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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  
2018 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 again to devote this issue of the AMWA Journal to showcasing our conference content.

First, let me thank our volunteer reporters who attended and have provided brief reports of many of the open sessions presented this past November in Washington, DC. These brief reports are designed to share some basic information from each session so that those who could not attend 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 2019 conference, perhaps this glimpse into what you’re missing may help clarify your decision!

Claire L. Jarvis leads off our postconference content with an expanded report on the “Jam Session for Early-Career Freelances” with commentary from Freelance Forum contributors Brian Bass, Melissa Bogen, Sherri Bowen, Lori De Milto, and Cathryn D. Evans. Bart Harvey, MD, MSc, PhD, MEd, FRCP, FACPM, is the recipient of the 2018 Harold Swanberg Distinguished Service Award; his award address can be found on page 18. Next, we present several of our Open Session reports.

Additional postconference coverage can be found as an online-only supplement (https://www.amwa.org/page/Members_Only_Issues), including a presentation by Stacy Robison, MPH, MCHES, recipient of the John P. McGovern Award; additional Open Session reports; information from several of our exhibitors; and reproductions of our conference posters.

But that’s not all!

In addition to these postconference contributions, the print issue also contains a feature article in the Science Series section, as well as articles in the Around the Career Block, Statistically Speaking, and In the Service of Good Writing sections; and AMWA News ... including a report from the Annual Business Meeting, a report on AMWA’s Inaugural Medical Writing Executives Forum, an update on the Chapter Advisory Council, information about the AMWA Medical Communication Compensation Survey, and a message From the President by Cyndy Kryder.

But wait, there’s more!

I am pleased to announce that with this issue we will begin publishing open access abstracts with each of our feature-length articles. These abstracts can be accessed by members and nonmembers via our online Table of Contents on the Journal web page. If you are considering submitting a feature-length manuscript, please read the new abstract criteria in our Instructions to Contributors (www.amwa.org/contribute).

In closing, I hope you find this insight into the annual Medical Writing & Communication Conference to be of value. As you can see, if you missed it, you missed a lot! I hope to see you at the next conference in San Diego, California, later this year!

Yours in AMWA,
—Jim
ABSTRACT
The aging of the Baby Boomer generation and the general rise in life expectancy continue to expand the proportion of older adults (≥65 years of age) across global and US populations. As the adult years progress, so do the chances for a diagnosis of cancer. The need to determine whether evolving trends in cancer treatment benefit an aging population is vital. Immune checkpoint inhibitors (ICIs) represent a radically new approach in modern cancer treatment. They target the immune system instead of the disease and unleash the body’s natural defenses against tumor growth. ICIs are valued for their reduction in toxicity and superior treatment effect compared with many conventional therapies. Although clinical trial results show generally comparable efficacy and safety in younger and older populations, the proportion of older cancer trial participants does not accurately reflect the general population. This article describes the body’s cycle of immunity in combatting mutations and how ICIs can aid the most vulnerable aspect of that cycle. The article discusses the challenges and possible opportunities in an aging immune system, the immune-related side effects of ICIs, and the role of genomic biomarkers in predicting response to treatment. Regulators and activists are advocating for better representation of older patients in clinical trials; however, comprehensive investigation into the risks and benefits of immune-modulating therapies for this growing population is still needed.

Figure 1. Incidence of cancer diagnosis in the United States by age. Data are from the US Cancer Statistics Working Group.5
the median age for cancer diagnoses is 66 years,6 and by 2030, it is estimated that 70% of cancers will occur in those 65 and older.7 Given these trends, understanding how emerging cancer treatments benefit an older population becomes critical.

ENTER THE IMMUNE CHECKPOINT INHIBITORS
In recent years, breakthrough immunotherapies launched a flank attack in the seemingly endless war against cancer, and further developments are unfolding rapidly. Unlike chemotherapies that essentially assault all rapidly growing cells, and unlike targeted therapies (eg, tyrosine kinase inhibitors) that interrupt cellular signaling to restrict tumor growth,8 immunotherapies target the immune system instead of the disease.

Among the various attempts to fortify the immune system’s power against cancer, immune checkpoint inhibitors (ICIs) have gained the widest attention for improving efficacy and reducing toxicity. Direct-to-consumer advertisements now frequent American television, promoting KEYTRUDA (pembrolizumab) and OPDIVO (nivolumab) among other ICIs. Announcements of US Food and Drug Administration (FDA) approvals chime routinely across pharmaceutical and financial news for a litany of indications, from non–small cell lung cancer (NSCLC) to bladder cancer. In October 2018, immuno-oncology took center stage with the announcement of Drs James Allison and Tasuku Honjo being awarded the Nobel Prize in Physiology or Medicine “for their discovery of cancer therapy by inhibition of negative immune regulation.”9 A burly, blues-playing Texan, Allison developed the first approved ICI, cytotoxic T lymphocyte–associated antigen 4 (CTLA-4) monoclonal antibody. The approval of ipilimumab for advanced or metastatic melanoma initiated the cascade of later approvals, most of which sprang from Honju’s discovery of the programmed cell death protein type 1 (PD-1) and correlating ligand (PD-L1) checkpoint.

ICIs have raised the bar for oncology therapeutics, delivering previously unseen rates of long-term durable response and stability. However, their effect as monotherapies still reaches only a portion of patients, with clinical trial objective response rates typically running from 35% to 40%.10 Nevertheless, whether ICIs offer substantial promise for an aging population has not received focused investigation.

OLDER PATIENTS ARE UNDERREPRESENTED IN CLINICAL TRIALS
Historically, cancer trials have not enrolled older participants at levels reflecting comparable real-world demographics. In 2004, 36% of participants were ≥65 years old compared with 60% of those diagnosed (P < .001),11 yet this had improved from 25% compared with 63% (P < .001) in 1999.12 Common health complications in older patients can represent barriers to clinical trial enrollment. Furthermore, data from clinical trial participants ≥65 years of age may not mirror actual outcomes for the general population.13 Older adults not only exhibit wide-ranging differences due to genetic predisposition, environmental conditions, and lifestyle habits but also may present with various coexisting diseases, concomitant medications, or poorer performance status than their younger counterparts. Complications often include other disorders related to immune decline, such as infections and cardiovascular disease. Frequently, preexisting chronic conditions confound the early detection of cancers in older adults, often causing unfortunate diagnostic delays.

Research and advocacy groups have begun earnestly pursuing solutions to the disparity. The FDA and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) now warn against unjustified exclusions (eg, >75 years of age), once common.14,15 Recent recommendations from the American Society of Clinical Oncology and Friends of Cancer Research call for a loosening of eligibility criteria to allow prior or concurrent malignancies—as long as such provisions would not compromise safety and efficacy endpoints16; the American Society of Clinical Oncology also advocates for the inclusion of special subgroup analyses to better inform cancer management for older adults.15

IMMUNOSENESCENCE AND “INFLAMMAGING”
The traditional concept of immunosenescence considers immune aging as a progressive and unavoidable degeneration, associated with an increase in infections and autoimmune reactions. Over time, the production, cytotoxicity, and endurance of T cells lessen, and the power of the innate immune system declines.17 A characteristic low-level inflammation (“inflammaging”) resulting from decades of exposure to allergens, viruses, and other antigens induces greater concentrations of inflammatory cytokines. The normal shrinking of the thymus (from which T cells originate) in adulthood and its eventual transition into fatty tissue reduces the production of naive T cells in older adults.

An emerging perspective now challenges the conventional notion of immunosenescence, however.18,19 Some researchers advocate for distinguishing between normal immune aging and maladaptive immune aging and further suggest that the label immunosenescence be retired.20 This new view considers the possibility that immune aging may be more of a valuable adaptation than a blanket downfall. New data suggest that although immune changes do result in disease, they may work to extend survival and foster longevity when interpreted from an evolutionary context.17 Researchers in aging immunity from Stanford University investigating the differences between healthy and maladaptive immune aging summarize...
these changes as an evolutionary variation in homeostasis—“sometimes necessary and beneficial and sometimes harmful to the aging host.” Although “teaching old dogs new tricks” may become harder with the decline of naive T cells brought on by aging, evidence suggests that a healthy aging system may act to compensate for thymic involution and other age-related changes.19

THE PROTAGONIST IN THE CHECKPOINT STORY: THE T CELL
James Allison describes the intervention of ICIs as “unleashing” the immune system’s dynamic response to disease.22 Allison credits these advances not to a greater understanding of the disease process but to the in-depth investigation into the workings of T cells. Fifty years ago, the distinction of the T cells and the involvement of the thymus were still radical notions.23 Today, an elaborate understanding of the T cell’s mutable nature is still unfolding.24 From a naive state, T cells differentiate and diversify, adapting after each encounter with a new antigen. In this way, an “intelligence” develops, with some becoming memory T cells. Enabled by cytokine interleukin-7, they are equipped for future specialized combat. T cells can be categorized into 3 types:

• **Cytotoxic T cells (CD8+ T cells)** assault cancer cells, other pathogens (“non-self”), and damaged cells that could disrupt the balance of health.

• **Helper T cells (CD4+ T cells)** activate cytotoxic T cells and other lymphocytic functions.

• **Regulatory T cells** (Tregs; also called suppressor T cells) avert autoimmune abandon by suppressing immunity and protecting “self.”

THE CYCLE OF CANCER IMMUNITY: WHAT GOES WRONG AND HOW ICIs HELP
The role of the immune system is to maintain the body’s homeostasis, the workings of which some have compared with driving a car. To maintain control, the driver applies the gas and brake pedals in a complex interchange in response to road conditions. Likewise, not only must the immune system mount attacks to keep pace with any new mutations or other malignant antigens, but it must also suppress autoimmune momentum to avoid damaging the body. The “brakes” of the process, the immune checkpoints, are the vulnerable aspect of the cancer-immunity cycle (Figure 2).25 Cancer cells can bypass these regulatory pathways, flying under the surveillance radar by passing as self instead of non-self.

As part of an intricate exchange between the innate and adaptive processes to search for and destroy tumor cells (immunosurveillance), the primed T cell then divides, proliferates, and disperses a trained T-cell brigade into the bloodstream to patrol for and eliminate the tumor cells. At this point, tumor cells may enter into immune-editing, co-opting the mechanism that protects against autoimmune assault. Once tumor cells evade elimination, they can remain seemingly dormant (in equilibrium), meanwhile mutating to circumvent the impediment and develop neoantigens.26 Tumor cells may then escape from the immune battlegrounds altogether, resulting in metastasis or recurrence. ICIs can reverse this corruption by
disengaging the brakes and keeping receptors and ligands that
work to suppress immunity from binding together.27

The currently approved ICIs work by blocking 1 of 2 check-
point pathways (Figure 3) that connect T-cell receptors to cor-
responding tumor-antigen ligands. The pathway where CTLA-4
binds to the B7 ligands (CD80, CD86) impedes immunity early
in the process (eg, within the lymph nodes, lower right of
Figure 3). The PD-1/PD-L1 checkpoint applies the brakes later
in peripheral areas (eg, where solid tumor is located, lower
left of Figure 3). At least 23 other inhibitory and stimulatory
immune pathways are currently being investigated in approxi-
mately 95 early-phase trials.28

IMMUNE-RELATED ADVERSE EVENTS
Compared with the predictable and intense severity of che-
motherapy toxicities, the generally reduced toxicity of ICI
therapeutics is a welcome relief for many. The side effects of
chemotherapy often interfere with the completion of adequate
treatment for older patients, because of treatment discontinu-
ation and reduced dosage to avoid the effects.29 Nonetheless,
ICIs can have unwelcome side effects and can occasionally be
severe and even deadly (<1% across ICIs).20,31 Immune-related
adverse events (irAEs) are primarily inflammatory reactions
triggered by immune stimulation but can affect any organ
system. Manifestations involve the skin (eg, itching and rash),
eyes, intestines (eg, diarrhea, colitis), lungs (eg, interstitial
pneumonitis), endocrine systems (eg, thyroid, adrenal), and
nerves (eg, peripheral neuropathy), among other organ sys-
tems.32 Life-threatening toxicities have included pneumoni-
tis, colitis, and pancreatitis.33 A meta-analysis that included
>11,000 patients in 73 ICI trials found irAEs of any grade to be
considerably higher in patients receiving CTLA-4 treatment
(53.8%) compared with PD-1
(26.5%) and PD-L1 treatments
(17.1%) (P < .001).28 Although
patients with preexisting auto-
nimmune disorders are predict-
ably vulnerable to irAEs, even
grade 3 and 4 irAEs prove to be
manageable with immune-sup-
pressive treatment (eg, cortico-
steroids).34,35

ICIs are generally consid-
edered to be as well tolerated in
older patients as in younger
patients.12,35 Nonetheless, an
understanding of pharmacody-
namic effect and toxicity of ICIs
in older patients is not yet solid,
primarily because of the contin-
ued underrepresentation of that
population in clinical trials and
possibly because of suboptimal
reporting.28 For those >75 years
of age, the literature conflicts on
rates of toxicity.34,36,37 Clinical
care for older patients receiving
ICIs will likely necessitate closer
monitoring than standard pro-
cedures: for instance, watching
for dehydration and renal insuf-
ciency with an irAE of diarrhea
and watching for an increased
risk of bone fracture with
extended corticosteroid use.
KNOWN EFFICACY FOR OLDER PATIENTS

In general, clinical trials of ICIs find comparable effects in older and younger populations. A 2016 meta-analysis compared ICI efficacy between younger (<65 years) and older patients (65 years to 75 years). The subanalysis of overall survival (OS) that included 4,725 patients found the survival benefit with ICIs to be consistently superior to that of controls, regardless of age (hazard ratio [HR] = 0.75, 95% confidence interval [CI] = 0.68 to 0.82; P < .001 for younger patients and HR = 0.73, 95% CI = 0.62 to 0.87; P < .001 for the older group). In those >75 years of age, the OS benefit was not significant and in some studies was not superior to that of standard treatments. Although many researchers agree that insufficient statistical power could be more responsible than age for the reduced benefit in the oldest group, most speculate that the influence of ICIs may weaken in older adults. Nonetheless, although new cancer diagnoses in patients >75 years make up >25% of new cancer cases, this population is dramatically underrepresented in clinical trials.

Investigational combinations of ICIs with radiation therapy, chemotheraphy, tyrosine kinase inhibitors, and other immunotherapies are being studied. Combination ICI therapy, using nivolumab with low-dose ipilimumab, received FDA approval in July 2018 for the treatment of colorectal cancer with specific genetic markers. Although the combination proves superior to nivolumab alone for patients <65 years of age, the combination elicits more severe toxicities for all populations and provides mixed results in progression-free survival and OS for older-aged subgroups.

WHAT’S OLD IS NEW

A recent translational study from the Wistar Institute in Philadelphia investigated responses to anti–PD-1 therapy associated with the aged tumor microenvironment of patients with melanoma. Using regression analysis, the team estimated that patients >60 respond to anti–PD-1 more efficiently than younger patients, with a probability of progression decreasing 13% for each decade of life for patients treated with pembrolizumab. Their hypothesis pointed to the depletion of Tregs resulting from immune aging as the cause. Because Tregs suppress CD8+ T-cell proliferation, a lower ratio of Tregs to CD8+ T cells within tumor tissue, when combined with anti–PD-1 therapy, may allow the body to “step on the gas” against tumor, without having to counteract the brakes at the same time. The authors propose that such results may inform future approaches to improve the efficacy of anti–PD-1 therapy in younger patients by depleting Tregs within the tumor microenvironment before the start of anti–PD-1 treatment. Further research is needed, and the full results from the Wistar study’s long-term OS analysis are awaited.

GENOMIC BIOMARKERS GIVE INSIGHTS INTO PREDICTING EFFECT

Why some patients respond well with ICIs and others do not motivates researchers to investigate which proteins might indicate treatment effect. Predictive biomarkers represent a major advance toward precision or “personalized” therapies. Most anti–PD-1 monoclonal antibody approvals specify treatment for those with higher tumor expression of PD-L1 as determined by genetic profiling, with thresholds of both ≥1% and ≥50% (based on the statistical significance and current manual immunohistochemical methods). The summer of 2017 saw a radical change in oncology therapeutic approvals when the FDA approved pembrolizumab based not on the original location of the tumor but on the expression of a genetic biomarker (ie, microsatellite instability–high or mismatch repair deficiency [MMRd] genetic marker). These are mutated proteins in some solid tumors picked up by immunohistochemical testing.

Tumor mutational burden (TMB), which measures the number of somatic (acquired) mutations present within tumor tissue, may not only be a more accurate biomarker than PD-L1 but could also shed light on the efficacy of ICIs in older patients. Many common solid tumors express a high TMB (eg, melanoma, squamous cell NSCLC, small-cell lung cancer, urothelial cancers, and MMRd-positive cancers). Researchers believe that high-TMB tumors harbor neoantigens that can be readily targeted by activated T cells. A 2017 meta-analysis evaluating 27 cancer types showed a clear and significant correlation between TMB and objective response rate for anti–PD-1/PD-L1 therapeutics, regardless of PD-L1 expression (P < .001, Figure 4). Another systematic review highlighted 150 patients treated with ICI monotherapies whose tumors expressed various somatic mutations on next-generation sequencing. Patients with high-TMB tumors (≥20 mutations per megabase) had nearly 3-times-higher response rates than those with low to intermediate TMB levels (58% compared with 20%, P = .0001), corresponding to progression-free survival (HR = 0.34; 95% CI = 0.23 to 0.50) and OS (HR = 0.33, 95% CI = 0.19 to 0.58). These results correlated to genomic profiling of >100,000 patient tumors from >500 distinct cancer types, revealing significantly increased TMB levels associated with advanced age (P < 1 × 10−36).

CONCLUSION

Researchers agree that immune-oncology is still in its infancy, yet the advent of ICIs has woken science to the vital role of the immune system in eradicating tumors. Many discoveries in the nuances of lymphocytic signaling, prognostic and predictive biomarkers, and the workings of tumor microenvironment sprang from the last decade of research in ICIs and other dawning immunotherapies such as adoptive T cell...
transfers and cancer vaccines. Moreover, endeavors in immunotherapies have shed new light on the importance of a healthy and diverse gut biome, the awareness of which could spur better public health. However, these signals of progress do come with high financial costs, as the development of ICIs has garnered tremendous resources, prompting concerns that commercial competition for the ICI market has driven costs irresponsibly skyward. Reuters reported in 2017 that anti–PD-1 therapy, the medicine alone, cost on average $13,000 per month.49 Surely this equates to a burden on seniors, Medicare, and resources for other critical research.

As the population ages, health care professionals must increasingly address the distinct needs of older cancer patients. Dr Harvey Cohen from the Center for Aging and Human Development at Duke University commented, “Given the demographic trends, one might say that all oncologists need to become geriatric oncologists.”50 Although evidence regarding the effect of ICIs on older patients is still limited, efforts to mirror real-world demographics within clinical trial populations are improving the gap. Moreover, there are hopes that enhanced collection and analysis of real-world data and the trend to integrate real-world evidence into product labeling and post-marketing activities of novel therapeutics may fortify our understanding of the efficacy and safety of ICIs for older patients. Nonetheless, advocates agree, much more work is needed.15

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Figure 4. Tumor mutational burden across tumor types measuring responsiveness to anti–PD–1/PD–L1 therapies. Median number of coding somatic mutations per MB of DNA in 27 tumor types or subtypes among patients who received inhibitors of PD–1 protein or its ligand (PD–L1). Data on the x axis are shown on a logarithmic scale. MB, megabase; MMRd, mismatch repair deficiency; MMRp, mismatch repair proficiency; NSCLC, non–small cell lung cancer; PD–1, programmed cell death protein type 1; PD–L1, programmed cell death ligand type 1. From the New England Journal of Medicine, Yarchoan M, Hopkins A, Jaffee EM, Tumor Mutational Burden and Response Rate to PD–1 Inhibition, 377, 2500–2501. ©2017 Massachusetts Medical Society.45 Reprinted with permission.

References
Cytotoxic T lymphocyte–associated antigen 4 (CTLA-4)—This protein receptor binds to CD80 and CD86 (2 of the manifold corresponding target, and adaptive immunosuppression begins.

CTLA-4

Programmed cell death protein type 1 (PD-1)—When bound to its ligand (PD-L1), this receptor protein on cytotoxic T cells applies the “brakes,” keeping the immune system from destroying healthy cells.

T cells—Functioning primarily within the adaptive immune system, T cells originate as progenitor cells in bone marrow and mature in the thymus (thus the T).

Tumor mutational burden (TMB)—A biomarker that measures the number of mutations expressed by a specific tumor.

Regulatory T cells (Tregs; also called suppressor T cells)—These T cells moderate the function of other types of lymphocytes to maintain homeostasis.


In keeping with the theme of this issue, several of our Freelance Forum contributors—Brian Bass, Melissa Bogen, Sherri Bowen, Lori De Milto, and Cathryn D. Evans—have provided their own unique insights into topics raised.

Moderators
Andrea R. Gwosdow, PhD, President, Gwosdow Associates Science Consultants, LLC, Arlington, MA
Theresa E. Singleton, PhD, Owner and Principal Scientific Writer, Singleton Science, LLC, Beverly, MA

Fifty attendees came to AMWA’s inaugural “Jam Session for Early-Career Freelances.” Approximately one-fifth of the room was considering a move into freelance medical writing; the rest had up to 6 years of experience running their own writing business. Andrea Gwosdow, PhD and Theresa Singleton, PhD moderated the energetic discussion, sharing advice from their many years as successful business owners. They encouraged all attendees to ask questions (and they did!) on many topics, which are summarized below. Members of the Freelance Forum have joined virtually to add their comments (indented) to the topics that were discussed.

Money and Paper
What to Do About Health Insurance?
The first issue raised by session attendees concerned finding health insurance. Some freelances in the room were covered by their spouse’s insurance or lived in a state such as Massachusetts where there were plenty of plans. However, other attendees lived in states with few satisfactory or affordable federal health care plans for self-employed residents.

**BB:** Health insurance is evil, but you have to have it. When I started my business in 1989, I was paying about $750 a month for what was at the time a fantastic “group of 1” fee-for-service family plan with two $250 deductibles and a maximum annual out-of-pocket (OOP) limit of $2,500. It covered our family of 4. Today I’m paying about $1,100 per month for a health maintenance organization (HMO) plan with a $6,200 deductible and a $7,900 annual OOP ... and it covers only me! I sympathize with people who live in states with limited insurance choices. Having lived in New Jersey, and now Florida, I’ve only ever really had 2 to choose from—bad and worse.

**MB:** Several years back, I joined the Freelancers Union (https://www.freelancersunion.org/), which is free to join, because they offer health insurance throughout the United States. When the rates went up, I began buying my health insurance through the NY State of Health Marketplace (https://nystateofhealth.ny.gov/). For 2019, single coverage in the plan I selected costs me $487.50 per month.

**CDE:** I have not had success in finding a group health insurance policy; thus, I have always paid as a single member with Anthem Blue Cross. Yes, it is expensive—absurdly so given how little I utilize the system—but it is part of the cost of doing business, and really, the cost of living in the US.

What Counts as a Business Expense?
As business owners, freelances know that a lot of their “everyday” expenses could be listed as business expenses for the purpose of tax deductions, but it wasn’t always clear what should be recorded as a business expense. Seasoned freelances in the room discussed the different ways to track expenses and make the process of filing tax returns easy.

**BB:** I use QuickBooks for all my company’s finances, which makes it incredibly fast and easy to generate reports for my quarterly meetings with my accountant. At the end of the year, the tax return is a snap. Here are a few of the things I charge to my company as a business expense:
• Travel for business—planes, trains, automobiles (ie, mileage), hotels, Internet, taxis, parking, tolls, and meals
• Expenses related directly to projects—references, shipping
• Office supplies and equipment—paper, pens, toner, computers, monitors, printers, software, cell phone, landline, and phone
• Dues and subscriptions—newspapers, magazines, journals, my AMWA membership, my AMWA Freelance Directory listing
• Gifts—items I send to those I work with to say thanks at the end of the year

I use a business credit card for all business-related expenses. It’s a bad idea to mix the finances of your personal and professional life, even though, ultimately, unless you’re a C-Corp, all your company’s income flows through to your personal tax return.

MB: I send my receipts to Shoeboxed (https://www.shoeboxed.com/), where they scan them into PDFs. I can categorize the receipts and create expense reports and Excel reports. The Excel reports make it easy for me to prepare info for my accountant.

CDE: First, let me say that I pay many of my expenses with Visa/Mastercard whenever possible, so there is a permanent record, and I always keep receipts for anything paid in cash. I have a bookkeeper who handles QuickBooks, and she separates out relevant items from credit card statements. I do not track expenses electronically because it’s so easy to keep receipts and seems faster to me. You have to check your credit card statement every month anyway, so I just write in what each charge is for (eg, supplies, entertainment, educational expense, books). The bookkeeper inserts each expense into its appropriate category at various points during the year (eg, bimonthly or quarterly).

Most expenses that support your business are tax deductible.

The cost of office space is deductible, of course. If you work at home, the area used as an office is tax deductible as long as you’re not employed elsewhere as well. Your accountant will calculate the appropriate percentage of your rent or mortgage that you can claim. (Note that the guest bedroom used as office space is not okay; the office space must be 100% dedicated to your business.) All office supplies, reference books, subscriptions, and computer programs are tax deductible. Client gifts and their shipping costs are deductible expenses (eg, a box of chocolates for Christmas), as would be Christmas cards if you send them to clients.

Office equipment is tax deductible (either directly or by depreciation), and there are times when buying equipment saves you more in taxes than the actual cost of purchase. Aside from your computer(s), equipment like printers, copiers, recorders, and transcribers are tax deductible. Your iPad and iPhone also can be tax deductible depending on how you use them—as well as a video camera (in addition to your iPhone). Office furniture is also an expense to be deducted.

There are also some often-overlooked deductible expenses. For example, if you’re a writer (depending on the type of work you actually do and can prove you do), any purchased book or published material on any topic could be tax deductible. Travel to a health spa may be deductible, for instance, if you write an article about the experience. If you write scripts and/or produce videos, the purchase or rental of DVDs and music CDs might be deductible.

Most lectures, classes, and webinars (not just AMWA or DIA) are deductible if you deem them related to your business. Travel connected with professional education is usually deductible, as are substantial portions of your automobile and entertainment expenses.

NOTE: It is important to consider all your expenses carefully and discuss them with your accountant to determine whether or not they qualify as business deductions for you. Be aggressive about tax deductions. As long as it’s legal and you can document the expense, you can take the deduction—and you are entitled to it.

Creating Contracts

A good business contract protects freelances from unscrupulous clients and provides guidance to both parties in the case of unforeseen events during the project. A bad business contract can trap the freelance in an unfavorable agreement. New freelances wanted to know what information they should include in their new contracts, as well as what they should do if they noticed problematic clauses in a contract their prospective client sent them.

BB: The most effective contracts are the simplest. That’s why I use the simplest contract of all—none. When a client comes to me with a project, I take all their input about the scope of work and the deliverable and articulate it back to them concisely in my project estimate. This way there’s no question about what’s being done, what it’s going to cost, and how and when it’s going to be invoiced.

When I email the estimate to my client, I ask them in my cover note to let me know if they have any questions and whether I have their approval to proceed. When I receive their written okay, I effectively have a contract. No pages of gobbledygook and mumbo jumbo that lawyers can spend thousands of my dollars interpreting and arguing about. Many of my clients have contracts, but they’re more specific to the working relationship than to a particular project. These contracts include master service agreements (MSAs), nondisclosure agreements (NDAs), and confidentiality agreements (MCAs).
agreements (CAs). I rarely sign them without requesting changes—but the range of things I look for and the changes I seek to make are too detailed to go into here. Some clients occasionally send me a statement of work (SOW), which is project specific. The nice thing is, my estimates are so detailed that my clients typically copy and paste my language from my estimate into their SOW, which makes agreeing to it a snap.

**MB:** 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. I have had success in getting the time shortened in the contract.

**SB:** I disagree that a “good” business contract (and define “good”?)—or ANY contract at all—“protects freelances from unscrupulous clients” (and how do you determine that a client is “unscrupulous”?). In my experience, most contracts are vague in wording and don’t have clauses specifying contingencies/actions based on potential major blow-ups—things like unexpected changes in scope or delays in providing accurate source materials (and accompanying changes in timelines). In my opinion, the most important clause in any contract is a “reciprocal indemnification” clause, which basically protects both freelance and client from any responsibility for litigation brought upon either party from a third party. (Disclaimer: I am not a lawyer, so this may not be the exact definition of “indemnification,” but most contracts I have received have only had a one-way indemnification clause, favoring the client. From a very scary personal experience, a “reciprocal” indemnification clause is a MUST HAVE in my contracts now.)

Because contracts don’t usually have detailed project specifics, I usually prepare a “project expectations and assumptions” document, which is often a part of formal proposals or estimates I give. Although some clients have pasted this text from me into the formal contract, this has been rare. While probably not legally binding, my “project expectations and assumptions” document IS a written document outlining my understanding of the project scope, what the client is responsible for/will provide, what I will be responsible for/will provide, and what assumptions/caveats I have based on currently known information. I always say in this document that any changes to what I have outlined must be submitted to me in writing or that otherwise I will proceed with the project (with caveats/assumptions) as stated. In my 25+ years of freelancing, no client has ever submitted to me any written changes to this document of mine. Regardless, such a document is good to produce and send to your client as early on in a project as possible (and to revise, as necessary, should the scope unexpectedly change later).

**CDE:** A contract can be a simple letter of agreement written by you or the client or a lengthy document spelling out every move and expense. There’s no hard rule about what it should include. The most important points are

- A clear description of the product or service you will provide
- An outline of the project (included in or attached to the contract)
- Specification of background material to be used
- Due dates for the first draft for the client’s review and return for revisions/completion
- Number and extent of revisions you will provide
- If the fee is fixed, the specification of the fee that will be charged and everything the fee includes—and, equally IMPORTANT, what that fee does NOT include
- If the fee is hourly, the specification of the hourly rate (including a maximum number of hours, or “ceiling,” if appropriate)
- Provision for reimbursement for OOP expenses
- Payment schedule
- Provision for a late fee if the payment schedule is not honored
- Provision for a kill fee (early termination penalty) if the project is canceled
- Copyright assignment (Try to tie it in with payment, so YOU own copyright until all bills have been paid, after which THEY own all rights. This means they cannot use any material written by you until your bills have been paid.)
- If you are not a bylined author or a declared “expert” in the medical field, the limits of your liability for content belong solely to the client. However, if you are a physician or claim other medical/therapeutic/statistical expertise, then of course you will need to accept liability for the content produced by you. Make sure to include a section of the contract that states you are free of any liability for medical content. Especially with a pharma/biotech/contract research organization (CRO)/hospital/HMO client, the company is 100% liable for content, as they select and/or provide all background material and they always have final say on the end product (unless you have specifically agreed otherwise!). Try not to pay the high cost of liability insurance when it is not actually necessary. Consult your attorney if you need clarification and ask him/her to give you the correct wording to put in the contract, if you need assistance. Some years ago, the AMWA Journal published “sample contracts” from me as well as a few other members.
People and Payments

Transitioning into Freelance Medical Writing

For those in the room who hadn’t yet made the jump into freelancing, a recurrent question was “How do you know you’re ready to take your first job?” For new freelances who had never run their own business, the jump into self-employment seemed daunting. Session attendees worried about taking on projects they were unprepared for and didn’t want missteps to jeopardize their career.

BB: Knowing when it’s time to make the leap into freelancing full-time is like knowing when to swallow a mouthful of shredded coconut—you’re never really done chewing, and it’s never really ready to swallow. Yet some people know it. I knew it. I had worked for small companies for all of my career to that point. Big companies, to my dismay at the time (but to my advantage ultimately), never had an interest in hiring me. After watching yet another great and talented boss bury his company because he had no business sense, I realized I couldn’t go to work for another one. Yet I also couldn’t bark again up the big company tree. So, starting my own business was the only option. So far it’s worked out pretty well.

Yes, it’s daunting to leave the supposed security of a regular paycheck and benefits for the seeming uncertainty of freelancing. But I have several friends who have found themselves out of work in their late 50s and early 60s due to outsourcing or downsizing (or as the investors who win big on downsizing like to call it, “right-sizing”). They’re discovering there aren’t many options for them to continue earning what they’re used to. In that sense, I’ve been “out of work” every day since August 19, 1989. I’ve just been too busy working to notice. And the good thing is, I’m not likely to fire myself. (Spoiler alert: Sometimes my boss is a jerk!)

MB: I suggest starting slow while still working in your other career. I was working as an in-house journals production supervisor and took freelance editing gigs to work on at night and on weekends. One of the freelance editors I was supervising referred me to my first client, and I eventually made the leap when my commute (to my next in-house job) became too long.

When I started full-time freelance editing, I had the good fortune of having a domestic partner who had a full-time job with a steady income. His weekly income helped during the erratic start-up months and while I became used to the 30-day delay in payments.

As far as taking projects you are unprepared for, begin by accepting projects that you know you can handle, usually the kinds of projects you have done before. It helps to create some successes for yourself, so take easy projects with generous deadlines.

The most important misstep to avoid is missing deadlines. At the outset of each project, I confirm the deadline or ask for more time if I need it. It’s important to alert clients if a deadline is unrealistic. I send periodic emails while working on the project to provide a status report.

LD: It’s so much easier to start a freelance business today than it was when I was starting out in 1997. You can easily learn how to set up and manage your business online, through free resources and books and online courses. Building a strong network of other freelances will also help you learn what to do and what not to do. More experienced freelances are a great source of advice and can help you troubleshoot problems.

But no matter how well you prepare, you’ll still face obstacles and make mistakes. They’re part of running any business. If you believe in yourself and are willing to take risks, you’re ready. If you don’t, freelancing probably isn’t the right choice for you.

CDE: A freelance medical writer already should have extensive experience as a medical writer in an employed or other capacity before freelancing. Even a physician or experienced PhD scientist should have written articles for him/herself and published them somewhere before trying to get paid by a client to do professional medical writing. (Unless you choose to do the project “on spec” and receive payment only if the work is up to standard and the client is happy with it. This is not something I recommend unless you really are desperate because you can always write things you like for your local paper, thus acquiring experience and samples.)

Never lie to a client about your experience. If you have never done a sales training project or a clinical study report, for instance, do not claim that you have. If they want someone with specific oncology or cardiology experience and you don’t have this, say so.
Finding Your First Clients

Although some session attendees had begun their freelance medical writing career after being approached by a prospective client, others approached prospective clients first. A freelance’s first client could be a colleague or connection, or they could be an unknown cold caller. Finding those first clients before you have much experience is the biggest hurdle most medical writing freelances face when getting started. How do you search for and approach prospective clients?

BB: Without a doubt, the best way to launch your freelance business is by leveraging relationships and opportunities that already exist. If you’re really good at what you do, people who know you will be glad when you start freelancing because now they can hire you to do it for them. I know a lot of freelancers who have actually started by freelancing for the company they just left to start their business. Personally, I think that can be potentially limiting to your income because the company knows what they were paying you and they won’t appreciate having to pay you a lot more. In my opinion, cold calling doesn’t really work. You have to kiss a lot of frogs. I prefer making clients want to cold call me. Say what? Yes, you read that right. (Warning: I’m about to get on my AMWA soapbox.) I attribute a great deal of my success to my years of volunteering for AMWA. Working as a volunteer leader for my chapter and at the national level not only gave me tremendous experience and confidence, but it also gave me great visibility. Combine that with presenting live at chapter and national conferences, writing articles for the AMWA Journal, and giving webinars. Then add my various social media activities. In addition to building me into the professional I am today, all of this has also built my reputation as a professional medical writer. That, in turn, has built my business.

MB: The annual AMWA conferences provide great opportunities to network in an environment that hardly feels like “networking.” At each conference, I’ve gotten job leads by chatting with as many people as possible, not necessarily about work. Becoming active by volunteering and building relationships within AMWA has led to many work referrals. People who get to know you and your work will feel more confident about recommending you or using you themselves. Besides networking, I use 2 tactics for finding prospective clients: job lists and LinkedIn. My LinkedIn profile attracts clients who approach me, but I also read LinkedIn posts and find prospective clients to contact.

