Vaccines
A Hot Topic Once Again
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CALENDAR OF MEETINGS
PREFACE
Inform, Inspire, Motivate

You see it on the AMWA website, and you see it in every issue—the AMWA Journal’s 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 AMWA as a professional organization.”

As Editor-in-Chief, my role is to pursue or develop content that supports that mission. As such, I am tasked, in part, to pursue content on topics of interest to medical communicators in a wide range of work settings, with fair, evidence-based balance; to solicit content from subject matter experts on trends and issues in medical communication; and to create innovative ways to enhance Journal content and its delivery.

I believe (and I hope you agree!) that the Journal does provide content that informs and/or educates the readership. I have over my brief tenure sought also to provide content that is thought-provoking and perhaps inspiring.

In our last issue, we published “Worst Practices for Writing CME Needs Assessments: Results From a Survey of Practitioners,” by Donald Harting, MA, MS, ELS, CHCP and Andrew Bowser, ELS, CHCP. With simultaneous publication in the Alliance for Continuing Education in the Health Professions Almanac, our goal was to motivate both writers of needs assessment and those who pay for that writing to cast a more critical eye and thereby elevate the work.

With this issue of the Journal, I am hoping to continue to move from inspiring to motivating—by providing content on emerging trends and topics that not only are of interest to medical communicators but also require our active intervention.

We recognize the challenges to scientific publishing being posed by predatory journals and their publishers, which employ practices that undermine the quality, integrity, and reliability of published scientific research. Thus, I am pleased to publish the “AMWA–EMWA–ISMPP Joint Position Statement on Predatory Publishing.” I hope this statement will motivate our readers to be more aware of predatory publishing practices, to be vigilant in helping their authors avoid unintentional publication in predatory journals, and to avoid perpetuation/citation of works from those publishers.

We are deeply concerned by the growing threat of hesitancy of parents to vaccinate their children against preventable infectious diseases. Thus, I am pleased to reprint “The Salzburg Statement on Vaccination Acceptance,” recently published in the Journal of Health Communication, by Scott C. Ratzan, MD, MPA, and colleagues in the International Working Group on Vaccination and Public Health Solutions. I hope this statement will motivate our readers to improve identification of disproven/inaccurate false claims about vaccine safety, include information from robust scientific sources, and widely disseminate reliable, accurate vaccine information in plain language.

Larry Lynam, DSc, and Melory Johnson continue to shine the harsh light of scientific reality on the misinformed anti-vaccine movement in their Topical Feature, “Vaccines: A Hot Topic Once Again.” I hope their article will motivate our readers to help restore collaboration between healthcare providers, vaccine manufacturers, and the general public by encouraging more effective, scientifically validated communication.

Finally, in her Everyday Ethics article, “Conflicts of Interest: When Things Go Bad and Lessons Learned,” Tami Ball, MD, reminds us that medical communicators should take extra care around disclosures to protect both themselves and the individuals for whom they work. Just as ethical behavior strengthens confidence in the integrity of the medical literature, so unethical (or even just sloppy) behavior can call into question the integrity and validity of biomedical research. I hope her article will motivate our readers to doggedly pursue transparent disclosure of COI to help keep the scientific literature credible.

As Tami says, “Ultimately, the lives and well-being of patients depend on rigorously good science.” And, I might add, on credible medical communication.

In all, this issue contains content from dozens of contributors, content that reflects the interests, concerns, and expertise of medical communicators. I hope that it will inform, inspire, and, perhaps, motivate you.

Yours in AMWA,
~Jim

JAMES R. COZZARIN, ELS, MWC
Vaccines: A Hot Topic Once Again
Larry Lynam, DSc¹ and Melory Johnson, VN²
¹Principal, The Lynam Group, LLC, Coral Springs, FL
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ABSTRACT
Since Edward Jenner’s day, there has been a steady improvement in vaccine science, including numerous advances in production, quality, efficacy, and safety. Vaccines have long been regarded as one of the most significant contributions to public health since clean water. Yet, for as long as there have been vaccines, there has been an anti-vaccination movement. The 18th century “anti-vaxxers” posed arguments eerily similar to those raised today. Twenty-first century anti-vaxxers repeat the same antiquated and discredited sentiments as did those in Jenner’s day, only with updated scare-tactics and more embellished “truths.” Although their claims are scientifically illogical, sadly, their propaganda has had a profound influence. The success of the anti-vaccine movements has not only led to a resurgence in measles, which was declared eliminated in the United States in 2000, but also threatens to reverse the progress made against other deadly infectious diseases. Although vaccines have steadily evolved, making great strides in controlling or eliminating many infectious diseases and improving our quality of life, their legitimacy is under ill-informed assault. However, as medical communicators, we can help restore collaboration between healthcare providers, vaccine manufacturers, and the general public by encouraging more effective, scientifically validated communication. Constructive communication strategies might help restore trust in medical authorities and combat the inaccurate narratives from paid celebrities and dubious social media platforms—the modern vehicles for ancient anti-vaccine messages.

