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Cover photos credit: EPNAC.com

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, FRCPC, 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
Learning From Our Aging Population: Studying Immune Checkpoint Inhibitors Sheds New Light on the Changing Immune System

Liz Kuney / Independent Medical Writer & Editor, Syracuse, NY

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 combating 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.

Not long after World War II, an unprecedented bloom in the birth rate gave rise to the Baby Boomer generation. In recent decades, medical advances have made 100-year birthdays almost commonplace. Today, there are approximately 50 million people aged 65 years or older living in the United States. They make up more than 15% of the total population, up from 10% in 1970. By 2060, predictions nearly double to 95 million, bringing the portion of older Americans to a quarter of the total population. In other countries, the hike has been even steeper; in Japan, the older population is already a quarter of the total population, up from 7% in 1970. And in Germany, the figure is 21%, up from 13% in 1970.

As we age, the number and frequency of genetic mutations that can transform into cancers multiply. In fact, after the age of 50, the likelihood of a cancer diagnosis climbs dramatically until the later 80s (Figure 1). Currently in the United States,

![Figure 1. Incidence of cancer diagnosis in the United States by age. Data are from the US Cancer Statistics Working Group.](Images: stock.adobe.com © RachelKolokoffHopper, © luckbusiness, © DavidPrado © khwaneigq © logoboom)
the median age for cancer diagnoses is 66 years, and by 2030, it is estimated that 70% of cancers will occur in those 65 and older. 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 chemotherapy that essentially assault all rapidly growing cells, and unlike targeted therapies (eg, tyrosine kinase inhibitors) that interrupt cellular signaling to restrict tumor growth, 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.” 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%. 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), yet this had improved from 25% compared with 63% (P < .001) in 1999. 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. 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 commonplace. 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 endpoints; the American Society of Clinical Oncology also advocates for the inclusion of special subgroup analyses to better inform cancer management for older adults.

**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. 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 naïve T cells in older adults.

An emerging perspective now challenges the conventional notion of immunosenescence, however. Some researchers advocate for distinguishing between normal immune aging and maladaptive immune aging and further suggest that the label immunosenescence be retired. 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. 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

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Figure 2. Cancer-immunity cycle. After an initial skirmish with the tumor antigen by neutrophils, the APCs (typically dendritic cells) engulf the necrotic remains and carry the digested fragments (tumor–associated antigen) as evidence to inform T-cell reserves. The primed T cell divides, proliferates, and disperses to patrol for and eliminate the tumor cells. APC, antigen-presenting cell; CTL, cytotoxic T lymphocyte. Reprinted from *Immunity*, 39/1, Chen DS, Mellman I, Oncology Meets Immunology: The Cancer–Immunity Cycle, 1-10, 2013, with permission from Elsevier.25
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 checkpoint pathways (Figure 3) that connect T-cell receptors to corresponding 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 approximately 95 early-phase trials.28

IMMUNE-RELATED ADVERSE EVENTS

Compared with the predictable and intense severity of chemotherapy 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 discontinuation 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).30,31 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 systems.32 Life-threatening toxicities have included pneumonitis, 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 autoimmune disorders are predictably vulnerable to irAEs, even grade 3 and 4 irAEs prove to be manageable with immune-suppressive treatment (eg, corticosteroids).34,35

ICIs are generally considered to be as well tolerated in older patients as in younger patients.12,35 Nonetheless, an understanding of pharmacodynamic effect and toxicity of ICIs in older patients is not yet solid, primarily because of the continued underrepresentation of that population in clinical trials and possibly because of suboptimal reporting.36 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 procedures: for instance, watching for dehydration and renal insufficiency with an irAE of diarrhea and watching for an increased risk of bone fracture with extended corticosteroid use.

Figure 3. The CTLA-4/B7 and PD-1/PD-L1 checkpoints and blockers. Once a T cell with a matching receptor (TCR) receives the summons (shown here within a lymph node), the TCR binds to the major histocompatibility complex (MHC–1) expressed on the APC. This communication between T cell and APC (lower right) includes the binding of the CTLA-4 and B7 ligand complex (CD80 and CD86) checkpoint. Blocking these proteins from binding with anti–CTLA-4 therapy is effective against some solid tumors (eg, melanoma). When a T cell arrives at the peripheral tumor and the TCR links to MHC–1 on the tumor, the corresponding PD-1/PD-L1 checkpoint can be interrupted to prohibit tumor evasion (lower left). APC, antigen-presenting cell; CTLA-4, cytotoxic T lymphocyte–associated antigen 4; MHC–1, major histocompatibility complex 1; PD-1, programmed cell death protein type 1; PD-L1, programmed cell death ligand type 1; TAA, tumor–associated antigen; TCR, T-cell receptor. Image compliments of Dr Guido Hegasy, via Wikimedia Commons (https://commons.wikimedia.org/wiki/File:11_Hegasy_CTLA4_PD1_Immunotherapy.png). This file is licensed under the Creative Commons Attribution–Share Alike 3.0 Unported license. No changes were made to the image.
KNOWLEDGE OF OLDER PATIENTS
In general, clinical trials of ICI 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, chemotherapy, 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).