LD: If you’re a new freelance, you probably have a lot more experience than you think you do. Medical writing that you’ve done in a job or in school is experience. Networking is the easiest way to get your first client. But you need to have or build a strong network where people trust you before they’ll give you referrals or work and before you can ask for referrals. Building a strong network takes time. Another effective method for getting clients is direct email. This involves developing a list of the clients you want to work with and crafting a customized direct email for each client. Each direct email must show that you understand what the client needs and can help the client meet those needs.

CDE: If you are an experienced medical writer, you already have many contacts in the health care field, including prior employers, coworkers, people you met at conventions, etc., so call or send them a resume to let them know you are now self-employed as a freelance medical writer. Ask them for projects, and if they do not have any, ask them to pass along your resume and to give you the names of others they know who might have work for you. Have a website/LinkedIn page listed on your business card or other printed marketing tools. Network with everyone you know in any field to tell them what you are doing, as they may know others in the health care field.

Do not be shy about making cold calls—just be sure you have planned the call, scripted yourself, and are prepared to answer questions about your background and experience and why this person should retain you for a project.

Do not try to get assignments in areas unfamiliar to you. Stick with what you know and have done in the past. Not only is this judicious for a new freelance, but it enables you to estimate jobs properly because you have done specific types of projects in the past. Later, when you have more experience as a self-employed freelance writer/communicator, you can expand more easily into other areas.

As mentioned above, take the SCORE workshop on starting your business and also take the one on marketing your business—it’s a great experience, and you get to meet more people with whom you can network!
Raising Your Rates
Freelances do not always feel comfortable raising rates with existing clients, even when it becomes a necessity. How often should freelances raise their rates? How do you inform your existing clients that your business rates are going up without losing them as clients? Perspectives within the room differed: some freelances consistently raised their rates every couple of years; others raised their rates with new clients and gradually phased out the older clients on lower rates.

BB: By charging by the project instead of by the hour, page, or word, I never seek to raise my rates. I look for opportunities to raise my income, and I do that every day, with every project. There are 2 tricks to this, although they really aren't very tricky at all.

The first trick is working on me. How can I work more efficiently, more effectively? What mistakes do I make that slow me down and how can I avoid them? Simply put, I'm continuously working at being better at what I do. Even if I do a project today for the same amount of money I did it for a year ago, if I can do it faster now, I make more money. Then I use the extra time to do more work, effectively raising my income without raising my rate.

The second trick is working on my estimates. I evaluate every project after the fact to see exactly how profitable it was. If it was really profitable, I analyze why it was so profitable and look for opportunities to do more of those types of projects. If it wasn't very profitable, I analyze what went wrong. Did I estimate too low? Did I let myself get duped by project creep? Did I make a mistake? Or was there a circumstance beyond my control that turned an otherwise profitable project into a not-so-profitable one? With this knowledge, I can correct, adjust, or fine-tune to make the project more profitable the next time, or I learn to avoid similar projects in the future.

MB: Here is a template for an email on raising rates:
Effective April 1, 2019, my hourly fee for editing will be $XXX. I hope that <your company> will still be able to use my services at this new rate as I especially enjoy working <with you, on project X, etc>. Please confirm this rate change is OK.

SB: I raise my rates with long-time (3+ years) clients pretty rarely (at least consider asking for an increase at the 3-year mark) and try to institute it at either calendar year time or contract renewal time. Almost never (well, actually never) has any client refused a request from me for a rate increase. I've never had to justify a rate increase (although I could if I had to, and I've used the AMWA Salary Survey before if questioned about an initially proposed rate). But it's true that having a "base" hourly rate has been important to me to offer to new clients, and if those new clients say my rate is too high, I have actually said (politely, I hope) that this is the rate I'm getting from existing or other new clients, so if you'd like me to work for you, this rate is nonnegotiable. (I have to admit that I don't feel sad if those new clients say "we can't afford you.")

LD: When I raise my rates, I do this at the beginning of the New Year. I just use the new rates on my invoices. This is the way the vendors I worked with raised their rates when I managed communications for Temple University's business school before I launched my freelance business. If I have a client who is sensitive to costs, I let them know about the rate increase before I work on my first job that year.

As a new freelance, you'll probably be doing work for at least some lower-paying clients at first. These clients probably won't pay higher rates, so you'll have to phase them out as you get more experience. Start new clients at the "regular" rate for the type of medical writing. The AMWA Salary Survey and networking with other freelances will help you figure out what to charge.

CDE: Raise your rates when you feel you are no longer in the ballpark compared with others in the field. I have both raised and lowered rates, for instance, depending on the project and the client. If you want to get rid of a client, definitely raise your rate 25% or more so that he or she will go away without you having to fire him/her. If you love the client, speak frankly about the $$ and ask them to accept a rate increase of 10% to 20%, keeping in mind that you can always vary your rates depending on the client as well as the type of project. If you love a client and he or she cannot pay an increased rate, see if you can get a higher volume of work or if he or she will refer you to others so you can acquire additional work (at the higher rate). Please feel free to contact me personally at evans-cathryn@aol.com if you have further questions about this.

At the end of the session, Andrea noted that “a key learning objective of the session was to make connections with peers who can serve as a resource after the conference.” Andrea and Theresa hope the “Jam Session” accomplished this goal.

To work toward that goal, Andrea and Theresa encouraged the participants to stay to network and find a “buddy” they could connect with throughout the year. “Having a business buddy to connect with when I have a business question throughout the year has been very helpful to me and to the growth of my freelance business,” said Andrea.

We hope some of the freelances who asked questions will return to the “Jam Session for Early-Career Freelancers” next year to share their wisdom with the newest crop of writers!

Claire Jarvis is a freelance in Atlanta, Georgia.

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Good afternoon. It is humbling to have been given the honor of receiving this year's award and to deliver this year's Swanberg Award Address. Please indulge me as I take this opportunity to focus on the award's namesake and share with you what I have learned about William Harold Swanberg, Sr. During my presentation, I will start by telling you a little about this year's award recipient (me) and then tell you about us (the current 66 Swanberg Award recipients), but mostly I will tell you what I have learned about Dr Swanberg, the award's inaugural recipient and, since 1962, the award's namesake.

My association with AMWA began in 1994, while I was in the midst of writing my doctoral dissertation in epidemiology. During a meeting with one of my thesis supervisors, I was asked about my education and understanding of grammar and other aspects relevant to effective writing. I admitted that I was much more of a classical maths and sciences student. With her suspicions confirmed, in a lovely motherly but assertive way, she spoke to me about the writing challenges that were evident in drafts of my dissertation. Not long after that "tutorial" with my supervisor, I was reading the current issue of the American Journal of Epidemiology (every science discipline has a blue journal, and for epidemiology it's the American Journal of Epidemiology) ... and what did I find? An advertisement for membership in AMWA! After learning more about AMWA, I decided that joining AMWA and taking as many of the writing-relevant workshops as AMWA had to offer might be a great way to begin to address the learning needs my supervisor had recently pointed out. And so began my now nearly 25-year AMWA membership.

I don't know if AMWA still advertises in journals about membership to AMWA, but in 1994 it did, and I am forever grateful. While none of us got to meet Leonardo, over my nearly quarter century as an AMWA member, I've had the pleasure of meeting, learning with, and becoming friends with many other wonderful fellow AMWA members!

After joining AMWA, I signed up for and took my first AMWA workshops in 1995, "Organizing the Biomedical Paper" led by Martha Tacker and "Tables and Graphs" led by Pat Cornett at the Michigan Chapter Conference (and a few years later, I realized that Martha and Pat were both Past Presidents of AMWA). Living in Toronto, Michigan was only a 5-hour drive away, so it was almost like attending a "local" conference.
In the Fall of 1995, I attended my first AMWA Annual Conference, which was held that year in Baltimore. It was also the first time I had the pleasure of meeting AMWA’s then Executive Director, Lillian Sablack. While that conference enabled me to take another workshop or two, I had to leave the Baltimore Annual Conference to get home to defend my doctoral dissertation—to the surprise of my principal supervisor, who wondered what I had planned to do if I didn’t get back in time?! (But I did.)

My first years in AMWA were spent taking as many writing-related workshops as I could—probably at least 15 and perhaps as many as 20, which led to 3 core certificates, and the advanced one too. This allowed me to begin to fill in the gaps that my supervisor had pointed out in 1994. They included workshops on grammar, sentence structure, punctuation, paragraphing, word use, and many more. It also allowed me to begin to meet and make many AMWA friends, especially fellow Canadian members!

In 1999, I co-led my first AMWA workshop, “Core Statistics” with Tom Lang, again at the Michigan Chapter Conference. Thank you, Tom! At the 2001 and 2002 Annual Conferences, I had the wonderful opportunity to co-lead “Advanced Data Presentation” and “Making Effective Slides” with Howard Smith and Edie Stern, respectively. Thank you, Howard and Edie, for those opportunities and your wonderful friendship and support over the years!

To date, I’ve had the privilege and pleasure of leading 7 different workshops for a total of 101 offerings (and by the end of this Annual Conference, that number will be 104). For me, AMWA just keeps on giving ... and continues to be a wonderful home.

And now, receiving this award. I truly am humbled and honored to stand here and to join the 65 previous recipients, some of whom are here tonight, and I would now ask them to stand and be recognized.

So, what do we know about the current group of 66 Swanberg Award recipients? Well, we know that when they received the award, they had been members of AMWA for an average of 24 years, ranging from 4 years (Christy Nicholas in 1989) to 33 years (Jonathan Rhoads in 1987, fellow Canadian Elvira Stahl in 1991, and Norman Grossblatt in 2008). And for those of you who have or are about to take AMWA’s Core Statistics workshop (or self-study module), 24 years is both the mean and median. It’s a symmetrical distribution, but not really bell-shaped. In any case, I regress (pun intended?).

And what else do we know about these 66 award recipients? Well, 60 of them were or became AMWA Fellows. AMWA Fellowships began being awarded in 1952, and all but 1 of those 60 received their AMWA Fellowship prior to receiving the Swanberg Award. I don’t think Elliott Churchill is here, but she is that previous award recipient/Fellow who received her fellowship after receiving the Swanberg Award—both recognitions (in 2007 and 2008, respectively) were very well deserved, but the timing was unique.

Thirty-one of the 66 previous Swanberg recipients served as Presidents of AMWA. AMWA’s first President was Dr George Lake (not a previous Swanberg Award recipient) who served in 1940/1941.

In addition, 16 Swanberg Award recipients have also received the Golden Apple Award. Since the Golden Apple Award was only initiated in 1986, it is only Swanberg recipients in what I will call the “modern era” who would be eligible. And for me, that modern era begins in 1986 when not only was the Golden Apple Award initiated, but AMWA’s “Miss Edie” Schwager was also the celebrated Swanberg recipient—and Edie is the earliest Swanberg recipient whom I had the pleasure of meeting.

Finally, 10 Swanberg Award recipients have also received the President’s Award, which is also a relatively recently initiated award, being presented for the first time in 1981.

Of the 32 modern-era Swanberg Award recipients, 13 (41%) have received at least 3 of the recognitions described above. And, with his receipt of the Golden Apple Award at this year’s Annual Conference, Art Gertel became the first “grand slam” Swanberg Award recipient, now having received all 4 of these additional recognitions to complement his 2009 Swanberg Award. Congratulations Art!!
known then) for “unusual and distinguished service to the medical profession.” And the 1952 Annual Conference was made even more memorable because Dr Walter C. Alvarez—another important AMWA member—received AMWA’s then Honor Award for “distinguished contributions to medical literature.”

In 1962, AMWA’s Distinguished Service Award was renamed in honor of Harold Swanberg and became known as the Harold Swanberg Distinguished Service Award.

This is a picture of Harold Swanberg, BSc, MD, FACP ScD, wearing what I believe is his AMWA Fellowship pin on his lapel, and above him on the left are, I believe, the seals of AMWA and of the Society of Academic Achievement (SAA), which will be discussed later.

So, who was William Harold Swanberg, Sr? He was born in 1891, completed a BSc and then his MD in 1916, and then became a fellow of the American College of Physicians. At that point in time, I believe there were only 2 colleges—the American College of Physicians and the American College of Surgeons—because medical and surgical specialties hadn’t been formally developed or recognized at that time. More specifically, Swanberg was a physician, with a special interest and expertise in aspects of radiology, particularly treatment employing isotopes and nuclear materials. He was also a medical writer/editor—which included both founding a medical journal (Radiologic Reviews) and serving as its Editor-in-Chief.

In addition to being a cofounder of AMWA, he was AMWA’s Life Fellow and Honorary Life President. He was also AMWA’s inaugural Secretary/Treasurer, serving from 1940 to 1960—a record that I don’t think will ever be broken! And he also served as an AMWA historian, pulling together a 236-page history of the association’s first 25 years, which was published in 1965.

There is little doubt that Swanberg was AMWA’s “heart and soul” for the association’s first 2 decades!

In 1920, just 4 years after he graduated from medical school, Swanberg’s oldest son, William Harold Swanberg, Jr, was born (the father went by their middle name, Harold, while “junior” went by the first name, Bill/William). In 1924, Swanberg founded his first medical journal, the bimonthly Radiologic Review. So, 8 years after graduating from medical school, he had founded a medical journal and served as its Editor-in-Chief.

In 1935, he became the inaugural Secretary/Treasurer of the Mississippi Valley Medical Society, and served in that role until 1961. Swanberg also played a key role in the founding and ongoing support of that organization. In 1935, Swanberg’s daughter, Nancy, was born. In 1939, Swanberg transitioned Radiologic Review to become the Mississippi Valley Medical Journal so that it could serve as the society’s journal. The Mississippi Valley Medical Society also had a Distinguished Service Award, which was awarded to Swanberg in 1946. On September 25, 1940, Swanberg and 5 others founded the Mississippi Valley Medical Editors’ Association at a meeting held in Rock Island, Illinois. Eight years later they decided—actually, I believe Swanberg decided—that a more far-reaching association was needed to facilitate the growing interest of medical editors to get together and to support and learn from one another, so the association was renamed the American Medical Writers’ Association.

AMWA was incorporated as a not-for-profit organization in 1951, and a year later became an affiliated society of the American Association for the Advancement of Science (AAAS), which provided AMWA with a seat on the AAAS Board of Directors. I am not sure when AMWA’s affiliation with AAAS ended (or why).

Swanberg’s career as a medical writer began very early. His first 2 publications preceded his graduation from medical school and arose from his interest about nerves as they pass through the spine, about which there was great conjecture and even more argument at the time. As a result, he decided (2 years before graduating from medical school!) to carry out an anatomic study in cats and in 1914 published a monograph entitled The Intervertebral Foramen, which was reviewed in the Boston Medical and Surgical Journal (the forerunner of the New England Journal of Medicine).

Because critics questioned the human relevance of cat anatomy, Swanberg carried out a second study in humans and, in 1915 (so only a year later!), he published another monograph called The Intervertebral Foramina in Man, which was also reviewed in the Boston Medical and Surgical Journal.

Following those 2 monographs, Swanberg published “Anterior Dislocation of the Atlas Following Tonsillectomy” in JAMA in 1919—just 3 years after he had graduated from medical school. Given the period of time, it should not be surprising that Swanberg received much of his training from and subsequently served as a physician-radiologist with the US Army. In fact, “Anterior Dislocation of the Atlas” is a case study describing work he did in the military.

In 1921, he described a study of 11 cases entitled “Gunshot Injuries to the Brain” that was published in the American Journal of Roentgenology. A footnote in that article indicates it also served as the thesis that Swanberg submitted with his application for membership into the American Roentgen Ray Society—an organization that was founded in 1900 and still exists today.
In 1922 and 1923, Swanberg had 2 publications in the Illinois Medical Journal. Actually, the one in 1923, “Effect of X-Rays and Radium Rays on Malignancy,” is the first of many subsequent articles relevant to his major clinical and research interest—radiology, and more specifically, radiotherapy.

Through the 1940s and ’50s, Swanberg published in the Mississippi Valley Medical Journal on a wide range of radiotherapy topics that included radiation treatment of cervical cancer, the use of the radium-D ophthalmic applicator, and varying the fractionation in the x-ray treatment of malignant tumors. Many of his articles, addressing topics such as carrying cases and applicators for therapeutic radioactive materials, highlight the “state of the art” at that time, with doctors personally transporting radioactive materials, perhaps even on house calls—and leaving those houses to “glow” for many years after?! It should be noted not much was known about the benefits and risks of radiation therapy at that time.

But Swanberg’s interest was not limited to radiotherapy. He also wrote about Blue Cross and hospital coverage, hearing conservation, the interface between medicine and osteopathy, and a topic that remains controversial today: the fluoridation of drinking water, including its relation to cancer.

Swanberg’s quest for formal training in what he called “medical journalism” or “medical editing and writing” began as early as 1954. This particular interest in education dovetails with probably his greatest passion—ensuring that bright, young Americans received an appropriate education to best prepare them for a suitable career path. Notably, this includes his 1958 and 1959 publications entitled “Let’s Improve the Curriculum in Our Public Schools” and “Let’s Win the Cold War of the Classrooms” that were published in the Mississippi Valley Medical Journal.

In 1951, Swanberg combined passion for education with his love of the profession, which led him to cofound AMWA’s Educational Committee. His cofounder was Richard Hewitt, who not only served as the committee’s first chair but also received AMWA’s Distinguished Service Award in 1954 and served as AMWA’s President in 1955/1956.

The mandate of the Educational Committee was “to study ways and means of improving medical writing and journalism, especially in cooperation with educational institutions, foundations, and corporations.” The committee’s initial efforts were focused on the design, development, and offering of appropriate curricula for undergraduate and ultimately graduate programs in medical writing and editing. By the fall of 1954, there were undergraduate and graduate programs being offered at 3 universities—Illinois, Missouri, and Oklahoma. Perhaps it’s a sign of the times, or perhaps just another indication of Swanberg’s drive and persistence, but I’m quite sure that today you would not be able to move from conception to implementation of new university curricula in just 3 years.

In 1952, Swanberg was also responsible for conceiving and launching AMWA’s first (and only) manuscript editing service. And as he didn’t have enough things to do, he also coordinated it. If you look down at the bottom of the pictured advertisement, you will see that those who wished to submit a manuscript for editing were directed to send it to Swanberg. And while Swanberg administered AMWA’s editing service, he had recruited a professor of journalism to do the editing. The service was described as being created “to help physicians improve the quality of medical writing in the papers they submit to medical journals.” Of course, also being a medical journal editor, I believe Swanberg fully understood that the service would also make his and his fellow medical editors’ jobs that much easier. As noted in the first annual report about the service, Swanberg noted that the “chief aim [of AMWA’s editing service] is to help authors say what they want to say, in their own styles, yet with precision, economy, and felicity.” And it appears he accurately perceived the demand for such a service, as there were more than 375 manuscripts received and edited during the first 5 years of the service.

In 1957, the fees for the editing service were raised—from $4 to $5 for the first 1,000 words (and from $3 to $4 for the next 1,000). At about the same time, Swanberg appears to consider that the work being carried out by AMWA’s editing service could also be done by other medical writers and editors. To determine this, and to begin to facilitate others doing this
Swanberg believed the American school curriculum needed to be overhauled so that students could be better prepared, and if something wasn't done, America risked falling behind Russia in this important national resource.

The final aspect I'd like to address (as you can appreciate, Swanberg could be the topic of a daylong seminar—he just keeps giving and giving) was Swanberg's concern for high school education and its ability to identify and support bright students in pursuing applicable careers, particularly those pathways requiring suitable postsecondary education and training. Swanberg was concerned not only for the students but also for the country and the roles those students would play as American adults.

Much of Swanberg's concern, which he articulated in his 1959 *Mississippi Valley Medical Journal* article entitled "Let's Win the Cold War of the Classrooms," was underlined by 1954 data that he presented concerning the “educational expectations of American 14-year-olds.” Those data indicated that 1 in 10 of the brightest 25% of high school students did not even graduate from high school. Further, only 2 in 5 of those top 25% of high school graduates even entered postsecondary education, with only 2 in 3 of them ultimately graduating from college. That is, in 1954, it was estimated that only 1 in 4 of the brightest 25% of high school students would successfully complete a college education (and with less than 1 in 10 “average” high school students graduating from college). Swanberg viewed these results as a national emergency.

Swanberg was quite knowledgeable about and motivated by the Russian educational reforms that had been introduced under Communism that led the Russian educational curriculum to become stricter and more informative. In contrast, Swanberg was not supportive of the more permissive American educational curriculum that he believed ill prepared American students. I think I can almost hear Swanberg asking, “What does a teenager know about what he or she needs to know at that age?” Swanberg believed the American school curriculum needed to be overhauled so that students could be better prepared, and if something wasn't done, America risked falling behind Russia in this important national resource.

Swanberg's recognition of this need and his efforts and contributions in this area began in the 1930s. In 1935 (the same year the Mississippi Valley Medical Society was founded, he became its first Secretary/Treasurer, and his daughter was born), his advocacy concerning high school education led to the first vocational guidance program and guidance counselor being initiated at his local high school in Quincy, Illinois. You might take this for granted—doesn't every school have guidance counselors? Apparently, they did not in 1935 ... but they got one in Quincy because of Harold Swanberg!

In 1956, Swanberg developed and provided funding for the Swanberg Collegiate Education Foundation. This was yet another example of Swanberg “walking the talk” and another of several initiatives where Swanberg literally put his money where his mouth was. This foundation provided postsecondary educational scholarships to assist families of bright high school students, to better enable more of those “brightest 25%” to attend and succeed at postsecondary education. (Of note, AMWA was a cosponsor of the foundation for its first 5 years, until 1961.)

But Swanberg's educational initiatives were not limited to only launching those scholarships, because in the same year (1956), in partnership with the Quincy, Illinois, Kiwanis Club, Swanberg developed and launched the Quincy Major Learning Program, to better enable a larger proportion of high school students in Swanberg's home town of Quincy to successfully enter and graduate from postsecondary education. Continuing his work with the Kiwanis and their network of chapters across the country, this “action program” evolved into a national and, by 1959, into an international program. Again, from local to international in just 3 years; Swanberg didn't sit around. Oh, and the name evolved too ... it became known as the Society of Academic Achievement. (Remember that SAA seal in the picture?)

Swanberg had a heart attack in 1960 and was told by his doctors that he needed to slow down. Yet, 5 years later, he assembled a 236-page history of the first 25 years of AMWA (Thank you to Scott Thompson for making a copy of it available to me!). Like so many things in Swanberg's life, he had a very unique perspective—including, it appears, on what “slowing down” means—although even he admitted that he could not continue to maintain all of his many and varied commitments (some that he had maintained for more than 2 decades).

Now, this seemingly boundless energy and zeal didn't stop with Harold Swanberg. I also learned that while neither of his biologic children (he also had 2 step-children) followed in his medical footsteps, both followed in his medical writing/editing
ones! William Harold Swanberg, Jr, began working in 1936, at the age of 16 years, as an editorial assistant with his father’s journal, Radiologic Reviews. It also appears that William also became a founding member of AMWA in 1940, and remained a member until his death in 1987. William also worked as one of the managing editors of the Journal of the Association of American Medical Colleges, assisting in its transition into the Journal of Medical Education (the journal is now known as Academic Medicine).

Harold’s daughter, Nancy Swanberg Isaacs, also a lifelong AMWA member, trained as a teacher and taught medical writing at Baylor College of Medicine. She was awarded an AMWA Fellowship in 1963.

In closing, I’d like to give the final word to a select group of Swanberg’s peers. The citation for his 1952 Distinguished Service Award described him as “persistence with patience, ideals with practicality, progressiveness with conservatism, and unselfish with humanitarian interest first.”

Charles Lyght, AMWA’s 1957-1958 President and its 1961 Distinguished Service Award recipient, described in his presidential “state of the association” summation that “AMWA would never have been started, had it not been for the foresight and vision of one man, and it could not have survived the early tough, lean years had it not been for the enthusiasm, drive, single-mindedness and unstinted generosity of the same man. But of even greater significance is the fact that AMWA would fall into immediate difficulties were his experience, tireless energy, and inspirational inventiveness withdrawn or the freely available facilities of his office no longer accessible.”

W. D. Snively, AMWA’s 1963-1964 President and the first recipient of the 1962 renamed Swanberg Distinguished Service Award, remarked, “For with characteristic insight, Dr Swanberg had seen the need for an organization dedicated to medical communication and had done something about it. Many of us see needs but do nothing to fill them. Dr Swanberg is obviously of a different cloth.”

And finally, Morris Fishbein, AMWA’s 1958-1959 President, the 1956 recipient of AMWA’s Distinguished Service Award, and a former editor of the Journal of the American Medical Association, stated that “Under the leadership of Harold Swanberg, AMWA was dedicated to the highest ideals. Because AMWA was founded on such solid ground, it grew and attracted many leaders in the field. These fine achievements were due primarily to the devotion and leadership of Harold Swanberg.”

Harold Swanberg died in 1970. Now, nearly 50 years later, what would Swanberg think? I believe he would be pleased and proud of what AMWA has become and what it continues to achieve.

In closing, I am sincerely humbled and honored to join Dr Swanberg and the other 64 Distinguished Service (aka Swanberg) Award recipients, even more now that I have gained a greater appreciation for the wondrous life and accomplishments of Dr William Harold Swanberg, Sr! Thank you for your attention and the opportunity to address you.

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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 2018 recipient is Robert M. Califf, MD, MACC. His acceptance speech will appear in a future issue of the Journal.

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 2018 recipient is Stacy Robison, MPH, MCHES. You can read her acceptance speech in our Online-Only Supplement (https://www.amwa.org/page/Members_Only_Issues).
A PRACTICAL INTRODUCTION TO THE CLINICAL EVALUATION REPORT (CER) AND HOW TO MAKE IT COMPLIANT WITH MEDDEV 2.7.1 REVISION 4

Speakers
Thomas Stone, JD, CER Manager, Global Medical Writing and Translation, Kent, WA
James Vinton, PharmD, CER Lead Writer, Global Medical Writing and Translation, Kent, WA

By Ana Jakimenko, PhD

A clinical evaluation report (CER) is the result of the clinical evaluation process. Clinical evaluation is a methodologically sound, ongoing procedure to collect, appraise, and analyze clinical data about a medical device and to evaluate whether there is sufficient clinical evidence to confirm compliance with relevant essential requirements for safety and performance when using the device according to the manufacturer’s instructions for use (MEDDEV 2.7.1 revision 4).

The purpose of a CER is to gather data to support safety, performance, and benefit-versus-risk analysis of the device intended for sale in the European Union market by the Notified Bodies. A CER is an objective, unbiased, standalone (without any ties to previous CERs) document. Under MEDDEV 2.7.1 revision 4, a clinical evaluation plan (CEP) should be drafted and approved before CER writing begins. See Figure 1 for an example CER table of contents.

1. Summary
2. Scope of the clinical evaluation
3. Clinical background, current knowledge, state of the art
4. Device under evaluation
   a. Type of evaluation
   b. Demonstration of equivalence (as needed)
   c. Clinical data generated and held by the manufacturer
   d. Clinical data from the literature
   e. Summary and appraisal of clinical data
   f. Analysis of the clinical data
      i. Requirement on safety
      ii. Requirement on acceptable benefit/risk profile
      iii. Requirement on performance
      iv. Requirement on acceptability of side effects
5. Conclusions
6. Date of the next clinical evaluation
7. Dates and signatures
8. Qualification of the responsible evaluators
9. References
10. From MEDDEV 2.7.1 revision 4, June 2016

The Summery is the first item on the list of contents, but this section is written last. The CER’s Scope must be clearly stated and supported by data in the succeeding sections. CER objectives must be tied to safety, performance, and risk-versus-benefit outcomes.

The State of the Art (SOA) section is a new requirement, mandated by MEDDEV 2.7.1 revision 4. Its purpose is to establish a baseline for how the device compares to existing therapies for the specific medical condition falling under the device’s intended use. “State of the art” means that
• the device is currently clinically accepted;
• it has its own scope with clearly described goals, methodology for literature search, results, and conclusions sections; and
• it is outlined in the CEP and focused.

For the SOA literature search, one should
• choose broad terms and a shorter time frame (generally 2 to 5 years from the current date) and
• conduct it separately from the literature search for clinical data for safety and performance of the device.

The Device Under Evaluation part of the CER content must state whether the device is new to the market.

According to MEDDEV 2.7.1 revision 4, device equivalence must be demonstrated at the following levels:
• Clinical characteristics
• Technical characteristics
• Biological characteristics

New regulations make claiming equivalence to a competitor’s device nearly impossible, because they require a complete data disclosure agreement between 2 competitors.

The CER essential requirements remain the same. A CER must provide evidence on device safety and performance when used according to the manufacturer’s instructions for use, lay out benefits versus risks, and explain the acceptability of any side effects.

Literature searches should be reproducible, use multiple databases, and use verified methodology. MEDDEV 2.7.1 revision 4 requires that stricter inclusion criteria be applied to the clinical literature. The SOA and clinical data literature searches are performed separately with results documented separately.

MEDDEV 2.7.1 revision 4 mandates an inclusion of postmarket surveillance documents or drafted plans thereof into a CER: the postmarket surveillance, postmarket clinical follow-up results, and claims matrices.

The CER conclusions must be explicit, defensible, and unambiguous. MEDDEV 2.7.1 revision 4 requires more frequent CER updates for high-risk devices and specifies qualifications for CER writers and reviewers. CER writers and reviewers must have a PhD or MS degree plus 5 to 10 years of medical writing experience.

Overall, MEDDEV 2.7.1 revision 4 makes CER writing more complex, requires greater attention to detail and analysis, and emphasizes the validity of data presented. The presenters suggested a strategy for approaching the writing of a CER (Figure 2).
### Table: Intended Use Essential Requirements

<table>
<thead>
<tr>
<th>Intended Use</th>
<th>Essential Requirements (1, 2, 5 or 1, 3, 6)</th>
<th>Current Knowledge/State of the Art</th>
<th>Published Medical Literature</th>
<th>Pre-clinical Data (eg, benchtop, animal)</th>
<th>Clinical Data from Mfr (including PMCF)</th>
<th>Risk Management Data</th>
<th>Post-market Surveillance Data (Mfr and other databases)</th>
<th>IFU</th>
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<tr>
<td>1st Intended Use</td>
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<td>Acceptability of Side Effects</td>
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<tr>
<td>2nd Intended Use</td>
<td>Safety</td>
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</table>

All sources reach similar (consistent) conclusions regarding the device?

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**Figure 2.** Presenters’ suggested general strategy for CER writing.

Enforcement of MEDDEV 2.7.1 revision 4 requirements for CERs is becoming increasingly strict as the Medical Device Regulation deadline of May 2020 approaches.

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### USING A FOCUSED AUTHORING STRATEGY TO CREATE A MESSAGE-DRIVEN DELIVERABLE

#### Speakers

**Elizabeth Brown, MS, PMP,** Managing Medical Writer, Merck & Co, North Wales, PA

**Kimberly Jochman, PhD,** Managing Medical Writer, Merck & Co, Apex, NC

*By Lisa Carricaburu, MBA*

Elizabeth Brown draws inspiration for her work from a surprising source: Dr Seuss. The children's book author is known to have said, “The writer who breeds more words than he needs is making a chore for the reader who reads,” and Brown takes that sentiment to heart. She and colleague Kimberly Jochman practice a focused authoring strategy with that end in mind.

“It’s basically a way to preserve the very valuable real estate in your document and the attention of your reader by allowing the key messages to come through,” Brown said. “You might find that some of your sections are even longer under this approach, but all the fluff … will be removed.”

Three questions are central to focused authoring (Figure 1):

1. Is the text needed?
2. Is the text clear?
3. Is the text accurate?
Even before addressing these questions, though, Brown and Jochman recommend that you assess and understand your audience and explain the approach to get buy-in from collaborators.

**Assess Your Audience**
Who is your audience and what does it hope to get from your document? Once you know whether you’re writing for regulatory reviewers or health care providers, for example, you can tailor your document to meet their specific needs. Regardless, “they are going to be busy,” Brown said. Work hard to gain and keep their attention.

**Get Buy-In**
Your team needs to be just as aligned with a focused authoring strategy as you are, Brown said. “It’s really about … taking a proactive approach [to let them know] this might be different than what [they’re] used to and unexpected. In some cases, it creates a lot of anxiety,” she said. “Help your team understand that even though it’s different, it’s better” (Figure 2).

**Focused Authoring**
Once you’ve taken these initial steps, begin addressing the 3 key questions.

**Is the Text Needed?**
Assuming that you are writing for regulatory reviewers, you can eliminate unnecessary text by doing the following:
- Tailor your introduction to your audience
- Avoid descriptions of methods in results sections
- Make sure not to repeat data presented in tables

“There are always team members who want to add more information to the introduction,” Jochman said. You have to remind them to focus on the key messages a regulatory reviewer really needs to know.

Similarly, don't agree to summarize methods in a results section because a team member fears that reviewers won't read the methods section. Instead, cross-reference from the methods to the results, she said.

Finally, keep most data out of the text. “A table is going to do a better job of communicating your results than words ever could,” she said.

She acknowledged that key values and other numbers sometimes are needed in the text. Consider placing them in parentheses in the text, or add a smaller version of a large results table to the text to highlight key results.

**Is the Text Clear?**
To ensure that text is clear, you need to maintain consistency, consider format, and be concise.

The best documents communicate information in “one voice,” using consistent terms and parallel structure throughout. Brown recommended working with your team to develop a lexicon early in a project to establish conventions, for example, for how you will refer to a study participant.

As for formatting, “consider using bullet points or other visual cues instead of lengthy sentences or paragraphs,” said

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**Setting Team Expectations**

**Sample “Reviewer Email”**

Please note that a focused authoring style was used throughout this document. Below is a list of aspects of other styles that you may be used to seeing in past CSRs/manuscripts/etc but are now handled differently. This new approach really helps the reader stay focused on key messages.

<table>
<thead>
<tr>
<th>INSTEAD of…</th>
<th>EXPECT to SEE…</th>
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</thead>
<tbody>
<tr>
<td>Repetition of methodology in the results sections…</td>
<td>…very brief “reminders” with cross-references to the relevant sections, and only when absolutely necessary.</td>
</tr>
<tr>
<td>Lots of numbers from in-text tables repeated in the text…</td>
<td>…text that describes the results and keeps the focus on the key points, without “cluttering” the text with lots of numbers.</td>
</tr>
<tr>
<td>“Roadmaps” describing what will be discussed in the current and subsequent sections…</td>
<td>…no roadmaps, as the navigation pane and table of contents provide information about what is coming up.</td>
</tr>
<tr>
<td>Descriptions of in-text tables (eg, Demographic information for all enrolled subjects is summarized in [Table 10-1])…</td>
<td>…launching right into describing the results, with the table cross-referenced at the end (eg, “Of the subjects enrolled in the trial, approximately half were female, and the majority were white and 68 years of age [Table 10-1]).</td>
</tr>
</tbody>
</table>

**RULE of THUMB:** Every word in a sentence should either serve a grammatical purpose or should help to drive our “story” forward!
Brown. In addition, consider using a figure or table instead of text. “Visual organization of information is easier to read and interpret.”

You can make text more concise by asking whether you can read each sentence out loud in one breath. Ask yourself:

• Is this semicolon the best choice?
• Is this sentence 2 lines or fewer?
• Does this word add value?

If you answer no to any of these questions, your sentence is too long. “Rewrite it. Try again. It’s OK,” Brown said. “Love your red pen.”

Is the Text Accurate?

“When we say accurate, we don’t necessarily mean verified from the source document,” Jochman said. “This type of accuracy is more about whether the words you’re using accurately reflect what you mean.”

You can achieve accuracy by first establishing an order and sticking with it. If you’re going to talk about an active treatment group followed by a placebo group, for example, always talk about the active treatment group first.

Next, use consistent comparison language. “You can talk about the number of subjects who survived, or the number who died, but don’t talk about both unless there’s a reason,” she said.

Start with the most important information, use precise statements, and avoid too many comparisons. “Limit the discussion of subgroup analyses when they’re similar to what’s published about the group as a whole,” Jochman said.