Today, vaccines are dominating our health news, as once again, we face infectious diseases we thought were eradicated from our everyday lives. The World Health Organization declared that, next to clean water, vaccines are the single most important public health advancement in modern history.¹ Despite this proclamation and our advances in medicine and science, however, the anti-vaccination movement has become more effective than ever. Even with our miraculous strides toward eliminating diseases that once devastated entire populations, we find ourselves, yet again, face-to-face with misinformed “anti-vaxxer” propaganda.

Presently, Ebola is spreading in the Democratic Republic of the Congo (DRC), where, for the first time since its discovery in 1976, a vaccine is available. Despite this momentous breakthrough, we find vaccine implementation hindered and distribution delayed by geographic challenges, financial shortcomings, political obstacles, and—worse still—by warring factions, misinformation campaigns, and anti-vaxxers. Failure to contain this currently isolated crisis could have adverse global impacts. After more than 2,000 Ebola deaths in the DRC, the outbreak has now spread into neighboring Uganda.² Moreover, as the DRC fights Ebola—and cholera—they are also now fighting measles! Since January 2019, more than 100,000 measles cases, entirely preventable by vaccine, have claimed the lives of an additional 3,000 Congolese.³,⁴

To find the origins of the anti-vaccination movement, we need only to look at the first vaccine and the public health program that was initiated to rid the world of what was then its most deadly and destructive infectious disease: smallpox.

A HISTORY OF VACCINES
Smallpox, a virus believed to have jumped species from animals to humans, has ravaged mankind since the time of the ancient Egyptians, killing 20% to 30% of an affected population with each outbreak. The disease would devastate a community, leaving its survivors permanently scarred with pox marks from erupted skin pustules anywhere on their bodies. Permanent blindness was also a common complication—but at least the survivors were immune and spared from repeating the horror when it returned. And it did return—repeatedly.⁵

Before Vaccination, There Was Variolation
For centuries, people realized that if they survived, they would be immune. So much so that early Eastern and Middle Eastern
physicians inoculated their patients with pustule fluid from smallpox lesions. They observed that variolation (inoculation with infectious material) could lessen the severity and complications of the illness, which was preferable to becoming infected naturally.5

The practice can be traced back to 1,000 BC in India and to 16th century China. Historians credit Lady Mary Wortley Montagu, a severely scarred smallpox survivor and wife of an 18th century British diplomat posted in Turkey, with introducing variolation to Great Britain. Wanting her children to be spared infection, Lady Montagu had them variolated in Constantinople.6,9

Variolation had much room for improvement (Table 1).5,8 The practice was neither standardized nor regulated, and worse still, left a significant number of people with syphilis. Although under normal circumstances syphilis was sexually transmitted, this incurable disease, which was considered to be the second biggest scourge of the day, was transferred to healthy individuals through smallpox variolation.5 However, when you consider the consequences of a smallpox outbreak, you can understand why so many people, even knowing the consequences, willingly agreed to variolation. It did not guarantee an ideal outcome, but at least it offered hope (Table 2).8,40,49

### Beyond Variolation Was Vaccination

Edward Jenner was hardly the first to note that dairymaids rarely contracted smallpox, hence their smooth, unblemished skin. In 17th century England, a commonly used expression to compliment a lady was, "Your skin is as smooth

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<td>Although variolation was not without risks to the person variolated (as well as others exposed to them while it ran its course) and did leave a patient with permanent scarring, it seemed a preferable alternative to the disease manifestation via natural infection. Yet there was a significant opposition to the practice, and those arguments sound very similar to the so-called modern anti-vaccine movement.</td>
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<th><strong>The Pro–Variolation Crowd</strong></th>
<th><strong>The Anti–Variolation Movement</strong></th>
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<td>Not unlike today’s celebrity endorsements of a position, the variolation proponents had endorsements from Benjamin Franklin, who lost a child to smallpox, as well as Thomas Jefferson, who had his entire family variolated and then vaccinated when that process became available. The importance of infectious diseases and its societal effects were not lost on Gen. George Washington. In 1775, when he was commander of the Continental Army, he recognized the devastating effects disease could have on an army’s readiness, and he ordered all of the Revolutionary War troops that had not previously been diagnosed with smallpox to undergo variolation. The technique they used is described as removing the fresh pus from a smallpox pustule, adding it to water, and soaking a thread and needle in the water. The needle and thread were then threaded under the skin of the person to be inoculated.8</td>
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<td>When variolation was introduced in the United States, there was a significant, and on occasion violent, opposition to it. In 1721, during the height of the Boston smallpox epidemic, Massachusetts Rev. John Williams wrote that these inoculations were the work of the devil.48 That same year, a bomb was hurled through the window of a different Boston minister. Attached to the explosive was the message: “Cotton Mather, you dog, dam you! I’ll inoculate you with this; with a pox to you.” Fortunately, the explosive didn’t detonate.49 The attack on the reverend was not a religiously motivated act of terrorism. It was a violent response to Mather’s active promotion of smallpox inoculation. Clearly before there were vaccines and anti-vaccine sentiments, the anti-variolation movement was already actively engaged in their own war against medical progress.</td>
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as a milkmaid’s. However, Jenner was the first to be credited for discovering that acquiring mildly irritating cowpox protected a person from contracting the more lethal smallpox. He successfully demonstrated that a smallpox infection could be prevented by inoculating a person with the material from a cowpox pustule. To distinguish his new process from variolation, Jenner named it vaccination.6,7,11

