher its own instruction manual?
- Is genetic memory carried in a community that has survived trauma or lived in an altered environment?
- How should you tell your child about the outcomes of a genetic test for a life-ending or dramatically life-altering illness?
- How do we talk about the coming world in which editing human DNA is possible within the context of a global legacy of violent eugenics?

Mukherjee uses a number of epithets before every section and before every chapter of the book. Although unusual, this tonally prepares the reader for the multitude of atmospheres reflected in the small sample of questions above.

As might be expected of a professor skilled at sparking conversation, Mukherjee ends the last chapter before the epilogue with a list of items reminiscent of the learning objectives of a lecture. He modestly calls it a possible opening to a manifesto for the post-genomic world.

As I research and write about science, health, and genomic literacy, I am challenged by addressing the distrust of medical science built on legacies of violence. Dr Mukherjee sustains audience trust by discussing his family periodically alongside passionate patients who became researchers and study subjects. Importantly, he discusses disability as a mismatch between function and environment and speaks respectfully about the biology behind homosexual and transgender lived experiences. Absolutely anyone can walk away from this book and have a seat at the table where we talk about who we are and where we want genomic technology to take us.

**Reviewer:** Elizabeth Schiavoni
*Elizabeth Schiavoni, MS, is a Genetics, Genomics, and Bioinformatics graduate of the Jacobs School of Medicine and Biomedical Sciences and a Global Health graduate of Georgetown University. She is a freelance writer and editor in Buffalo, NY.*
The Vaccine Race: Science, Politics, and the Human Costs of Defeating Disease

Meredith Wadman

New York, NY: Viking, 2017, Hardcover, 448 pages, $30.00

The Vaccine Race: Science, Politics, and the Human Costs of Defeating Disease by Meredith Wadman invites the reader into the laboratories of scientists who eradicated epidemics. In the prologue, Wadman creates space for reflection on some of the most lauded accomplishments of the postwar era. She does not shy away from describing the exploitation of prisoners, African Americans, the poor, and the mentally ill. Before beginning chapter 1, Wadman asks the reader what practices are currently accepted, encouraged, or unchallenged that will make future generations wonder about our morals. Anyone interested in shifts in scientific culture and values through the 20th century to today will learn from The Vaccine Race.

The Vaccine Race unfolds in three legs: “The Cells,” “Rubella,” and “The WI-38 Wars.” Wadman weaves the expansive network of researchers in the history of vaccine development around Leonard Hayflick. He is most widely recognized for Hayflick’s Limit, which describes the aging of cells in culture. “The Cells” details Hayflick’s early career at the Wistar Institute and the development of human cell lines from aborted fetuses for live vaccine development. “Rubella” discusses the role of Hayflick’s cells in creating rubella vaccines alongside competitors during the 1964–1965 rubella epidemic. Lastly, “The WI-38 Wars” is an account of the rejection, acceptance, and commercialization of Hayflick’s Wistar Institute 38 cell line. The pace resembles the growth of a cell population in culture. The pages turn faster and faster as the biographical, historical, and scientific facts mount to reveal political intrigue and power struggles—ethical dilemmas invisible to most players.

Wadman accurately depicts the day-to-day decision-making that would never make it into a biodisaster thriller, but these details glaringly highlight the banal truth behind medical violence toward society’s most vulnerable. Orphanages, prisons, charity hospitals, and institutions for the mentally ill were natural choices for proof-of-concept studies, safety trials, and efficacy trials. As the Archbishop of Philadelphia commented in 1959, “Our research teams want these infants because they are always available in quantity and under conditions which permit a wide variety of controls.”

Wadman echoes consent and compensation questions made popular by Rebecca Skloot’s 2010 work The Immortal Life of Henrietta Lacks, which tells the story of a woman whose cells became an incredibly profitable cell line without her knowledge. Similarly, Mrs X of Sweden was never informed that her aborted fetus was used to create WI-38 in 1962. Great pains were taken to hide this from her while regulators sought proof that she was healthy enough for the fetus’s cells to be used in vaccine production. Her medical record was eventually sent to US researchers without her consent.