Reducing bias also improves accuracy. Watch for the following to detect possible bias:

• Opinion presented as a statement of fact
• Absolutes (always, never, certainly, totally)
• Approximate terms used inconsistently (“Have consistent standards for when to use ‘most’ or ‘the majority,’” Jochman said.)

Follow these tips to streamline your writing, and Dr Seuss would approve.

“Unnecessary words create work for readers,” Brown said. “Our job as medical writers is essentially to take the work out of reading.”

Lisa Carricaburu, MBA, is Managing Editor, Informatics Decision Support, at ARUP Laboratories in Salt Lake City, UT.

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BUILDING A SUCCESSFUL FREELANCE WRITING AND EDITING BUSINESS

Speakers
Kristin Harper, PhD, MPH, ELS, Owner, Harper Health & Science Communications, LLC, Seattle, WA
Mia DeFino, MS, ELS, Founder, DeFino Consulting, LLC, Chicago, IL

By Karen Potvin Klein, MA, ELS, GPC, MWC®

Harper and DeFino began the session by reporting the results of a survey of AMWA members conducted in spring 2018. Overall, they received 114 responses from freelances. Respondents cited $100 to $150 per hour as the most common rate they charged, and most said they worked in publications or regulatory. Two-thirds reported that repeat clients are a substantial part of their business. However, the biggest challenges cited by respondents involved getting enough business. For example, 32% of respondents expressed problems finding clients, 21% said they had concerns about making enough income, and 19% cited challenges in marketing their business. Their handout shared at this Open Session (available at: https://cdn.ymaws.com/www.amwa.org/resource/resmgr/conference/2018/handouts/SuccessfulFreelanceBusiness_.pdf) was created in part through suggestions from survey respondents.

Harper and DeFino then explained their “lessons learned” and advice on how to build a successful freelance writing and editing business. A number of session attendees were new to freelancing, and Harper and DeFino had several suggestions about ways to get started:

• Provide samples of your work for potential clients, even if you are volunteering.
• Network and seek out opportunities for professional development regularly.
• Tell everyone you know that you’re beginning your own writing and editing business.

Harper and DeFino stressed the importance of referrals to a freelance writer and editor. First, referrals allow you to spend time working, not marketing your services. Second, referrals likely already know your rates; if they seek you out, they think your work merits that cost. Third, an enthusiastic source of referrals can have huge positive downstream effects on your business.

So how do people get referrals? Although not all companies will want to share the names of their favorite freelance writers, that is not so in academia. But if clients are truly invested in your success (and good ones should be), they will be happy to mention you when asked for recommendations.

Along with referrals, Harper and DeFino stressed the value of repeat clients. They provided some tips about how to be a stand-out to your clients, such as

• Attend in-office meetings if possible. Face-to-face makes a difference!
• Do all the right things—on time, on budget. Don’t assume that professionalism is a given (it’s not).
• Be available to valued clients even if it means reshuffling your day. But don’t overpromise what you can deliver.
• Commit to staying on top of your game—keep up with best practices, and take time for professional development.

With regard to finding more clients, Harper and DeFino suggested that you ask yourself 3 questions regarding potential clients; if the answer is “no” to any of these questions, they are not the best fit:
• Will they be a source of repeat business?
• Are their rates in line with your expectations?
• Is their material of interest to you?

On the other hand, they cautioned against having 1 client take up more than 25% of your time. If you become too dependent on 1 income stream, you are less empowered to push back if an undesirable situation arises. They recommended telling such clients you’re too busy, and possibly referring them to other writers and editors.

Volunteering is one proven way to broaden your business. Interest groups (Women in STEM, ELAM, etc) can use volunteer services and may subsequently become solid referral networks for future business. Harper and DeFino also commented that volunteering reduces the isolation of freelancing.

The presenters recommended diligently tracking how time is spent—administration, billable time, and so on—and reviewing it weekly. Two recommendations were:
• Regularly reassess your billing rates. Don’t be afraid to raise rates; good clients will understand the value. Bad ones will argue about it; if so, weed them out over time.
• Can you remove distractions where you work? They lead to procrastination.

Finally, Harper and DeFino noted that taking care of yourself is the best way to promote your business.

Karen Potvin Klein, MA, ELS, GPC, MWC®, is the owner of Clarus Editorial Services, a biomedical grant consulting and manuscript editing company in Winston-Salem, NC.

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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 (https://www.amwa.org/page/Members_Only_Issues).
Experienced recruiters can help medical writers advance their careers. Many medical writers, however, do not know how to effectively work with recruiters, and some (eg, freelance medical writers) may not think they need to work with recruiters.

Lindsey Summers, MBA, agreed to share some thoughts with us on why recruiters can be medical writers’ assets, how to identify and effectively work with a recruiter whose experience matches your need, and the dos and don’ts of working with a recruiter.

Ms Summers is Director, Pharmaceutical Consulting Division, at Green Key Resources, Denver, Colorado. She is a seasoned third-party recruiter specializing in helping companies hire medical writers and has been providing guidance on career advancement in medical communications to medical writers for more than a decade. She has led workshops on career paths in medical communications and frequently offers advice through LinkedIn and AMWA’s Engage Forum.

Journal: Can recruiters help medical writers advance their careers? If so, how?

Summers: The answer is yes! For medical writers who are applying for a job, recruiters can provide insights about the company that you are applying to. They may even know the hiring manager, the team, and the culture of the organization. They can also help you prepare for interviews and negotiate a salary.

It is important to remember, however, that all recruiters are not equally experienced. Make sure you vet the recruiter you are working with and make sure the recruiter understands your field and knows what you are looking for in your next opportunity.

Journal: AMWA members possess different experiences and diverse backgrounds. Who would benefit the most from working with recruiters? Aspiring medical writers who wish to break into the field, medical writers with extensive experience who want to change jobs, or all of them?

Summers: First, I think it is important for medical writers to understand that there are 2 types of recruiters: corporate recruiters and third-party recruiters. Corporate recruiters work internally at a company either as permanent employees or contractors; they are dedicated to that one company only and are paid a base salary or an hourly rate. Third-party recruiters generally work for agencies and recruit for many companies for permanent jobs, contract jobs, or both; they typically can help only experienced medical writers because they are paid by clients to find what they are looking for in a medical writer.

Third-party recruiters rarely help people who are transitioning from one field to another. Even though we know many people in the industry, a company is not going to pay us to find someone they can easily find on their own. However, if you are willing to take a contract-based project and are available to work onsite, a recruiter may be able to help you find such an opportunity. Contract jobs are often a great way to break into a field. Although you probably need to meet all of an employer’s requirements for a permanent job, you may need to meet only 60% of the requirements for a contract job because the company can “try before they buy” with a contract/temporary position.
Journal: What are your top 3 tips for aspiring medical writers who strive to break into the medical writing field?

Summers: Great question! Here are my suggestions. First, know what you want to do and why you want to do it. I cannot tell you the number of people who say “I want to be a medical writer” but haven’t done any research on the types of roles out there when I communicate with them over the phone or through email.

Second, pay attention to details when you apply for a job. Most importantly, make sure your resume is up to par and PLEASE do not just rely on spell checking. This is where true quality control comes in. For example, spell checking will not catch “clinical trail” when it is supposed to be “clinical trial.” In addition, if you are a new medical writer, you most likely will be asked to take a writing test, so make sure you check and double check your product.

Third, let your communication skills shine. Make sure all your communication pieces (emails, letters, etc) with prospective employers, recruiters, hiring managers, and colleagues are top notch. Send a “thank you” note after your interview to show your follow-up and writing skills. After all, you are a writer and you might as well showcase your work!

Journal: What’s your advice for experienced medical writers who plan to change jobs?

Summers: My best advice is to engage with people in your network, including past and current coworkers and managers, people you cross-functionally work with, college friends, people you know through professional organizations such as AMWA, and trusted recruiters. Before you hit the “apply” button on a job posting, try to first reach out to those you know who work in the company, or recruiters who work with that company. Often, it is the person who is known to the team who gets the position.

Journal: Recruiters can be valuable to those who seek a full-time job, but can they help freelance medical writers grow their business? If so, how?

Summers: Yes, we can. There are recruiters of all types. Some work on permanent jobs, some fill contract positions, and some work with freelance medical writers who have their own businesses such as LLCs and S Corps. Over the years, I have placed many freelance writers in part-time roles and connected them with companies that they otherwise would not have found. It is extremely important, however, to keep a recruiter as your point of contact once he or she has already made the connection for you. It is not ethical to go around the recruiter and reach out directly to the hiring manager or the human resources department during the hiring process, and companies frown upon this type of practice.

Journal: Like medical writers, recruiters have different levels of experience and different working styles. What’s your advice for medical writers on choosing recruiters?

Summers: Make sure you get to know your recruiters. Ask them in what areas they specialize and with which companies they work. Interview them like you would interview a company with which you are considering working—but expect questions back in return. For example, I would not be your best choice if you are looking for a medical education-related job because I do not work in that area. However, I would be a great option if you are looking for a job in regulatory writing because that is where 85% of my medical writing recruiting experience lies. Most recruiters will be very honest and upfront about what they can and cannot help with.

Journal: Medical writers sometimes receive phone calls or email inquiries from different recruiters about the same position. Does it matter for the medical writer regarding which recruiter to choose?

Summers: It depends on the type of position and the company. Some companies work with 50+ recruiting firms for Vendor Management System jobs, for which we must help qualified applicants submit their applications as soon as possible. In any case, you want to make sure that the recruiter you work with knows how to highlight your experience so you can stand out among other applicants. Some companies may work with only 3 to 5 recruiting firms on a position. In many cases, the recruiters are peers and they are all good at what they do. Again, vet your recruiters, but also expect to get vetted yourself.

Journal: What is your advice for freelance medical writers who wish to get a full-time job? Do they have to start from the very beginning (eg, get an entry-level job first)?

Summers: No, if you are an experienced freelance medical writer, you do not have to start with an entry-level job. You should utilize your network and see if any of your current or former clients would be interested in hiring you as a full-time employee. If you have already demonstrated your skills to a company or to someone on their team, getting hired by the company will be the path of least resistance. And this is how most jobs are obtained. Another good way to get hired is contracting at a company as a W2-based, temporary employee first. This arrangement gives the company an opportunity to
get comfortable with you before converting your temporary position into a permanent job.

For companies that consider hiring freelances as full-time employees, the biggest concern is the freelance's willingness to stay with one client on one project and not expect a wide range of opportunities. For freelance medical writers who are considering full-time positions, try to think of freelancing as going wide and working as a full-time employee at a company as going deep.

**Journal: What can medical writers expect from recruiters with whom they work? Is it reasonable for a medical writer to ask for feedback even if he or she doesn't get an offer?**

**Summers:** It depends. All recruiters are not the same. Again, evaluate the recruiters you work with first. Can you ask for feedback? Sure, you can. However, third-party recruiters may not always receive feedback from the companies they work with, and internal corporate recruiters may not feel comfortable sharing. Providing feedback can be a slippery slope. Many people want feedback, but once you share feedback with them, they get defensive and argumentative, and it does not always end well. I have shared feedback with applicants in the past and regretted it because the candidates went directly to the top management at the company afterward and argued their points. For this reason, many recruiters choose not to share feedback even if they have it.

**Journal: What are the dos and don'ts when working with a recruiter?**

**Summers:** Here are some dos and don'ts:

**Do:**
- Be collaborative
- Be honest
- Follow up

**Don't:**
- Be pushy
- Go around your recruiter
- Be difficult to work with
- Disappear at the interview or job-offer stage

**Journal: Should a medical writer engage a recruiter only when looking for a job? Or should a medical writer maintain a professional relationship with a recruiter all the time?**

**Summers:** This is what networking is all about. You always want to be ready for what is next, so try to maintain a professional relationship with not only a few good recruiters but also current and past colleagues, people you know through professional organizations, alumni at your college, and so forth. In addition, be open to helping others. It is karma. To get, you must give. You do not want to ask for something when you need it. If you must, put it on your calendar to remind yourself to be active. For example, comment on or “like” a LinkedIn post once a day, participate in discussions on the AMWA Engage Forum once a week, send a note to a prior colleague once a month. Be consistent and follow the ABCs: Always… Be… Connecting.

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For Safety’s Sake
Part 2: Reporting of Adverse Event Data

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“The sea is endless when you are in a rowboat.”
—Adolfo Bioy Casares, The Invention of Morel

At the end of Part 1,¹ we left our medical writer Jeremy pondering the adverse event data from the clinical trial in which Judy, our patient with recently diagnosed type 2 diabetes, had participated. To write the clinical study report (CSR), Jeremy has received all of the data from the trial, and for the analysis of safety, there are tables showing various different kinds of data, including assessments of clinical laboratory variables, vital signs, and electrocardiograms. For the purposes of this article, our focus is on the adverse event data. Even this topic is a broad one, and we can only provide a high-level overview in this short paper.

The adverse events Judy experienced—fainting due to hypoglycemia, a rash, and a sprained ankle—have been coded using the Medical Dictionary for Regulatory Activities (MedDRA) and put together with events experienced by other patients in the study. The data for these events are summarized in Table 1. This is the way they would be presented in the source table of all adverse events provided to Jeremy. (This is merely a sample for our discussion. In reality, of course, the source table would be much longer and contain many other kinds of events.) The table shows the numbers and percentages of patients in each treatment group with adverse events by preferred term (PT) and system organ class (SOC).

What can Jeremy conclude from these data? He begins by looking for differences in percentages of patients with adverse events in the 2 treatment groups. Of the events reported for Judy, there is only 1 item with a notable difference, and this is hypoglycemia, the medical term for low blood sugar levels, which was used to code Judy’s fainting attack. There is a slightly higher percentage of patients with hypoglycemia (and of those with any adverse event in the SOC metabolism and nutrition disorders) in the Wonderdrug (WD) group than in the Comparator group, and this will need to be noted in the CSR.

Analyzing Adverse Events in a Study Report: Aims and Obstacles
After spending some time trawling through long adverse event tables, looking for noteworthy differences between the treatment groups, Jeremy starts to feel overwhelmed by the sheer quantity of data. He feels as if he is lost in an endless sea without any oversight of the bigger picture. He has

Table 1. Summary Data for the Whole Trial Population for the Kinds of Adverse Events Judy Experienced (All Adverse Events Table)

<table>
<thead>
<tr>
<th>MedDRA SOC PT</th>
<th>Wonderdrug N = 652</th>
<th>Comparator N = 326</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>156 (23.9%)</td>
<td>63 (19.3%)</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>122 (18.7%)</td>
<td>46 (14.1%)</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>9 (1.4%)</td>
<td>6 (1.8%)</td>
</tr>
<tr>
<td>Rash</td>
<td>3 (0.5%)</td>
<td>2 (0.6%)</td>
</tr>
<tr>
<td>Injury, poisoning, and procedural complications</td>
<td>7 (1.1%)</td>
<td>5 (1.5%)</td>
</tr>
<tr>
<td>Joint injury</td>
<td>2 (0.3%)</td>
<td>0</td>
</tr>
</tbody>
</table>

All data are invented for the purpose of this paper.
MedDRA, Medical Dictionary for Regulatory Activities; PT, preferred term; SOC, system organ class.
¹MedDRA uses British spelling.
to remind himself of the ultimate purpose of analyzing adverse events and other safety data: to identify those adverse events that are caused by the drug (the technical terms are “adverse effects” or “adverse drug reactions”). Knowing the adverse drug reactions allows patients and their doctors to make informed decisions about whether to use a drug, based on full details of its benefits and risks. With this in mind, Jeremy looks at the difference between the treatment groups for hypoglycemia (18.7% of patients on WD vs 14.1% of those on Comparator) and wonders how he can determine whether this is just a chance difference or an indication that WD increases the risk of hypoglycemia. The decision is difficult because many factors besides medication play a role in the occurrence of hypoglycemic events. In a randomized trial, we can assume that the proportions of patients who, like Judy, go too long without eating and exhaust themselves on shopping trips and subsequently have a hypoglycemic episode should be similar in the 2 treatment groups. The key question is whether a difference of just over 4% between the treatment groups represents an effect that is due to the use of WD.

Unfortunately, classical statistics is of little help in answering this question. Over coffee, Jeremy chats to his statistician colleague Michaela about the problem and asks her why adverse event tables don’t include P values for identifying “true” differences between the treatment groups. Michaela explains that the statistical methods to determine whether a test medication is more efficacious than a comparator cannot be applied to analyzing safety. This is because clinical trials are generally not designed to detect differences in safety events (eg, hypoglycemia) but are rather designed to show differences in an efficacy endpoint (eg, concentration of hemoglobin A1c). The number of patients needed in the study is calculated to be able to show a difference in the primary endpoint.

Michaela explains that evaluating the safety of a drug is not like evaluating its efficacy, mainly because there are so many more things to look at than a single parameter. In a mid-size study, there will be hundreds of different adverse events. If we were to test statistically for differences between groups for particular adverse events, we would likely get some P values below .05, but these will almost certainly include some chance findings because we would have to perform a large number of tests. In fact, as soon as we perform more than 1 test on any given data set, we increase the probability of “false positives,” which is why statistical tests for efficacy need to be adjusted for multiple testing.

Jeremy returns to his desk aware that it will not be possible to draw firm conclusions about which of the adverse events reported were caused by WD on the basis of data from this single trial. All he can do is describe the data accurately, identifying any notable differences between the treatment groups.

This is an important step toward identifying the adverse drug reactions attributable to WD.

After completing the section on the most frequent adverse events, Jeremy has to write sections on a number of other subsets of adverse events. At least 6 dimensions of adverse events are of interest for regulators and pharmaceutical companies:

- **Timing:** whether an adverse event occurred before, during, or after the study treatment, and how long after the start of treatment
- **Seriousness:** whether an adverse event met the criteria for being classified as serious (i.e. it was fatal, life-threatening, required a patient to be hospitalized or prolonged his/her hospitalization, resulted in persistent disability, or was a birth defect)
- **Intensity (sometimes called “severity”):** whether an adverse event was of mild, moderate, or severe intensity
- **Relatedness:** whether an adverse event was considered by the investigator to be possibly related to the study drug (often called “drug-related”)
- **Leading to discontinuation or other actions with the study drug:** whether an adverse event led to dose modification, interruption, or discontinuation of the study drug (called “other significant adverse events” in the ICH E3 guideline)
- **Of special interest:** whether an adverse event met prespecified criteria for an adverse event of special interest (AESI) in the trial population

All of these categories of adverse events are important for characterizing the safety profile of a drug, and a medical writer needs to check all of them for imbalances between the treatment groups. It is not uncommon for particular events to fall into several of these categories (eg, a serious adverse event may also be severe and may also lead to discontinuation). Medical writers should bear in mind that it is helpful to make clear to the reader when an individual event is being discussed in several different sections of a report (eg, by using cross-references).

One category that looks particularly helpful for identifying those events that are adverse drug reactions (ie, caused by the study drug) is the one called “drug-related” adverse events. However promising the term “drug-related” may seem, this category in fact simply represents investigators’ assessments of whether it is possible (often phrased as: “cannot reasonably be excluded”) that an adverse event was caused by the study drug. Investigators use their medical judgement to make this assessment and take into account considerations of timing, the study drug’s mechanism of action, and its known safety profile. However, especially at the early stage of development, a drug’s adverse effects are not fully known, and therefore the assessment of the investigators will be based on their medical intuition. When a drug is relatively new, investigators treating
individual patients in a clinical trial cannot have the full picture yet. Furthermore, in a double-blind trial, investigators do not know which treatment a particular patient is receiving, so there will also be drug-related adverse events in the placebo arm. Some years ago, the US Food and Drug Administration questioned the value of this category. In their guidance to reviewers of New Drug Applications, they state that analyses of drug-related adverse events based on investigator assessments are “generally not expected to provide much useful information in assessing causality.” In some parts of the world, however, this category is regarded as important.

Of particular interest to regulatory authorities are those adverse events that are serious (especially if they result in death). As outlined in Part 1, serious adverse events need to be reported rapidly to the sponsor, and some serious adverse events need then to be reported to the regulatory agencies. Imbalances between treatment groups in the percentages of patients with serious adverse events need to be carefully examined.

Regulators and pharmaceutical companies are also greatly concerned about adverse events that result in a patient discontinuing study medication. If many patients discontinue a drug because they cannot tolerate the side effects, this is clearly very important information about the overall safety of the drug and may compromise any beneficial effect the drug may have. If the percentage of patients who stop taking the study drug because of adverse events is high, the drug will likely never make it to market.

All serious adverse events and events leading to discontinuation need to be carefully scrutinized to try to determine whether they could be causally related to the study drug. This is done using all available information, going beyond the investigator’s assessment of “relatedness.” To support the evaluation, these categories of adverse events are not just analyzed in summary tables but are also included in the CSR at the individual patient level. So-called “patient safety narratives” are written, which summarize all important safety information for an individual patient. Narratives are usually only written for patients who had safety events that fell into certain prespecified categories (eg, serious adverse events, deaths, discontinuations). Jeremy needs to write a patient narrative for Judy (of course, he knows her only by her trial identification number), whose sprained ankle was classed as serious because of her overnight hospital stay (see Part 1). In the patient narrative, Jeremy summarizes all the available safety information. He will do the same for other patients as necessary. In large trials, the number of such narratives may easily run into the hundreds.

**AESIs: Digging Deeper into the Data**

Often, it is known at the clinical trial planning stage that certain kinds of adverse events occur more frequently in patients with the condition that is being studied or are likely to be caused by the drug under study. Such information may also come from a competitor drug that is from the same class of drugs (ie, that is chemically or biologically similar to the drug under study). Because of their clinical importance, these adverse events will often be defined by sponsors as AESIs. These will then be described in the clinical trial protocol, and study physicians will be instructed to record the circumstances and nature of any such events in more detail than is usual for other adverse events.

The definition of an AESI has to be broad enough to capture all events that are likely to represent the same underlying medical phenomenon, condition, or safety signal. A useful tool for ensuring that all such events are considered in the analysis is the “standardised MedDRA query” (SMQ). SMQs are groupings of MedDRA terms, usually at PT level, that relate to a defined medical condition or area of interest.

In the trial Judy took part in, hypoglycemia was defined as an AESI, and Dr Chu had to complete a special page of the electronic case report form that requested a number of additional details about Judy’s hypoglycemic fainting episode (see Part 1). When Jeremy reaches the AESI section of the CSR, he has to summarize all the data collected on hypoglycemia in the course of the trial. He first makes an in-text table showing the main findings (Table 2).
The numbers of patients shown in this table as having reported “hypoglycemic adverse events” are slightly higher than those shown for “hypoglycaemia” in Table 1. This is because the SMQ for hypoglycemia covers all MedDRA PTs that are indicative of hypoglycemia, and not only those events coded to the PT “hypoglycaemia.” Jeremy notices that when analyzed at the SMQ level, there is still a difference between the treatment groups, with more patients reported with hypoglycemia in the WD group than in the Comparator group.

The additional data collected and summarized for hypoglycemia as an AESI tell us more about the severity of the events. We can see from the data in Table 2 that, although hypoglycemia was more frequent in the WD group than in the Comparator group, lower percentages of patients in the WD group than in the Comparator group reported hypoglycemic events in the worst 2 severity categories (“required assistance” and “symptomatic and blood glucose <3.0 mmol/L”) and were given therapy, discontinued from the study medication, or were hospitalized as a result of the hypoglycemia.

Thus, it appears that even though hypoglycemia is slightly more frequent with WD, the hypoglycemic events are more severe with the Comparator. Based on these data, it is difficult to draw a conclusion as to which treatment is “safer” with regard to hypoglycemia.

The adverse event tables that Jeremy is working with summarize the numbers of patients who experienced an event, rather than summarizing the numbers of events. As soon as a patient has a certain event, this is entered into the database. This happens each time the patient reports a symptom to the study physician. If a particular patient has the same event multiple times during the study, it is entered in the study database each time it occurs. In standard adverse event tables, however, the patient is counted only once for each category of event (see Part 1 for more detail). This standard approach is helpful for determining the probability that patients will experience a particular adverse event, but the standard analysis does not tell us how many such events patients are likely to experience or when the events are likely to occur.

When an adverse event is common in a patient population, as hypoglycemia is in people with type 2 diabetes, we are not just interested in the so-called “crude incidence” of the event (ie, the percentage of patients reporting it) but also in how many times each patient experiences it and how long after starting treatment the events occurred. Table 2 gives us this more detailed information: we can see that very low percentages of patients in both groups had more than 3 episodes of hypoglycemia. We also have data on the time from the start of treatment to patients’ first hypoglycemic adverse event, and

<table>
<thead>
<tr>
<th>Table 2. Summary of Characteristics of Hypoglycemic Adverse Events</th>
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<tbody>
<tr>
<td></td>
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<tr>
<td>N = 652</td>
</tr>
<tr>
<td>Patients with hypoglycemic adverse event,a  n (%)</td>
</tr>
<tr>
<td>Severity (worst episode), n (%)</td>
</tr>
<tr>
<td>Required assistance</td>
</tr>
<tr>
<td>Symptomatic and blood glucose &lt;3.0 mmol/L</td>
</tr>
<tr>
<td>Symptomatic and blood glucose ≥3.0 mmol/L and &lt;3.9 mmol/L</td>
</tr>
<tr>
<td>Action taken, n (%)</td>
</tr>
<tr>
<td>Therapy given</td>
</tr>
<tr>
<td>Discontinuation of study medication</td>
</tr>
<tr>
<td>Required hospitalization</td>
</tr>
<tr>
<td>Number of episodes, n (%)</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2-3</td>
</tr>
<tr>
<td>4-5</td>
</tr>
<tr>
<td>&gt;5</td>
</tr>
<tr>
<td>Time to onset of first episode, n/N at risk (%)</td>
</tr>
<tr>
<td>≤7 days</td>
</tr>
<tr>
<td>&gt;7 to ≤28 days</td>
</tr>
<tr>
<td>&gt;28 to ≤56 days</td>
</tr>
<tr>
<td>&gt;56 days</td>
</tr>
<tr>
<td>Exposure-adjusted incidence rate (per 100 pt- yrs)</td>
</tr>
</tbody>
</table>

All data are invented for the purpose of this paper.
Pt-yrs, patient-years.
aBased on hypoglycemia SMQ.
these data tell us something interesting: patients in the WD group seem more likely to experience hypoglycemia within the first 4 weeks of treatment, but after that, the incidence of new cases is similar between the groups.

Another limitation of comparing crude incidences is that it does not consider the duration of study drug intake. It is important to know whether an adverse event occurs quickly after starting the medication or whether it takes some time before such an event occurs. In the world of safety analysis, the length of time a patient or a group of patients takes a drug is called “exposure” because, during this time, patients are exposed to the drug under study. The comparison of crude incidences does not take into account the length of patients’ exposure to the drug and follow-up in a clinical trial. A diabetic patient who is followed up for 2 years is more likely to report hypoglycemia at some point than a patient who is followed up for 12 weeks, simply because she has much more time (opportunity) to have a hypoglycemic event. Using crude incidences to summarize adverse events can be very misleading when the exposure differs between treatment groups. Such differences can easily arise if patients in 1 treatment group are more likely to convert the drug once it is on the market. For example, large development programs in type 2 diabetes research may comprise some 20,000 patients, but the population of people who have type 2 diabetes and may take the drug is many millions. At the level of an individual trial but for a whole clinical development program comprising a potentially large number of trials. When a company applies for marketing authorization for a new drug, the safety data from all relevant clinical trials are pooled, and the analysis of adverse events and other safety variables to establish the drug’s safety profile is performed on this large data set.

A better way of comparing adverse event incidences in such situations is to use exposure-adjusted incidence rates. To do this, the total number of patients in each treatment group experiencing a given adverse event is divided by the total exposure of that group in years. This gives the exposure-adjusted incidence rate for each patient (on average) per year (called “per patient-year”). In clinical trials, this number is often multiplied by 100 to give the rates per 100 patient-years. This measure uses the collective exposure duration for a given group of patients to convert the frequency of patients with an event into a number that also reflects the duration of exposure. However, a downside of this approach is that the numbers may become very hard to relate to and lose their direct clinical usefulness (eg, how do we interpret incidence rates like 56.2 per 100 patient-years compared with 54.7 per 100 patient-years in terms of risk for the individual patient?).

We can see from Table 2 that the exposure-adjusted incidence rate for hypoglycemia in the 2 treatment groups is quite similar, which suggests that the difference in the crude incidences may be partly due to differences in exposure. These could have arisen if a higher proportion of patients on the Comparator than on WD discontinued treatment early in the trial.

**Beyond the Single Trial: Establishing a Drug’s Safety Profile**

When Jeremy has completed all the sections on safety in his CSR, a somewhat clearer picture of the safety profile of WD emerges. It is possible that some adverse events are more frequent in the group of patients that received WD, and this could be an indication that these events are caused by WD.

However, a single clinical trial, even a big one, is never sufficient to characterize the safety profile of a drug. Just imagine that WD causes a very rare side effect, one that is so rare that only 1 in 1,000 people who take the drug would get it. In our trial we had 652 patients in the WD group; thus, it is quite probable that we would not see a single patient with this rare event. Our chances of detecting this rare event get better if we look at more patients treated with WD. In order to have a 95% chance of detecting an adverse effect that occurs in 1 in 1,000 patients, we would need a clinical trial population of 3 times as many patients (ie, 3,000 patients)—this is called the “rule of 3.” The more patients are analyzed, the better the chance of seeing rare and very rare events. For this reason, the full evaluation of the causality of adverse events and the subsequent characterization of a drug’s safety profile are performed not at the level of an individual trial but for a whole clinical development program comprising a potentially large number of trials. When a company applies for marketing authorization for a new drug, the safety data from all relevant clinical trials are pooled, and the analysis of adverse events and other safety variables to establish the drug’s safety profile is performed on this large data set.

Taking data from a whole clinical program is clearly an improvement over considering data from only a single trial, but even large clinical development programs involve far fewer patients than the number of patients who will be using the drug once it is on the market. For example, large development programs in type 2 diabetes research may comprise some 20,000 patients, but the population of people who have type 2 diabetes and may take the drug is many millions. At the time of approval of a drug, the safety database of any given drug is necessarily limited. Therefore, drug makers are obliged to collect any safety information they can get for every drug they have on the market. This surveying for potential safety signals is called “pharmacovigilance” and uses not only clinical trial data (for example, post-authorization trials to evaluate safety in large populations) but also reports of adverse reactions from physicians and consumers, literature reports, and other sources. Over the years, the legislation with regard to pharmacovigilance has become tighter and more complex, and pharmaceutical companies are required to undertake detailed regular reporting to the regulators.

**Future Directions in Safety Analysis: The Patient Perspective**

The current standard approach for analyzing adverse events,
as described above, is strongly determined by the concerns of regulators (such as the US Food and Drug Administration). However, awareness is growing that regulators and patients have different perspectives on drug side effects. Regulators need to make sure that any drug that is sold is safe and that it achieves improvements in patients’ health without causing harm. However, any medicine has unwanted effects. Regulators need to look at the entire patient population and need to make sure that for the majority of people, the benefits of taking a drug outweigh the risks. Only when this is the case and any unwanted effects can be handled, can regulators approve a drug. For this reason, they require sound evidence of a drug’s effectiveness and a comprehensive analysis of all unwanted effects seen during clinical development. Regulators want to establish a comprehensive safety profile for a particular drug, and so they look at all the safety data available: not just adverse events but also changes in clinical laboratory parameters, vital signs, and scores in patient-completed questionnaires. When it comes to adverse event data, regulators rely on the events as recorded by physicians based on what patients tell them. The study doctors translate the patients’ words into medical terms that are then coded via the MedDRA system, and they judge the severity of all events. In the recording of adverse events, study physicians serve as “filters” and may separate observations they think medically important from ones they regard as trivial. Evidence suggests that clinicians tend to record adverse events reported by patients selectively and to downgrade the severity of patients’ symptoms.

The perspectives of patients are likely to be very different, but these have rarely been given much weight in clinical research to date. Depending on the seriousness of their disease, patients may be primarily interested in knowing whether a drug will help them. With regard to risks, they want to know whether the unwanted effects will interfere with their daily life. Patients seem not so interested in lists of adverse reactions in the package insert. They are usually not fazed by rare serious events, as they rightly assume that they are unlikely to get them. They want to know whether they personally have a chance of getting a serious side effect. Unfortunately, nobody is able to tell them their personal risk because people differ in their genetic and biochemical make-up. Even if a side effect is fairly common with a certain drug, this does not necessarily mean that a particular person will get it.

Up to now, direct patient experiences of a drug’s side effects—for example, as recorded in patient-completed questionnaires—have only rarely been collected and analyzed in clinical trials. Regulators, therefore, cannot know what patients think about a particular drug’s side effects. There is currently a broad movement to increase the involvement of patients in drug development, and arguments have been made for greater use of direct patient reporting of symptoms experienced while taking a drug. Given recent advances in technology that would facilitate the collection of such data (eg, apps and wearable devices), it is likely that the patient perspective will become more prominent in the evaluation of drug safety in the future.

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**Reference**


**RESOURCES**


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Many common English nouns describe the relationship that one person has with someone else. Common examples include kinship terms (mother, father, daughter, son, sister, brother, etc). For example, your grandmother is a mother, but she is not your mother. She is your mother’s mother. Agent nouns can also imply relationships. Agent nouns (which usually end in -er, -or, or -ist in English) identify the entity that is performing an action. Thus, they imply a relationship between the agent and the activity and sometimes an object. For example, someone who uses a computer can be described as a user of that computer. A pianist is someone who plays the piano. So when we use a word that implies a relationship, we must think carefully about whether the relationship that we are implying really exists.

Patient

Many years ago, I overheard a heated discussion between a psychiatrist and an activist from a group that described itself as representing “mental health consumers.” The activist was angry because the psychiatrist referred to his patients as patients. The activist wanted the psychiatrist to refer to them as consumers, instead. The psychiatrist refused. He explained, “I am a medical doctor, and the people I treat are my patients.” Theoretically, this dispute could be solved by paying attention to the dictionary definitions of the words. The term mental health consumers makes no sense. One can consume goods and services, but one cannot consume health, mental or otherwise.

Of course, it is understandable that the activist was opposed to the careless use of the term mental patient or even psychiatric patient. Not only is the term stigmatizing, but it implies a relationship that may not exist. Many of the mentally ill people who are living on our sidewalks or in our prisons in the United States are not getting any psychiatric care at all. People with untreated mental illnesses are no psychiatrist’s patient, nor are they consumers of medicinal products or mental health services. We should refer to someone as a patient only when we are talking about the relationship that the person has with a health care professional (such as a doctor, a dentist, or a nurse) or a health care institution (such as a hospital) or the care that the person is receiving from those professionals and institutions.

People who are staying at the hospital during their treatment can be described as inpatients. People who are receiving treatment at the hospital without being admitted to the hospital can be described as outpatients. Of course, individuals who are being held in a hospital or other institution (such as a prison) against their will can be described as inmates.

Patient Versus Client

When you go to a doctor, you are that doctor’s patient. But when you retain a lawyer, you become that lawyer’s client. Often, the word client means someone who engages the advice or services of a professional, such as a lawyer. The word client can also be used to refer to a customer, which means someone who is buying goods or services from someone else. Also, the people who are receiving services from a social service agency can be referred to as clients, even though they are not paying for the services. Some health care professionals have clients and patients. For example, when I bring my dog to the veterinarian, the dog is the veterinarian’s patient but I am the veterinarian’s client. The dog is the one who is receiving the veterinary care, but I am the one who hired the veterinarian to provide it.

There has been a great deal of debate lately about whether the people being served by the members of a particular profession (eg, psychotherapists) should be described as patients or clients. In principle, I think we should use the term patient for people who are receiving biomedical services and client for people who are receiving psychosocial services. Of course, many professionals deliver a mixture of biomedical and psychosocial services, so the dividing line can be hard to draw. For that reason, editors should err on the side of caution and use the terminology that is standard for the profession in question.
Patients, Subjects, Participants
A doctor’s patients are patients; but when their treatment is part of a clinical study, those patients are also subjects. The US Code of Federal Regulations defines a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information. The word subject implies that the person is serving as a source of data to the investigator. The subject can also be the investigator’s patient, if there is a doctor-patient relationship between them. We can also use the words participant for someone who actively cooperated in the study and volunteer for someone who came forward to take part in the study.