Timing Is Everything
Despite centuries of variolation, smallpox still ravaged 18th century Europe. It claimed more than 400,000 lives each year and left almost one-third of its survivors blind and nearly all permanently scarred.7 During that century, 4 European monarchs died from smallpox, and so many heirs to the Hapsburg throne perished that the lineage changed 4 times.12 Even as Jenner conducted his cowpox experiments, a severe smallpox outbreak devastated the Spanish court, causing King Charles IV to order the entire royal family variolated. In 1798, the king went so far as to issue an edict to variolate every citizen in Spain. This decree was controversial, as the risks and consequences of variolation were notorious. As fortune would have it, King Charles was presented with a copy of Jenner’s work. It so impressed the king that he mandated the variolation decree to be switched to vaccination. So, by 1800, nearly all of Spain had been vaccinated.12,13,14 Unfortunately, despite (or perhaps because of) their enormous success, the seeds of the anti-vaccination movement were planted.11,13,14

Back then, as now, politics played a significant role in public health matters. Smallpox was not the only problem plaguing King Charles’ reign. Napoleon’s armies invaded Spain, and the British, under Lord Nelson, defeated both the Spanish and the French at Trafalgar. Economically, Spain was dependent on its New World colonies; however, because smallpox was sweeping its colonies and disrupting productivity, the Spanish treasury suffered. The king and the entire Spanish monarchy not only had an image problem but also a financial one. A solution to address both was thus designed and deployed: a smallpox vaccine expedition.12-14

The world’s first public health vaccination program was launched. From 1804 to 1810, the Spanish Royal Expedition, popularly known as the Balmis–Salvany Expedition, traversed the Americas and the Pacific, vaccinating hundreds of thousands of people across the Spanish colonies (Figure 1).11

They established vaccine boards, headed by government and Catholic Church officials, to keep vaccine production and programs continuing in every Spanish domain they visited. King Charles’ edict even provided vaccines to all citizens and residents throughout the Spanish Empire—free of charge.11,13,14

Figure 1. The Spanish Royal Expedition to distribute the Jenner smallpox vaccine. Also known as the Balmis–Salvany Expedition, the expedition departed Spain in 1803 with Dr Francisco Javier de Balmis as its leader and Dr Jose Salvany as his assistant along with 22 Spanish orphans that were inoculated sequentially throughout the voyage and replaced with additional orphans at stops along the expedition as needed. At a stop in Colombia, the expedition split, with Salvany leading a team overland through the South America colonies and Balmis sailing on with the remaining group to Mexico and then crossing the Pacific to the Spanish colonies in the Philippines. In 1807, Balmis sailed back to Spain via the Pacific. Salvany continued leading his team toward its destination in Argentina, but, stricken with illness almost from the start, he died in Bolivia in 1810. The expedition continued on without him. By all accounts the expedition, considered the world’s first public health vaccination campaign, was considered a success for the public health of the colonies and the political heath of the Spanish king and his government.13

Orphans: The Original Biomedical Vials
As Jenner predated modern pharmaceutical practices—even predating the pharmaceutical industry—keeping his vaccine viable was a challenge from the start. Jenner devised a process whereby material was extracted from a pustule, preserved on a glass slide, and sealed with paraffin while under a vacuum. However, the process was not as effective or efficient as passing the virus directly "arm to arm" from a cowpox-infected individual to an uninfected individual. The Spanish authorities agreed, and arm-to-arm transmission became the distribution method of choice.12,13,15

Throughout history, there have been 2 societal groups long viewed as expendable: prisoners and orphans. Prisoners were large, took up space, ate a lot, and required armed guarding; orphans were small, ate less, and could be tended by a capable nun (yet another sacrificial group). So, with the Royal Medical Committee’s agreement, the Church’s blessing, and the king’s decree (but no ethical regard), orphans became the world’s first official biomedical transportation “containers.”7,11,16

Because the virus inside a pustule was only viable for 4 to 10 days and the voyage took weeks, serial inoculations would need to occur throughout the Atlantic crossing. Calculations were made, and 22 orphans, the orphanage rector, the medical team, and the crew boarded the ship to the colonies. Upon reaching Colombia, Balmis and Salvany, the expedition leaders, split up to expedite the mission (Figure 1). Salvany took a
People who were vaccinated became immune to smallpox, avoiding even the mild case of smallpox to be expected with variolation, and, as a bonus, did not acquire syphilis. One would presume then that vaccination—a sure way to prevent the most dreaded disease known to humankind—would be an instant success, but one would be wrong: with vaccination came the anti-vaccine movement. Although vaccines and vaccination programs have evolved dramatically since Jenner’s day, surprisingly, the positions of the anti-vaxxer movements have not.