It is now more commonly taught that research harming participants in any way is unacceptable, no matter how highly advantageous the results. The Vaccine Race continuously demonstrates what harm is possible under the silent pressure of conformity. In a field that is tasked with looking toward the future, it is imperative to also look to the past.

Reviewer: Elizabeth Schiavoni

Elizabeth Schiavoni, MS, is a Genetics, Genomics, and Bioinformatics graduate of the Jacobs School of Medicine and Biomedical Sciences and a Global Health graduate of Georgetown University. She is a freelance writer and editor in Buffalo, NY.

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Celebrating the work of the year past and the promise of the year to come, at the annual business meeting AMWA leaders shared reports, welcomed new officers, and opened the floor to members for a town hall.

**Business Meeting**

President Lori Alexander opened the business meeting with a recap of “an extraordinary year for AMWA.” The year’s major initiatives included the updating of AMWA’s governing documents and structure for consistency and compliance with state and federal laws, and implementing a new chapter affiliation agreement to define and support the relationship of the national organization and local chapters.

The initiative was an emotional one, Alexander acknowledged, and members’ responses “demonstrated their passion for AMWA and the community we serve,” she said, “and reaffirmed the shared responsibility that we have to further our mission and serve our members.”

Alexander thanked and recognized the chapter delegates who lent their voices to the governance document updates. She also recognized the executive committee, who “partnered with the AMWA staff and leveraged our combined strengths, knowledge, and relationships to guide the organization through an amazing year.”

Treasurer Julie Phelan gave the 2016-2017 financial report, reporting positive net income with significant investment gains (see Annual Financial Report on next page).

Alexander introduced the 2017-2018 Officer Candidates, who were selected by the nominating committee, approved by the Board of Directors in April, and, with no opposition, assumed their positions. Alexander passed the presidential gavel to President Kathy Spiegel as Spiegel assumed her new role. In return, Spiegel presented Alexander with a plaque and commemorative gavel for her service to AMWA.

In Spiegel’s inaugural address, she first announced the new Board of Directors (photo). She expressed her enthusiasm to work with the new board, and emphasized how seriously she took her new position: “You may never see this again, but I’m wearing a dress—and I’m not wearing Birkenstocks.” Spiegel also celebrated the success of the 2017 national conference and mentioned her excitement for the 2018 conference in Washington, DC.

Initiatives of past years will continue to shape AMWA’s coming years, Spiegel said, such as the 2014 strategic planning initiative and the updated governance structure. Members agree that local networks are valuable, she said. To empower members to organize such events, AMWA introduced “LNCs” (pronounced “links,” for local networking coordinators), who can be in areas with or without a formal chapter structure. Their introduction has already sparked higher activity in some regions, Spiegel said, adding a “plug” for volunteers to sign up as LNCs.

This past year, leaders also voted to streamline the Board of Directors from nearly 40 to 12-16 members, formed the Chapter Advisory Council to keep chapter voices strong, and committed to increasing the board’s diversity in medical writing expertise across employer settings and career levels, Spiegel said.

AMWA has also invested in new technologies, including the Engage online community and new AMWA website. This year’s Executive Committee goals, Spiegel shared, are to develop new educational offerings and member resources, including continuing education for more experienced members. “We’ve learned that developing online classes is neither easy nor cheap,” Spiegel laughed. “In fact, we have a lot to learn, but we are getting better and more efficient.” AMWA is improving its skills in creating these online tools, Spiegel said, so we can look forward to more such tools in the future.

As Spiegel closed this business meeting, she made a final call for volunteers—as LNCs, workshop leaders, subject matter experts—“If you have ideas, if you have time, please consider volunteering at the chapter or national level. Your contribution will really be valued.”

“With the support of the AMWA Board, the committees, the chapters, and all of you,” Spiegel said, “it will be a memorable and valuable one for all of us.”
Town Hall
After the business meeting, Spiegel invited her fellow Executive Committee members to join her as a panel and hear the questions and concerns of the organization. Jim Cozzarin moderated the session. Members raised the following topics.