In principle, I think we should use the term patient for people who are receiving biomedical services and client for people who are receiving psychosocial services.

Clients, Consumers, and Customers
The words client, consumer, and customer also imply a relationship. The word client generally refers to someone who is receiving some sort of service, and possibly goods as well. If you are a client, then you are the client of the person or firm that provided those services and goods. In contrast, the word consumer refers to someone who is buying and/or using goods, or possibly services. If you are a consumer, then you are a consumer of those goods and/or services. A customer is someone who purchases goods or services from someone. The purchaser is the customer of the person or firm that provided the goods and/or services. If you work in advertising, you mainly try to find ways to help your clients persuade consumers (or at least potential consumers) to become their customers.

As medical writers, we often write for a professional audience, such as doctors or nurses. However, we also often write for a general audience. The members of that audience are often described as “consumers,” even though they are not necessarily consuming anything. Often, the members of a general audience are described as “patients,” even if they are not seeing a doctor. Thus, it might be more appropriate to describe that audience as a lay audience and its members as laypersons.

Mothers, Parents, Caregivers
When I started working as a medical editor, it was commonplace for people who were writing about pediatrics to assume that a child’s primary caregiver would be the child’s mother. Yet even back then, many children were being reared by other family members or by legal guardians. For that reason, we must be careful about the word that we use for referring to the person who is responsible for a child’s care. “Parent or legal guardian” is wordy. Caregiver seems like a better choice. A caregiver is a family member or paid helper who regularly looks after a child or a sick, elderly, or disabled person. The caregiver may (but might not) be the person’s parent or legal guardian.

Diabetic, Schizophrenic
In English, we often use nouns to modify other nouns (attributive nouns), such as when we say “diabetes complications” to mean the complications of diabetes mellitus. We can also turn nouns into adjectives (denominal adjectives) to express that one noun is related to another. For example, the noun diabetes gave rise to the denominal adjective diabetic. The adjective diabetic can be used to express that someone has diabetes mellitus (a diabetic patient) or that something is the result of diabetes mellitus (eg, diabetic ketoacidosis). We also often turn adjectives into nouns (nominalized adjectives). The denominal adjective diabetic has been nominalized (ie, used as a noun) to mean a person with diabetes. However, many people object to the use of these nominalized denominal adjectives derived from disease names. Some people complain that a disease, such as diabetes or schizophrenia, is something one has, not something that one is. They urge us to say “person with diabetes” or “person with schizophrenia”—to remind us of the humanity of people who are ill.

Laurie Endicott Thomas is a freelance medical writer and editor. She is the author of 5 books, including Not Trivial: How Studying the Traditional Liberal Arts Can Set You Free (www.nottrivialbook.com) and Thin Diabetes, Fat Diabetes: Prevent Type 1, Cure Type 2 (www.thindiabetes.com).

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AMWA President Kathy Spiegel, PhD, MWC®, welcomed attendees to the 2018 Annual Business Meeting for AMWA members. The purpose of the Annual Business Meeting is for members to hear reports from the President, Treasurer, and President-Elect and to witness the election of officers.

**President’s Report**

Spiegel went on to provide some highlights of accomplishments this year. AMWA expanded its marketing program by implementing its first promotional videos (membership, conference, corporate member–focused, volunteer, and freelance) and increased digital marketing efforts through growth in paid social media, Google display networks, and paid search.

AMWA added webinars and interactive online learning activities to its portfolio and will soon be launching the Learning Objective activity.

An electronic delivery format was implemented for the Essential Skills self-study workbooks and certificate quizzes.

AMWA launched an initiative to recruit educators for the corporate training program, AMWA workshops, and other education programs.

Model chapter bylaws were created to guide chapter leaders as they update their bylaws this year. In addition, new resources for chapter leaders were created, including a new private online community in Engage.

AMWA worked with the Northern California Chapter leaders to organize and produce the Pacific Coast Conference and worked with the Mid-Atlantic, Greater Chicago, Southwest, and Carolinas chapters to support their chapter conferences.

AMWA supported members in the Pacific Southwest area to explore the feasibility of forming a new chapter.

Resources were created for Local Networking Coordinators (LNCs).

A task force was approved for an enhanced Medical Communications Compensation Survey.

The inaugural Medical Writing Executives Forum—Preparing for the Future of Medical Writing in Pharma and Biotech—was held at the 2018 Medical Writing & Communication Conference.

Computer-based testing was implemented for the Medical Writer Certified® (MWC®) examination at testing centers around the globe, and the MWC® candidate handbook, examination form, examination policies and procedures, examination registration, and study guide were all updated.

Spiegel expressed her gratitude to the members of the Board of Directors who gave an abundance of their precious time to implement these initiatives. This group partnered with the AMWA staff to leverage their combined strengths, knowledge, and relationships and to guide the organization through this busy year.

**Treasurer’s Report**

AMWA Treasurer Julie Phelan, MD, MBA, presented a financial report for the period of July 1, 2017, to June 30, 2018. She stated that an independent financial audit of these numbers will take place over the next month.

AMWA ended the year with a net income of $259,031. Major sources of program revenue were member dues, the Annual Conference, and education programs.

Overall expenses were under budget by 17% for the year because of unbudgeted nonprogram income, the negotiation of the office lease, and a concerted effort to contain costs. Investment income for the fiscal year was $120,093 (net of investment fees), which includes realized and unrealized gains on investments of $93,592.

As of June 30, 2018, AMWA had $1,644,076 in short-term and long-term investment reserve funds. The reserve fund falls within the target of keeping an amount equal to 6 months to 1 year of annual operating expenses in the account. AMWA Endowment funds totaled $187,200, and McGovern funds totaled $155,366.

Phelan indicated that it had been a pleasure serving as AMWA’s treasurer this past year and thanked the Budget and Finance Committee for their work on reviewing and commenting on the financial report information and for helping AMWA update its investment policy.

**Slate of Officers Announcement, Election, and Changing of the Guard**

Spiegel returned to announce the slate of officers and preside over the election and changing of the guard. In accordance with the AMWA bylaws, the Nominating Committee presented the slate of officers for 2018 to 2019 to the Board.
of Directors at its meeting in April. The Board approved the slate, and the membership was notified of this slate 60 days before this meeting (sidebar).

AMWA’s bylaws contain a provision for additional nominations to be made in writing. No additional nominations were received. The bylaws state that a nominee who is unopposed for any office shall be elected automatically. Therefore, the following slate of nominees were elected as AMWA officers for 2018 to 2019, led by Cyndy Kryder, who, as President-Elect, automatically assumed the office of President.

**2018-2019 Officers:**
- President: Cynthia L. Kryder, MS
- President-Elect: Ann Winter-Vann, PhD
- Secretary: Gail Flores, PhD
- Treasurer: Julie Phelan, MD, MBA
- Immediate Past President, Kathy Spiegel, PhD, MWC®

Introduction of 2018–2019 Board of Directors

In her first task as President, Kryder reported that the new AMWA Board of Directors is composed of the officers (above), 6 At-Large Directors, the Chair of the Chapter Advisory Council (CAC), and the AMWA Executive Director (ex officio). The new At-Large Directors and CAC Chair were previously approved by the outgoing Board.

**2018-2019 At-Large Directors:**
- Brian Bass, MWC®, Chair and Board Liaison, Communications Committee
- Noelle Demas, MSTC, Board Liaison, Member Recognition Committee
- Elise Eller, PhD, Board Liaison, Chapter Leader, Online Community
- Melory Johnson, VN, Board Liaison, Local Networking Coordinators
- R. Michelle Sauer Gehring, PhD, Chair and Board Liaison, Annual Conference Program Committee
- Theresa Singleton, PhD, Board Liaison, *AMWA Journal* Editorial Board

Katrina Burton, BS, Chair and Board Liaison, Chapter Advisory Council

**Ex Officio**
- Susan Krug, MS, CAE, Executive Director, AMWA

Kryder ended the Business Meeting by saying that she is thrilled and honored to be able to work with these accomplished members over the coming year.
As I sit in my office writing the President’s column for this issue of the AMWA Journal, a huge winter storm is descending upon the East Coast. Forecasters are predicting feet of snow in some areas, ice, and even rain in others. It will be a mixed bag, for sure, but even as the snow swirls outside my window, I’m reminded that by this point in January (yes, that’s when I’m writing this), I have survived the darkest days of winter; each day we gain an additional minute or two of daylight. There’s a metaphor in that for sure.

Individuals looking to develop careers in medical communication may experience dark days as they struggle to gain the training and access the resources they need to get hired. I’m reminded of an email exchange I had with a health and fitness professional who wanted advice about breaking into the field of health and medical communications. She had been floundering for nearly a year and still hadn’t figured out what to do. As I always do when I get such requests (and I get them often), my first recommendation was to join AMWA for all it has to offer. AMWA’s mission, after all, is to promote excellence in medical communication and to provide educational resources in support of that goal. There is no better place to start than AMWA, in my opinion.

Flip the calendar forward 2 years, and this individual had emailed me again, eager to tell me that she had finally joined AMWA. Her question: “I’m an AMWA member. Now what?” Her query made me realize that she’s probably not the only AMWA member asking this question. Paying your membership dues is not enough. To reap a benefit, members need to be familiar with AMWA’s educational programs, resources, and benefits, so let me sketch a road map you can navigate—new member or not—to guide you so that you can make the most of your AMWA membership.

Building and advancing a career in medical communication requires you to get to know people in the industry and to have them get to know you. A good place to begin is on Engage, AMWA’s virtual community. Create a profile and then read through the discussions and peruse the resources posted there. As you become comfortable, ask your own questions and answer others when you have something to contribute. The members who are active on Engage are a collegial group who are always willing to share information. From advice on the best type of standing desk or how to alleviate workplace stress to questions about proper grammar and punctuation, you’ll find it on Engage.

Attending AMWA events in your local area is another way to learn about the industry and to meet your colleagues. Find out what you can about local events and then go to them, talk with people, and pass out your business cards. To find AMWA members in your geographic region, search by city and

FROM THE PRESIDENT
You’re an AMWA Member. Now What?

Cynthia L Kryder, MS / 2018–2019 AMWA President
state in the AMWA member directory. Periodically check the Events Calendar on the AMWA.org home page, which lists local as well as national events.

Be sure to take advantage of AMWA’s free monthly webinars for members. You’ll learn about them through the AMWA Update sent to your inbox twice a month. AMWA also posts about them on LinkedIn (make sure to join the AMWA LinkedIn group) and on Facebook. Topics vary, but the webinars are free to AMWA members, so why not attend?

A great way to build your network is by volunteering for AMWA. Get your feet wet by volunteering at the chapter level, where volunteers are always welcomed. We have volunteer positions for committee members as well as for Local Networking Coordinators (LNCs), affectionately called Links (https://www.amwa.org/page/Local_Networking). These people organize networking events in their local areas. The events don’t need a structured program or speaker; they are simply made up of AMWA members who get together to meet one another and talk about whatever comes up in the conversation. Anyone can become a LNC.

To stay up to date on industry news and trends in the field of medical communication, be sure to read Medical Communication News, a member benefit delivered via email twice a month. This e-newsletter provides an executive summary of noteworthy articles pertaining to the medical communication industry.

Finally, I firmly believe we need to invest in ourselves if we want to be successful. So, take a look at AMWA’s educational offerings, in particular our self-study modules and online activities, and dive in.

Speaking of AMWA Education, I’m excited to report that AMWA has hired a full-time Director of Education, former AMWA President Lori Alexander, MSTW, MWC®. Lori’s work history, extensive service as an AMWA volunteer, and experience as an educator within the field of medical communication make her uniquely qualified for this position. Lori has been an effective volunteer, mentor, and leader. With her understanding of the diverse needs of the various constituencies that make up AMWA’s membership, Lori was able to hit the ground running when she joined the staff in January.

This is an exciting time for our organization. As we learned at the inaugural Medical Writing Executives Forum in November, a number of unmet educational needs exist, especially with regard to medical communicators working in the biopharma setting. With a Director of Education on board, AMWA is ideally positioned to create new educational activities and resources to meet those needs and to do so in a timely manner. If you haven’t done so already, I urge you to read about the outcomes of this event in the summary article, “Preparing for the Future of Medical Writing in Biopharma: AMWA’s Inaugural Medical Writing Executives Forum,” which appears in this issue.

A Career in Medical Communication:
Steps to Success

Learn about the skills and attributes needed to be a successful medical communicator and discover opportunities in the field.

www.amwa.org/career_steps
Preparing for the Future of Medical Writing in Biopharma: AMWA’s Inaugural Medical Writing Executives Forum

Joan Affleck, MBA, ELS; Cynthia L. Kryder, MS; Kathy Spiegel, PhD, MWC®, and Ann Winter-Vann, PhD
1Executive Director and Head of Medical Writing, Merck & Co; 22018–2019 President, American Medical Writers Association; 32018–2019 Immediate Past President, American Medical Writers Association; 42018–2019 President Elect, American Medical Writers Association

Abstract
Executives of medical writing departments share unique yet common concerns, needs, and perspectives and can benefit from engaging one another in an exchange of ideas and experiences. At its annual Medical Writing & Communication Conference in November, 2018, the American Medical Writers Association (AMWA) convened executives of medical writing departments at 22 of the world’s top biotech and pharmaceutical companies to discuss workforce trends and advancements in medical writing, elaborate on best practices, develop solutions to challenges, and exchange ideas and strategies with peers in a rare collaborative environment. Also attending the forum were executives from several companies that provide regulatory medical writing and consulting services and the head of a university degree program in biomedical communications. This article summarizes that discussion.

Introduction
The American Medical Writers Association (AMWA) is the resource for professional medical communicators. Its mission is to promote excellence in medical communication and provide educational resources in support of that goal. To gain insight into the common concerns among executives whose responsibility it is to recruit, train, and manage professional medical communicators, AMWA has created the Medical Writing Executives Forum. This annual invitational event aims to identify opportunities for executives to optimize the functioning of their medical writing departments while preparing their teams for future challenges and opportunities in the industry. The inaugural Medical Writing Executives Forum was held in November 2018, concurrently with AMWA’s annual Medical Writing & Communication Conference. Joan Affleck, MBA, ELS, Executive Director and Head of Medical Writing at Merck & Co, chaired the forum, which was hosted by Kathy Spiegel, PhD, MWC, 2017-2018 AMWA President, and moderated by Ann Winter-Vann, PhD, 2018-2019 AMWA President Elect. The theme of the inaugural Medical Writing Executives Forum was “Preparing for the Future of Medical Writing in Pharma and Biotech.”

Forum attendees represented medical writing departments at 22 of the world’s top biotech and pharmaceutical companies, as well as several companies that provide regulatory medical writing and consulting services and a university degree program in biomedical communications.

Workplace Trends Affecting Medical Writing Teams
Whether the audience is a regulatory agency or the public, telling the scientific story of new drugs and treatments for diseases depends on skilled medical communicators. These professionals are expected to perform in a changing environment where they must balance regulatory requirements with organizational demands to streamline processes, operate cost-effectively, and do more with less. Forum attendees identified several workplace trends that are affecting the medical writing teams they manage (Table 1). Two of these trends elicited the bulk of the discussion: automation/artificial intelligence (AI) and remote work/outourcing.

<table>
<thead>
<tr>
<th>Table 1. Workplace Trends Affecting Medical Writing Teams Today</th>
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<tbody>
<tr>
<td>Artificial intelligence</td>
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<td>Automation</td>
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<tr>
<td>Compressed timelines</td>
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<tr>
<td>Data transparency</td>
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<td>Flat organizational structures</td>
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<td>Lean authoring</td>
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<td>Outsourcing</td>
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<td>Remote employment</td>
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<tr>
<td>Strategic leadership challenges</td>
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<tr>
<td>Streamlined processes</td>
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Automation/AI
In the past, companies created document templates that were based on their interpretation of regulatory agency guidelines or simply their own internal corporate processes and needs. More recently, companies have begun collabo-
rating to revise existing templates (ie, clinical study reports) or to develop new templates where no industry standard existed before, such as protocols or lay-language patient summaries. Standardized templates will allow for automation across related documents within a company and even across the industry.

The next step beyond automation is AI. One forum attendee noted that AI in medical writing is not yet upon us, but predicted that it “will explode upon us unexpectedly.” The challenge will be to incorporate AI tools into work processes and to prepare medical writing teams to use them. Communicating the benefits of these tools will be essential. Security of AI was also a concern.

Managers generally viewed AI positively, noting that it could remove the drudgery involved with creating certain components of regulatory documents while allowing medical communicators to focus on more engaging aspects of document creation. Nevertheless, AI is not intended to replace medical writers. Forum attendees cautioned that technology cannot be the driver; medical communicators should be empowered to provide guidance for the development of AI and automated systems.

Remote Work/Outsourcing
Forum attendees agreed that remote work affords access to a larger pool of talented writers and can offer writers a quiet space for uninterrupted writing. Managers noted, however, that managing from a distance is demanding on 2 levels. First, it is difficult for managers to remotely manage their direct reports. Second, and perhaps more importantly, it is equally challenging for writers to manage their remote teams from a distance, as it can be difficult to assert authority when you are not seen. These challenges are not insurmountable, however. Where opportunities for face-to-face meetings are few, the proposed solution was to leverage technology to increase trust and build relationships among remote team members. This involves scheduling meetings on a regular basis and investing in webcams so that team members can see and communicate with one another in real time. Ensuring that webcam meetings are efficient and useful for all participants requires the cultivation of a webcam culture wherein remote workers feel comfortable using the technology to interact with colleagues.

Recruitment and Retention
It was no surprise that attendees reported being challenged in recruiting and retaining talented medical communicators (Tables 2 and 3). Executives agreed that the pool of talent is decreasing and that the quest to find qualified employees who can serve the industry has become difficult, especially as the population of experienced medical communicators ages. As one participant noted, medical writing is a craft that is learned through intensive, structured training. Consequently, writers need hands-on experience with regulatory documents and with teams in order to develop expertise.

Table 2. Challenges in Hiring and Training New Medical Communicators

<table>
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<th>Challenge</th>
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<td>Baseline experience uneven or lacking</td>
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<tr>
<td>Lack of formal and standardized training programs</td>
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<tr>
<td>Lack of soft skills and emotional intelligence</td>
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<td>Limited pool of tech-savvy candidates</td>
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Table 3. Factors Influencing Retention of Medical Communicators

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<th>Factor</th>
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<td>Clearly defined career path options</td>
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<td>Desire for more work–life balance</td>
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<tr>
<td>Flexibility versus specialization (therapeutic areas and document types)</td>
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<tr>
<td>Increased clinical trial complexity</td>
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<tr>
<td>More lay-oriented documents</td>
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<tr>
<td>Need to work as part of the team rather than in isolation</td>
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<tr>
<td>Systems changes</td>
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<tr>
<td>Technology requirements</td>
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</table>

Investing in proper training can enhance retention. Several forum participants expressed a preference for apprenticeships of 3 to 5 years to train medical communicators. However, it is difficult to support writers through that level of training on the job. Mentorships were discussed as another option, if the medical writing team is large enough and if senior writers can be trained in how to mentor effectively and are provided adequate time to mentor.

A mutual concern is getting the medical writer from a junior to a senior level. Retaining writers longer than 2 to 3 years is difficult, especially because many companies have adopted flat organizational structures. Managers are being tested to find ways to keep junior-level writers content, engaged, and motivated in their work when growth opportunities are few.

Working in a regulatory environment where most projects are large and intense and where compressed timelines have become routine has adversely affected employee retention. In the past, writers were assigned a large, fast-paced project and upon completion moved to a less-intense assignment to give them time to regroup before the next large project. Today the trend is for writers to move from one intense project to another with no time in between, which is extremely stressful and leads to employee burnout. Managers who can protect their writers from this level of stress are able to provide their employees with a better work–life balance and have better retention. However, this strategy requires commitment from management.
How to keep experienced writers engaged is another issue that managers face. Forum attendees concurred that supporting flexibility drives engagement and retention, whereas pigeonholing writers into 1 particular therapeutic area or document type has no benefit.

**Soft Skills and Emotional Intelligence**

Managers want writers who have the experience and scientific and regulatory knowledge to bring insights, input, and scientific and medical value to their teams. In addition, managers desire writers who have the soft skills and emotional intelligence that enable them to bring leadership, negotiation, and conflict-resolution skills to the team. The days of being able to write as a lone entity are over.

Managers noted that the soft skills that allow writers to succeed at working remotely are the same skills that enable them to work well with their teams. Desirable soft skills include:

- Communication
- Conflict resolution
- Critical thinking
- Leadership
- Negotiation
- Problem solving
- Teamwork
- Time management

Managers acknowledged that soft skills are probably among the toughest skills to develop. Nevertheless, they can be taught. Successful soft-skills training requires medical writers who are eager to develop these skills and live, face-to-face training opportunities to learn and practice them. Managers recognized that soft-skills training was another way to engage experienced medical writers.

**Next Steps**

Regardless of the type or size of their company, it was clear that managers of medical writing teams all struggle with the same issues: finding and developing medical writing talent, managing remote teams, retaining skilled writers, and meeting organizational expectations. It was extremely rewarding to hear how these leaders have embraced the challenges, recognized the need to evolve, and applied creativity within their organizations to develop skilled medical writers and efficient medical writing departments.

AMWA has the opportunity to support leaders to not only train and encourage existing medical communicators but also to prepare the next generation of medical communicators to meet future workplace demands in the biopharma industry. AMWA will be assembling a Medical Writing Executives Advisory Council to discuss the feedback received at the forum, identify key areas for future training, and develop goals and objectives for this initiative. With engaged leaders such as those who participated in the inaugural Medical Writing Executives Forum, we feel confident that we will be successful in our mission to promote excellence in medical communication and provide educational resources in support of that goal.

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**Chapter Advisory Council: Making Strategic Strides**

Katrina Burton / Chair, AMWA Chapter Advisory Council

The strategic structure of an organization is important because it provides a sense of direction and outlines measurable goals. For organizations such as the American Medical Writers Association (AMWA), strategic oversight and planning from the AMWA Board of Directors (BOD) has led to a number of committees and work groups over the past year that have brought about positive changes. One such group is the Chapter Advisory Council (CAC), a group that includes a representative from each of the 15 chapters.

Approved by the AMWA BOD, the CAC is charged with maintaining a connection between chapter leaders and the AMWA BOD. To ensure that chapters continue to have a voice in the strategic direction of the organization, each chapter president was asked to appoint a chapter member to serve as a representative on the CAC. The purpose of the CAC is to advise the AMWA BOD on the organization’s strategic direction as it affects the chapters and to bring forth issues that may impact chapters and the national organization.

The CAC is chaired by a representative from the CAC who is appointed by the AMWA President. The CAC also has support from an AMWA staff member who works closely with the Chair and members of the CAC. The CAC meets via teleconference 3 times a year and in person at the annual Medical Writing & Communication Conference. The organization was fortunate to work with an impressive group of members for the inaugural year of the CAC (Table).

**A Year in Review in DC**

In the fall of 2018, the CAC met at the annual Medical Writing & Communication Conference in Washington, DC. The AMWA
BOD and Conference Planning Committee helped organize a lunch meeting for the CAC, inviting special guests including AMWA BOD members Gail Flores, Elise Eller, and Melory Johnson. The in-person meeting held at the conference also serves as a transitional meeting for incoming CAC representatives. Incoming 2018-2019 CAC representatives Leslie Neistadt (Mid-America), Lisa Carricaburu (Rocky Mountain), and Shara Pantry (Florida), also attended the meeting, along with AMWA staff.

The Council reviewed the 2017-2018 year, sharing feedback on how the CAC was able to help inform and impact strategic decisions of the organization. The first task for the CAC was to develop a comprehensive report about the top issues faced by chapters. The Council identified 3 main areas of concern, which included governance, tools, and procedures. Although not new issues, the report confirmed that these top issues were shared by most chapters and that the AMWA BOD’s strategic direction to help support chapters in these 3 areas continues to be important.

The CAC also had a chance to review and submit feedback on the chapter bylaws template and the Chapter Leaders Tools and Resources. The latter is an important chapter resource that was launched by the Chapter Support Committee, which included Melory Johnson, Elise Eller, and AMWA staff members Shari Rager and Sharon Ruckdeschel. In addition to sharing input on important organizational developments, the CAC received a plethora of information, such as summaries of the AMWA BOD meetings, Chapter Activity Trends Reports, updates about AMWA’s Privacy Policy, and notices about the Medical Writing Certification Commission’s new study guide, testing centers, and examination dates.

CAC representatives were encouraged to share this information, as well as detailed notes from CAC meetings, with their chapter leaders.

Looking Ahead
With input from CAC representatives, a CAC job description was developed to help clearly define the role of the CAC representative, guide chapter presidents in identifying the appropriate member to fulfill the role, and create a strategic foundation for the organization as it grows and evolves within the medical communications industry.

The CAC plays an important role by helping to guide chapter leadership with strategic decisions while staying connected to the AMWA BOD. As the CAC focuses on 2018-2019 priorities, the goal is to continue to be a strategic voice for chapters and another resource for chapter leaders. The CAC provides an opportunity for chapter members to get involved with important decisions and contribute to the success of chapters and the organization.

We welcome the new 2018-2019 CAC members and returning members for another great year of strategic thinking and implementation!

Table. The 2017-2018 Chapter Advisory Council Roster

<table>
<thead>
<tr>
<th>Chapters</th>
<th>Representatives to the CAC</th>
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<tbody>
<tr>
<td>New England</td>
<td>Andrea Gwosdow, PhD</td>
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<tr>
<td>Empire State-Metro New York</td>
<td>Anjani Shah, PhD</td>
</tr>
<tr>
<td>Delaware Valley</td>
<td>Julie Munden</td>
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<tr>
<td>Mid-Atlantic</td>
<td>Jill Roberts, MS</td>
</tr>
<tr>
<td>Carolinas</td>
<td>Jennifer Bridgers, MS, MWC*</td>
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<tr>
<td>Southeast</td>
<td>Kim Kowreik, PhD</td>
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<tr>
<td>Florida</td>
<td>Irvin Peralta, MBA</td>
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<tr>
<td>Ohio Valley</td>
<td>Sarah Dobney, MPH</td>
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<tr>
<td>Greater Chicago Area</td>
<td>Sarah Prins, PhD</td>
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<tr>
<td>North Central</td>
<td>Mary Knatterud, PhD</td>
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<td>Indiana</td>
<td>Barbara Lightfoot, CCRP</td>
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<td>Southwest</td>
<td>Katrina Burton</td>
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<tr>
<td>Mid-America</td>
<td>Heather McNeill, MA, ELS</td>
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<tr>
<td>Northern California</td>
<td>Barbara Arnoldussen</td>
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<tr>
<td>Rocky Mountain</td>
<td>Brittany Hodges, PhD</td>
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</table>

We welcome the new 2018-2019 CAC members and returning members for another great year of strategic thinking and implementation!
Money. It’s on everyone’s minds. Salary and pricing questions are very common inquiries received by the association. Did you know that federal law can affect how the organization shares that information? Antitrust concerns can be mitigated by using historical data, reporting aggregated data rather than identifying individuals (or small groups of individuals), and having the data managed by an independent third party. More information can be found on the Federal Trade Commission website (https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/dealings-competitors/spotlight-trade).

The AMWA Medical Communication Compensation Survey collects and reports compensation information in a way that maintains compliance with these laws, using a third-party research firm (Association Research, Inc [ARI]) to conduct the survey and analyze the results. Results from the survey will help you understand the marketplace without compromising the privacy of individual participants.

As savvy consumers of information, you know how critical it is to the generalizability of the results for the sample to have appropriate representation across the field of medical communication and to have a high response rate. All AMWA professional members will receive survey invitations; medical communicators who are not members are also eligible to participate.

How can you help?

• add amwa@associationresearch.com to your safe sender list so you receive the survey invitation
• contact salarysurvey@amwa.org if you did not receive your survey invitation
• consult the survey FAQs on the AMWA website (www.amwa.org/salary_survey_faqs) as needed and complete the survey as accurately as you can
• encourage other medical communicators who are not AMWA members to contact salarysurvey@amwa.org to request a survey invitation

This survey is for you. And we need you to make it happen!
2019 AMWA Medical Writing & Communication Conference
NOVEMBER 6-9, 2019
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Trends and Opportunities for Medical Communicators

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Dr. Julia Forjanic Klapproth, Senior Partner
Master Skills — Owning the process, leading with expertise, lighting up a room
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 again to devote this issue of the AMWA Journal to showcasing our conference content. First, let me thank our volunteer reporters who attended and have provided brief reports of many of the open sessions presented this past November in Washington, DC. These brief reports are designed to share some basic information from each session so that those who could not attend 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 2019 conference, perhaps this glimpse into what you’re missing may help clarify your decision!

This online-only supplement continues to share additional postconference coverage that we just couldn’t fit into the print issue, including a presentation by Stacy Robison, MPH, MCHES, recipient of the John P. McGovern Award; additional Open Session reports; information from several of our exhibitors; and reproductions of our conference posters.

I hope you find this insight into the annual Medical Writing & Communication Conference to be of value. As you can see, if you missed it, you missed a lot! I hope to see you at the next conference in San Diego, California, later this year!

Yours in AMWA,
~Jim
You’ve all probably considered the question of whether medical writing is art or science, or both. Rather than rehashing that debate, I’m going to talk about the heart and science of medical writing. About 5 years ago, some CommunicateHealth employees dreamed up an idea to help spread the word about health literacy. It would be a weekly email and we would keep it short, sweet, nice, and conversational so it wouldn’t take up too much of our readers’ time. We would include some fun pictures so people would look forward to it every week, and We Heart Health Literacy was born. Today we have over 2,500 enthusiastic followers and growing. Adam, our creative director who does the doodles that everyone loves, is who you surely meant to give the award to. Thank you, Adam. I can take no credit for those.

We also had another purpose with We Heart Health Literacy. We wanted to bring more heart into medical writing. In a culture that values self-control and bodily perfection, being sick or even just being old can lead to feelings of shame and inadequacy. We wanted to encourage our leaders to use everyday words to interact with their audience, to normalize embarrassing questions and reduce shame and stigma.

When I say “heart,” I’m mostly talking about empathy. It turns out empathy is incredibly powerful. Empathy in health care has been shown to improve patients’ emotional health, symptoms, and psychological responses and to increase medication adherence and increase patient satisfaction. In other words, feeling seen and heard makes patients more likely to listen to and follow the recommended course of action.

Why is this happening? One of the main reasons is that empathy builds trust. And because you are all science nerds like me, here’s the basic science from the Harvard Center for Neuroeconomics. There’s a correlation between the amount of oxytocin a person’s brain produces and the level of trust they feel in any given situation. Researchers found a direct link between oxytocin levels and empathy, which is essential for creating trust. The higher the oxytocin, the higher the empathy—the deeper the trust.

What does empathy have to do with health literacy? A lot! One of the main ways we empathize is in our language. To create meaningful communications—whether they’re health websites, patient handouts, or journal articles—we need to know our readers and care about their lives. How do we show empathy in our writing? Can we make people feel seen and heard just with our words? Yes, we can.

I want to share with you 6 things we can do to build empathy in our writing.

First, write clearly and use familiar terms. You have to reach patients intellectually if you’re going to engage them emotionally. This means using familiar language, defining technical terms, and breaking information into short chunks that can be easily digested. We know that stress and illness compromise our ability to understand and retain health information.

The second thing we can do is normalize it. People who are sick or uncomfortable are often scared. Making an experience seem more common can help. For example, “Some people with herpes find that they experience ‘X.’” Or, “Many people who have been abused by a partner have done ‘Y.’” Normalizing.

Third, put yourself in the patient’s shoes. Consider for a minute: What would it be like to live with a health issue you don’t fully understand? What type of information would ease your concerns and even improve your condition?
Fourth, acknowledge emotions. Negative emotions like fear and shame can get in the way of clear thinking and healthy choices. You can make it a little easier for your readers by acknowledging their feelings. You could say, “It may be hard to talk to your doctor about your concerns, but it’s important.”

Fifth, be encouraging. Pay attention to your tone. If you’re writing about a sensitive topic, keep things positive. Consider including a message of hope. Like, “It’s normal to feel overwhelmed at first, but lots of people have learned to live with a catheter and you can too.”

And finally, be credible and be explicit. Explain research results plainly and precisely. It’s one of our greatest challenges as medical writers. But it’s essential to building trust. Many of your readers will compare multiple sources as they seek to understand their diagnosis and treatment, so it’s essential that we’re credible.

I’m going to give you an extreme example here of what I’m talking about when I talk about empathy, or lack of empathy, in our writing. This is from a denial letter from a health insurance company. You may have actually seen this—it made the rounds in the news. I’ll just read you the first few lines here. It says, “You requested man-made arms. Your arms were amputated.” It turns out the claim was denied because the doctor was out of network, but that’s not what comes across in this letter. It turns out that this company came to be a client of ours. We worked with them on some revised language, which led to increased levels of consumer satisfaction overall with the brand. The company’s JD Power consumer ratings were up 18 points after this project. So, there’s also a very strong business case for using plain language in our writing.

Empathy is critical to business too. There’s a direct link between empathy and commercial success. Businesses are more profitable and productive when they act ethically, treat their staff well, and communicate with their customers. We found this to be true at CommunicateHealth. My wife and I started the company 10 years ago in our attic. It’s true that I was 30 years old at the time—you can do the math. We now have 65 employees! Our goal was to make a difference in the world but also in the lives of our employees. We do this by offering flexible schedules, paid parental leave, and unlimited paid time off, and we’ll all get next Tuesday off to get out and vote. We’re creating a different kind of company and business. Plato is credited as saying, “Be kind, for everyone you meet is fighting a hard battle.” We could change this quote to read, “Be kind, for every one of your readers is fighting a hard battle.” And by empathizing with your readers, by not talking down to them, but instead meeting them where they are, using their language, putting yourself in their shoes, you’re putting the heart in medical writing.

At a time when our government is trying to erase entire groups of people—transgender people, undocumented people, people with disabilities, gay people, people with preexisting conditions, women—Your Words Matter. By rejecting the stereotype of the noncompliant patient, by sharing a personal story, by choosing a patient-centered term, by simply changing a pronoun in your writing, you are sending a powerful message to your reader. That message is, “I see you.” And that is the heart of medical writing.

Thank you so much for this award. It really touches my heart. And I can think of no higher honor than being recognized by my peers in this way. Thank you so much.

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References
GRANT EDITING BASICS: APPEALING TO REVIEWERS

Speaker
Meagan Ramsey, PhD, Manager, Proposal Development Unit, Center for Integrative Research in Critical Care, University of Michigan Medical School, Ann Arbor, MI

By Karen Potvin Klein, MA, ELS, GPC, MWC®

In this session, Meagan Ramsey suggested concrete ways in which medical editors can help investigators submit more competitive research grant applications. Because the National Institutes of Health (NIH) is the nation’s primary funder of biomedical research and has the most complex structure, this session focused on its process and structure—although many recommendations could apply to other funders.

At some institutes within the NIH, fewer than 10% of all applications are funded. In addition, strict page limits make the crafting of a convincing narrative a challenge. Thus, all proposals, in addition to proposing innovative and important work, must be well written and carefully prepared to have any chance for funding. As Ramsey stated, this is a golden opportunity for editors to play a key role in facilitating applicants’ success.

Ramsey began by noting that medical editors seeking to document their value could start with the fact that on its own website, the NIH recommends that grant applicants seek out editorial guidance. However, as became clear from attendees’ perspectives of reviewers. She noted that medical editors could provide value by helping to educate grant applicants—especially trainees or early-stage faculty members—about the process of submitting NIH applications. This is important because understanding the audience (in this case, grant reviewers) and what the funder wants are 2 essential components of any successful application, regardless of the science it proposes.

Editors are well positioned to provide value to investigators in other ways as well. For example, prospective applicants must be up to date regarding forms, instructions, and deadlines—all of which change, sometimes without much advance notice. So, the editor can be a reliable source for accurate information and suggestions on how to address new requirements. One example Ramsey gave is the NIH’s recent announcement about a change in wording of the “Scientific Premise” section; because this is new to investigators and they may have questions, editors can help interpret the NIH’s announcement and suggest ways to respond to it.