THE ANTI–VACCINATION MOVEMENT

The First Anti–Vaxxers

The religious leaders of Jenner’s day were already split between those who supported and those who opposed first variolation and then vaccination. Even among practitioners of variolation, vaccination was met with mixed acceptance. Money played a significant role. Variolation had been a popular and profitable business for many of its practitioners. From the start, Jenner made his vaccines available free of charge to all physicians and set up vaccination clinics in his community for those who could not afford to be vaccinated. Profit is a strong motivator, and when interfered with, progress is often the enemy of the profiteer.

On more than a few occasions throughout their journey, the vaccine teams of the Spanish Royal Expedition met resistance in particular colonies in which the vaccine had arrived in advance. In those colonies, profiteers who obtained Jenner’s vaccine set up lucrative vaccination businesses. They were not receptive to having a public health campaign interfere with their profits—not even one with a king’s decree. It required intervention on the part of both royal and religious authorities to overrule the for-profit vaccine practitioners. Fortunately, with their backing, the Balmis-Salvany expedition succeeded in completing their objectives in every Spanish domain they entered.

(As a side note, even though the anti-vaccine agitators, including the men of God, raised many religious and even financial objections to the first vaccination campaign, ironically, no one raised any ethical objections to their use of orphans as “biomedical vials.”)

As Was Then, So Is Now

We fear it is not possible for any argument or any form of suasion to stay the tide of folly and ignorance which is now raging against one the most beneficent discoveries ever permitted to man. The chief actors in the anti-vaccination movement are men upon whom all statements of fact and argument would be wasted.

This excerpt was from an editorial titled “The Anti-Vaccination Agitators,” published in the British Medical Journal on October 9, 1869. From the release of the first vaccine, the anti-vaccination movement plagued the medical community (Figure 2). So much so that in 1910, Sir William Osler, fed up with the activists, dared them to expose themselves to smallpox—and promised to pay personally for the resulting funeral expenses. His offer received no takers.

As is the case today, opposition to vaccines then was not only manifested in financial, skeptical, and theological arguments but also in political and legal ones. In the mid-19th century, after Britain passed laws making it mandatory for parents to vaccinate their children against smallpox, anti-vaccine activists formed the Anti-Vaccination League. Their mission: to protect the liberties of the British people, which were being “invaded” by Parliament’s intrusive vaccination laws. The pressure these agitators exerted on the Parliament eventually compelled passage of an act removing penalties for not abiding by the vaccination laws and allowing parents who did not believe in vaccines to opt out.

Today, the situation remains much the same. In the United States, mandatory vaccination requirements for school attendance and other licensed childcare facilities traditionally maintain our herd immunity. However, in recent years, there has been a rise in vaccination exemptions because of philosophical or personal beliefs. Because of these leniencies (which led to the worst measles outbreak in more than 20 years), in May this year the California State Senate passed a bill (SB-276) to tighten California’s school immunization law. Opponents of the bill called it unprecedented and a dangerous intrusion on the personal liberties of parents and their children. Some agitators called Senator Richard Pan, California’s bill sponsor, a tyrant and encouraged supporters to abandon the bill and save their souls. Others went so far as to label it a crime against humanity.

Historically, the origin of misinformation starts with valid scientific debate based, one would hope, on accurate data presented after a rigorous peer review. Unfortunately, today’s debate around the safety and efficacy of vaccines calls that assumption into question. The premise of the current anti-vaccination movement is a fraudulent journal paper published in 1998 by British physician Andrew Wakefield. Even though
the *Lancet* eventually retracted Wakefield’s article in 2010,29 12 years of damage had already been done. By the time of retraction, the debate was spun to conform to the anti-vaxxer agenda. Through the power and momentum of social media and other news sources, fear of vaccines and myths against them were already well established worldwide.

**Heard of the Herd?**

Herd immunity is fundamental to the success of vaccination programs. Control of many vaccine-preventable diseases is contingent on a significant proportion of the population being immune.30 Depending on the disease, the percentage of individuals required to be vaccinated to achieve herd immunity in a community ranges from 30% to 95%.31 Individuals who do not vaccinate, whether they like it or not, are part of the herd; they are just unprotected herd members, relying on the rest of us who do vaccinate for their preservation.

Not only are unvaccinated children at higher risk of developing vaccine-preventable diseases than vaccinated children, they put at risk genuinely exempt children (eg, those too young to be vaccinated) as well as the medically exempt (eg, immunodeficient) populations of all ages.32,33

**Victims of Their Success**

Even though vaccines are one of the most successful contributors to global health34 and are among the top 10 most significant public health achievements of the 20th century,35 the advent of effective immunization has led to the re-emergence of anti-vaccine agitation. Ironically, because morbidity and mortality from vaccine-preventable diseases are at an all-time low,36 the reactions from vaccines (adverse health events attributed to the vaccine) appear to be more common than the diseases. This paradox has led many cynics to perceive vaccines as unnecessary and even harmful.37

As those deadly childhood infections that were so abundant in bygone days become rare (thanks to the schedule of vaccines available today), people grow complacent. They forget the devastation that so many of these diseases once wrought on populations worldwide. As complacency grows, so does distrust in vaccines—and with that, a resurgence in the anti-vaccination movements.21,38 Anti-vaccine sentiment gains momentum when the media allows widespread dissemination of false information, erroneous science, and anecdotal claims of harm from vaccines. With the amount of insanity disguised as science or good parenting posted all over social media and the Internet today (Figure 2), vaccination opposition can only be expected to become invigorated and gain momentum.