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 x 10⁻⁶).

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 postmarketing 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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**References**


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.
Cytotoxic T cell (also CD8+ T cell or killer T cell) — T cells.

Antigen-presenting cells (APCs) — On their own, T cells cannot detect pathogens. Immune cells that first attack a pathogen—for instance, phagocytes (“cell devourers”)—carry antigen fragments with major histocompatibility complex (MHC) proteins (defined below) back to the T cells within the lymphatic system. T cells are then activated to find the corresponding target, and adaptive immunosuppression begins.

Cytotoxic T lymphocyte–associated antigen 4 (CTLA-4) — This protein receptor binds to CD80 and CD86 (2 of the manifold B7-1 and B7-2), and the resulting checkpoint downregulates (ie, sends an inhibitory signal to T cells).

Cytotoxic T cell (also CD8+ T cell or killer T cell) — This white blood cell kills tumor cells when activated.

Dendritic cell — This immune cell operates at the intersection of the innate and adaptive arms of the immune system; an APC that induces T-cell activation and differentiation.

Mismatch repair deficiency (MMRd) and microsatellite instability–high (MSI-H) — These are 2 genetic markers associated with various solid tumors (eg, colorectal and endometrial).

Immune checkpoint inhibitors (ICIs) — These monoclonal antibodies (mABs) are designed to disrupt the regulatory interaction where cancer can prevent its own elimination by manipulating the adaptive immune system.

Immune-editing — This describes the interaction between tumor and the immune system as a 3-phase process of elimination, equilibrium, and evasion.

Innate immune system — A portion of the immune system that prompts an immediate, short-lived, and blunt attack, characterized primarily by inflammation.

Class 1 major histocompatibility complex (MHC-1) — This is a protein molecule that carries antigen–specific information and unites with corresponding T-cell receptors (TCRs) to activate the adaptive immune system.

Neutrophil — This short-lived, highly active white blood cell acts as a first-responder at a site of inflammation.

Phagocyte — This white blood cell engulfs an antigen when cleaning up after the innate immune system’s initial attack.

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) — This is a predictive 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.


Jam Session for Early-Career Freelances

Report by Claire L. Jarvis

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/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.
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/why 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 freelancers 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 freelancers will also help you learn what to do and what not to do. More experienced freelancers 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 freelances 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 your 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.

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 (but 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 evanscathryn@aol.com if you have further questions about this.

At the end of the session, Theresa 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 Freelances” next year to share their wisdom with the newest crop of writers.

Claire L. 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!!

**Swanberg Award Recipients**

- AMWA member for an average of 24 years (ranging from 4 to 33)
- 60 (91%) of 66 were or became AMWA Fellows (first awarded in 1952)
- 31 (47%) of 66 served as AMWA Presidents (first served in 1940-1941)
- 16 (50%) of the 32 recent recipients have received the Golden Apple Award (first awarded in 1986)
- 10 (31%) of the 32 recent recipients have received the President’s Award (first awarded in 1981)
- 13 (41%) of the 32 recent recipients have received at least 3 of the above recognitions, and…
- 1 (3%) of the 32 recent recipients have received all 4 of the above recognitions! (Congratulations to Art Gertel!)

But where did it all start? Who was that original Swanberg Award recipient? In 1952, Dr William Harold Swanberg, Sr, received the inaugural Distinguished Service Award (as it was
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 expectancies 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.

Table 1. Example CER table of contents from MEDDEV 2.7.1 revision 4.

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 Summary 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).
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?

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

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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.

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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>Hypoglycaemia¹</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 any 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 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 (e.g., 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 (i.e., 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).
STATISTICALLY SPEAKING

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 2. Summary of Characteristics of Hypoglycemic Adverse Events