As Ramsey explained in her overview of the NIH’s structure, its 182 review panels (called “standing study sections”) will reflect the priorities of the NIH’s different institutes, and the perspectives of reviewers. She noted that medical editors could be “ideal middlemen” because they know how to meet an audience’s needs for information and understand the need to stay up to date about details of proposal submission and review.

After reviewing the steps of proposal submission, initial review by the NIH, and scientific review by the study section, Ramsey then provided a list of issues she most frequently encounters in 4 major sections of an NIH application.

- **Introduction:** Applicants who submit revised applications summarize the changes in a 1-page introduction. Ramsey noted that an editor is especially well equipped to organize this response and improve the tone (ie, alter subjective or defensive statements) of this critically important section.

- **Specific Aims:** This 1-page precis is a “snapshot” of the proposal and needs to appeal to reviewers for them to score it favorably. Ramsey said the biggest issue she sees is an overly ambitious plan (too many specific aims).

- **Significance and Innovation:** These sections should be separate in focus, but Ramsey noted that she often reorganizes text and suggests clarifications to better fit the NIH requirements and meet reviewers’ expectations.

- **Approach:** In this section, applicants describe the planned experiments. Yet as Ramsey noted, some proposals lack key details to convince reviewers of feasibility. For example, reviewers expect to see a section explaining potential issues and alternative approaches if a hypothesis falls short or if technical problems arise. She also noted that some applications do not directly address the scientific hypotheses.

This session provided an entrée to the NIH proposal submission process for those unfamiliar with it and illustrated the strategic value medical editors can add to applicants’ teams. The slides from this session (accessible to AMWA members at https://www.amwa.org/page/2018sessions) also included good advice about the formatting and visual appeal of text.

Karen Potvin Klein, MA, ELS, GPC, MWC®, is the owner of Clarus Editorial Services, a biomedical grant consulting and manuscript editing company in Winston-Salem, NC.

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THE MISCOMMUNICATION EPIDEMIC: HOW CLOSE ARE WE TO FINDING A CURE?

Speaker
Cynthia L. Kryder, MS, CCC-SP, Medical Communication Consultant, Phoenixville, PA

By Jacqueline M. Mahon, MA

Although we’ve moved beyond our childhood tin-can-and-string attempts at communication, opportunities for misconstruing messages are still plentiful. As medical communicators, we find that these crossed lines can lead to project delays, lost prospects, frustration, conflict, and even the demise of relationships. Individual perceptions—what is “said” versus what is “heard”—are everything. Can we allow miscommunication...
to infect the estimated 70% of each day we spend communicating (ie, writing, reading, talking, listening)? Cyndy Kryder presented communication principles, causes of and remedies for miscommunication, and preventive medicine to help us improve and protect the health of this valuable time and effort.

**Ideal Communication**

In a perfect world, you send a message, the receiver hears and responds, you clarify, and the receiver confirms. In reality, however, multiple factors can intervene and disorder this seemingly straightforward pathway. You may be surprised to learn that 55% of an in-person message is delivered via nonverbal cues/body language and that only 7% is delivered by your actual words (Figure). Therefore, carefully consider your posture, facial expression, clothing, and other nonverbal cues when communicating face to face.

Additional causes of miscommunication include

- Being implicit (“When you get a chance, send me the estimate”) rather than explicit (“Send me the estimate this morning”)
- Using the wrong communication channel for your message – Synchronous or immediate: phone or live chat
  – Asynchronous or nonimmediate: voicemail, email, text, social media
  – Voice or personal: phone, voicemail, or live chat
  – Words or impersonal: email, text, social media
- Making assumptions, usually with a negative bias
- Rushing
- Choosing words haphazardly, without concern for clarity
- Poor listening skills
- Multitasking

**Biggest Pitfalls**

Distractions are legion in the 21st century. We have laptops, iPads, smartphones, earphones, email, streaming movies and television shows, LinkedIn, Twitter, Instagram, Facebook, etc. In the past, we learned to interact and communicate well with practice. Today, we have no opportunity for practice. Couple this scenario with the fact that we hear at 1,000 words per minute (wpm) while speech occurs at about 150 wpm, and the end product is the phenomenon of multitasking.

**Listening** can be considered to occur at 7 levels, with 1 representing the highest risk of misunderstanding and 7 representing the lowest risk:

1. Not listening
2. Pretend listening
3. Partially listening
4. Focused listening
5. Interpretive listening
6. Interactive listening
7. Engaged listening

The biggest communication problem is that we do not listen to understand. We listen to reply.

**Multitasking** is seductive because we hear quickly, and distractions compete for our attention. Therefore, effort is required to attain the higher levels of listening. Communicators can assist in this effort (Box). According to Earl K. Miller, PhD, Professor of Neuroscience, The Picower Institute for Learning and Memory at the Massachusetts Institute of Technology, the concept of “super-power” multitasking is a myth. In fact, we are toggling among tasks, and there is a “switch cost”—time required to realign—as we repeatedly refocus our attention. Multitasking has a place in our frenetic society, but only with an understanding of its true characteristics, which include surges in the reward hormone dopamine and the stress hormone cortisol, as well as slower or reduced performance.

**TIPS FOR SUCCESSFUL COMMUNICATION**

- Be alert to nonspecific client communication (eg, tone of voice and nonverbal cues such as body language and facial expression).
- Consider that millennial clients may not like phone calls.
- Do not simply discard an opinion or information with which you disagree. Collaborate to reach a compromise.
- If your communication partner is not listening
  – Use her name several times
  – Ask him to repeat what you have said
  – Send a follow-up email summarizing your communication
  – Fall silent until your partner pays attention
- Use the communication hierarchy: expend the most effort on what must be known, less on what should be known, and least on what could be known.
- Apply the Laws of Remembering: we remember best what is recent, frequent, impactful, and usable.
- Listen without judgement.

**Engaging in the Present**

The most successful communication occurs when all involved are fully present and cognizant of effective methods. If you are listening, and the topic, relevance, and next steps are not clear, then ask for these specifics. If you are communicating and
unsure of accurate reception, then be explicit, align your nonverbal cues with your message, and repeat the must-know information at the end.

We can all improve as communicators and listeners. The cure for the miscommunication epidemic is attention. Healthy communication increases the likelihood of successful projects, smoother and more pleasant workdays, and strong professional relationships.

Jacqueline M. Mahon, MA, is Principal of Acorn Freelance, Philadelphia, PA, as well as a Medical/Health Writer & Communications Consultant.
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THE CSR SIMPLIFICATION PROJECT: CREATING A CLEAR, COMPLIANT, AND CONCISE CSR

Speakers
Mitzi Allred, PhD, Director Clinical Operations, Merck, Philadelphia, PA
Diane Petrovich, PhD, Medical Writer, Clinical Operations, Merck, Philadelphia, PA on behalf of the Merck CSR Simplification Team

By Madison Hedrick, MA
At Merck, the clinical study report (CSR) process and structure have been retooled and revised to ensure that the company’s CSRs not only facilitate the job of the Health Authority Reviewer (reviewer) but also fully leverage the efforts and expertise of the reviewers and authors that Merck employs.

The CSR Simplification Project is a part of the movement within Merck to simplify documentation for clinical studies. The revised CSR template and process utilize focused authoring principles, leverage the electronic environment, address disclosure concerns, and build on structural authoring initiatives.

Overview of the Project
The Merck team used a logical and well-informed path to make the change from the dense CSRs to the new, Simplified CSRs (Table, Figure). As part of the project, a team of cross-therapeutic specialists collected cross-functional input, conducted benchmarking within the industry, and critically analyzed the CSR template and procedures.

Principles of Focused Author Writing Style
According to Elizabeth Brown, MS, PMP, and Kimberly Jochman, PhD, in their AMWA conference presentation,1 the benefits of focused authoring include that it
• Allows key messages to be identified easily
• Reduces writing, review, and quality control time
• Reduces redundancy to increase quality

This style is in contrast to that usually seen in CSRs, and even manuscripts, in that every word in the document should serve a grammatical purpose or move the document forward. Simplification of a CSR means that the document is no longer comprehensive, containing all study information; rather, it is

Table. Guiding Principles of the Simplified CSR

<table>
<thead>
<tr>
<th>Build on Industry &amp; Our Best Practices</th>
<th>Leverage the CPT</th>
<th>Team Benefits</th>
<th>Agency Reviewer Benefits</th>
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<tbody>
<tr>
<td>Embrace Focused Authoring Principles</td>
<td>Leverage Electronic Environment</td>
<td>Leverage the CPT</td>
<td>Compliant</td>
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<tr>
<td>No distracting redundancies or unnecessary descriptions</td>
<td>Build on structured authoring initiatives</td>
<td>Protocol is only 1 click away!</td>
<td>ICH E3, FDA, CFR, CORE Reference</td>
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<tr>
<td>Reuse reviewed &amp; approved text from protocol</td>
<td>Maximize immutable text</td>
<td></td>
<td>Reduce reviewer time</td>
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<tr>
<td>Minimize customization</td>
<td></td>
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<td>Reduce QC time</td>
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CFR, Code of Federal Regulations; CORE, Clarity and Openness in Reporting; CPT, core protocol template; CSR, clinical study report; FDA, US Food and Drug Administration; ICH, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; QC, quality control.
Comparison of Original CSR to Simplified CSR

The simplification of the CSR reduced the number of pages within the CSR from 27 to 4. The original CSR has lots of white space, whereas the new Simplified CSR is reformatted. The original CSR has 14 tables, whereas the new CSR has just 1 adverse event (AE) table. The original has repetitive text that restates the information already included within the tables, whereas the new CSR briefly summarizes the key methods and analyses. The original has a combined section describing both the methods and the results, whereas the new CSR has the key messaging for efficacy and safety information. The original has detailed descriptions of additional endpoints, whereas the new CSR includes only primary and secondary endpoints. The old CSR has paragraphs, whereas the new CSR has bulleted lists.

Detailed tables and slides indicating all changes to the CSR, providing a useful template, are provided by the speakers for reference on the AMWA website. For example, the Project Results section for the new Simplified CSR template now utilizes CORE for section 9, a streamlined version of sections 4 to 9 (linked to protocol), a focused-author-style revision for sections 10 to 12, and a clarified section 13. To see the other sections in their updated form, reference the slides available via AMWA.

Implementation of these changes requires communication, training, and reinforcement to achieve the best outcomes.

CANCER IMMUNOTHERAPY—OVERVIEW OF THE CURRENT LANDSCAPE

Speaker

Petra Volna, PhD, RPh, Senior Regulatory Documentation Scientist, Genentech, Inc, South San Francisco, CA

By Paul C. Dolber, PhD

Cancer immunotherapy may seem to have sprung from nowhere in the past decade, yet its development was the result of more than a century’s intense study of immunology. Dr Volna covered both the immunologic advances and resulting immunotherapeutic modalities in this wide-ranging presentation.

Four steps are required for an effective immune response, whether the targets are conventional pathogens or cancer cells. (1) The foreign antigens must be recognized and presented to cytotoxic T cells to cause their activation. Antigen-presenting cells of the innate immune system, particularly dendritic cells, carry out this step. (2) Activated T cells must then travel to the site of the targets and (3) kill the targets. (4) Finally, memory T cells must develop to complete the eradication of the targets and maintain control against further incursions.

Because the same rules apply to cancer cells and pathogens, it is puzzling that the immune system does not prevent cancer. In fact, the immune system does detect and suppress tumor formation, a process known as immune surveillance. In

Reference

1. Brown E, Jochman K. Using a focused authoring strategy to create a message driven deliverable. Presented at: AMWA Medical Writing & Communication Conference; November 1-3, 2018; Washington, DC.
the long run, however, this surveillance may act as an evolutionary force to promote the development of more problematic cancer cells, which can avoid T cells or induce changes in the tumor microenvironment that inhibit both T-cell infiltration and T-cell activity. Several immunotherapies are being developed to deal with these problems.

**Checkpoint Blockade**
Activation of T cells requires binding of antigen to the T-cell receptor and co-stimulation through the cluster of differentiation 28 (CD28) receptor. The activated T cell soon expresses the checkpoint protein cytotoxic T lymphocyte–associated protein 4 (CTLA-4), which prevents further co-stimulation by competing with CD28 and markedly reduces T-cell activity. Similarly, maintained T-cell production of the checkpoint protein programmed death 1 (PD-1), as well as PD-1 binding to programmed death ligand 1 (PD-L1) expressed by tumor cells, reduces T-cell activity. Delivery of antibodies against these checkpoint inhibitors often rescues T cells from exhaustion, restores T-cell antitumor activity, and cures cancers.

**Therapeutic Cancer Vaccines**
Cancer results in the development of mutations and thus new antigens (neoantigens). When presented on the cell surface by major histocompatibility complex (MHC) proteins, these neoantigens promote T-cell activation via dendritic cells. Such neoantigens could be used for the development of anticancer vaccines. Efforts using neoantigens have been problematic because they are usually unique to each patient. However, recent technological advances are making use of patient-specific vaccines plausible.

**Chimeric Antigen Receptor T Cells**
T cells isolated from melanoma patients’ tumors can be expanded and stimulated in vitro, then returned to the patient, where they often successfully attack the remaining tumors. This “adoptive cell transfer” also underlies the use of chimeric antigen receptor (CAR)-T cells, whose cell receptors are genetically modified to yield antibody-based receptors that bind to cancer cell–specific proteins. This bypasses reduced tumor cell MHC expression and the need for T-cell co-stimulation. Finding an appropriate target remains a problem for most cancers.

**T Cell–Engaging Bispecific Antibodies**
This treatment uses antibodies having one limb that binds to CD3 protein on the surface of T cells and one limb that binds to cancer cell–specific surface proteins. T-cell receptors are linked to CD3 and activate T cells through them; antibody binding to CD3 directly activates the T cells. Because the other limb is bound to cancer cells, this brings the activated T cells into contiguity with the cancer cells to ensure the T cells can kill the cancer cells. As with CAR T-cell therapy, finding an appropriate cancer-cell surface protein is a problem.

**Preventative Vaccination**
This therapy is now used for one virally induced cancer. After it was shown that human papillomaviruses (HPVs) can cause cervical and other cancers, vaccines were developed and are now used to prevent the initial HPV infections. HPV vaccination is already reducing cervical cancer incidence.

Whether as scientists or as potential patients, it is gratifying to be witness to the fruition of over a century of hard immunologic work in the form of increasingly effective cancer immunotherapies.

Paul Dolber, PhD, is a Senior Scientist II at the University of Texas Medical Branch in Galveston, TX.

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**LARGE, COMPLEX FREELANCE MEDICAL WRITING PROJECTS: BEST PRACTICES**

**Speakers**
- **Debby Berlyne, PhD**, Freelance Medical Writer and Editor, Rockville, MD
- **Tom Drake, MA, CMPP**, Director, Global Outcomes Group Inc, Reston, VA

*By Margaret M. Burke, PharmD*

Increasingly, freelance medical writers are being hired to work on complex medical writing projects that previously were the purview of in-house writing staff. This trend is being driven by downsizing of medical affairs and writing departments within the biopharmaceutical industry and advancing technology that improves Internet connectivity allowing for global collaboration. “The majority, probably 80%, of medical writing is no longer performed in house,” said Tom Drake, yet the need for creating large, complex documents still exists. Managing large writing projects among several individuals and over long distances presents many challenges. This presentation explored the roles of project team members, discussed key challenges in the process, and offered best practices to successfully deliver such projects.

There is no standard definition for a complex freelance medical writing project. The speakers provided their working definition and several examples of what they consider a complex freelance project (Table 1). The Academy of Managed Care Pharmacy dossier example was then used to illustrate challenges and possible solutions in the case studies that followed.

The speakers discussed aspects of building a team of qualified freelancers from both an agency and a freelance perspective. An agency’s job is to build the right team, which requires assessing the nature of the project and selecting freelancers who are not only skilled but also a good match for the project. Team members may include a team lead, project manager, lead
writer, support writers, editors, graphic designers, and a client liaison. Debby Berlyne explained, “Each project is unique and requires its own configuration. You have to think in advance what it will be. Some of these were roles we didn't think of in advance. That's why we want you to know about it so you don't repeat our mistakes.” Freelances should confirm the parameters of their participation early on, including deliverable requirements, payment schedule, and a clear delivery schedule for all drafts.

The responsibilities and desired characteristics of each team member’s role were discussed in depth. Particular attention was given to how the team lead, project manager, and lead writer roles differ (Table 2).

Potential problems during a project and possible solutions for each were illustrated using several case studies. The speakers emphasized that with large, complex documents, it is particularly important to present a single voice and a consistent format. The problems addressed included document version control, having too many source documents, and team members not meeting deadlines or turning in poor-quality work. An example of one case study is shown (Table 3).

The speakers closed by providing a summary of best practices developed from their experience in successfully managing teams of freelances in delivering complex documents (Table 4).

Margaret M. Burke, PharmD, is a medical writer with Precision Medical Writing, LLC, near Hartford, CT.

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**Table 1. Complex Freelance Medical Writing Project**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>More than 2 freelance writers</td>
<td>AMCP dossier</td>
</tr>
<tr>
<td>A primary editor, possibly more</td>
<td>GVD</td>
</tr>
<tr>
<td>At least 1 additional team member</td>
<td>HTA</td>
</tr>
<tr>
<td>A need for research writing, editing, and formatting</td>
<td>Publication plans for products with multiple indications</td>
</tr>
<tr>
<td>100 or more pages</td>
<td>Master slide decks</td>
</tr>
<tr>
<td>3 or more months to complete</td>
<td></td>
</tr>
<tr>
<td>Multiple sections needing different writing skills</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2. Key Team Members Roles**

<table>
<thead>
<tr>
<th>Team Lead</th>
<th>Project Manager</th>
<th>Lead Writer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identifies and hires freelances</td>
<td>Needs to understand project content</td>
<td>Responsible for document consistency and quality</td>
</tr>
<tr>
<td>Manages budget and payments</td>
<td>Needs to know team members</td>
<td>Creates any needed templates</td>
</tr>
<tr>
<td>Communicates with client</td>
<td>Assigns tasks to team members</td>
<td>Answers content-related questions</td>
</tr>
<tr>
<td>Assigns tasks</td>
<td>Monitors progress and communicates with team lead</td>
<td>Reviews work of other writers</td>
</tr>
<tr>
<td>Oversees project timelines</td>
<td>Finds needed resources</td>
<td>Manages version control</td>
</tr>
</tbody>
</table>

**Table 3. Case Study—Version Control**

<table>
<thead>
<tr>
<th>Problems Encountered</th>
<th>Possible Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outdated version of document online</td>
<td>Agree on file name rules during initial call</td>
</tr>
<tr>
<td>2 team members working on different versions</td>
<td>Assign a single keeper of each file</td>
</tr>
<tr>
<td>Wrong version submitted to client</td>
<td>Single shared online folder of current version with subfolders for older versions</td>
</tr>
<tr>
<td></td>
<td>Use online document management tools</td>
</tr>
</tbody>
</table>

**Table 4. Best Practices**

<table>
<thead>
<tr>
<th>Do</th>
<th>Don't</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schedule internal kickoff meeting with team members</td>
<td>Let client communication lapse</td>
</tr>
<tr>
<td>Schedule separate kickoff call with client and all team members (record it!)</td>
<td>Let delays escalate</td>
</tr>
<tr>
<td>Assign project manager and lead writer</td>
<td>Submit sloppy work to meet deadlines</td>
</tr>
<tr>
<td>Assign only 1 writer to each section</td>
<td>Deliver subpar work early or on time if excellent work can be delivered a bit later</td>
</tr>
<tr>
<td>Keep all team members up to date on project status</td>
<td>Admit problems to client</td>
</tr>
<tr>
<td>Track status of all project elements</td>
<td>Forget ongoing communication with all internal team members</td>
</tr>
<tr>
<td>Verify abilities of all freelances</td>
<td></td>
</tr>
<tr>
<td>Use multiple reviews of all work</td>
<td></td>
</tr>
<tr>
<td>Have backup activities for each team member</td>
<td></td>
</tr>
<tr>
<td>Make contingency plans for potential problems</td>
<td></td>
</tr>
<tr>
<td>Negotiate reasonable deadlines with client</td>
<td></td>
</tr>
<tr>
<td>Keep client informed of unexpected issues</td>
<td></td>
</tr>
</tbody>
</table>

AMCP, Academy of Managed Care Pharmacy; GVD, global value dossier; HTA, health technology assessment.
THE POWER OF STORY IN SCIENCE COMMUNICATIONS

Speakers
Cynthia Lollar, MFA, MAA, Digital Content Manager, Web & Multimedia Branch, Office of Communications & Public Liaison, National Cancer Institute, Rockville, MD
James Mathews, MA, Associate Director, Office of Cancer Content, Office of Communications & Public Liaison, National Cancer Institute, Rockville, MD

By Katherine Molnar-Kimber, PhD

Humans have been learning about life from stories for millennia. Conveying complex information as stories can help the general public and medical professionals not only grasp key health information but also absorb how that information affects them and their world on an emotional level, which can enhance its recall. Cynthia Lollar and James Mathews emphasized the differences in tone, structure, and aim between presenting the evidence-based facts in a report and presenting the information in a story.

They explained that “Informational content is designed primarily to help the audience DO or UNDERSTAND something, quickly and easily.” The facts needed for finding a clinical trial or applying for a grant can be presented in a straightforward manner, like a path. Lollar and Mathews described the parts of the informational content as:

- **Lead:** Includes the most important information, including who, what, when, where, and why.
- **Body:** Expands on the details, such as other background information and quotes.
- **Last Information:** Has the least importance.

In comparison, a story presents many of the facts in a winding, human-centered journey, so that you feel something such as tension, humor, suspense, curiosity, fear, wonder, or impending change. The speakers explained that “The human brain is wired to focus on, respond to, and remember stimuli that evoke our emotions.” The brain’s limbic system processes the data from our 5 senses and activates our bodies to respond physically (e.g., muscle relaxation or higher heart rate), emotionally (e.g., change in mood), and intellectually (e.g., better memory).

Thus, stories are a vital complement to the evidence-based facts in reports to illustrate important health and scientific concepts. But most patient materials and scientific documents do not use storytelling formats, thereby missing out on connecting people to the health and scientific information on an emotional level that often makes it easier to remember.

Mathews described the basic elements of story:

- Sensory details
- Characters who want something
- A plot that poses obstacles to that desire as the story moves toward a climax or resolution

He provided an example, breaking it up into multiple parts to enhance the suspense of following the adventures of his characters throughout the interactive presentation. Some unintended, short-lived IT challenges during the presentation added to the suspense, and Mathews and Lollar demonstrated resourceful strategies as they kept the story rolling.

Mathews included quotes to punctuate the essential points for storytelling. For example, Alfred Hitchcock’s quote, “a good story is real life … with all the boring parts taken out,” emphasizes that each bit of information in the narrative nonfiction story needs to fulfill a dramatic purpose. Thus, planning involves not only choosing and organizing true facts along the narrative path to readily engage the attention of the audience, but also choosing which aspects are unessential and left out. A story has a

- Compelling character with a defined goal
- Journey through conflict/complications toward that goal
- Character altered by a dramatic series of events that culminate in a climax or emotionally significant resolution

Further, the character is an individual (not a stereotype) described with sensory detail. She or he wants something intensely but faces obstacles. As challenges are overcome (or not), the character changes with time. The storyline encompasses the journey and its relationships to past events and potential future happenings. The essential conflict is identified and agitated or enlarged. Stories often embrace nonresolution. The ending can be a resolution or a change with a surprising nonresolution.

Lollar discussed the work of the science communicator Randy Olson, author of Houston: We Have a Narrative, which boils down the classic story structure into “And/But/Therefore.”

- **And:** Introduces the protagonist and the scene, describing their normal or ordinary world.
- **But:** Describes the inciting event and the moment of change or transformation. Often, the story involves multiple challenges, and each requires action.
- **Therefore:** Describes the changes, partial resolutions, transformations, and final resolution due to the challenges and conflict.

Lollar and Mathews provided many insights on writing narratives in their presentation. Lollar also examined examples from several different digital communication platforms, including YouTube (#IamHHS Deb Cotter, https://www.youtube.com/watch?v=-uaBiiWMHdM), Twitter, and Facebook for the And/But/Therefore storytelling.
structure. They also provided a handout with a list of references for further reading here.

In summary, if you are writing patient materials, consider structuring the information in a storytelling narrative using Lollar’s and Mathews’ insights and techniques. The And/But/Therefore technique may also be incorporated into the writing of slide presentations, abstracts, posters, and scientific manuscripts formatted in the classic IMRAD (Introduction, Methods, Results, and Discussion) structure.

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NETWORKING FOR INTROVERTED FREELANCERS: HOW TO GET BETTER RESULTS WITH LESS STRESS

Speakers
Lori De Milto, MJ, Lori De Milto Writer for Rent LLC, Sicklerville, NJ
Genevieve J. Long, PhD, Genevieve J. Long, PhD, PC, Hood River, OR

By Jennifer Fricker, BA

Many freelances choose to work for themselves and by themselves because doing so fits well with their introverted personality. However, one part of the freelance lifestyle is not a natural fit for introverts—the need to network.

Networking is essential for finding new clients, learning about the field, getting inside information, and avoiding the mistakes of others. Other freelances understand you and your challenges and can inspire you, support and validate you, and help you combat isolation. Lori De Milto and Genevieve Long can both attest to the power and value of these connections—they even met one another at an AMWA Annual Conference!

So how can an introvert best approach the challenge of networking? The most important first step, according to De Milto and Long, is to have the right attitude. When asked what words they associate with networking, the audience at this open session gave such answers as “stress,” “awkward,” “dread,” and “insincere.” Much of this negative view stems from the perception of networking as self-marketing. But Long says the goal of networking is not selling yourself—that is obnoxious and feels uncomfortable. Instead, as De Milto advises, your goal in networking should be to give more than you take: “Collaboration always beats competition.”

For an introvert, meeting and talking with new people can be draining. Focus your networking efforts strategically so that your investment of energy is well spent. Target people who are looking to hire your type of freelance by joining specific professional associations, like AMWA. Try volunteering for your local AMWA chapter; having a task to focus on, like setting up chairs or handing out badges, can make attending an event less intimidating.

In-person networking is the most effective. The right preparation can help: practice your “elevator speech,” which should include how you benefit clients, what you do, and who you work with. This short blurb is not to sell yourself, but rather to give the other person some context to interact with you. Bring business cards and dress professionally. If possible, reach out to a few attendees ahead of time whom you want to meet, and set up a specific time and place to get together, such as during a beverage break between sessions.

When you're at the event, smile and be confident and approachable, don't talk too much about yourself, and end each conversation well. Focus on the other person, by saying, “I know there are lots of people here, and I don't want to keep you!” Jot down notes on the back of their business card so that you can remember the context of how you met when you follow up later. Keep in mind there are likely lots of other introverts around you who are reluctant to make the first move themselves and would welcome your opening comment or question. Chat with the people who sit next to you in a session or who are standing in line with you to reach the buffet. And when attending a multiday event, schedule frequent breaks for “alone time” to rest and recharge.

After the event, review the business cards you received and reach out to people you think could be helpful to you (and you to them) with a LinkedIn invite and/or an email saying it was nice to meet.

What about networking online? Social media, such as LinkedIn, can be effective, but you must rank high in search results to be found by clients. This takes engagement—sharing useful, relevant content (news and tips, not self-promotion) with your connections in posts and comments.

Whether in person or online, once you’ve made connections, keep them strong by sharing resources, connecting people, and giving referrals. The more you give, the more you will receive: focusing on others, rather than yourself, is the secret to networking without stress.

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YOU CAN’T POSSIBLY UNDERSTAND HOW I FEEL (BECAUSE I WON’T TELL YOU): THE RIDDLE OF FEEDBACK

Speaker
Robin Whitsell, BA, BPh, President, Whitsell Innovations, Inc, Chapel Hill, NC

By Jennifer Fricker, BA
In this open session, Robin Whitsell shared that survey results have found that most employees appreciate both positive and negative feedback but that most do not receive valuable feedback, or any feedback at all. Lack of feedback leads to disengagement and withdrawal, so how can we improve at providing effective feedback to our colleagues? And how can we seek out and act on constructive feedback for ourselves?

First, Whitsell reviewed common pitfalls to avoid when giving feedback:
• **The “good news sandwich.”** Believe it or not, many managers are actually taught this terrible technique of sandwiching bad news between 2 pieces of positivity. However, it is much better to be straightforward and avoid mixed messages.
• **Making a molehill out of a mountain.** This is another method of “softening the blow,” but when managers overly qualify and minimize negative feedback, the employee is left with the mistaken impression that what happened was not a big deal.
• **Not giving any feedback.** Managers may hesitate to give feedback because they aren’t sure how to say something, are too busy, or are waiting for the perfect time—these all lead to avoidance of giving feedback at all.
• **They/everyone/the team.** Feedback characterized as coming from “them” or “everyone” or “the team” makes the recipient feel ganged up on, paranoid, and betrayed.
• **Drive-by.** Feedback delivered in a “drive-by” leaves the recipient with no chance to respond or ask questions, meaning they are not prepared to address the problem.
• **Disneyland feedback.** Nonspecific, all-positive feedback doesn’t contain anything constructive to take forward and work on.

Whitsell then reviewed the trifecta of effective feedback (Figure). The best feedback exhibits those 3 elements and is followed by an invitation providing the opportunity for clarification: “Do you want to talk about this more?”

Face-to-face and in-person delivery of feedback is best. The next best option, for those interacting remotely, is a video call. If video is not an option, then a phone call or an IM chat provides a better opportunity for back and forth than an email. If feedback must be delivered via email, remember, “Don’t type angry!” It’s better to cool off first. Also, don’t wait forever for exactly the right time or to come up with exactly the right words—better to open the conversation in an imperfect way than never to have it at all.

What about receiving feedback? If no one has said otherwise, we might assume that everything is fine; in reality, however, that might not be the case. How do we solicit constructive feedback and then act on it?

Here are some ways to ask for feedback
• “I’m working on X; have you noticed anything that might help me?”
• “In the past I’ve been told X; have you seen this?”
• “Do you have any observations that would help me improve?”

To then act on the responses you receive, you need to overcome any initial defensive reaction. Don’t deflect with excuses or justifications—really listen, instead. Three magic words may help you listen and absorb feedback: “Tell me more.”

Don’t ask for feedback when you are not ready to hear it, such as when you’ve just finished a stressful project or are feeling emotionally drained. It also helps to ask for feedback from peers with whom you have an established, trusting relationship.

Whitsell concluded the session with a little bit of homework. Try it yourself! Make 2 lists of names: (1) For whom do you have feedback? (2) From whom do you need feedback? Then, ask a trusted colleague to ask you in 3 weeks if you have reached out to those people.

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THINK AND COMMUNICATE VISUALLY

Speakers
Cynthia L. Kryder, MS, Medical Communicator, Phoenixville, PA
Lori Alexander, MTPW, ELS, MWC®, President, Editorial Rx, Inc, Fort Myers, FL
Jia You, Interactive Graphics Editor, Science Magazine, Washington, DC

By Brian Bass, MWC®
Medical writers are story tellers, and stories are told best when we combine words and visuals. For this reason alone, this session was an invaluable opportunity for attendees at the 2018 Medical Writing & Communication Conference.
Cyndy Kryder explained that the mind processes visuals much faster than words. She demonstrated this point by challenging the audience to identify the most memorable aspects of several examples. Research dating to the 1980s shows that visuals boost learning and comprehension, but it’s taken decades for us to think about how visuals impact what we write. According to Kryder, visuals are also more persuasive. Studies show that people only read 20% to 28% of the words on a page, but that visuals can break through the scanning.

She outlined several strategies for selecting the appropriate visual to support your content:
- Pie charts are an effective way to express parts of a whole
- Bar graphs are a clear means of presenting values in categories
- Tables are ideal for communicating comparisons and highlighting specific values
- Line graphs are an efficient means of tracking trends over time

Kryder urged the audience to think outside the box by considering other types of visuals beyond simple charts, graphs, and tables. She suggested isotype arrays to help readers visualize risks and rankings, word clouds to visualize commonalities and diversities, visual scales such as the Faces Pain Scale, and infographics to communicate a central story. It’s important for writers to use the right tools for the right audience, and to keep visuals simple and digestible.

Lori Alexander impressed the audience with data on the degree of information overload to which we are all exposed, noting that infographics can help us process that information more efficiently. Today we’re exposed to 5 times more information than in 1986. We consume more than 100,000 words in an average day, yet as Kryder pointed out earlier, we only read up to 28% of them. Alexander explained that the challenge is especially great when it comes to the amount of medical information to which the average person is exposed. It is estimated that the amount of available medical information will double every 73 days by 2020, which is now just 1 year away.

According to Alexander, data visualization as discussed by Kryder enables medical writers to present data with clarity and objectivity. In contrast, infographics enable us to tell a complete story that not only includes data but also leads the reader to a conclusion. As a result, infographics have an inherent degree of subjectivity to them.

Of particular relevance to medical writers, Alexander pointed out that today infographics are gaining traction in the clinical setting with health care professionals. They’re easy to digest, fun to share, and extremely engaging. She pointed to the popularity of visual abstracts and video abstracts as examples of this growing trend. The trick to creating an effective infographic is that you must be able to think visually. In her opinion, medical writers need to start thinking beyond words—thinking of themselves as medical communicators and embracing the use of images to bring greater communicative power to their work.

Jia You discussed the process of visualizing data in science and medicine. She explained that the key element of effective visual communication in medical communications is design—the combination of concise wording, clear graphics, logical color and contrast choices, and ensuring those elements tell the story accurately and completely. She presented a framework that graphically represented the wide range of visuals that may be used in communicating science and medicine. Visuals can range from being precise to general, and from explanatory to exploratory.

Through a number of examples, You showed how line graphs facilitate precise reading of data points while the use of angles, areas, and color intensity are suitable for depicting general trends in the data rather than providing precise readings. Color hue is an effective way to categorize information but is ineffective when it comes to representing quantities. However, she warned attendees that when using color they must keep in mind that approximately 5% of the US population is color blind.

Similar to the strategies Kryder provided earlier for selecting visuals that are appropriate to support your content, You outlined the several options for depicting different types of data visually:

<table>
<thead>
<tr>
<th>Depict</th>
<th>Visual Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change over time</td>
<td>• Line graph</td>
</tr>
<tr>
<td></td>
<td>• Column graph</td>
</tr>
<tr>
<td></td>
<td>• Calendar heat map</td>
</tr>
<tr>
<td></td>
<td>• Circle timeline</td>
</tr>
<tr>
<td>Comparison</td>
<td>• Paired column graph</td>
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<tr>
<td></td>
<td>• Proportional symbol</td>
</tr>
<tr>
<td></td>
<td>• Radar graph</td>
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<tr>
<td></td>
<td>• Parallel coordinates</td>
</tr>
<tr>
<td>Part-to-whole relation</td>
<td>• Pie chart</td>
</tr>
<tr>
<td></td>
<td>• Stacked column graph</td>
</tr>
<tr>
<td></td>
<td>• Grid plot</td>
</tr>
<tr>
<td></td>
<td>• Tree map</td>
</tr>
<tr>
<td>Correlation</td>
<td>• Scatter plot</td>
</tr>
<tr>
<td></td>
<td>• Line + column graph</td>
</tr>
<tr>
<td></td>
<td>• Bubble chart</td>
</tr>
</tbody>
</table>

Throughout their presentations, the speakers provided a wealth of resources, which they have also made available online. You can access their resources here.

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

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IDENTIFYING EXPERIENCE AND EXPERTISE TO SUCCEED AS A MEDICAL WRITER

Speakers
Damiana Chiavolini, MS, PhD, Instructor, UT Southwestern Medical Center, Dallas, TX
J. Kelly Byram, MS, MBA, ELS, CEO, Scientific and Medical Communications Lead, Duke City Consulting, LLC, Albuquerque, NM
Anne Murray, PhD, Scientific Research Writer, UT Southwestern Medical Center, Dallas, TX

By Vicki VanArsdale, MS
This interactive session focused on career development for both freelancers and those who work in house in academia, although the lessons learned are broadly applicable. Attendees heard 3 different perspectives on how to leverage their expertise and background to enter or advance in medical writing and editing and received actionable advice on job-seeking practices, transferable skills, and continuing education.