**Hesitation Matters**

The rise of global vaccine hesitation poses a dire threat to the health and lives of communities everywhere. For example, as a direct consequence of not reaching the immunization threshold for MMR (mumps, measles, rubella) vaccines, people of all ages have fallen victim to recent outbreaks of measles, which had been declared eliminated in the United States in 200039-43 (Figure 3).52

Research has shown that even pro-vaccination folks can become confused by all the anti-vaccine propaganda, leading them to question their choices. Because so many people lack a rudimentary understanding about vaccines, they are particularly vulnerable to the anti-vaxxer’s disingenuous crusades38,44,45 (Table 3).

**THE ROLE OF THE MEDICAL WRITER**

The benefits of vaccination extend far beyond the prevention of diseases. Vaccination makes good economic sense and
Table 3. Frequently Cited Anti-Vaccination Websites and Their Claims

www.facebook.com/StopMandatoryVaccinationNow

“The history of vaccination is a history of collateral damage. The German documentary ‘Wir Impfen Nicht!’ - ‘WE DON’T VACCINATE!’ was produced by the German freelance journalist Michael Leitner. It demonstrates by means of official documents and statistics that no vaccination has ever had a positive, protective effect.”

“WE DON’T VACCINATE!” investigates the claims made by doctors, multinational corporations or health officials, who promote vaccination as a safe and effective preventive medical intervention.”

www.vaccinepapers.org

“Vaccinepapers.org provides detailed, science-based and objective information about the dangers of vaccines. We are most concerned about aluminum adjuvant toxicity and immune activation-mediated brain injury. Vaccinepapers.org is the first to make this hugely important scientific research accessible to the public.”

www.stopmandatoryvaccination.com

“Vaccination is a medical treatment administered to an otherwise healthy individual. Virtually all other invasive medical interventions occur only once someone has fallen ill. Vaccination, like most medical treatments, can involve some risk. And therefore it should be undertaken only after careful consideration of its risks versus its benefits. The dangers of vaccines are real, can be substantial and life-long, and for some, life ending.”

www.thetheopleschemist.com

“Parents should question vaccine safety and effectiveness by using vaccine exemption. Instead of using an unproven hypothesis to question parents who have opted out, pro-vaccine parents should be questioning the safety and effectiveness of vaccines. With dozens of vaccines being forced on the public, some healthy skepticism could go a long way toward raising a vibrantly healthy child… herd immunity is nothing more than a silly catch-phrase used to scare and bully parents into vaccinating their kids. Don’t fall for it parents, keep using the vaccine exemption forms to legally avoid them.”

www.facebook.com/StopMandatoryVaccinationNow

“Myth: The diseases for which one is vaccinated are deadly and without vaccination, we would have epidemics of these diseases with untold numbers of deaths. Do you know what is in a vaccine? Do you know why ALUMINUM - a powerful neurotoxin - is added to vaccines? Do you know why the brains of some children SWELL UP and then irreversible damage OR DEATH - is created after a vaccination? Get the truth before we are censored out of existence: watch Vaccines Revealed, a free 9-part series featuring over 20 vaccine experts: http://bit.ly/2o0b5Cp”

Figure 3. States reporting measles cases in the United States in 2019. From January 1 to August 22, 2019, 1,215 individual cases of measles have been confirmed in 30 states. This is an increase of 12 cases from the previous week. This is the highest number of cases reported in the U.S. since 1992 and since measles was declared eliminated in 2000.\(^3\)^

\(^{3}\)Cases as of July 18, 2019. Case count is preliminary and subject to change. Data are updated every Monday on the Centers for Disease Control and Prevention website.

CONCLUSION

As the authors of this article, we are not attempting to provide answers; our goal is to generate productive conversations. We are telling the story of the origin of vaccines and the anti-vaccination movement in the hope they may inspire conversations that lead to constructive and positive outcomes.

From studies conducted on competing media messages shown to parents about the safety of vaccines, we know that people respond to personal experiences, value systems, and levels of trust in healthcare professionals when deciding whether or not to vaccinate. Thus, to combat the scare tactics peddled by the
anti-vaccination agitators and persuade on the real risks and benefits of vaccines, perhaps we need to focus on those exact things: experience, values, and trust.

In our opinion, these data suggest that emphasis might need to be placed on building relationships within communities. As medical communicators, we have an opportunity to initiate understanding and collaboration between industry, healthcare providers, and the general public. We can try to encourage physicians to listen to their patients’ concerns without judgment and communicate vaccine messages that do not appear dictatorial or dogmatic. Maybe with sensitivity and empathy we can help parents move toward trusting medical professionals and health authorities again, and away from relying on the opinions and subjective truths of celebrities and their friends on Facebook. Perhaps then, such formidable viruses as measles and Ebola can be eradicated from our global communities once and for all.