<table>
<thead>
<tr>
<th></th>
<th>Wonderdrug</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 652</td>
<td>N = 326</td>
</tr>
<tr>
<td>Patients with hypoglycemic adverse event, ( ^a ) n (%)</td>
<td>132 (20.2)</td>
<td>49 (15.0)</td>
</tr>
<tr>
<td>Severity (worst episode), n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Required assistance</td>
<td>5 (0.8)</td>
<td>6 (1.8)</td>
</tr>
<tr>
<td>Symptomatic and blood glucose &lt;3.0 mmol/L</td>
<td>19 (2.9)</td>
<td>24 (7.4)</td>
</tr>
<tr>
<td>Symptomatic and blood glucose ≥3.0 mmol/L and &lt;3.9 mmol/L</td>
<td>108 (16.6)</td>
<td>19 (5.8)</td>
</tr>
<tr>
<td>Action taken, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapy given</td>
<td>19 (2.9)</td>
<td>28 (8.6)</td>
</tr>
<tr>
<td>Discontinuation of study medication</td>
<td>3 (0.5)</td>
<td>4 (1.2)</td>
</tr>
<tr>
<td>Required hospitalization</td>
<td>1 (0.2)</td>
<td>2 (0.6)</td>
</tr>
<tr>
<td>Number of episodes, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>105 (16.1)</td>
<td>38 (11.7)</td>
</tr>
<tr>
<td>2-3</td>
<td>18 (2.8)</td>
<td>9 (2.8)</td>
</tr>
<tr>
<td>4-5</td>
<td>3 (0.5)</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>&gt;5</td>
<td>6 (0.9)</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Time to onset of first episode, n/N at risk (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤7 days</td>
<td>11/652 (1.7)</td>
<td>2/326 (0.6)</td>
</tr>
<tr>
<td>&gt;7 to ≤28 days</td>
<td>57/638 (8.9)</td>
<td>14/324 (4.3)</td>
</tr>
<tr>
<td>&gt;28 to ≤56 days</td>
<td>39/572 (6.8)</td>
<td>21/307 (6.8)</td>
</tr>
<tr>
<td>&gt;56 days</td>
<td>25/541 (4.6)</td>
<td>12/279 (4.3)</td>
</tr>
<tr>
<td>Exposure-adjusted incidence rate (per 100 pt-yrs)</td>
<td>56.2</td>
<td>54.7</td>
</tr>
</tbody>
</table>

\( ^a \)Based on hypoglycemia SMQ.

All data are invented for the purpose of this paper.
Pt-yrs, patient-years.

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
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 than those in the other to discontinue study treatment.

A better way of comparing the 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 (e.g., 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 (i.e., 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**


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).

Author contact: laurie@gorillaprotein.com
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.

Selection Process for the Board of Directors
The process starts with a call for interest in the positions. AMWA strives to have a Board that is representative of the organization’s membership, looking for diversity in geography, job setting, and expertise.

The Nominating Committee reviews the candidate profiles from the interest forms, prepares a slate of elected officer nominees, and submits this slate to the Board for consideration. Once the slate of officers is approved by the Board, it is circulated to the AMWA membership. Additional nominations may be made in writing according to the bylaws. Nominees who are unopposed for office are declared automatically elected at the Annual Business Meeting held during AMWA’s Medical Writing & Communication Conference.

The Nominating Committee may also recommend members to serve as At-Large Directors of the Board. Each At-Large Director is nominated by the President-Elect and approved by the Board.

All Board members take office after the election of officers at the Annual Business Meeting and serve for a term of 1 year or until their successors are appointed.

Kathy Spiegel passes the gavel to incoming President Cynthia L. Kryder.
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...
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.
Preparation 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/outsourcing.

<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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<tr>
<td>Compressed timelines</td>
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<tr>
<td>Flat organizational structures</td>
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<tr>
<td>Outsourcing</td>
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<td>Strategic leadership challenges</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 colla-
through intensive, structured training. Consequently, one participant noted, medical writing is a craft that is learned population of experienced medical communicators ages. As decreasing and that the quest to find qualified employees who (Tables 2 and 3). Executives agreed that the pool of talent is in recruiting and retaining talented medical communicators 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.

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 |
| Baseline experience uneven or lacking |
| Lack of formal and standardized training programs |
| Lack of soft skills and emotional intelligence |
| Limited pool of tech-savvy candidates |

| Table 3. Factors Influencing Retention of Medical Communicators |
| Clearly defined career path options |
| Desire for more work–life balance |
| Flexibility versus specialization (therapeutic areas and document types) |
| Increased clinical trial complexity |
| More lay-oriented documents |
| Need to work as part of the team rather than in isolation |
| Systems changes |
| Technology requirements |

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 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!

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**Table. The 2017–2018 Chapter Advisory Council Roster**

<table>
<thead>
<tr>
<th>Chapters</th>
<th>Representatives to the CAC</th>
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</thead>
<tbody>
<tr>
<td>New England</td>
<td>Andrea Gwosdow, PhD</td>
</tr>
<tr>
<td>Empire State-Metro New York</td>
<td>Anjani Shah, PhD</td>
</tr>
<tr>
<td>Delaware Valley</td>
<td>Julie Munden</td>
</tr>
<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 Korwek, PhD</td>
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<tr>
<td>Florida</td>
<td>Irvin Peralta, MBA</td>
</tr>
<tr>
<td>Ohio Valley</td>
<td>Sarah Dobney, MPH</td>
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<td>Greater Chicago Area</td>
<td>Sarah Prins, PhD</td>
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<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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<td>Mid-America</td>
<td>Heather McNeill, MA, ELS</td>
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<td>Northern California</td>
<td>Barbara Arnoldussen</td>
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<td>Rocky Mountain</td>
<td>Brittany Hodges, PhD</td>
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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!

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If you are interested in learning more about the CAC, please contact Katrina Burton.

**Author contact:** kbmkghtes@yahoo.com
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!

It’s time to talk money.

AMWA’s 2019 Medical Communication COMPENSATION SURVEY

Contribute to the most in-depth study on compensation in the field of medical communication.

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