Becoming a Medical Writer
The panelists work in the medical writing field in different capacities, and each had a different point of entry. Murray had no experience in medical writing but was able to get her foot in the door as an in-house professional by leveraging her science background. She was in the right place at the right time; they needed a medical writer, and she was able to cross over after demonstrating her writing skills. Chiavolini worked as a biomedical researcher who left the bench for a career in academia. Byram is a freelance who runs her own company; she is only taking clients by referral now. She started in publishing but got interested in science and medical writing.

Although their paths differ, the panelists agree that networking and continuing education are keys to developing a medical writing career. Byram said it’s important for medical writers to grow their skill set, to expand into other areas, and to mentor and help each other. She said someone once told her “network or don’t work,” so introductions and network building are essential. Chiavolini suggests networking at AMWA’s Annual Conference and following up with new contacts to nurture relationships and have access to new opportunities. AMWA Engage is another good way to connect with peers.

Tips on Entering Medical Writing as an In-House Professional
- Research potential employers (benefits, job satisfaction)
- Modify your CV or resume to fit each job posting
  - A potential boss may be more interested in scientific expertise and may allow for writing skills to develop over time
  - Highlight writing/editing experience gained during school or at prior jobs
- Clarify uncertainties about the job posting, tasks, salary potential, and professional development during the interview
  - Salary negotiations
    - Read AMWA’s latest Salary Survey
    - Academia notoriously pays less but has better benefits
    - Offer a salary range acceptable for personal needs

Tips on Entering Medical Writing as a Freelance
- Freelances are hired to provide expertise and solve problems, so experience and expertise are essential
- Understand total (direct and indirect) financial requirements and have clients with the potential for ongoing work before leaving a paying job
- Define your value proposition (what makes you stand out)
- Have a business philosophy and a set of guiding principles
- Clients are the boss
- Learn how to negotiate and manage expectations; contracts
- List goals
  - Full-time or part-time?
  - Consistent or intermittent?
  - Retirement
- Considerations: Self-motivation, problem-solving ability, organization skills, working alone
- Assess possible distractions: Children, household chores
- Comfort level with uncertainty: Cash flow management, benefits

Byram said, “If you’re risk averse, [freelancing] may not be the path for you.” Freelancing is a full-time business, and it’s up to the freelance to make things happen. She recommends consulting with an accountant to determine what tax filing status is better: for example, sole proprietor or LLC.

Surviving Versus Thriving as a Medical Writer
Networking, nurturing relationships, mentoring, and continuing education are keys for thriving as a medical writer. Murray said she attends AMWA conferences to expand her education via workshops and open sessions. In house, she broadens her rapport with scientists by eating lunch with them periodically and stays in touch through email.

In her role as an in-house instructor, Chiavolini introduces herself to new faculty and sets up an in-person meeting; she also uses email and encourages them to attend sessions on various aspects of scientific and medical writing. She also encourages faculty to reach out to her very early in the grant application process to allow time to improve grantmanship and quality of writing. Chiavolini said AMWA is an invaluable resource and said to find allies on the job who support professional development and conference attendance.

As a freelance, Byram maintains her relationships with clients via open communication. She vets clients before working with them to assure a good fit but knows when to let a difficult client go. She said AMWA and peer mentoring are essential; she belongs to a group in New Mexico that
meets quarterly. All freelances should revise their business plans yearly and include a budget for professional development and continuing education. Byram offered this advice: “There’s enough work for everyone, but find a niche where you can flourish.”

A session handout, with extra tips and advice, can be found here.

Vicki VanArsdale, MS, is freelance writer and health care marketing communications specialist near Washington, DC.

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INTRODUCTION TO HEALTH ECONOMICS AND OUTCOMES RESEARCH (HEOR) FOR WRITERS

Speakers
Beth Lesher, PharmD, BCPS, Pharmerit International, Bethesda, MD
Catherine Mirvis, BA, Pharmerit International, Bethesda, MD

By Valerie Sjoberg, MAc, MWC®

Health economics and outcomes research (HEOR) exists across a variety of sectors in the health care industry and can provide ample opportunities for medical writers who are interested in the field. In this session, Beth Lesher and Catherine Mirvis presented an overview of HEOR, ways that health sectors use HEOR, and how writers with science and nonscience backgrounds can break into HEOR writing and editing.

Overview of HEOR

According to Lesher, HEOR focuses on the economic, clinical, and humanistic outcomes of various health care interventions and can play an important role in demonstrating the value of a product. Evidence for HEOR can be gathered from a variety of sources, including studies, registries, chart reviews, and patient-reported outcomes. HEOR is used by academic institutions, pharmaceutical companies, health plans, health care professionals, and others to

• Identify unmet needs
• Supplement randomized controlled trials with real-world evidence
• Address evidence gaps
• Promote patient-centered research
• Help develop and evaluate cost-containment strategies
• Adapt data to different populations
• Respond to changes in market environments
• Comply with health technology assessment submissions

In the United States, HEOR evidence is most commonly used by pharmaceutical companies, and it can be applied throughout the product lifecycle (Table 1).

Table 1. HEOR Evidence in the Pharmaceutical Product Lifecycle

<table>
<thead>
<tr>
<th>Trial Phase</th>
<th>HEOR Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preclinical</td>
<td>Exploratory research, gap analysis, very early modeling, market assessment, key opinion leader research</td>
</tr>
<tr>
<td>1 and 2</td>
<td>Market assessment, early modeling, piggyback studies, gap analysis, burden-of-illness studies, patient-reported outcomes development/testing/validation</td>
</tr>
<tr>
<td>3 and 3b</td>
<td>Payor assessment, registries, pricing and reimbursement, model development and validation, comparative effectiveness research, Academy of Managed Care Pharmacy dossier, piggyback studies, value message development, global value dossier</td>
</tr>
<tr>
<td>Post-launch</td>
<td>Phase 4 studies, comparative effectiveness research, retrospective studies, Academy of Managed Care Pharmacy dossier, model refinement, database analyses, global value dossier, piggyback studies, prospective observational studies, chart reviews, health technology assessment, safety surveillance, registries</td>
</tr>
<tr>
<td>Loss of exclusivity</td>
<td>Safety surveillance, comparative effectiveness research, health technology assessment, real-world studies, global value dossier</td>
</tr>
</tbody>
</table>

HEOR, Health Economics and Outcomes Research.

Health care decision-makers, such as pharmacy and therapeutics (P&T) committees within a hospital or insurance company, also frequently use HEOR evidence to influence their choices. Lesher described how P&T committees (often composed of clinicians, a lawyer, quality assurance personnel, and a lay member) determine which of 2 drugs will be offered at their hospital by weighing the clinical and economical outcomes associated with each drug (Table 2).

Table 2. Sample Drugs Reviewed by Pharmacy and Therapeutics Committee

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Cost per Tablet</th>
<th>Efficacy</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug A</td>
<td>1 tablet daily</td>
<td>$1.25</td>
<td>77%–80%</td>
<td>Nausea, vomiting, irreversible hepatotoxicity (5%)</td>
</tr>
<tr>
<td>Drug B</td>
<td>1 tablet daily</td>
<td>$1.50</td>
<td>78%–80%</td>
<td>Nausea, headache</td>
</tr>
</tbody>
</table>

The Writer’s Role in HEOR

The field of HEOR offers opportunities for writers (Table 3) who come from a variety of backgrounds. Whereas Lesher arrived to HEOR by receiving her PharmD, working as a pharmacist, and completing a medical writing fellowship, Mirvis arrived by completing an English degree and gaining exposure to science as an intern at the National Cancer Institute.
Writers with a medical background can leverage their existing skills to break into the field, and writers without a medical background can also bring valuable assets to the HEOR space, including expertise with Microsoft Word, insight into nonexpert audiences, strong writing mechanics, and an ability to organize ideas. Mirvis recommended that these writers enhance their medical knowledge by brushing up on statistics, learning about different health audiences, and taking workshops through the American Medical Writers Association.

Educational resources exist that can help those interested in HEOR professional development. The Professional Society for Health Economics and Outcomes Research offers short courses in HEOR. The Academy of Managed Care Pharmacy holds 2 national meetings annually that involve education in the pharmacy space. Finally, HealthEconomics.com provides education and research related to HEOR. These resources, in addition to leveraging existing writing skills, may help writers who are interested in HEOR find opportunities in the field.

Note: The slides for this presentation are available on the AMWA website here.

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### INSTRUCTIONAL DESIGN: WHERE DO YOU FIT IN AS A MEDICAL WRITER?

**Speaker**

Deborah Anderson, PhD, MT(ASCP)SH, *DGA Medical Communications, Langhorne, PA*

**By Haifa Kassis, MD**

**Instructional Design**

The term “instructional design” may not sound familiar to some medical writers, simply because they were never formally taught this concept during their education. However, many medical writers incorporate the principles of sound instructional design in their work without realizing it. In most instances, these skills come from learning while on the job.

Instructional design is the practice of creating content that ensures efficient and effective learning. For medical writers, this means that—before beginning the writing process—they must think about the goals of education, the needs of the learners, and what the end product will look like.

- **Goals of education:**
  Large educational programs are usually broken down into smaller educational activities, each with its own learning objectives and tasks. These learning objectives should specifically describe what the audience will better be able to know or do after the completion of each activity. The medical writer should strive to understand what each activity aims to achieve and how all of the educational activities will work together to meet the goals of the entire program. Tasks and postactivity assessments are often used to determine whether educational activities were successful in helping the learners achieve the learning objectives.

- **Learners’ needs:**
  The medical writer should learn as much as possible about the learners. Who is the audience? What is their level of knowledge and education? What are their educational needs? How will this educational activity contribute to their work or everyday life? Are there any language barriers or cultural differences to consider? All of these factors greatly impact how the medical writer should construct the content.

- **End product:**
  The medical writer should also ask in which format the audience will receive the content. Will the activity be presented electronically or in print? Will it be viewed on a laptop, tablet, phone, or something else? Which technology and programming capabilities will be used to build the activity? Will the medical writer be assisted by graphic designers and software programmers? Will interactivity with the audience (e.g., live surveys) be feasible and to what extent? Does the activity need to be monitored? All of these factors must be taken into consideration to ensure that content is developed and presented to the learners properly.

**Microlearning**

With the rush of today’s life, learning trends have shifted toward shorter and faster educational formats. Microlearning is a type of educational product that includes 3- to 5-minute bursts of content presented to learners via the written word, graphics, or videos. To be effective, microlearning activities must be

- **Bite sized:**
  Content should be focused, take no more than 3 to 5 minutes to view, and stand alone without other educational pieces.

- **Content focused:**
  The activity should provide just the right amount of

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**Table 3. Opportunities for Writers in HEOR**

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

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information the learners need to achieve the learning objective (note that “objective” is singular; microlearning is specific to learning 1 objective).

- **Learner centric:**
  Content should be delivered with a platform that allows the learners to become engaged and immersed in the activity to drive the learning process.

- **Accessible:**
  The activity should be immediately available when needed by the learners, as well as having the flexibility to be delivered to whatever device the learner is using.

- **Relatable:**
  Content that evokes strong feelings and emotions is more likely to leave an impact on the learners.

- **Easy to retain:**
  Content should be relevant to the learners’ lives, which makes it easier to remember.

Examples of microlearning videos include powerful snippets that teach viewers—in a just a few minutes—very specific information about a topic, such as how to switch a phone to low-battery mode, how to fill out a consent form, what the structure of the heart valves is, how a diabetes drug works, and how a pulmonary embolism is formed. (These are just a sampling of the video snippets used to drive home content to learners during Dr Anderson’s presentation.)

Communicating highly complex medical content to a professional audience in 1 or 2 microlearning videos is not a replacement for a full-fledged learning program, but it can be an effective way to explain difficult topics or provide an alternative method to achieving learning objectives. As microlearning is able to disseminate quick, effective, and powerful messages to large audiences, it may also be used by clinicians to help explain a specific disease, therapy, or clinical trial to patients or the general public.

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**WHAT’S NEW IN THE AMA MANUAL OF STYLE**

**Speakers**

Stacy Christiansen, MA, Managing Editor, JAMA, and Co-Chair, AMA Manual of Style, JAMA Network, Chicago, IL

Annette Flanagan, RN, MA, Executive Managing Editor, JAMA Network, and AMA Manual of Style Committee, Chicago, IL

Cheryl Iverson, MA, Co-Chair, AMA Manual of Style, JAMA Network, Chicago, IL

By Laurie Anne Walden, DVM, ELS

The AMA Manual of Style is updated between editions to reflect changes in policy and style. Stacy Christiansen, Annette Flanagan, and Cheryl Iverson discussed revisions that have already been implemented and upcoming changes for the 11th edition, scheduled for publication in 2019.

**Manuscript Preparation**

Iverson discussed reasons for upcoming changes in reference styling (Table 1). For example, omitting periods after DOIs and URLs in reference entries facilitates accurate link copying. All elements within tables and figures (column headings, axis labels, etc) will be set in sentence-style instead of title-style capitalization. Table titles will continue to use title-style capitalization.

**Table 1. Reference Updates in the 11th Edition of the AMA Manual of Style**

- Publishers’ locations no longer included
- Online references: URLs moved to ends of reference entries and not followed by a period (style already implemented for DOIs)
- Examples added for social media and digital references: tweets, blog posts, databases, etc

**Style and Terminology**

The 11th edition will include numerous style updates (Table 2). Christiansen said that allowing *they* to be used as a gender-neutral singular pronoun helps preserve patient confidentiality and has been implemented by other style guides.

The new edition will include grammar guidelines for social media. For clarity, posts about scientific content should use standard capitalization and punctuation and avoid potentially confusing shorthand (such as *U* for *you*).

Further, the new edition will update guidelines for describing socioeconomic status and people with addiction. These

**Table 2. Selected Style and Terminology Updates**

- Use of *they* as a singular pronoun allowed in certain circumstances (sentence rewrite preferred)
- New entries added to list of nonhyphenated terms (eg, *open access journal*)
- New entries added to abbreviation list: ACL (anterior cruciate ligament), LGBTQ (lesbian, gay, bisexual, transgender, and queer), MERS (Middle East respiratory syndrome), and more
- All fellowship designations, including non-US fellowship designations like FRCP, no longer included in bylines
- **Health care:** still 2 words
- Space added between the number and the degree symbol in temperatures (“37.5 °C,” not “37.5° C” or “37.5°C”) per SI notation
recommendations avoid assigning labels (eg, \textit{low income} instead of \textit{the poor}). Other terms, such as \textit{naseated}/\textit{naseous}, will be added to the Usage section. Spelling and spacing variations will be added, with JAMA Network preferences indicated in bold (eg, \textit{data set}/\textit{dataset}).

The Genetics section will specify using italicized gene symbols or gene descriptions instead of gene aliases: write “\textit{TP53}” or “tumor protein p53 (Li-Fraumeni syndrome) gene,” not the gene alias “p53.” Whether gene symbols need expansion depends on context, said Christiansen. The stylebook will follow the Human Genome Variation Society recommendation to avoid the terms \textit{mutation} and \textit{polymorphism}, preferring terms such as \textit{sequence variation} and \textit{allelic variant}.

**Measurement**
The Statistics and Mathematical Composition sections will add terms (eg, \textit{multivariable}/\textit{multivariate}) and new examples. New to the 11th edition will be the SI convention of inserting a space between the number and the degree symbol in measures of temperature, such as in “temperature of 37.5 °C” (not “37.5°C”).

**Technical Information**
Information on typography, tagging, and display will be combined into a single chapter. The new edition will also include discussions of XML and the JAMA Network single-source workflow.

Guidelines such as those of the Committee on Publication Ethics and the International Committee of Medical Journal Editors (ICMJE) will be added to the Resources section. In the publishing glossary, terms such as \textit{CD-ROM} and \textit{fax} will be removed; \textit{cloud}, \textit{IP address}, and others will be added.

**Editorial Assessment**

**Corrections**
Retraction and replacement is a new option for correcting some published articles. Twenty-one percent of retractions occur because of errors, not misconduct, said Flanagin. Pervasive errors are mistakes (such as coding errors) that occur before the data are analyzed, propagating incorrect numbers throughout the manuscript. Retraction and replacement, which does not carry the stigma of full retraction, is available for articles with pervasive errors that change the findings. In these cases, journals can publish an author’s letter of explanation; replace the article, retaining the original DOI but not adding a retraction watermark; and publish a PDF with corrections highlighted.

**Authorship**
The new edition will update authorship roles (Table 3). JAMA Network journals have begun to accept some requests for shared first authorship. Two corresponding authors can be listed in some cases.

<table>
<thead>
<tr>
<th>Table 3. Updated Authorship Roles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contributors</strong></td>
</tr>
<tr>
<td><strong>Authors</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Collaborators</strong></td>
</tr>
<tr>
<td><strong>Group Authors</strong></td>
</tr>
</tbody>
</table>

**Data Sharing and Access**
The ICMJE now requires data sharing statements for articles reporting clinical trial results, as outlined in the \textit{AMA Manual of Style}. The new edition will also include discussions of public access models (no author fee, journal holds copyright), open access models (article processing charge, author holds copyright), and predatory journals.

**Finding Style Updates**
Updates are posted on the \textit{AMA Manual of Style} website. Readers can ask style questions on Twitter (@AMAManual) and read about scientific communication topics at the AMA Style Insider blog.

For more details from the conference presentation, see the session slides on the AMWA website (https://www.amwa.org/page/2018sessions).

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**REGULATORY COMPLIANCE FUNDAMENTALS FOR PROMOTIONAL AND EDUCATIONAL WRITING IN LIFE SCIENCES**

**Speaker**
Ilyssa Levins, President, Center for Communication Compliance (CCC), New York, NY

**By Ilyssa Levins**

The US regulatory environment affects the development of materials prepared and submitted by medical communicators. That’s why an understanding of the fundamental regulatory requirements for promotional content is imperative.

Government regulators like the US Food and Drug Administration (FDA) expect companies and their agents...
(which include medical writers paid by a company) to adhere to regulations for promoting drugs and medical devices. Under FDA rules, companies are not permitted to make promotional claims that are not consistent with the labeling or that suggest that a drug or device is safe and effective for a specific use that is not in the approved labeling.

This means that anyone communicating about a prescription health care product must understand the definition of product labeling and how to make compliant claims supported by the product labeling. This includes the use of market research, competitor information, patient quality-of-life data, and disclaimers, among other areas.

Moreover, the number 1 reason companies receive enforcement letters is failure to adequately disclose risk information. There must be an accurate and nonmisleading impression of both the product’s benefits and risks.

Do you know the basic regulations? Test yourself on a few fundamentals here.

The FDA has a well-established enforcement program against companies and individuals who violate the law and regulations governing promotion.

For medical writers specifically focused on data communications, the FDA recognizes that scientists must share information, and that the public and investors are entitled to scientific information as it is evolving, before the product is approved. To address this, the FDA permits “scientific exchange”—a regulation that permits companies to discuss scientific data regarding a prescription product before approval, if that information is objective, fairly balanced, and includes balancing risk information. However, at no point until FDA approval may the company claim that the drug or device is safe and effective. When this exchange is nonpromotional in nature, it is regarded as acceptable from an enforcement standpoint and is known unofficially as a “safe harbor”; that is, these are the circumstances when the FDA is not likely to take enforcement action.

For a free mobile application that makes it easier to search warning letters, send an email to ilevins@communicationcompliance.com.

Evaluate your professional development opportunities here. 

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REGULATORY WRITING FOR THE DIGITAL ERA—A PARADIGM SHIFT

Speaker
Becky Nuttall, Lead Medical Writer, EMD Serono Research and Development Institute, Inc, Rockland, MA

By Leslie Kowitz, MA, ELS

Regulatory Climate Today
Today’s regulatory climate sees the pharmaceutical industry’s push to accelerate time to market along with new Health Authority (HA) requirements for succinct, fully electronic submissions. Beginning in 2019, both the US Food and Drug Administration (FDA) and European Medicines Agency will only accept electronic submissions—no more paper. What does this climate mean for regulatory writers?

Becky Nuttall believes regulatory writers have a unique opportunity to influence the design and message of regulatory documents, which may ultimately help to get important medicines to patients faster by alleviating unnecessary burdens on HA reviewers.

Since the Prescription Drug User Fee Act (PDUFA) passed in 1992, FDA approval times for New Drug Applications and Biologics License Applications have decreased significantly, from more than 2 years (prior to PDUFA) to approximately 11 months (in 2017). Although approval time has decreased, the percentage of applications approved on the first cycle has changed little, and although companies and patients appreciate shorter approval times, reviewers are under pressure to assess more applications in less time. Enter the skilled regulatory writer, equipped with a toolkit for the digital age.

Writing for the Regulatory Reviewer
Many of us learned to “tell the story” when writing for regulatory agencies, which implies the reviewer will read a document in a linear fashion. However, in today’s ever-changing world of smartphones, apps, online media, and more, regulatory writers must design documents to account for the way busy HA reviewers actually read on screens. That means using keywords, scannable subheadings, navigational links, strategically placed white space, paragraph chunking, and ultimately less focus on dense text.

Leveraging Research From Other Disciplines
Researchers from fields such as Web design and library science have compiled a rich body of knowledge from studies on subjects ranging from eye-tracking and reading patterns to information architecture and the effect of layout on comprehension. Some of the important findings show that people who read on screens tend to

• Read in a zig-zag pattern on screen (following an F-pattern)
• Read by skimming rather than word by word
• Spend 80% of reading time on the left half of the screen
Think differently about content when seeing it outside of Microsoft PowerPoint slides. This technique allows teams to craft key messages outside of the final document using Nuttall shared her positive experiences working with teams

How can we avoid these pitfalls?

• “People rewrite what has already been wordsmithed.”
• “There are too many reviews and reviewers.”
• “There is never enough time.”
• “Documents are written without a plan.”

Common complaints in regulatory writing groups include

• “Documents are written without a plan.”
• “There is never enough time.”
• “There are too many reviews and reviewers.”
• “People rewrite what has already been wordsmithed.”

Putting Key Messages First
Nuttall recommends starting with the key message at the beginning of a paragraph, followed by supporting details that back up that main point (deductive reasoning model). Starting with the key message is the most direct approach and ensures the reviewer focuses on that message first without getting bogged down in the details, which can cause reviewers to skip key information.

Designing documents for the way reviewers read on screen (not on paper) should guide our writing and development decisions, such as strategically placing hyperlinks and using the left side of the screen for focused keywords and subheadings. Nuttall suggests that rather than putting links to tables or other sections up front, we should focus the reviewer’s attention on the key message first, then offer links to supporting details. For example, does it make sense to write “Tables X, Y, and Z may be found in Section 15.2.3” at the very beginning of a section in the clinical study report? Or does it make more sense to put that last—allowing the reviewer to focus on key messages first?

Too much information can be damaging. Beware if one of your experts says, “Go ahead and keep it in—it couldn’t hurt.” More times than not, this indicates ancillary details that can detract from key information you are trying to impart.

Reimagining Document Development
Common complaints in regulatory writing groups include

• “Documents are written without a plan.”
• “There is never enough time.”
• “There are too many reviews and reviewers.”
• “People rewrite what has already been wordsmithed.”

How can we avoid these pitfalls?
Nuttall shared her positive experiences working with teams to craft key messages outside of the final document using Microsoft PowerPoint slides. This technique allows teams to think differently about content when seeing it outside of a “document” format. Teams usually have an idea about desired study outcomes even before database lock or the end of a stability study, so craft your key statements using base-case scenarios and fill in the data later.

Engaging Your Team
As the regulatory writer, you can educate and guide your team in this systematic approach to developing regulatory documents that fit the current climate.

1. Use a “shell” PowerPoint slide to align on key messages (provide examples and instructions to team members to fill in). Use bullet points for supporting messages to be used as new topic sentences.

   Example of a key message: *WonderDrug 10 mg, given orally twice daily in subjects with Disease who are on standard of care, significantly reduced Symptoms, with no increased safety risk, compared with placebo/active.*

2. Transfer bullet points as-is to the shell. Determine strategic placement. Flesh out paragraphs and check for text density. Aim for ≥3 to 4 paragraphs per page.

3. Determine logical architecture. Can you put some details into tables? Do all the results need to be up front, or can they be placed later in the document?

4. Review the document for searchable words that would be of interest for a regulatory reviewer. Do your key statements begin with the keyword (active voice)? Can you rearrange the sentence to bring the keyword(s) to the left of the screen?

   Example of a “safety” keyword: *Cardiac toxicity (including pericardial effusion, hypotension, and cardiac ischemia/infarction) was balanced across treatment arms.*

5. Ensure navigation is optimized. Do titles of tables and figures reflect what is actually in them? Are they succinct, or do they contain too much detail? Do subheadings give navigation prompts on the left side as to what information is contained in the document?

6. Conduct a final key message search. Cut and paste the key messages from your document (which should be the first sentence in each paragraph) into another blank document. Compare it to the original PowerPoint file. Is everything you wanted to say there? Is there any information loss or additional information creep?

Nuttall presented a case study, in which her team developed a briefing package for the FDA using this technique and emphasized that reviewer feedback was extremely positive. These steps present a practical approach to help you guide your team toward an improved process for developing regulatory documents that fit the current climate.

Leslie Kowitz, MA, ELS, is a freelance medical editor and writer near Oakland, CA.

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By Vicki VanArsdale, MS

Madison Hedrick used her presentation as a platform to offer her perspective on medical writing and to provide practical advice for those just starting in the field (targeted level of experience: <3 years). At the time of this presentation, she worked full-time for an academic medical institution and performed freelance work on the side—she now has a new role as a senior medical writer for a large research support firm.

From Pre-Med Student to Medical Writer
Hedrick wanted to be a doctor, so she took a lot of pre-med classes and had a double major in biology and technical writing. But as she gained hands-on experience working with patients, she realized that she didn't enjoy it. She started looking for other career options and eventually realized medical writing was the perfect fit for her interests and skills.

She started applying for jobs even if she didn’t have the qualifications—hoping she’d get lucky and that something would pan out. She finally got a call back from someone who saw her potential. Although she wasn’t qualified for the position, she was offered $25 an hour to write grants. She jumped at the chance and learned everything she could as she went along. The grants she worked on were eventually funded for more than $100 million, which increased her value as a grant writer and enabled her to get more work writing grants and manuscripts.

Use AMWA to Increase the Chances of Success
Hedrick became very active in AMWA early on. She offered these tips on making the most of an AMWA membership:

• Create a LinkedIn profile and keep it up to date and full of content
• Check the job boards daily and apply
• Join a local AMWA chapter and get involved
• Go to the conferences to learn and to network with peers
• Use AMWA’s Engage to connect and collaborate with others
• Refer to AMWA’s Salary Survey to set appropriate rates

She recommends reading the posts on AMWA’s Engage daily and joining the conversation, whether to ask questions or respond to others. She said the more you connect with people, the more they get to know you, and you never know where that can take you. Networking has helped her tremendously: she’s President-Elect of the AMWA Southeast Chapter and is on the AMWA National Membership Committee.

Practical Advice for Those New to the Field
“Know your worth and don’t take things below your value,” Hedrick said.

Those new to medical writing face a challenge: how to get a job in the field and gain experience when many job postings call for 2 years of experience. Hedrick suggested getting mentors to guide the way, using Google to conduct research to learn new types of medical writing skills, and learning by doing. When working as a freelance, full-time or on the side, she thinks it is okay to keep rates slightly lower if you are benefiting by gaining experience, but be sure to increase those rates as knowledge increases and skills improve. Working for free or for deeply discounted rates is not recommended. She also reminds those who do offer discounted rates that it may be difficult to increase the rate with that client in the future, which could be costly.

Refer to AMWA’s Salary Survey to get an idea about appropriate rates because rates vary by sector (eg, pharmaceuticals), service (eg, editing versus writing), location, and level of experience. Hedrick said, “Never put the rate under $40 an hour even when you’re starting out.” One audience member said working for extremely cheap rates hurts the entire industry and makes it harder on everyone to make a living. Hedrick agreed.

Other ways to gain experience:

• Volunteer to write grants or other medically focused documents for nonprofit organizations or AMWA
• Browse FoundationCenter.org for grant-writing opportunities
• Write articles for the AMWA Journal or other publications
• Leverage any undergraduate, graduate, or doctoral work involving scientific writing
• Apply for entry-level jobs in the field and work in house (for a university, for example)
• Don’t be afraid to apply for jobs—even those you may not feel qualified for or that may not be perfect for you
• Take notice of writing errors on websites that are relevant to the field; you could offer to copy edit to get your foot in the door of a nonprofit research organization, for example.

Marketing is also important. Networking and word of mouth go a long way toward growing a medical writing career. It’s also important to have a current LinkedIn profile and to make a point to engage and actively use it to connect with peers, industry leaders, recruiters, and possible clients. If freelancing, it’s extremely important to have a website that conveys your expertise and experience. Hedrick uses a simple website builder called Wix; another audience member uses Squarespace. Everyone should keep an updated curriculum vitae or resume on a laptop or smartphone to send out at a moment’s notice. Also, be sure to always use a professional email address.

Vicki VanArsdale, MS, is a freelance writer and health care marketing communications specialist near Washington, DC.

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ELEVATING THE PATIENT VOICE: OPPORTUNITIES AND CHALLENGES FOR MEDICAL COMMUNICATORS

Speakers
Samir Shaikh, MBA, Deputy Director of Patient Affairs, US Food and Drug Administration, Washington, DC
Catina O’Leary, PhD, LMSW, President and CEO, Health Literacy Media, St. Louis, MO
LaTasha Lee, PhD, MPH, Senior Manager of Partnership Engagement, Sickle Cell Disease Clinical Trials Network at the American Society of Hematology, Washington, DC

Moderator
Monique Pond, PhD, AAAS Science & Technology Policy Fellow, Bethesda, MD

By Wendy Kluender, PT
Medical communicators have a unique opportunity to assimilate information and the results of medical research and share it over a variety of platforms with professionals, study participants, and their caregivers. The panelists at this session came from a variety of backgrounds and were able to share with the medical communicators in attendance some ideas for improving patient engagement in research studies and drug development.

The session focused on 3 main areas that are integral to the process of patient involvement in clinical studies:
• Engaging patients in their care and decision-making
• Enrolling, engaging, and keeping patients in clinical trials
• Collaborating with patients at all phases of the trial

Engaging Patients in Their Care and Decision-Making
All panelists agreed that there can be barriers to patient engagement in health care and decision-making. Much of this can be attributed to a lack of understanding of the process and a lack of effective communication from the professionals working with the patients in clinical trials. Catina O’Leary shared with the group that we need to consider that medical testing can be unpleasant and may affect participation. Samir Shaikh also pointed out that patients may be tapped multiple times for each segment of the investigation and that this can be a negative experience if they don’t understand the process.

Medical communicators need to provide information in understandable terms to these patients. The value and importance of the study participants should be made clear as well, to improve engagement.

According to LaTasha Lee, the American Society of Hematology provides some clinicians with pocket guides that help them discuss treatment options with patients. Care is taken to make sure educational materials are patient focused. They are trying to look holistically at the barriers participants in clinical trials experience in order to give them a voice in the clinical trial process.

Enrolling, Engaging, and Keeping Participants in Clinical Trials
Patients with rare conditions can be difficult to find for enrollment in studies and drug trials. Once these patients are found, they tend to be tapped for multiple studies, which can be a hardship on them. To find new participants, researchers may reach out to clinicians, emergency medical services, clergy, psychologists, and other professionals in the community.

One surprising resource for this dilemma has been the use of social media. Dr O’Leary reported that they have used social media successfully to find new patients, understand their unique issues, and discover how they are comfortable talking about and trying to manage their conditions. Once patients have enrolled in a study, researchers must continue to understand and address participation barriers to keep participants engaged and make them feel valued by researchers.

Collaborating With Patients
Participant collaboration during all phases of trials and studies is another way to improve engagement. Mr Shaikh pointed out that patient councils can collaborate with researchers and drug developers to come up with data collection plans that work for each unique population. Dr Lee shared that by pulling in the patient voice, participants can begin to feel like part of the team, and the research then becomes more meaningful to them.

What about study results? Participants in these studies and drug trials want to know and understand the results. According to Dr O’Leary, researchers don't hold up their end of the deal if they fail to share study results effectively. This can negatively affect future participation in studies and marginalizes the participants. Trial summaries have been best received by participants when results are presented first in a thorough but simple and relevant way. Audience testing ensures the effectiveness of materials.

Additional information on patient-focused drug development can be found on the US Food and Drug Administration website at www.fda.gov by typing “voice of the patient reports” in the search bar.

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MEDICAL WRITING PROFESSIONALISM: COMPETENCY MODELING, APPLICATION, AND EXAMINATION

By Vicki VanArsdale, MS  
This session provided an overview of the 2017 DIA Medical Writing Competency Model and how medical writers and their supervisors can use the model for professional development and competency testing. Also, the AMWA Medical Writer Certified (MWC®) credentialing program was discussed.

DIA Medical Writing Competency Model  
Developed by the DIA Medical Writing Community Working Group, the DIA Medical Writing Competency Model defines what knowledge, skills, abilities, and behaviors (KSABs) a competent medical writer should possess. It was created in 2009 but updated in 2017 to reflect current trends. Clemow was an integral part of the revision process, along with a team of industry professionals with 419 cumulative years of combined medical writing experience across sectors, companies, and geographic locations.

The Competency Model covers the scope and breadth of the medical writing profession and is broken into sections: KSABs, work functions (tasks/activities), and additional information (general abilities, certifications). Each section contains information for all medical writers as well as for those in a particular niche. For example, all medical writers would have similar KSABs, but more specific KSABs are noted for publication writers versus regulatory writers (Table 1).

Application of the DIA Competency Model  
The Competency Model is a resource that can be used to create or revise job descriptions and create checklists and screening tools to assess the skills and abilities of prospective employees. Additionally, managers can use the assessments to set goals and to explain how medical writers will be measured against expectations in their professional development plans. Medical writers can use the Competency Model to perform a self-assessment, so they are better prepared for discussions with their managers and their performance reviews. Career paths can also be explored, and a technical ladder can be created. Clemow offered an example (Table 2).

Clemow said it’s important to retain good employees, so the Competency Model can also be used to base assignments on a medical writer’s competencies and interests, to provide resources and training, and to facilitate knowledge sharing. For example, a list of internal subject matter experts can be maintained so that if someone needs help writing protocols, they can quickly reach out to someone with that expertise.

Aspiring medical writers and those already working in the field should know what makes a good medical writer. Clemow said, “You have to be able to write and communicate, but what’s also really important is knowing your science, knowing how to be a project manager, and having quality soft skills, meaning how you interact with people.” Soft skills relate to the behaviors in the KSABs, such as conflict resolution and how to respond to review comments.

AMWA Medical Writer Certified Examination and Credentialing  
Designations such as Medical Writer Certified (MWC®), Board of Editors in the Life Sciences (BELS), or Certified Medical Publication Professional™ (CMPP), to name a few, can help medical writers and editors stand out from the competition.

The Medical Writing Certification Commission oversees the MWC® program and is responsible for everything from setting eligibility requirements to developing examination content.

<table>
<thead>
<tr>
<th>Who</th>
<th>Knowledge, Skills, Abilities, and Behaviors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All Medical Writers</strong></td>
<td>(K, S) Industry guidelines, project management skills, science, communications techniques</td>
</tr>
<tr>
<td></td>
<td>(A) Deliver written/visual communications that tell a scientific narrative, author content for cascade-level messaging</td>
</tr>
<tr>
<td></td>
<td>(B) Act with the highest ethical standard, demonstrate judgment-based thinking</td>
</tr>
<tr>
<td><strong>Regulatory Writers</strong></td>
<td>(K, S) Standardization initiatives (eg, ICH), regulatory authority regulations and guidance</td>
</tr>
<tr>
<td></td>
<td>(A) Prepare regulatory submission communication strategy, prepare documents for e-publishing</td>
</tr>
<tr>
<td><strong>Publication Writers</strong></td>
<td>(K, S) Publication guidelines (eg, GPP3), reporting guidelines (CONSORT)</td>
</tr>
<tr>
<td></td>
<td>(A) Prepare publication plan strategy, prepare publication documents</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Role</th>
<th>Abilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical Writer</strong></td>
<td>Write documents within a team environment</td>
</tr>
<tr>
<td><strong>Senior Medical Writer</strong></td>
<td>Evaluate, analyze, and interpret medical literature with minimal supervision</td>
</tr>
<tr>
<td><strong>Principal Medical Writer</strong></td>
<td>Serve as a medical writing lead for submission–related documents</td>
</tr>
</tbody>
</table>
and addressing appeals. Since its inception in 2015, 75 people have earned the MWC® credential, and that number continues to increase yearly.