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Since 1989, the American Medical Writers Association (AMWA) has been conducting periodic surveys of compensation for medical communicators. Thank you to those of you who responded to this year’s survey! In 2019, for the first time, AMWA contracted with a third party, Association Research Inc (ARI), to conduct and analyze the survey. This allowed for more rapid analysis of the results than in past surveys. We are pleased to reprint for you below the Executive Summary of the results of AMWA’s 2019 Medical Communication Compensation Report, as provided by ARI.

As our members are well aware, a survey can only show association but not causality. The presented salaries and rates do not assign a cash value to any compensation beyond salary or fees (for example, health insurance or tuition reimbursement), precluding a direct comparison of employee and freelance earnings. The condensed nature of a summary does limit the amount of information displayed and the conclusions that can be drawn.

More detailed information and interpretation will be forthcoming in a variety of ways, for example in a presentation and discussion at the annual Medical Writing & Communication Conference in San Diego and in print media. It is the hope of the AMWA Board of Directors and of the Salary Survey Task Force that this information will be of great use to our members.

Additionally, contracting with ARI has allowed the creation of an interactive “compensation calculator” tool for members. This tool leverages the wealth of data obtained through the survey and can be accessed only by members and only via the AMWA website: www.amwa.org.

* * *

EXECUTIVE SUMMARY

The American Medical Writers Association (AMWA) conducted its 2019 Medical Communication Compensation Survey during the first quarter of 2019 to determine prevailing annual income and fee levels in 2018 as well as study the different factors affecting the pay of medical communicators. For many medical writers, the survey results constitute a dependable basis for employers to use when setting salary ranges, and for employees and freelancers/contractors to reference when negotiating salaries and contract fees. Overall, 1,418 individuals (1,141 members and 263 nonmembers1) completed the online survey, yielding a response rate of 20%. About two-thirds (938) of the respondents were employees and one-third (480) were freelances.

The study requested the annual total income before taxes earned in 2018 by employed medical communicators as well as gross/net income and standard hourly fees for freelances. Respondents were asked first for their employment status—employee or freelance—and based on their answer they were directed to the appropriate section of the survey to complete. All individuals were asked to provide information about their age, gender, experience, education, certification, region of work, and AMWA membership. Both part-time employee respondents as well as all freelance respondents were asked to report the number of hours worked per week. For freelances, those reported work hours were used to determine their full-time/part-time status for compensation purposes. Full-time freelance was defined as working 32 or more total work hours (billable+nonbillable) as reported in the survey.

ALL RESPONDENTS

The majority of medical communicators responding to the 2019 survey were female (83.4%). The average age was approximately 48 years, and the average number of years working for pay as a medical communicator was 12. About one-third of respondents held a PhD (37.4%) or a master’s degree (31.6%) as their highest level of education, more than three-fourths (77.4%) did not have an AMWA Essential Skills certificate, and four in 10 (41.1%) had the ELS (Editor in Life Sciences) certification. Nearly half of all the respondents had a degree in science (47.2%) while 9.0% had a degree in English, quite similar to the proportions observed in the 2015 survey. On

1 Self-reported counts for a non-required survey question; does not add to total.
average, freelance respondents were older (52 years compared to 46 years) and more experienced (15 years vs 11 years) than their employed counterparts.

<table>
<thead>
<tr>
<th>All Respondents</th>
<th>Income (before taxes): 2015 &amp; 2019</th>
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</thead>
<tbody>
<tr>
<td>Employed Full-Time</td>
<td>Freelance Full-Time</td>
</tr>
<tr>
<td>Mean</td>
<td>Median</td>
</tr>
<tr>
<td>2019</td>
<td>$108,444</td>
</tr>
<tr>
<td>2015</td>
<td>$90,200</td>
</tr>
<tr>
<td>% Change</td>
<td>20.2%</td>
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</tbody>
</table>

The average total income before taxes in 2018 for full-time employed medical communicators was $108,444 (n=845), higher than the 2015 mean salary of $90,200 (n=732). The median total income in 2018 was $97,000 and the interquartile range (the difference between the third and first quartiles) was $54,000. Part-time employees worked an average of 27 hours per week and earned a mean total income of $83,112 (n=32) in 2018. The average gross income for full-time freelances in 2018 was $154,296 (n=164), higher than the mean income of $131,400 (n=154) reported on the 2015 survey, and the median gross income was $114,500 for both years. Part-time freelances worked an average of 22 hours per week and earned a mean gross income of $73,897 (n=252) in 2018.