Sustaining local engagement. Members expressed concern for starting and supporting local activities, especially in the wake of the chapter restructuring. Officers suggested the following:

- Volunteering as LNCs to encourage networking and engagement in areas without a formal structure.
- Encouraging those without a chapter to seek partnerships with other chapters to stay active.
- Taking for example the Florida chapter’s new engagement initiatives such as First Thursdays.

Resources for advanced writers. What is AMWA doing for members in mid-to-late careers? Spiegel indicated that expanding educational offerings for advanced writers is a central goal for the coming years, and she encouraged these seasoned members to volunteer as workshop leaders and share their expertise.

Gratitude for a friendly, welcoming conference. A new member expressed thanks and congratulations for an approachable, collaborative, and informative conference.

New selection process for the Board of Directors. The process starts with a call for interest in the positions. AMWA strives to have a Board that is representative of the organization’s membership, looking for diversity in geography, job setting, and expertise. The Nominating Committee reviews the candidate profiles from the interest forms, prepares a slate of elected officer nominees, and submits this slate to the Board for consideration. Once the slate of officers is approved by the Board, it is circulated to the AMWA membership. Nominees who are unopposed for office are declared automatically elected at the annual business meeting held during AMWA’s annual conference.

In the future, the Nominating Committee will also recommend the at-large Directors of the Board. Each at-large Director is nominated by the President-Elect and approved by the Board. All Board members take office after the election at the business meeting and serve for a term of 1 year or until their successors are appointed.

Katelyn Le, MS, is a medical writer at Leidos Biomedical Research, Inc. in Rockville, MD.

Author contact: kwernerle@gmail.com


By Julie L. Phelan, MD, MBA

It has been a pleasure serving as treasurer for AMWA over the past year, and I am pleased to provide this financial report for the fiscal year ending June 30, 2017.

AMWA began the fiscal year in a strong financial position and continued to invest in new initiatives, so members have access to valuable and timely education, resources, and member benefits.

We created a new AMWA website with the most compelling and relevant content, added a variety of online education programs to our portfolio, and launched a new Freelance Directory. We engaged local networking coordinators (LNCs, or “Links”) to initiate new local member activities, and now, more AMWA members are getting together to network and learn from each other. We secured a managing editor and an editor in chief for the AMWA Journal, and this flagship publication continues to be an important resource for our members. AMWA also expanded efforts to connect with a wider audience through the use of digital marketing and analytics.
Financial Performance
AMWA’s net income for the year was $176,106 with significant investment gains contributing to the results.

Revenues
AMWA’s program revenue for the fiscal year was $1,836,186. Membership, the annual conference, and education and certificate program income continue to be major sources of revenue, providing 91% of AMWA’s revenue for the year. Net investment income accounted for $181,525, representing 9% of AMWA’s total revenue for the year.

Expenses
AMWA invests in programs, products, and services that bring value to members and the medical writing community. Total program expenses for the fiscal year were $1,841,604 with 24% of the expenses going to produce the annual conference, 22% of expenses being used to fund member services and benefits, 10% of expenses funding the online education program, and 9% of expenses funding the certificate program.

Reserves
Reserves are the accumulation of funds over time that enable the organization to withstand an emergency or to invest in new programs. Unrestricted reserves of 6 to 12 months of annual operating expenses represent a standard target for not-for-profit organizations. With budgeted annual operating expenses of $2,007,900 for the fiscal year from July 1, 2017, to June 30, 2018, the target for AMWA’s reserves ranges from $1 million to $2 million. AMWA’s unrestricted short- and long-term investment reserve level of $1,547,740 on June 30, 2017, was within that targeted range.

AMWA’s restricted Endowment and McGovern funds totaled $174,363 and $148,566, respectively, as of June 30, 2017.

Financial Position
An organization’s financial position is reflected in its asset and liability holdings. AMWA is well positioned to pay its obligations and invest for the future. Total assets were $2,503,083 as of June 30, 2017, and the organization’s liabilities totaled $879,953.