The DIA Competency Model is the backbone of the MWC® examination. The Competency Model's domains are represented by questions covering presenting, interpreting, organizing, evaluating, and gathering information. There are also questions about ethics. Therefore, learning the Competency Model's content is helpful in preparing for the examination, Clemow said. Other tips he provided were to attend AMWA workshops and review notes, to set up a self-study syllabus based on the content outline, and to review the recommended resources. Sample topics on the examination include epidemiology, writing mechanics, patient education, project management, statistics, and regulatory submissions.

How to Earn the MWC®

Certain criteria must be met to apply for the MWC® exam. Some of the requirements are having a bachelor's degree and a minimum of 2 years of paid, full-time work experience in the field. Activities that constitute 2 years of relevant experience include the preparation of

- Patient education brochures, news articles, Web content, and books
- Journal articles for health care professionals and biomedical researchers
- Continuing education monographs for health care professionals
- Regulatory documents for government agencies
- Grant proposals for research scientists and institutions
- Sales training and marketing materials for the pharmaceutical industry

A PDF version of the presentation slides can be found at amwa.org/2018sessions. The Competency Model is available to DIA members through its Medical Writing Community. The Competency Model is also published:


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FROM PROTOCOL TO PACKAGE INSERT: A DATA JOURNEY

Speakers

Alex Rohall, BA, Senior Manager, Medical Writing, PROMETRIKA, LLC, Cambridge, MA
Christine Quagan, BA, Senior Medical Writer, PROMETRIKA, LLC, Cambridge, MA

By Dawn Hayward, BS

The information on a package insert (PI) for a New Drug Application (NDA) or Biologics Licensure Application (BLA) contains critical information health care professionals (HCPs) and patients need to assess the usage, risk, and safety of a drug. This session covered 3 key sections of the PI:

- Indication and Usage
- Adverse Reactions and Adverse Events
- Clinical Studies

These sections come from the data, the speakers explained, which journey from clinical investigators to databases to statisticians to medical writers who convey the message in the submission document. In 1966, the Fair Packaging and Labeling Act required detailed descriptions on the label, now called the PI, to determine efficacy and risk. Throughout this process, medical writers refer to the “guidance,” which contains suggestions on how to frame the content on the insert, and the physicians labeling rule, which summarizes content for HCPs.

Indication and Usage

Alex Rohall spoke about the Indications and Usage section of the PI, which must answer 3 major questions:

- What is the drug used for?
  - Treatment, cure, or prevention of a “recognized disease or condition”
- Who is the drug intended for?
  - Population, including age group
- What are other parameters the population must have?
  - The drug could be concomitant therapy for another medication

A Limitations of Use section describes the consequences, risks, or fatal adverse events (AEs) associated with a drug. Rohall then gave an example that addresses both: “Drug X is indicated for the treatment of hypertension in adults and pediatric patients 1 year of age or older. In patients younger than 1 year of age, Drug X can adversely affect kidney development.”

Adverse Reactions and Adverse Events

Christine Quagan spoke about the Adverse Reactions section of the PI. An adverse reaction (AR) is an effect reasonably associated with the drug, whereas an AE is an effect that may or may not be associated with the drug. The sponsor, who oversees the clinical studies, will look at how many people experienced an
effect, whether it occurs at a higher rate than with placebo, and whether the medical literature on that drug class gives similar effects. The guidance suggests that incidences greater than or equal to 10% of the treatment group with twice the rate of placebo may be reasonably associated with the drug.

The introductory sections include a disclaimer stating that AR rates may vary from trial to trial, a database description giving the number of patients on drug and placebo, timing and type of study (randomized, single, or double blind), dosage, and criteria for inclusion, which gives the rate of incidence for the particular AR used as a cutoff. Next, data from the Integrated Summary of Safety (ISS) are provided for ARs in the following manner, in which examples from pooled studies were shown:

1. The most common ARs are listed first and grouped by body section.
2. The numbers of patients having the ARs are listed with the percentages in both drug-treatment and placebo groups.
3. The ISS, although itself not included in the PI, contains information from all trials associated with the drug. Although individual studies may have a high rate of a particular AR, if the rate does not meet the cutoff, it will not appear in the ISS.

Quagan lastly explained that the study protocol determines when to collect, follow-up, and how to assess the severity of an AE, its relationship to the study drug, and reporting serious AEs.

**Clinical Studies Section**

Rohall spoke about the clinical studies included in the PI; although not every study makes it into the PI, the US Food and Drug Administration (FDA) has seen all the data. Those studies included best represent how a drug is used properly, how the drug is effective for the indication, and the conditions for which the drug cannot be used. The Clinical Studies Section contains 3 important subsections:

- **Study Design**
  - Gives the number of patients taking drug and placebo and type of study
- **Population**
  - Describes percentages of patients who participated in the study, including age, sex, and ethnicity
- **Endpoints**
  - Describes the parameters tested to determine the effectiveness of a drug

Tables that follow this detail statistics of the endpoints used in the study. All endpoint data are given during submission in the Integrated Summary of Effectiveness. Rohall explained that endpoint selection is based on current medical literature, data from the clinical program itself, and suggestions from the FDA, which may have “input from experts in the field.” The study protocol will detail how endpoints are collected and analyzed for the trial.

Last, the speakers emphasized that the draft label is not the final product. The draft labeling is submitted and finalized through discussions with the FDA during the NDA/BLA review of all the clinical data. Changes are made from new data, new formulations, new indications, and new medical findings.

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**WHAT SHOULD A MEDICAL WRITER KNOW ABOUT GENE THERAPY AND GENE EDITING?**

**Speaker**

*Elise Eller, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc, Lafayette, CO*

**By Shara Pantry, PhD**

The central dogma dictates that genetic information flows from deoxyribonucleic acid (DNA) to ribonucleic acid (RNA) to protein. DNA, which contains genes, is packaged into chromosomes that are located in the nucleus. DNA in the nucleus is copied to RNA (transcribed) and processed into messenger RNA (mRNA). The mRNA is transported to the cytoplasm, where it is interpreted (translated) into amino acids that are linked together to make a final product (protein). Proteins direct a variety of biological functions in the human body.

When the original, template DNA is mutated, problems with the transcription or translation processes can occur. The potential ultimate result of the mutation is a nonfunctional or dysfunctional protein and, in turn, a genetic disease or disorder. To correct genetic disorders, the majority of currently available drugs target the faulty protein. However, genetic disorders may potentially be corrected by targeting the mRNA or the template DNA itself. Two technologies have emerged that have the potential to treat or cure human genetic disorders by introducing new DNA to the cells (gene therapy) or fixing the faulty DNA (gene editing).

The use of both gene therapy and gene editing is on the rise, and it is important for the medical writer community to understand the science of gene therapy and editing, the ethical concerns for the use of these tools, and the regulations governing the two.

**Gene Therapy**

The goal of gene therapy is to treat or cure a genetic disorder by introducing DNA or RNA into the cell to augment the defective gene without modifying the organism’s DNA. The therapy gene, which codes for a functional protein, is put into a viral vector and delivered to the target cells. The most commonly used viral vectors are adenoviral- or retroviral-based.
Gene therapy vector delivery can occur in vivo or ex vivo. For in vivo gene therapy, a viral vector containing the therapy gene is injected directly into the organism. For ex vivo gene therapy, the patient’s cells are removed, the therapy gene is introduced into the cells, and then the cells are transplanted back into the patient’s body. Ex vivo gene therapy is favorable because it is more efficient and less likely to elicit an immune response; however, it cannot be used for all cell types.

Potential Pitfalls and Problems With Gene Therapy

- **Delivery**: Highly efficient and cell type–specific delivery is often difficult to achieve.
- **Immune response**: Gene therapy vectors are viewed as foreign by the patient’s immune system and may elicit an immune response that results in severe disease. This can be avoided with ex vivo delivery.
- **Integration site**: Integration sites are random and may disrupt the function of critical genes, such as tumor suppressor genes.
- **Commercial viability**: Gene therapy is expensive and often used for rare disorders that affect only a small population.

Gene Therapy Regulation in the United States

In the United States, gene therapy is regulated by the Food and Drug Administration’s Center for Biologics Evaluation and Research (CBER). CBER oversees biological and related products, including vaccines, cellular and gene therapies, and devices related to cellular and gene therapy products. New gene therapy products are approved using the Biologics License Application process.

History of Gene Therapy Trials and Approvals

The first gene therapy trial, aimed at treating adenosine deaminase deficiency, occurred in the United States in 1990. However, a gene therapy trial–related death in 1999 drastically slowed the progress of the field. After this incident, increased measures for monitoring gene therapy trials were implemented in the United States; consequently, the United States did not approve its first gene therapy product until 2017. China and the European Union, however, saw their first gene therapy approvals as early as 2004.

Two of the new US-approved gene therapy products, KYMRIAH and YESCARTA, are chimeric antigen receptor (CAR) T-cell therapies. This technology, currently being used to treat cancers, engineers the patient’s immune cells to treat his or her cancer. As a part of the process, a patient’s T lymphocytes are removed and altered to express a CAR on their cell surface that specifically recognizes cancer cells. The CAR T cells, once reintroduced into the patient’s body, help to identify and attack cancer cells throughout the body.

Gene Editing

Gene editing alters an organism’s DNA sequence, rather than augmenting gene expression. Common gene editing systems include:

- Zinc Finger Nucleases
- Transcription activator–like effector nucleases
- CRISPR-Cas9

Currently, the most popular gene editing system is the CRISPR-Cas9 system (another enzyme, CPF1 [CRISPR from Prevotella and Francisella 1] is also being investigated). CRISPR (clustered regularly interspaced short palindromic repeats) was originally identified in bacteria in the 1980s and serves as a form of acquired immunity in bacteria. CRISPR is a family of short, repetitive DNA sequences in a bacterium’s genome that read the same forward and backward. In between the repetitive DNA sequences are DNA spacers derived from viruses that previously infected the bacterium. The pieces of nonbacterial DNA maintained in the bacterial genome help the bacterium to identify new infecting viruses that are similar. The CRISPR DNA serves as a guide for the Cas9 (CRISPR-associated protein 9) enzyme, which cuts the DNA in a sequence-specific manner.

For research purposes, the CRISPR-Cas9 machinery can be delivered in vivo or ex vivo and can be used to precisely edit target DNA sequences. To accomplish this, a synthetic CRISPR guide RNA specific to the target DNA sequence is coupled to the Cas9 enzyme. Once the DNA is cleaved, the dysfunctional gene can be removed, replaced, or revised.

Potential Pitfalls and Problems With Gene Editing

- **Delivery**: Guide RNA–Cas9 machinery may be too large to be packaged into viral vectors. Lipid nanoparticles and other methods are being explored as an alternative for delivery.
- **Efficiency**: For gene editing treatment to work, knockout efficiency of 60% to 95% is needed, which can be difficult to achieve.
- **Off-target effects**: Editing specificity is dependent on the design of the guide RNA, and other areas of the organism’s genome may be edited at areas other than the target site. In vitro and cell-based assays will likely be needed to demonstrate minimum off-target effects before approving gene editing products. Research is currently being performed to find alternatives to Cas9 or ways to improve Cas9 efficiency.
Ethical Concerns With Gene Editing

So far, most clinical applications for gene editing target somatic cells for the treatment of various medical conditions. However, the field of gene editing is moving toward gene editing of germline (reproductive) cells, which would affect an individual as well as any offspring. Most researchers have stayed clear of germline editing. However, in 2015, China announced the successful editing of human zygotes that were not intended for pregnancy and drew concern from the research community worldwide.

Later in 2015, an International Summit on Human Gene Editing was held in Washington, DC, to address the scientific and ethical concerns surrounding human gene editing. The overall consensus was that germline editing should not be used to modify human embryos that are intended to establish a pregnancy and that technical issues should be addressed before germline editing is used in clinical settings. However, the summit did not call for a ban on germline editing for research purposes (Table).

Table. Overview of International Guidelines on Human Germline Editing

<table>
<thead>
<tr>
<th>Country</th>
<th>Policy Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Union</td>
<td>Germline editing/eugenics banned</td>
</tr>
<tr>
<td>United States</td>
<td>Germline editing may be permitted in the future with strict oversight</td>
</tr>
<tr>
<td></td>
<td>Research grants involving germline editing will not be reviewed by the National Institutes of Health</td>
</tr>
<tr>
<td>United Kingdom/ Sweden</td>
<td>Gene editing of human embryos is permitted for research purposes only</td>
</tr>
<tr>
<td>Japan</td>
<td>Draft guidance permits gene editing of human embryos with restrictions (not for genetic enhancement)</td>
</tr>
</tbody>
</table>

Thus far, there are no gene editing products approved for human use. However, there are 17 active/recruiting preclinical trials. The majority of these trials are being performed in China. However, there is currently 1 actively recruiting gene editing trial in the United States.

Gene editing can be controversial, but it has the potential to greatly alter the medical landscape of the world.

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CAN YOU TEACH AN OLD REVIEWER NEW TRICKS?

Speaker
Robin Whitsell, BA, BPh, President, Whitsell Innovations, Inc, Chapel Hill, NC

“Nothing’s going to change if you don’t change it,” Robin Whitsell said, closing out “Can You Teach an Old Reviewer New Tricks?” The presentation centered around ways to alleviate many of the common issues medical communicators have in working with reviewers. From simple annoyances like being late to meetings to more serious things like breaking timelines. Whitsell offered three basic steps to help train reviewers to be better team players: prepare, explore, and engage.

Prepare

Often, thorough and intelligent planning can ease many of the potential issues that arise with reviewers throughout a project. Whitsell noted that proper planning and preparation before the project kickoff meeting is an excellent place to start, giving the following tips:

- Obtain a list of meeting attendees and identify their roles—especially note the decision makers;
- Obtain or build a timeline;
- Look over the team calendar to identify any “showstopper” days that might create delays in the timeline (ie, holidays, planned vacations);
- Lay out a plan for escalation; and
- Highlight portions of the project that require the most reviewer attention.

Whitsell also emphasized anticipating issues that may arise with particular reviewers. By directing the reviewer’s attention to sections that need addressing—such as the data—and away from sections that have already been finalized, valuable time can be saved in the review process.

Explore

Whitsell suggested 2 main exploratory techniques that can be used to keep reviewers on schedule and cooperative: finding a champion and establishing a process. A champion is “a mentor—someone who can offer advice when you need it” and potentially lobby for you. It was noted, however, that “the goal of the champion is to have somebody who can help you without changing your team dynamic.” Additionally, it is important to set up a process for reviewers; it increases consistency and reduces redundancy. Whitsell noted that it was also crucial to establish a process of support for reviewers, which may help improve the relationship between writer and reviewer.
Engage
To have a successful working relationship with a challenging reviewer, we have to reframe our thinking…we’re not in conflict with a problem child, we’re engaging a problem child. To do so, communication is essential. When there are misunderstandings, questions, or conflicts, it is important to address them with reviewers. According to Whitsell, this can be done all throughout the process, including preemptively. The opportunities for reviewer engagement can come
• Right after the kickoff meeting with a follow-up email reaffirming timelines and commitments made in the session;
• When there are miscommunications;
• When deadlines or portions of work are missed; and
• When you’ve lost the audience and message in the narrative.

Particularly when reviewers miss deadlines, it is important to do what Whitsell calls The Circle Back: “when you reach back to any specific team member and talk to them about what’s missing, what you needed from them, or what they didn’t do.”

Ultimately, a difficult reviewer can be retrained to participate effectively on a project. Whitsell noted that by being clear, respecting your part in the problem, having a plan, and knowing when to escalate, you can help a reviewer become a helpful resource, enriching both the product and the experience. “Be well with what you’ve done,” Whitsell said, “and be well in your commitment to yourself to train your reviewers to treat you the way you deserve to be treated.”

QC DETOURS: IMPROVING THE QUALITY CONTROL PROCESS

Speakers
Amanda Pennington, Quality Reviewer and Medical Editor, Whitsell Innovations, Inc, Downingtown, PA
Pamela Fioritto, Quality Reviewer and Medical Editor, Whitsell Innovations, Inc, Cleveland, OH

By Shannon Hach, MD, ELS
In the development of clear and accurate medical and scientific documents, the quality control (QC) team is responsible for maintaining the integrity of materials while adhering to allotted timelines and budgetary constraints. This process requires documents to move along a course that is sometimes fraught with roadblocks. Toward the end of the journey, the QC specialist ("QCer") is in the driver’s seat and is often faced with the challenge of hitting a bump (or multiple bumps) in the road. In this session, Mandy Pennington and Pam Fioritto sought to highlight the most common roadblocks and provide a collaborative forum to identify solutions.

Prior to the conference, Mandy and Pam surveyed 11 QCers. Initially, they sought to define QC. Respondents predominantly identified the following tasks: reviewing grammar, spelling, and punctuation; checking data; confirming adherence to format and style; and copyediting. A QCer was defined as the person who performs these roles and is often expected to complete “other duties as assigned,” thus becoming a “Jack of all trades.”

The survey also assessed the most common types of documents prepared by QCers, as well as their most common work settings. Of the respondents, 72.7% worked mostly on regulatory documents, 36.4% worked on manuscripts/peer-reviewed publications, and the remaining 27.3% worked on educational, marketing, or public relations materials. The majority of respondents worked in pharma/biotech (44.4%) or freelance businesses (33.3%). Respondents had worked in QC for an average of 3.9 years.

Asking about the likes and dislikes of working in QC, the survey was able to identify the most common issues facing QC specialists. The top frustrations or roadblocks included (1) unreasonable or limited timelines and (2) issues with source documents (ie, inconsistent annotation and writers not providing or specifying location of the materials).

The session participants were asked to participate in small groups and to brainstorm problem-solving ideas for each issue. The following tables (Table 1 and Table 2) describe the solutions suggested by the audience.

Table 1. Managing Timelines

<table>
<thead>
<tr>
<th>Timelines With Preparation Time</th>
<th>Timelines Without Preparation Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Develop a clear process in advance and train writers and QCers in that process, thus avoiding roadblocks in the first place</td>
<td>• Check document to better predict a promised deadline</td>
</tr>
<tr>
<td>• Clearly train writers in annotation style</td>
<td>• Split work with others if too complex</td>
</tr>
<tr>
<td>• Have QCers clearly communicate any changes that are made to annotations</td>
<td>• Make a priority list: identify what MUST be done vs less important issues</td>
</tr>
<tr>
<td>• Involves QCer from kick-off throughout the project so that they can provide input about time needed for review</td>
<td>• Manage expectations: establish what can and cannot be accomplished within the allotted time</td>
</tr>
<tr>
<td>• Use metrics to establish formulas for typical project vs more complex project timelines</td>
<td>• Use rolling comments: send document in “chunks” so that writer can address while QC continues simultaneously</td>
</tr>
<tr>
<td>• Ensure that the end client understands and adheres to their timeline for feedback, and clearly define who gives feedback to whom, and when</td>
<td>• Consider notifying client that an increase in budget may be necessary to allow for additional QCers to meet higher expectations/ expedited turnaround time</td>
</tr>
</tbody>
</table>
What Is Pharmacovigilance?

Mari Welke, BS, MA, believes pharmacovigilance writing is medical writing, although there are many similarities. Mari Welke described the similarities and differences between pharmacovigilance and clinical development writing (also known as medical writing), the content of several pharmacovigilance documents, and how to get started in a pharmacovigilance writing career.

**Basics of Pharmacovigilance Writing**

**Speaker**

Mari Welke, BS, MA, *Director of US Operations, Trilogy Writing & Consulting, Durham, NC*

**By Anastassia Hirlinger, MS**

Medical writing has not traditionally included pharmacovigilance writing, although there are many similarities. Mari Welke believes pharmacovigilance writing is medical writing and shared her knowledge about pharmacovigilance at an AMWA conference session to help bridge the divide. In this session, Welke described the similarities and differences between pharmacovigilance and clinical development writing (also known as medical writing), the content of several pharmacovigilance documents, and how to get started in a pharmacovigilance writing career.

The common thread among all solutions was communication. We are, after all, medical communicators, and this should come naturally to us. The audience and presenters noted that this forum was an excellent way to get writers and QCers together, have dialogue, and offer feedback to one another. It was suggested that more sessions that focus on QC processes and project management would be valuable to attendees at upcoming regional and national AMWA conferences.

Shannon Hach, MD, ELS, is a BELS-certified freelance medical editor and the owner of STAT editing, LLC, near Pittsburgh, PA.

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### Table 2. Managing Issues with Source Documents

- At the outset of the project, create “shell” folders for all source materials; as each person passes off the document and source materials, he or she should be responsible for ensuring the correct documents are in the right place and that no folders are empty.

- Develop a clear training process that describes annotation style, fact checking procedures, and QC and editing tasks, as well as a consistent method of communicating location of and access to the most recently updated source documents; ensure all writers, medical editors, and QC specialists are ushered through the training process and clearly understand it.

- Create a master list of resources (eg, Excel spreadsheet or PDF) for quick access to source documents (perhaps with a hyperlink to the location of each resource).

- Benefit-risk analysis
- Company core data sheet (CCDS)
- Development safety update report (DSUR)
- Periodic benefit-risk evaluation report (PBRER)
- Addendum to clinical overview (ACO)
- Signal assessment report
- Safety analysis report
- Risk management plan (RMP)
- Risk profile

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**Pharmacovigilance Documents**

Several important pharmacovigilance documents were discussed in this session:

- Development safety update report (DSUR)
- Risk management plan (RMP)
- Periodic benefit-risk evaluation report (PBRER)
- Addendum to clinical overview (ACO)
- Signal assessment report
- Safety analysis report
- Company core data sheet (CCDS)
- Benefit-risk analysis

The first 4 of these documents are periodic reports written for external regulatory agencies, and the last 4 are cumulative reports that are mostly for the benefit of the company that holds the product marketing authorization.

Welke described the reports written for external agencies as having many common sections and shared some details about each of them. The DSUR summarizes the product’s safety in clinical studies and shows whether the product is safe to continue to study in people. The RMP describes the risk management system and how the sponsor is limiting the risks to people using the product. The PBRER summarizes the benefit-risk profile and shows if the product’s benefits outweigh the risks in the marketplace. The ACO summarizes all safety data accumulated since the product’s marketing authorization or since the last renewal.

The documents written for internal use are frequently cumulative reports that primarily serve as an analysis of product-related data. The signal assessment report evaluates the safety of a single event or related group of events associated...
with validated safety signals. The safety analysis report serves the same purpose as the signal assessment report for events that are not associated with validated safety signals. The CCDS summarizes a company's key messages to share about the product, and the benefit-risk analysis evaluates the benefits and risks of a product. All documents—whether for external or internal use—are interconnected; some even reiterate content in other reports.

Pharmacovigilance Writing
New pharmacovigilance writers should be familiar with the product, disease, and events that are the focus of their work. It is also important for new writers to familiarize themselves with the current guidance on their product, as it changes frequently and as there are many guidance sources (Figure).

Welke described the pharmacovigilance writing career as one in which you must adhere to tight work timelines, be able to accept that some data are missing, be able to analyze and provide opinions to your team, and know what the expected content is in each document. Welke also stated that “medical writer” search terms are generally not used to describe pharmacovigilance careers. The following are the search terms she suggested for a pharmacovigilance job:

- Pharmacovigilance Scientist/Analyst/Author/Writer/Manager/Specialist
- Safety Scientist/Specialist/Writer
- Periodic Report Scientist/Analyst/Manager/Officer
- Associate/Manager/Director of Pharmacovigilance

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Figure

![Figure](image_url)

Practical approaches - To begin

- Familiarize yourself with the current guidance(s):
  - ICH
  - EMA
  - US FDA
  - PMDA
  - Multiple country guidances
  - Significant guidance updates in the last 6 years
- Many guidances provide templates or at least required headings and expected content

Tools to Thrive in a Digital World

Speakers
Monica Nicosia, PhD, Independent Medical Writer, Nicosia Medical Writer, LLC, Bryn Mawr, PA
Kathy Boltz, PhD, Owner and Principal Medical Writer, On Point Scientific, LLC, Phoenix, AZ

By Ana Jakimenko, PhD
Many digital tools are created to assist small businesses in reduction of time spent on nonbillable, boring, and administrative tasks and in improvement of data security and efficiency of billable tasks. The main digital tools used by the speakers are shown (Figure).

The data generated using Microsoft Office Suite (MS Office) tools need to be stored, accessed, backed up, and shared. Data can be stored or backed up with local hardware and software or on the Cloud. The most important factors for choosing the local site versus the Cloud are

- **Costs:** The local site has a one-time cost, whereas Cloud-based services have an annual or monthly fee.
- **Responsibility:** The owner of a local site is responsible for maintenance of hardware and data security. If the data are deposited on the Cloud, the Cloud-based service provider will take care of that.

Local data backup generally uses a network-attached storage drive and a redundant array of inexpensive disks (RAID) with software. RAID replicates copies of data across the inexpensive disks to protect against hardware failure of any individual disk.

Nicosia advised attendees to follow the 3-2-1 rule for effective backup:

- Always have 3 copies of data
- Keep 2 copies on different types of storage
- Keep 1 (or more) copies of data offsite

The most commonly used Cloud-based data storage and sharing service among freelances in 2016 was Dropbox. An alternative, Egnyte, allows clients to access password-protected files and is cheaper than Dropbox. OneDrive, another alternative to Dropbox, is included in the MS Office 365 subscription.

Website Design and Hosting
Owning a website is a powerful marketing tool for freelance medical writers. The most popular website building and hosting tools among the freelances were GoDaddy, Bluehost, and Wix. In 2018, the best website builder for small businesses was Wix whereas the best website host was HostGator.

Travel and Data Security
To ease traveling, Boltz recommended using airline and hotel apps and an Expensify app to efficiently digitalize and categorize travel expenses. Anyone can monitor Internet...
traffic through public Wi-Fi networks (airport, coffee shop, etc). To protect one's privacy while traveling, Boltz recommended
• Hard shutdown of all electronics before going through customs
• Use of a purchased virtual private network before connecting to public Wi-Fi or use of your own network (eg, cell phone)

Recent data security breaches of companies like Yahoo and Facebook make the managing of passwords and login information vital for everyone. Best practices for enhanced data security are as follows:
• Use secure passwords everywhere
• Use different passwords for every account
• Use 2-factor authentication whenever it is available

Boltz suggested using password manager software such as LastPass or Dashlane to help create unique passwords and to always keep your smartphone locked with a 6-digit PIN. The MS Office 365 subscription keeps the software updated, which makes the use of Outlook for email a compelling solution for freelances. The editor's choices for small businesses are Intermedia Exchange Email and MS Office 365 Business Premium.5

Business Software
Online accounting services offer user-friendly interfaces and navigation and allow users to keep track of accounting and time spent working, accept credit cards payments, etc.5,6 The best free time-tracking app is Toggl, and the best integrated invoicing apps are Harvest, FreshBooks, and Paydirt.6 Working remotely through screen sharing has lots of options: Join.me, Cisco Webex, Zoom, UberConference, and Google Hangouts.

The 3 most popular citation management tools are EndNote, Zotero, and Mendeley. Other useful digital tools are FreeMyPDF (PDF unlocking), Unpaywall (full text finder), PerfectIt proofreading software (proofing), and transcribe (transcribes audio file into text).

For more information, the presenter's slides are available on the AMWA website at https://www.amwa.org/page/2018sessions.

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References

RESPONSES TO REGULATORY AUTHORITIES: MEASURE TWICE—CUT ONCE

Speakers
Julia Forjanic Klapproth, President and Senior Partner, Trilogy Writing & Consulting, Durham, NC
Art Gertel, Principal, MedSciCom, LLC, Lebanon, NJ

By Priyanka Ingle-Jadhav, MD, PhD, MWC®
Key interactions with regulatory authorities occur essentially at 2 stages of the drug development cycle. The first is prior to

Our Main Digital Tech Tools

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<td>Synology RAID NAS</td>
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<td>Dropbox</td>
<td>Dropbox, OneDrive via Office365</td>
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<td>Office365</td>
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<td>Expenses, invoices, estimates, time tracking</td>
<td>FreshBooks</td>
<td>QuickBooks Pro, Toggl</td>
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Figure
submission of a registration dossier to the regulatory agency, which comprises both formal and informal exchanges of information between the Sponsor and Agency. This can be in the form of Sponsor-requested meetings or responses to inquiries from the Agency. The other important interaction is in the postsubmission period of an application dossier, during which regulatory authorities pose questions to Sponsors requiring written responses.

With respect to the US Food and Drug Administration (FDA), the first kind of interaction, prior to submission of an application, is generally to get additional insights from the Agency on the sufficiency of available data and the planned clinical program. The Agency will provide recommendations for technical changes, the Clinical Development Plan, Investigational New Drug Application documentation, or a Special Protocol Assessment or will provide guidance on ways to resolve any critical issues that might affect the application approval process, going forward. These formal communications are clearly outlined in FDA guidance. A formal meeting request is made by the Sponsor to the Agency, stating clearly the meeting type requested. Depending on the type of meeting, a response on acceptance and format of the meeting is communicated by the FDA, usually between 14 and 21 calendar days after the request was made. Following this, the Sponsor is required to submit a meeting package (often referred to as a “Briefing Book”) 30 to 50 days prior to the scheduled meeting (depending on the meeting type). The pre-NDA/BLA (New Drug Application/Biologics License Application) meetings are usually held 6 to 12 months prior to the planned submission, to allow for a comprehensive review of the provided summary of relevant data generated during drug development. Thus, the meeting package should include details about any critical issues that may impact the application approval.

Postsubmission communications vary with different regulatory agencies. Although there are some significant differences in timelines for communication between the agencies, using a standardized approach to getting ready for and then writing responses to authority questions can make the process more efficient. The central theme is to be proactively prepared with a team capable of rapidly producing focused responses. This team should comprise key functions such as clinical operations; biostatistics; clinical pharmacology; preclinical operations; chemistry, manufacturing, and controls; regulatory affairs; medical writing; and document management. In order to have a well-managed and well-planned writing process, the team members should be assigned specific roles and responsibilities so that it is clear who should be doing what once the questions come in.

The team should initially get ready to address potential regulatory questions by performing a self-critical “gap-analysis” to identify the potential challenges that may be raised by the regulatory authorities. For example, these could include weaknesses of the drug or class of drug, deficiencies in the development program or data analysis, etc. This helps them identify what issues are expected so that the team can plan on likely deliverables that will be needed to support a response to each issue.

Timelines must be agreed on to manage who will deliver what pieces when, and these must be realigned, as needed, depending on the challenges that arise during the writing process. A tracking sheet for monitoring the status of responses in preparation (ie, in draft, in review, or finalized), open action items, and whether the responses will have appendices or literature is an essential tool for managing the process. The team is often writing several responses in parallel, and a tracking sheet helps keep effective oversight of each of these.

It is helpful to have a medical writer as a team coordinator who is capable of pulling the input from the contributing functions together and who is responsible for maintaining the tracking sheet. For larger teams and projects, which may require multiple medical writers assigned to subsets of responses, it is important to have a medical writer who has oversight across all the activities and who can coordinate the activities across all the areas.

Once the questions from regulators arrive, the team needs to distinguish which questions have already been addressed in preliminary work and which are new. It is important to triage the questions to identify which are more complicated and may need longer to prepare (perhaps external experts will need to be involved or fully new analyses will be needed) so that these can be prioritized by team. Questions that were not anticipated will need to have content authors assigned who can lead the discussion on response strategies. It is also important to identify issues that may require further contact with the regulator to clarify any areas of uncertainty.

Because FDA questions can arrive at any time, it is important to agree in advance on the process for action and on meeting frequencies after questions arrive, as well as to set goals for time to completion of the response. In the absence of official regulatory guidance for format and content of responses, it is advisable to keep the responses brief, well-structured, and consistent with the layouts and presentations from the dossier to make them reviewer-friendly and easy to read. References should be made to the identifying item number and location in the original briefing package to allow the reviewers to easily locate and access the initial positions. It is also imperative for the team to be strongly focused only on answering the questions asked and to not add any new data unless requested.

In the case of a Marketing Authorization Application to the European Medicines Agency, initial assessment reports at day 80 and day 150, which are sent ahead of the final consolidated list of questions at day 120 and day 180, are beneficial in helping to identify any such issues prior to the clock stop. Once an area of concern is identified in the preliminary questions, the team can begin to prepare their strategy for a response, which will then be refined after the final questions are received. If additional data analyses are required to address the anticipated queries, these can be initiated so they are ready to use if
the question remains in the final list of questions. The medical writer is ideally positioned to identify the parties responsible for supporting data and analyses that will be required to develop regulatory responses. They must have a good understanding of the development process and work closely with their team members in order to guide an efficient and effective preparation of position statements and responses to regulator questions.

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Reference

FIT FOR FREELANCE: HOME WELLNESS HEALTH SECRETS

Speaker
Reggie Wilson, MS, Founder, Fit for Freelance, Naples, FL

By Kelly Schrank, MA, ELS
Reggie Wilson began in public health and nutrition and transitioned to medical writing as an extension of his desire to help remote workers enjoy their work-life balance. The session began with a recommendation of a TED Talk by Simon Sinek called “Start with Why” (https://youtu.be/IPYeCltXpxw). Your why drives behavior. Reggie Wilson believes quality of life is a better motivator than just improving health. For instance, you should focus on the experience of the 5-minute walk rather than just doing it to check it off your list or lose weight. As he stated, “The most enjoyable effects are likely to get you walking again.”

Health components include family history, environment, and lifestyle. A low level of exercise is a risk for a number of chronic health conditions, including diabetes, pain, obesity, constipation, heart disease, arthritis, high blood pressure, cognitive disfunction, and stroke. Taking a break from work to stand up or walk for at least 1 minute makes a big difference in waist circumference, according to an article he cited, although he recommends a break of closer to 5 minutes. Overall, individuals should be striving to reach the Centers for Disease Control recommendations for activity levels: 150 minutes per week (22 minutes per day) of moderate exercise or 75 minutes per week of vigorous exercise.

There are immediate and long-term reasons to exercise. As Wilson said, right now (ie, sitting at the session or reading this article), there is less blood flow to the brain, and you have decreased focus and creativity; it takes more time and effort to stay locked in and produce mistake-free work. In the long term, a continued sedentary lifestyle will result in more cortisol, which is associated with anxiety, depression, weight gain, and heart disease at high levels.

His solution? Have the audience stand up and move around to a YouTube video called “Instant Recess” (https://youtu.be/tMuZ0__-Y7n4).

Physically active people are happier and more productive, according to a number of articles Wilson cited: participants in a 2-week exercise program also decreased their sensitivity to anxiety. Exercise can make a difference in whether you have a good day at work or a bad day at work.

Wilson created a wellness community with online tips, personal training, and support for freelancers and entrepreneurs who want to confidently work better: https://fitforfreelance.com/.


Home Wellness Recommendations:
• Take 1 Break an Hour
  – 5 minutes is optimal
  – Trade a coffee break for a walk
• Take Power Naps
  – 5-10 minutes
  – Use a timer
• Eat Healthy Snacks
  – Cut-up cucumbers
  – Almonds
• Get Regular Sleep
  – 7 hours/night
• Drink Water
  – Too little: get up to get more
  – Too much: more bathroom breaks

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37 TIPS FOR EFFICIENTLY WRITING SCIENTIFIC PUBLICATIONS

Speaker
Katherine Molnar-Kimber, PhD, President and Medical Writer, KMK Consulting Services, Kimnar Group, LLC, Worcester, PA

By Kristin A. Roynesdal, MS

Medical writers who work on scientific publications can improve their bottom line by adopting a productivity mindset and working more efficiently. During this session, Katherine Molnar-Kimber shared 37 efficiency tips for the planning, writing, and reviewing of scientific manuscripts.