EMPLOYEE (FULL-TIME) RESPONDENTS
Almost one-fifth of all full-time employees worked for a pharmaceutical company (19.9%), followed by clinical or contract research organization (14.0%) and medical communications company (13.9%). When asked about their primary type of work for their employer, two-thirds of the respondents were primarily involved in writing (65.8%), while 24.4% were involved in editing, and a small percentage was involved in quality control, research, or other. Most respondents held a midlevel, nonsupervisory position (39.6%) in their company, and one-fourth held a senior level, nonmanagement position. Only one-tenth of respondents held a senior level, management position (11.3%) and 8.8% were entry level. On average, the typical full-time employee had worked in their current company for nearly six years, and those with a formal people-manager role had approximately four direct reports. Most respondents were employed by companies in the US (92.8%), of which a considerable portion were employed by companies either in the Middle Atlantic (22.4%) or the South Atlantic (20.2%) regions. Those outside the US worked most often for companies located in Canada.

Full-time employed men earned a mean total annual income of $119,236, about $13,000 more than their female counterparts; however, the difference was not significant at the 95% confidence level when controlling for the effects of the highest level of education obtained and years of experience—both factors were positively correlated with income. Total income increased with years of experience as a paid medical communicator. The average salary for respondents with more than 10 years of experience was $129,363, about $23,000 more than those with 6 to 10 years of experience. Also, education had a positive impact on earned income, with respondents holding a PhD or other advanced degree as their highest degree obtained earning more in average salary than those with other degrees as their highest level. Employed medical communicators working in the US earned more than their non-US counterparts, $110,568 and $77,927, respectively. Among those working in the US, the highest average salaries for full-time employees were observed in the Pacific area ($138,646), followed by New England ($122,840) and the Middle Atlantic ($114,427).

Professional characteristics also affected the pay of employed medical communicators. These factors included the type of employer, main area of work, primary type of work (writing, editing, quality control, etc), number of employees in the company/organization, position level, direct reports, and tenure in current company/organization. Medical communicators employed by pharmaceutical and biotechnology companies earned the highest average salaries, at $145,433 and $140,596, respectively. On the other hand, the lowest average salaries were reported by those working in a medical school or university ($76,064), association or society for health care professionals ($80,620), and health care organization/provider ($81,065). Full-time employees who primarily work as writers earned more in average salary ($116,059) than those involved primarily in editing ($85,240). For both writers and editors, having management or supervisory responsibility resulted in higher salaries compared to those without these responsibilities. The differences in mean income by primary type of work and position level were significant at the .05 level, while adjusting for years of experience as a paid medical communicator.

In addition to cash compensation, employees received a variety of benefits of which the most offered were health insurance (93%), retirement savings plans (85%), and life and/or disability insurance (82%). The proportions receiving those benefits in the 2019 survey were higher than what was reported in the 2015 survey.

FREELANCE (FULL-TIME) RESPONDENTS
There were 480 freelance medical communicators responding...
to the survey, of which 179 were full-time. Similar to the 2015 survey, full-time was defined as working 32 hours or more per week. This includes billable and nonbillable hours. On average, full-time freelances worked 36.5 billable hours and 7.8 nonbillable (administrative tasks for business, marketing, billing, etc.) hours per week. Freelance respondents spent, on average, 5.3% of their total annual revenue on marketing their freelance business, and nearly half (49.4%) spent >0%-20% of their worktime at a client’s work site or other location outside their own workspace. Three in 10 freelance respondents (30.5%) were employed as a medical communicator for 10 or more years before becoming solely freelance; the typical respondent had worked solely as a freelance for 11 years. One-fifth of full-time freelances primarily worked for a pharmaceutical company (20.9%) or a medical communications company (19.2%). The majority of freelance respondents drew most of their income from writing (70.6%); only one-fifth relied mainly on editing (21.5%). The area of medical communication earning the greatest percentage of income for full-time freelances was regulatory writing (25.6%) followed by scientific publications (15.3%) and continuing education (11.4%). About one-third of full-time freelance respondents contributed the maximum amount allowed by law to a retirement account in 2018, and half the respondents stated that their business was more profitable in 2018 compared to 2017.

The average standard hourly rate for all freelances as of December 31, 2018, was $113 for writing, $93 for editing, and $103 for quality control (QC) or technical QC. These rates were higher than those reported for 2014 on the 2015 survey—$111 for writing and $71 for editing.

<table>
<thead>
<tr>
<th>Freelance Respondents</th>
<th>Standard Hourly Rates: 2015 &amp; 2019</th>
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<tr>
<td></td>
<td>2019 All Freelance</td>
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<tr>
<td></td>
<td>Mean</td>
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<tr>
<td>Writing</td>
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<tr>
<td></td>
<td>$113</td>
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<tr>
<td>Editing</td>
<td>$93</td>
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<tr>
<td>Quality Control</td>
<td>$103</td>
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</table>

For full-time freelances, the average hourly rate was $116 for writing, $97 for editing, and $103 for quality control. For part-time freelances and those working as part-time freelance in addition to being an employee, the average hourly rate was $109 for writing, $89 for editing, and $100 for quality control (QC) or technical QC. Hourly rates generally increased with years of experience as medical communicator, years employed as medical communicator before freelancing (for those who were employed before), and years of freelance experience. The average hourly rate also varied by the type of client that provided the highest percentage of freelance income; the average rate for writing was highest for those full-time freelances primarily working for a biotechnology company ($150) or a pharmaceutical company ($147), and the lowest for those primarily working for “other” client ($74), followed by a medical communications company ($117)². Moreover, freelances whose primary level of work was team leader on projects earned a higher average hourly rate for writing than those whose primary level was to write or edit projects with some guidance from client, $135 and $114, respectively.