Conclusion
Abercrombie and Associates, AMWA’s independent auditors, expressed an unqualified opinion regarding their audit of the financial statements for the fiscal year ending June 30, 2017. The full audit report is available to AMWA members upon request. An unqualified opinion states that the financial statements present fairly, in all material respects, an entity’s financial position, results of operations, and cash flows in conformity with generally accepted accounting principles. AMWA continues to be in a secure financial position as it continues expanding member benefits and resources into the next fiscal year.

Acknowledgments
Thanks to Calibre CPA Group PLLC for providing the financial data and to the members of the 2016-2017 Budget and Finance Committee for their review of reports and budgets: Kate Lothman, Alice Pappas, Judi Pepin, Kristina Wasson-Blader, Christine Wogan, and Jeanie Woodruff (and ex officio members Lori Alexander, Kathy Spiegel, and Susan Krug).

Author contact: Julie@biomedisysinc.com
Although by the calendar it has been a short time since I became president of AMWA, a lot has happened. Less than 2 weeks after our annual conference ended, President-Elect Cyndy Kryder and I attended an American Society of Association Executives meeting with our Executive Director Susan Krug and Deputy Director Shari Rager. It was an invigorating meeting with officers and executive staff of other non-profit associations, and we learned about association best practices and shared ideas. As experts in communication, albeit medical communication, we were surprised to learn more about how to communicate effectively, especially through email. The presenters also demonstrated some robust prioritizing activities.

A mere 2 weeks after the American Society of Association Executives meeting, I had the honor of chairing a CBI Medical Writers Summit in Philadelphia. AMWA was the association partner for the summit, and 2 directors-at-large from the AMWA Board of Directors (BOD), Theresa Singleton and Ann Winter-Vann, joined me at the meeting. Unlike AMWA’s Medical Writing & Communication Conference, the CBI Summit was a small day-and-a-half meeting of approximately 55 attendees, most of whom were mid- to advanced-career professionals. Our presence at the Summit stimulated interest in AMWA, from both current and former AMWA members, as well as from a few attendees who were new to medical communication. The final recap session led to an open discussion about AMWA and how attendees could volunteer for AMWA activities. We were encouraged with our reception, and we anticipate that our partnering with CBI on this event will lead to positive outcomes for AMWA.

I must admit that after the CBI Summit, I was looking forward to a quiet holiday season. That hope disappeared quickly with the publication on December 15, 2017, of a Washington Post article titled “CDC gets list of forbidden words: fetus, transgender, diversity.” Many organizations and medical journals rapidly published their responses, as the Centers for Disease Control and Prevention was still struggling to clarify the situation. Members of our BOD and our communications committee sprang into action and rapidly wrote and issued a statement in support of evidence-based medicine and clear communication and against censorship http://engage.amwa.org/blogs/american-medical-writers-association/2017/12/28/censorship-and-the-cdc-a-statement-from-the-amer. I was able to return to my holiday vacation with the knowledge that AMWA has a dedicated leadership and staff who were quickly able to investigate and issue a balanced statement supporting our values and our mission.

Finally, in January the 2017-2018 BOD held our first full face-to-face meeting at AMWA headquarters in Rockville, Maryland. As the BOD had already approved via teleconference the minutes from the meetings held during the annual conference in Orlando in November, we were able to immediately concentrate on setting our priorities for the year. AMWA leaders, whether at the board level, committee level, or chapter level, have almost limitless ideas of ways to increase AMWA’s value to members! Unfortunately, virtually every idea has an impact on our annual budget, which is not limitless. This brings me to my plea: please fill out or update your online profiles on the AMWA web site (https://www.amwa.org/page/ManageProfile_Custom). To most effectively serve our members, we need to know who you are. Over the past several years, we have based our programming decisions on data gathered through member profiles, as well as through member and conference attendee surveys. We are comforted by the fact that data collected through different surveys largely agree, but this could be just because we have a core of dedicated members who are diligent about responding to surveys. I am therefore asking each of you to go online and check your AMWA profiles. As those of you reading this may also belong to this core of dedicated members, please encourage your colleagues to do the same. Data-based decisions are only as good as the data they are based upon, and we want to make the best decisions possible. I thank you in advance!
The MWC Exam Is Coming to a Location Near You This June and December!