Planning for Publication
Before writing, planning can save medical writers significant time and stress. At the start, you should obtain clear, specific details about the project, including timelines, your responsibilities, team members, and ultimate publication goals (Figure 1). By clearly defining tasks, determining priorities, and setting a tentative schedule, many common problems encountered during writing and revision can be avoided. Additionally, “you want to make sure you get buy-in from all stakeholders,” explained Molnar-Kimber, to avoid delays during revision due to late reviewer input.

Delays can also be avoided by consulting relevant guidelines for determining authorship (eg, International Committee of Medical Journal Editors [ICMJE] recommendations) and reporting methods (the Enhancing the QUAlity and Transparency Of health Research [EQUATOR] network for clinical trials; Animal Research: Reporting of In Vivo Experiments [ARRIVE] for animal studies). If a target journal is known, its instructions should be examined to ensure the manuscript matches the journal’s scope and to identify journal-specific requirements, such as word or figure/table limits. Journals often provide author checklists, and some, such as Radiology, even provide public access to peer review checklists. Molnar-Kimber advised consulting these checklists early and often.

Figure 1. Specific details to clarify during the publication planning stage. ©www.gograph.com / artist: get4net, figure modified by Katherine Molnar-Kimber.

Writing Your First Draft
Molnar-Kimber encouraged writers to begin with the Results section “because everything in the document is dependent on the presented results.” The Methods should only include the steps taken to obtain the results. For the Introduction, sufficient information should be provided for the reader to grasp the rationale and understand the Methods and the Results. Finally, the Discussion should focus on the significance of the study’s results to the larger field. The Results section largely requires writing about numbers to describe comparisons or highlight differences that are statistically or clinically significant. To create clear sentences about numbers, Molnar-Kimber proposed using the “4 W’s” of writing:
- **Who:** Groups or subgroups
- **What:** Units of measurement
- **When:** Duration of analysis or year
- **Where:** Study site location or geographic population
- **How much:** Magnitude/direction of the effect or response

After the Results are complete, the Methods can be written. Here, you may question what steps must be included and what can be left out. To avoid confusion, Molnar-Kimber suggested listing the reagents used and asking 2 questions:
- Is this essential to reproducing the study?
- Would most readers need this information to understand the results?

If the answer to both questions is “yes,” this information belongs in the Methods. If the answer to the second question is “no,” the information can be placed in the supplementary file.

When working on the Introduction and Discussion, you may struggle with which section should cite contradictory data described in published articles. To minimize this deliberation, Molnar-Kimber provided a decision tree (Figure 2). Briefly, if the article spurred the investigators to alter the design or

Figure 2. Decision tree for selecting where to cite an article of contradictory data. Copyright 2018, Katherine Molnar-Kimber.
interpretation of the research in the current study, it should be cited in the Introduction. If not, it can be cited in the Discussion.

To minimize writer’s block and procrastination, Molnar-Kimber encouraged reading key references to gain context. She also cautioned against editing while writing, which can often hinder the flow of ideas. Instead, you should plan a time for editing separate from writing.

**Reviewing the Manuscript**

After writing is complete, you should spend time self-editing for structure, grammar, style, and consistency. Molnar-Kimber suggested using PerfectIt 3 software to save time during proof-reading and help fix inconsistencies in hyphenations or abbreviations.

When multiple people review a document, version control can be difficult to maintain. Several software programs are available to help manage the review process. Some, such as PleaseReview, allow multiple reviewers to work on the same document simultaneously. However, if the program allows only a single reviewer, Molnar-Kimber recommends training the team to sign the manuscript back in when stepping away from the computer to avoid unnecessary delays between reviews.

Just like writing, implementing productivity tips into your daily work requires planning and review. To supplement this, Molnar-Kimber provided a handout for writers to list their top 6 tips and prioritize them by helpfulness. For maximum efficiency, writers should implement the highest-priority tip consistently for 1 month, then assess its advantages/disadvantages and determine whether to continue its use.

**Online Resources**

A document file summarizing the session slides and handout content is available online.

The Radiology checklist for peer reviewers can be found at https://pubs.rsna.org/page/radiology/reviewer-checklist. To learn more about the PleaseReview software, visit https://www.ideagen.com/products/pleasereview.

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**CHALLENGES FOR BIOLOGIC AND BIOSIMILAR DEVELOPMENT: A CHEMISTRY, MANUFACTURING, AND CONTROLS (CMC) PERSPECTIVE**

**Speakers**

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

**Mary Ellis Bogden, BA, Senior Writer and Manager, Whitsell Innovations, Inc, Chapel Hill, NC**

**By Leslie Kowitz, MA, ELS**

Welcome to the world of CMC—chemistry, manufacturing, and controls. Teresa Chu and Mary Ellis Bogden took the audience on an information-packed tour of biologic drug development, analytical chemistry, and the emerging space of biosimilars. For many, this was not only an introduction into the differences between biologics and biosimilars but also an exploration of the complexities and challenges in drug development and manufacturing processes—topics often challenging for medical communicators. This report provides a general overview of the session’s focus on biosimilars. A more comprehensive article on biologic drug development and the analytical methods used to determine biosimilarity is planned for a future issue.

**The Goal of CMC**

To develop a new drug in the United States, a company must submit sufficient information to assure “the proper identification, quality, purity, and strength” of the product (21 CFR 312.23) in the form of an Investigational New Drug Application (IND). The CMC group is responsible for planning, driving, and overseeing studies and experiments that generate information required to write the Quality sections of the IND. In the case of biologics, Chu emphasizes that “the process is the product.” The process is as much a part of a company’s license as is the final drug product.

**What Are Biologics and Biosimilars?**

Before going further, we need a common lexicon to eliminate potential confusion (Table on next page).

**Brief History of Biosimilars**

Biosimilars are relatively new players to the US pharmaceutical industry, available only since 2015 (Zarxio from Sandoz, biosimilar to Neupogen), whereas the European Medicines Agency recorded their first biosimilar license in 2006 (Omnitrope from Sandoz, biosimilar to somatropin). Some of the early biologics approved in the 1990s saw their patents expire after 20 years in the early 2000s, making those fair game for other companies to try to create highly similar products. As of this writing, 13 biosimilars are currently available in the United States.
Developing Biosimilars Versus Biologics

So, a particular biologic product is moving off patent and you think it would be a great idea to create a biosimilar. How do you do it? Chu reminds us that the manufacturing process for biologics is proprietary, so only the original manufacturer knows how to produce their biologic product. Biosimilar companies therefore have to figure out how to make the product and show biosimilarity through analytical methods, which is not as simple as it sounds. Small-molecule drugs have well-defined chemical structures and can be analyzed to determine all their components. Known as the RLD when licensed by the originator (eg, Valium).

Biosimilar

“Follow-on” biologic that is highly similar to the RP, with an abbreviated regulatory pathway. Less expensive than the RP, manufactured by a company other than the originator (eg, Inflectra).

Small Molecule (Drug)

Created by chemical synthesis, these compounds are small (molecular weight <900 Da), have well-defined chemical structures, and can be analyzed to determine all their components. Known as the RLD when licensed by the originator (eg, Valium).

Generic

Small molecule, chemically identical to the RLD, with an abbreviated regulatory pathway. Less expensive than the brand name drug, manufactured by a company other than the originator (eg, diazepam).

Abbreviated Regulatory Pathway

One major difference between biologics and biosimilars is in regard to their regulatory approval pathways. Although biologics go through a lengthy and expensive research and development process, originator companies must also conduct 3 phases of clinical trials (healthy volunteers and target population) before submitting a Biologics Licensing Application—a significant financial investment (hence, their hefty price tag to patients).

In 2010, President Obama signed into law the Patient Protection and Affordable Care Act (which amends the Public Health Act) to create an abbreviated approval pathway for biological products that are “highly similar” to a US Food and Drug Administration (FDA)–approved product. The pathway is referred to as the Biologics Price Competition and Innovation Act (BPCI Act) of 2009. The goal of the BPCI Act is to facilitate market competition and regulatory approval and help get these medicines to patients faster and potentially for less money than the original biologics by leveraging existing safety and efficacy data previously reviewed by the FDA.

Although the pathway may be abbreviated for biosimilars, the FDA does not make it any easier for companies to license biosimilars. Reviewers employ the same rigor as with any original product. They evaluate applications for biosimilars on a case-by-case basis and look at the “totality of evidence.” In addition to the extensive analytical data required for showing similarity to the Reference Product, phase 1 and confirmatory clinical studies are usually required to show safety and efficacy of the biosimilar in 1 or more indications for which the original product is licensed.

Time will tell what changes may occur in the marketplace as a result of biosimilars competition. The goals of the BPCI
Act are promising to patients, but the challenges are high for those seeking success with biosimilars. With so many companies already vying for position, others are pulling out of the biosimilars space because there will not be enough room for everyone.

For additional information, see the FDA’s final guidance, Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product and Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, April 2015.

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YOUR FREELANCE BRAND: HOW TO STAND OUT IN A SEA OF FREELANCES

Speakers
Lori De Milto, MJ, Freelance Medical Writer, Lori De Milto Writer for Rent, LLC, Sicklerville, NJ
Kathleen Labonge, MBA, Freelance Medical Copyeditor, Write Point Editing Solutions, Greensboro, NC
Eva Stabenow, MA, German/English Translator, Wordplay Translations, LLC, Nashville, TN

By Kelly Schrank, MA, ELS
Freelances who want to “stand out” (ie, do less marketing and make more money) need to have a brand. “To clients, most freelance medical writers or freelance medical editors seem the same or similar,” says Lori De Milto. Having a brand—a personality for your business that evokes trust and makes clients think of you first—is a differentiator in a crowded market.

Although personal and business brands overlap for freelances, they are not the same. Business branding is how clients, potential clients, and colleagues perceive you as a business based on your visual images and key messages, whereas personal branding is more about your behavior and tone of voice online and in person, especially when networking. The session’s focus was on business branding.

Elements of a Brand
The elements of a brand include a logo, a tagline, a company name, a tone of voice, and colors. A logo is an image, symbol, other design, or just your company name in a nice design used to visually represent your business. A tagline is a memorable phrase or sentence that helps your audience understand what you do. It is used with the logo on your website and in other marketing materials. A company name could be a business name or just your name and title/what you do. Your brand’s tone of voice expresses the company’s values, personality, and way of thinking. A palette of colors associated with your business (normally a dominant and a secondary color, and sometimes an accent color) further cements the personality and professionalism of your business.

Brand Statement
The first part in developing a brand is creating a brand statement, which clearly and concisely explains
• Your services,
• Your target audience(s) or client types, and
• How you’re different from or better than other freelances.

You don’t actually have to be different from or better than other freelances; you just need to position yourself as different or better. For example, De Milto discussed how her brand focuses on delivering targeted medical content and doing this on time every time. Many freelances write content that’s targeted to the audience and meet their deadlines, so this isn’t unique. But De Milto thinks that using this in her branding makes her stand out in the minds of clients.

Base your positioning on the needs of your clients (eg, making the client’s life easier, doing the project right, and meeting deadlines) and your core values and personality traits (eg, dependable, efficient, and responsive). You need to develop your brand statement before you contact a designer for the rest of your branding.

Template for a Brand Statement
[My target audience] can count on me for [key services] delivered with [things that make me different, including core values and personality traits].

Working With a Designer
To prepare for the process, gather logos you like (those of other freelances or even other types of businesses), colors you like, your brand tone of voice, and images you like (such as icons or other images). De Milto suggests hiring a professional and avoiding sites like Fiverr.com.

Your designer will help you to choose colors that look good on the Web and in print and to develop a logo that looks great on your website, email signature, and business cards. The advice from the group for the design process was to be honest about what you like and don’t like and don’t develop “analysis paralysis.”

The session materials have more details and examples, such as the brands of Lori, Eva, Kathleen, and other freelances: https://www.dropbox.com/sh/25mlnxlwxjy49gg/AACBdD3CKgzYf-y4wGFKt_Dya?dl=0.
2018 CONFERENCE COVERAGE
OPEN SESSION REPORTS

Tips for Working with a Designer

- From Lori:
  - Be prepared
  - Be firm
  - Trust the designer
  - Get feedback

- From Eva:
  - Be specific about what you want (not just what you don’t like)
  - Trust your gut
  - If you love a color, your designer can recreate it

- From Kathleen:
  - Do your homework
  - Use a recommended designer
  - Don’t settle

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DISSECTING THE CRITICAL “SPECIFIC AIMS” PAGE OF AN NIH GRANT

Speaker
Madison Hedrick, MA, Medical Writer III, Wilson Carroll Research Services, LLC, Little Rock, AR

By Chandler Wilson Carroll
The Specific Aims page of the National Institutes of Health (NIH) grant application is the most important part of any NIH grant application. It is the primary marketing document for the entire proposal and exists to define the “big picture” and provide a roadmap for the research strategy.

In a single page, you must quickly gain the reviewers’ trust and confidence while also convincing them that your work is important to fund. You must convince them that you (or your client) are the best person to complete the work you proposed. For this reason, the Specific Aims section can be the most difficult to write.

Organization of the Specific Aims Page
- Overarching problem and goal
- Context and setting for the project
- Central hypothesis
- Specific aims and experimental overview
- Expected outcomes and impact of the project

General Guidelines: Tips
The Specific Aims page is all about selling ideas! It is crucial for setting the frame of mind for the reviewers. A Specific Aims page that leaves reviewers feeling distinctly not excited will likely color how they will feel concerning the sections that follow. Deliver a clear message:
- Offer something special
- Make it similar to a good news article:
  - Concise
  - Good headlines
  - Visually appealing
  - Easy to read
  - Comprehensible to a wide audience
- Remember your audience: ALL reviewers!

General Guidelines: The Reviewer
Many reviewers will only read the Specific Aims page. Visualizing the reviewers as a group and the individual reviewer as an audience member when writing your Specific Aims page is beneficial.

Reviewers are often overworked and tired and may only spend a few hours on your grant. They are knowledgeable about research design and methods as well as NIH grant mechanisms, but they may have little in-depth knowledge in the specific area the grant focuses on.

NIH Guidelines for the Specific Aims Page
“State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.”

“List succinctly the specific objectives of the research proposed, e.g., to test a state hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.”

Specific Aims Page in Four Sections
Part 1: Introduction
- Introductory Paragraph: Convinces the reviewers of a significant problem. This will scaffold your argument for your solution that is relevant to the mission of the funding agency.
- Opening Sentence: Identifies what the proposal is about and immediately relates it to the mission of the funding agency.
- Knowns: Brings the reviewer up to speed on the “current literature” and state of the field in < 5 sentences; ALL key points need to be introduced here (this is the framework for your concept).
• Unknowns: Problem(s) that need to be addressed.
• Frame the Problem: The problem points to that critical need that serves as the driving force for the proposal. Conclude with WHY the lack of a solution is an issue for this funding agency.

Part 2: The “What, Why, Whom” Paragraph
• Long-Range Goal (broad): Principal Investigator’s career goal, which should match the funding agency.
• Objective of the Application (narrow): The purpose of the project described to meet the critical need; must have a well-defined endpoint.
• Central Hypothesis (most narrow).
• Rationale: What will be possible after completion of the aims that is not possible now? What is the underlying reason to complete the project as it relates to the agency’s mission?
• Well-Prepared: Collective basis for the competitive advantage of your group. Convince the reviewers that you and your team have the solution to this critical need.

Part 3: The Aims
• Aims Paragraphs: Provide a logical, step-by-step development of key hypotheses and activities through which you will fulfill the objectives to address the critical need or problem.
• Each paragraph should collectively address the objectives; be conceptual, but not descriptive; and avoid aims that are dependent on the outcome of other aims. A formatting suggestion is provided below:
  Specific Aim 1—Brief, focused statement
  • subtext with more details, including measurements and comparisons
  Specific Aim 2—Brief, focused statement
  • subtext with more details, including measurements and comparisons
  Specific Aim 3—Brief, focused statement
  • subtext with more details, including measurements and comparisons

Part 4: The Payoff Paragraph (the Impact)
• Innovative/Transformative Statement: Should directly follow the aims/goals/objectives and build advocacy for the project.
• Expectations: Make sure these are specific and credible.
• Impact: How these outcomes will meet the identified need.
• Inspirational: How will this “change the world?”

After completion of the entire research strategy and Specific Aims page, it may be beneficial to go back and ensure that the following questions are answered:
• What are the impacts of your expected success—what will be the subject that was [not possible/not known] that will be [possible/known] with respect to the following:
  – Knowledge benefiting human health and disease; and
  – Advancement of your field of research?

After reviewing your answers to these questions, determine if they were well communicated in the Aims page so that the reviewer can locate these outcomes with ease.

Chandler Wilson Carroll is the managing member and founder of Wilson Carroll Research Services, LLC, in Little Rock, AR.

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UP YOUR EFFICIENCY GAME (WITH PERIPHERALS)

Speaker
Kate McKiernan, MA, Medical Writer/Editor, IMPACT Clinical, San Diego, CA

By Kelly Schrank, MA, ELS
Kate McKiernan has a unique perspective on peripherals, comparing how you interact with a video game through controllers to how you interact with Word through your mouse and keyboard. Her credentials for creating this session, she explained, included 28 years of video game experience. Her big question is how can we interact with computers better? Her goals include increasing how much money she makes, getting a return on the time and energy investment, having a better quality of life, and decreasing error and interaction cost.

She sets the stage with the following picture of her work area:

Shown above are USB cables, dual monitors with monitor arms, a separate number pad, and a gaming mouse.

Five Essential Peripherals
The first peripheral is helpful for those who have multiple
laptops (for instance, when different clients provide laptops to connect to their networks securely). A hub with USB-C cables allows you to have 1 set of peripherals connect to multiple laptops, saving space on the desktop, saving precious brain power not having to adjust to different laptops or peripherals, and saving time in not having to connect to/disconnect from different laptops. Estimated cost: $15.

The second peripheral enhances the convenience of dual monitors, something many medical communicators already have, but McKiernan takes this a couple of steps further by pivoting the monitors on monitor arms, so they can be repositioned quickly and easily as needed for different tasks. Her default mode has both monitors in portrait mode, which allows you to see more words at a time in Word documents and PDFs. Monitor arms can be clamped on the end of the desk or screwed into wood. Estimated cost: $200.

The third peripheral ensures productivity in a different way by protecting your Internet router with an uninterruptible power supply (UPS). When your power goes out, you usually lose Internet because your Internet router needs electricity, too. If you plug the router into the UPS, the router can stay on for another couple of hours. Kate McKiernan recommends not connecting everything to it, as that same UPS with “everything” on it will only last about 15 minutes. Estimated cost: not provided, as the prices can vary widely.

The fourth peripheral is a separate number pad. Her personal layout has the number pad on the left, with the keyboard in the middle and the mouse on the right. With this layout, the distance from keyboard to mouse is reduced, making you more efficient, and the numeric keypad, which has limited usability on a day-to-day basis, is out of the way unless you need it. Estimated cost: $10.

The fifth peripheral, which McKiernan says was actually her first and best change, is the gaming mouse, which “changes multibutton inputs into one button.” For example, Word lets you assign keyboard shortcuts, then the gaming mouse lets you execute multiple keystrokes with one button. She broke the process down into 3 steps: pick a common task, give the task a keyboard command (in Word), and assign the keyboard command (in the mouse). For example, assign a shortcut key to insert common symbols, apply styles, and change numbers to subscript or superscript or assign a keyboard shortcut to a macro. Estimated cost: $50.

**Caveats to Gaming Mouse**

- Administrator access needed
- For right-hand use only
- Wired only

**Advice for Adapting to Gaming Mouse**

- Choose tasks that are simple, done frequently, easily noticed when done, and easily undone
- Assign tasks to correct template (or Normal.dotm)
- Learn a new button 1 at a time
- Assign buttons logically
- Have the mouse controller layout on screen or printed out when getting up to speed
- Group buttons together by function, type of job, or whatever makes sense for your workflow
- EndNote has its own keyboard shortcuts; combine with the mouse

The session materials have more details on how to set up Word and the gaming mouse.

Kelly Schrank, MA, ELS, is a freelance medical editor and owner of Bookworm Editing Services, LLC, in Canastota, NY.

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**PREDATORY PUBLISHING: ISSUES AND ADVICE**

**Speakers**

Barbara Gastel, MD, MPH, *Professor, Texas A&M University, College Station, TX*

Barbara C. Good, PhD, *Director, Scientific Publications, NSABP Foundation, Pittsburgh, PA*

Mary Kemper, BS, *Medical Writer/Yoga Instructor, Mayfield Clinic/Glia Media, Cincinnati, OH*

**Moderator**

Kirby Snell, MFA, *Copyediting Client Manager, J&J Editorial, Cary, NC*

**By Kirby Snell, MFA**

This session on predatory publishing highlighted (1) some techniques used by predatory publishers to take advantage of authors, (2) strategies for identifying potential predators, and (3) how to respond. The panelists also touched on the larger impact and threat that predatory publishers can pose for academic and scientific publishing.

**What Is Predatory Publishing?**

A predatory publisher is an opportunistic venue that exploits the academic need to publish but offers little reward.
Common characteristics include the following:

- Their primary goal is to make money.
- They do not care about the quality of the work published.
- They make false claims or promises.
- They engage in unethical business practices.
- They do not follow accepted standards or best practices of scholarly publishing.

Of the approximately 28,000 scientific journals currently in existence, an estimated 8,000 to 10,000 are predatory, including potentially 1,200 to 1,500 predatory medical journals. Other predatory operations include fraudulent meetings, counterfeit impact factors, and hijacked journals (counterfeit websites stealing a real journal’s identity).

Identifying a Predator

Barbara Good walked the audience through a real-life case of identifying a potential predatory journal. Although the publisher’s website looked legitimate at first, many elements proved to be red flags, including a questionable mailing address, indexing information advertised only as “coming soon,” publication charges due at submission, journals in many disciplines all produced by the single publisher, poor use of English across the website, published articles of dubious quality, and no request for conflict-of-interest statements.

By watching for such warning signs and by asking themselves careful questions (Box), authors can guard themselves against potential predators.

Recognizing Valid Journals

Authors should take care, however, not to dismiss lesser-known but valid publications, such as small interdisciplinary journals or journals from developing countries. Barbara Gastel shared 2 cases of invitations she had received to peer-review or submit manuscripts, 1 from a questionable-sounding publication and 1 from an unfamiliar journal from overseas. Some investigating revealed that both titles were reputable, and she enjoyed rewarding experiences that would have been missed if she had disregarded the invitations too soon.

Predatory Publishing and Open Access

Mary Kemper highlighted the contributions of Jeffrey Beall, a Denver librarian who coined the term “predatory publisher” to define the threat to scholarly publishing by these deceptive journals that corrupt the gold model of open access (OA). He profiled predatory publishers on his blog Scholarly Open Access (2012-2017), which offered critical commentary on their questionable practices. Beall’s blacklist was an invaluable resource for academic authors and librarians, but it was also criticized for its shortcomings (e.g., the use of the term predator) and his critique of the OA social movement. Following consistent harassment by several notorious blacklisted publishers, Beall shut down his blog in 2017.

While Beall’s list is now inactive (although archived online), other resources for fighting predatory or illegitimate publishing exist, including Cabell’s International (which maintains both a whitelist and a blacklist) and Think Check Submit. The Directory of Open Access Journals also recently delisted more than 3,000 of its approximately 11,000 journals in an effort to crack down on predatory journals.

The Impact of Predatory Publishing

Although the pressure to publish—and, increasingly, the pressure to publish in OA—is significant, writers and researchers must be cautious when selecting venues and responding to invitations from unfamiliar publications to review or submit work. Most immediately, an author’s reputation is endangered by publishing in a journal that lacks peer review, is not indexed, or that publishes bad science. More broadly, predatory publishing damages the medical literature itself: publishing research that is pseudoscience or poorly done (or falsified) can eventually erode the medical literature base to the point that “truth” is not discernible.

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Questions to Ask

- Did you receive an obsequious-sounding email from the journal?
- Do they charge a very large or very small submission fee? On submission or at acceptance? Is the fee transparent on the site?
- Is the journal indexed? Are the metrics legitimate?
- Is the journal young?
- How quick is peer review?
- Does the publisher claim to publish many journals in varied fields?
- Are any editorial board members prominent researchers in the field, or anyone you recognize?
- Does the editorial office address seem legitimate?
- How does a sample article read?
- Was the journal or publisher on Beall’s list? Are any current Web resources evaluating them?
2018 CONFERENCE COVERAGE
OPEN SESSION REPORTS

MASTER THE DISASTER

Speakers
Brian Bass, MWC®, President, Bass Global, Inc, Fort Myers, FL
Larry Lynam, DSc, MA, SM, RM, Principal, The Lynam Group, LLC, Coral Springs, FL
Michelle Sauer, PhD, ELS, Principal Editor, RNA Editing, LLC, Cypress, TX

Moderator
Lori Alexander, MTPW, ELS, MWC®, President, Editorial Rx, Inc, Fort Myers, FL

By Larry Lynam, DSc, MA, SM, RM

With a dash of wit and a dose of practicality, this session created awareness around a variety of disasters that we each faced as freelances while attempting to keep life and business functioning. We can all agree that disasters come in many forms and fashions, and no one is really prepared for unanticipated challenges when they visit or stay for an extended time in your life. Disasters include the natural phenomena unique to our respective geographies (hurricanes, floods, blizzards) but also include the “unnatural” ones, such as health issues, caregiving for our loved ones, and travel and technologic nightmares. In the discussion of caregiving, we reframed the term “sandwich generation” (caregivers for both parents and children) to point out that not all sandwiches look alike, as “open-faced” sandwiches (caring for either parents or children) present similar issues that we have all experienced and created a work-around to overcome. We shared numerous problems related to travel and technology that we had to solve. Some of these nightmares were thrust upon us, and others were inadvertently self-inflicted. Nevertheless, in all cases, we had to think on our feet and solve the problem as best we could.

In addition to commiserating over shared woes, we outlined several goals and takeaways for our attendees. One key is to develop and use perspective—not all disasters have the same magnitude, and proper perspective can prevent exhaustion. Another theme that we all recognized was the degree to which we deployed humor as a coping mechanism and the importance of perfecting our coping skills before deployment is needed. In general, proper preparation includes improved communication tactics for both clients and family members. But there are nuanced solutions for more unusual obstacles, such as back-up equipment (and generators) to prepare for disasters.

An obvious but important skill was the development of a strong network. This theme played throughout our stories, as the importance of relationships, personal and professional, enabled us to overcome and get back on track.

Our attendees left with some actionable advice, and discussions were started for additional solutions for other possible disasters. Doors have been opened to expand this topic for the future.

Larry Lynam, DSc, MA, SM, RM, is a medical science writer and workshop facilitator with The Lynam Group, LLC, in Coral Springs, FL.

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University of California San Diego Extension
The Medical Writing Certificate program at the University of California San Diego Extension is designed to provide graduates with the foundational knowledge and skills needed to work as a medical writer in the commercial sector, government agencies, and/or academia. The certificate will equip scientists, communication professionals, and others with a strong biomedical and/or life sciences background to write specifically for scientific, education, or regulatory audiences. Course content is delivered in a fully online format, and students can finish the 22-unit program in 18 months. The course content culminates in an applied Capstone project, which prepares students to secure professional positions as medical writers in four distinct specialty areas: Continuing Medical Education Materials, Scientific Grants, Regulatory Writing, and Journal Article and Publication Development. Program faculty are dedicated educators and nationally recognized experts in their medical writing specialties. For more information on the program and our faculty, visit: https://extension.ucsd.edu/courses-and-programs/medical-writing-courses.

Viitai
The 2018 Medical Writing & Communication Conference in Washington, DC, was a well-organized, fun-filled event. Viitai develops and brings the best-quality applications to life science organizations. Our innovative applications are efficient, standards-aligned, regulatory filing-driven, scalable, and compliant with regulations, with intuitive UI.

Biostatistical Programming Studio (BPS) allows any biometrics team to become at least 20% more productive while filling the compliance gap. Nonclinical Study Tracker (NCST) manages nonclinical studies and substudies in a way that is compliant with FDA requirements.

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Contact us contact@viitai.com or visit www.Viitai.com.

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Checking medical text is time consuming and difficult. Text from multiple authors must be presented consistently. Every tiny mistake takes a toll on your credibility and makes readers question the underlying science. So even when deadlines are tight, you still have to deliver near-perfect submissions and grant applications. Imagine how you would feel if you could locate consistency mistakes instantly and had more time to focus on clarity and accuracy. PerfectIt checks the mechanical details so that you can focus on the text that matters.

PerfectIt helps find and correct consistency mistakes in hyphenation, capitalization, and italics, and ensures all abbreviations are defined. It also checks headings, lists, and tables. You can even customize it to check house style guides. PerfectIt has more than 7,000 users around the world, ranging from freelance professionals to Fortune 500 firms.

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Editorial Freelancers Association
The Editorial Freelancers Association (EFA) is a national, non-profit professional organization for writers, editors, copyeditors, proofreaders, translators, researchers, indexers, and other self-employed professionals in the modern publishing and communications industries. Founded in 1970, the EFA now has more than 2,500 members, many of whom have a background in medical communications. Learn more at www.the-efa.org.

The University of the Sciences Biomedical Writing Programs
The University of the Sciences offers 100% online programs in biomedical writing. Our current program choices are Master of Science in Biomedical Writing, Certificate in Marketing Writing, and Certificate in Regulatory Writing. The programs are
designed to accommodate working professionals, so classes are offered asynchronously, via webinar, or via other live online delivery methods in the evenings or on weekends. Courses are currently $1,000 per credit with potential additional discounts to AMWA members. All of our programs can be completed part- or full-time in 2 years or less.

USciences was the first accredited educational institution to develop and award a degree in biomedical writing. It continues to be one of the few to do so globally. All of our faculty, both full-time and adjunct, teach subjects in which they have had personal experience in industry; many continue to be currently engaged in those areas. Our industry links allow us to create experiential opportunities for our students.

The results of a recent review of our alumni indicate that approximately 80% of all graduates remain in medical writing or related areas of the pharmaceutical industry. We are proud members of the medical writing profession.

* * *

Board of Editors in the Life Sciences
In the early 1990s, in recognition of the need for an objective test of editorial skill, a group of senior life-sciences editors developed a process for testing and evaluating proficiency in editing. The result was the creation of the Board of Editors in the Life Sciences (BELS), which administers 2 examinations that focus on the principles and practices of scientific editing in English.

BELS examinations—one for basic certification and one for diplomate status—give qualified manuscript editors in the life sciences a way to demonstrate their editorial proficiency, afford potential employers a way to identify proficient editors in the life sciences, and help to establish a standard of proficiency in editing in the life sciences.

To be eligible for the basic BELS certification examination, which is offered 5 or more times per year at sites throughout North America and abroad, an editor must usually have a bachelor’s degree or the equivalent from an accredited academic institution and at least 2 years of relevant experience. BELS has certified about 1,500 editors in over 20 countries.

The BELS examination for diplomate status consists of review of a portfolio of edited material and requires 6 years of relevant experience.

For more information, visit www.bels.org.

* * *

Trilogy Writing & Consulting
At Trilogy, medical writing is our passion. As specialists in clinical regulatory documentation, we provide a service that is more than just writing. Our writers are integral parts of our clients’ teams: proactively planning, coordinating, and writing their clinical documents to meet timelines, with a readability that reduces the time for review and approval. We have been helping pharmaceutical companies and clinical research organizations of all sizes, worldwide, to streamline their documentation processes for over 16 years—either as support on a one-off document or the entire clinical development program.

We provide our clients with constructive advice on their projects: we guide our clients’ teams through the writing process and ask them the right questions in order to produce documents that communicate effectively. Our writers are trained to understand that our job is not to produce a data dump: it is to think about the data available and work with the team to pull out the messages and present them as clearly as possible, so that a reviewer can quickly find the information they are looking for and easily understand the story to be told.

Trilogy currently has more than 50 writers, who are located in Trilogy’s 4 offices in the US and Europe.
To view the following posters from the 2018 AMWA Medical Writing & Communication Conference, click here.

**Development of a Disease- and Compound-Specific Content Library**  
Susan Cupo, MS, and Mitzi Allred, PhD  
Merck & Co, Kenilworth, NJ, USA

**Creating and Evaluating an On-Demand Writing Workshop for a Large Research Institute: Reaching Out to Colleagues With Busy Schedules and Far-Flung Locations**  
Loretta Bohn, BA; Bill Ferris, MEd; and Julie Shogren, BA  
Multimedia Communication Services, RTI International, Research Triangle Park, NC

**Get to Know Your AMWA Member Benefits**  
Gail Flores, PhD; Madison Hedrick, MA; Haifa Kassis, MD; Al Saint Jacques, MBA; and Jin Zhang, PhD  
On behalf of the 2017-2018 AMWA Membership Committee

**Enhancing the Authorship Experience, One Survey at a Time**  
Amy Kuang, Brittany Jordan, Jeri Freeman, and William Glass  
Allergan plc, Irvine, CA, USA

**Expedited FDA Programs and Safety Label Changes**  
Priyanka Ingle-Jadhav, MD, PhD, Aff.MFPM  
CRC Pharma LLC Parsippany, NJ, USA

**Science Communication: Strategies for Communicating Clearly and Effectively with Laypeople**  
Beth Knight, PhD  
Whitsell Innovations, Inc, Chapel Hill, NC, USA

**Developing an Editorial Team: Tools for Sustained Success**  
Amy Martin,1 Alyssa Dallas,1 and Margaret Mathes2  
1RTI Health Solutions, Research Triangle Park, NC, USA; 2RTI Health Solutions, Manchester, UK

**Supporting Drug Development Programs: Where Do Medical Writers Fit In?**  
Teresa McNally, PhD, and Monique A. Pond, PhD  
Whitsell Innovations, Inc, Chapel Hill, NC, USA

**Medical Writing and Publication in the Age of Transparency: Trends, Challenges, and Good Practices**  
Yanni Wang, PhD, CMPP  
International Biomedical Communications, LLC, Frederick, MD

**Home-Based Medical Writing: Tips and Tricks**  
Dwyn DeSilver, BS, and Maureen Piotrowski, MBA  
Whitsell Innovations, Inc, Chapel Hill, NC, USA

**Evaluation of a Medical Writing Certificate Program’s Specializations, Student Information, and Workforce Data**  
Tim K. Mackey, MAS, PhD1,2; Robert Houghtaling, BA2; Donna Simcoe, MS, MBA, CMPP3; R. Michelle Sauer, PhD, ELD4,5; Lori Alexander, MTPW, ELS, MWC6; and Dikran Toroser, PhD, CMPP7  
1Department of Anesthesiology & Division of Infectious Diseases and Global Public Health; 2UCSD Extension; 3Simcoe Consultants, Inc; 4RNAEditing, LLC; 5University of Texas Health Sciences Center; 6Editorial Rx, Inc; 7AMGEN Inc
Navigation by the Numbers: A Look at the Benefits of Protocol Navigation Management at the National Institute of Mental Health (NIMH)
Charles B. Servis, BS¹; Anne Evans, MS¹; and Jeanne Radcliffe, RN, MPH²
¹Clinical Monitoring Research Program Directorate, Frederick National Laboratory for Cancer Research
Sponsored by the National Cancer Institute, Leidos Biomedical Inc; ²National Institute of Mental Health
Intramural Research Program

Summarizing Safety Data for Regulatory Submission Documents
Barbara S. Orban, MS
Whitsell Innovations, Inc, Chapel Hill, NC, USA

Training and Mentoring Model to Support the Transition to a Role in Medical Writing (Narrative Medical Writer and Clinical Technical Editor)
Carolina Salazar,¹ Cindy Marlene Fernández,¹ Yudy Brigith Artunduaga,¹ Catalina González,¹ Mary E. McKenna,² and Susan Sfarra²
¹MSD Colombia; ²Merck & Co, Inc, Kenilworth, NJ, USA

Protocols and Protocol Amendments: Effective Quality Review Steps
Sharad Wankhade, PhD
Merck & Co, Kenilworth, NJ