By David Clemow, PhD, MWC®
Chair, Medical Writing Certification Commission

The Medical Writing Certification Commission (Commission) is pleased to announce that the MWC Examination will now be administered via computer-based testing (CBT) at IQT testing centers (https://www.isoqualitytesting.com/locations.aspx) near major cities across the globe. Moving from paper-based testing to CBT will provide multiple improvements for MWC candidates that include well-controlled testing environments, local examination locations, and global testing locations, the latter of which will broaden the potential applicant pool to professional medical writers around the world. The MWC Examinations will be offered during 3-week testing windows in June and December:

**MWC Exam Dates: June 1-21, 2018**
- Application Deadline: April 23, 2018
- MWC Exam Registration Deadline: May 7, 2018

**MWC Exam Dates: December 1-21, 2018**
- Application Deadline: October 23, 2018
- MWC Exam Registration Deadline: November 7, 2018

The Commission recently enhanced the *MWC Examination Candidate Study Guide* and the *MWC Applicant and Candidate Handbook*. Study Guide enhancements include integration of the MWC Examination Content Outline, the newly developed Example Topic and Subtopic Categories, and the reworked Examination Preparation Recommendations. Additionally, the MWCC incorporated an amended list of Selected Examination Preparation Resources that is now categorized according to the core competencies (ie, the knowledge, skills, and abilities [KSAs]) that are assessed by the examination. These improvements are designed to clarify the topics that may be covered by the examination and make it easier for candidates to prepare for the examination and optimize their potential for success. Handbook updates include information regarding the new CBT delivery component and clarity regarding activities that constitute 2 years of paid medical writing experience.

For more information, visit the MWC web site: http://www.amwa.org/page/MWC.

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Swanberg Address continued from page 37

Just a few years into my AMWA membership, I was approached by Sue Dalton. Sue was currently DVC’s publicity chair, and she was ascending to the chapter presidency. Sue asked me if I would take over publicity. That’s where this, all of this, began. It was a kind and innocent invitation, and like choosing the path less taken, it has made all the difference.

Within a few years I was DVC chapter president, a role I not only never thought I would have but that I never thought I could do. After all, look at the people who had come before me with such knowledge and leadership ability. I had none of that, or so I thought. And if I had declined the invitation, my fear would have been realized, because knowledge and leadership ability are exactly what I have gained from these volunteer experiences.

Volunteering for AMWA is why I’ve been successful as a medical writer and as a freelance. Did I get clients? No. Did I get paid? No. I got confidence. Yes, I had some already from standing on stages and surviving Macy’s advertising department. But volunteering has given me a level of confidence I didn’t even know was possible for someone to have.

This confidence has enabled me to approach my life and my business without limits. Every day I walk into my office metaphorically wearing my green Teenage Mutant Ninja Turtles helmet and my swimming goggles, and I get to work. Is it perfect? No, I still fall down sometimes. But I’m persistent in my pursuit of perfection.

While I was teaching my daughters about the value of not being normal, they taught me a lesson, too. They taught me that as long as my family is okay, as long as no one’s bleeding, lost a limb, or in imminent danger, everything else will be okay, no matter how things seem at the moment. I’ll share with you another lesson my older daughter, Morgan, taught me when she was only about 10 years old. We were talking one day and she said something that I told her I had been thinking, too. I said to her what people commonly say in such situations: “Great minds think alike.” She looked at me with wide eyes and said in the most matter-of-fact tone, “No, daddy, great minds think for themselves.”

So this is where I am. A constant work in progress. It’s not the destination that matters, but the journey. Thank you for being an integral part of this wonderful journey I’m on and for the opportunity you have given me to find myself—for the moment, anyway. And especially, thank you for this great honor.
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