The average gross income or revenue for full-time freelances was $154,296, and the average net income (after taxes and expenses) was $106,947. For part-time freelances, the average gross income or revenue was $73,897 and the average net income or revenue was $53,592. Gross income for full-time freelances was higher for those with more years of experience and those with more years of freelance experience. Full-time freelances with more than 10 years of freelance experience earned, on average, $177,927 in gross income, compared to $124,039 for those with 5 years or less. As for type of client, freelances primarily working for a pharmaceutical company or a biotechnology company averaged the highest gross incomes, $231,798 and $206,333, respectively. Also, those whose primary work was writing earned more in gross income ($176,979) than those who did editing ($84,403). Furthermore, freelances whose primary level of work was team leader on projects made more in gross income than those whose work was write or edit with some guidance from client, $225,559 and $146,298, respectively. Full-time freelances who spend 50% or more of their total working time providing services in regulatory writing earned the highest average gross income ($206,400), followed by those who spend 50% or more of working time in sales training (biotechnology or pharmaceutical industry) ($173,235), marketing/advertising ($152,588), and continuing education ($146,801).

Gross income varied by region of work (location) from which the highest percentage of their income was earned in 2018. Full-time freelances earning income primarily in the West and Northeast regions of the US earned more in gross income than those in the South or Midwest regions. The average gross income for full-time freelances with income primarily in the Northeast region was $177,644, compared to $126,676 in the Midwest. Freelances with income primarily outside the US earned less in gross income than their US counterparts. The most frequent non-US locations were Japan and Canada.

² It should be noted that some client categories were not shown due to low counts.
The Salzburg Statement on Vaccination Acceptance

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EDITORS NOTE:
As the World Health Organization declared vaccine hesitancy to be one of the ten greatest global threats to human health in 2019, many have raised the need for more creative multi-sectoral, science-based approaches to vaccine communications. The global health establishment will need to respond to the opponents of vaccination with sustained rigor, as the erosion of trust in vaccination and other preventive measures can lead to lasting harm for public health. (See also articles in: Washington Post by Ratzan, Gostin, Bloom and Fielding; JAMA by Gostin, Ratzan and Bloom, and Financial Times by Ratzan.)

The Editor was invited to the Salzburg Global Seminars, an international NGO that brings together leaders in a number of fields to develop new strategies and ideas that address a wide range of societal issues including healthcare.

A new Salzburg Statement aimed at revitalizing Vaccination Acceptance around the world was developed by a newly-formed International Working Group on Vaccination and Public Health Solutions (IWG), authors herewith. It represents the consensus of a group of independent leaders in public health, law and medicine who are deeply concerned by the growing threat of hesitancy of parents to vaccinate their children against preventable infectious diseases.

The Salzburg Statement has already been signed by more than 60 public health leaders from Europe, Asia, Australia, Africa and the Americas with names in the references. It asserts an “unwavering commitment to universal childhood vaccination” and pledges to “support the development, testing, implementation and evaluation of new, effective, and fact-based communications programs” that will help parents, community and government leaders make appropriate decisions on childhood immunization, and ensure a continuous supply of needed vaccines.

We welcome readers of the Journal of Health Communication: International Perspectives to sign on at SalzburgGlobal.org as well as share widely.

Immunization represents one of the greatest public health achievements. Vaccines save lives, make communities more productive and strengthen health systems. They are critical to attaining the UN Sustainable Development Goals. Vaccination also represents value for investment in public health. It is undisputedly one of the most cost-effective ways of avoiding disease, each year preventing 2–3 million deaths globally.

We the concerned scientists, public health professionals, physicians, and child health advocates issue this Salzburg Statement along with the International Working Group on Vaccination and Public Health Solutions, proclaiming our unwavering commitment to universal childhood vaccination, and our pledge to support the development, testing, implementation and evaluation of new, effective, and fact-based communication programs.

Our goal is to explain vaccinations to parents or caregivers, answer their questions, address their concerns, and maintain public confidence in the personal, family and community protection that childhood vaccines provide. Every effort will also be made to communicate the dangers associated with these childhood illnesses to parents and communities since this information seems to have been lost in the present-day narrative. While vaccine misinformation has led to serious declines in community vaccination rates that require immediate attention, in other communities, particularly in low-income countries, issues such as lack of access, and unstable supply of vaccines need to be addressed.

Overview
One of the world’s most devastating diseases – smallpox – was eradicated in 1980 following a global immunization campaign led by the World Health Organization*. Vaccines have prevented hundreds of millions of childhood infectious diseases such as polio, measles, mumps, rubella, diphtheria, pertussis, tetanus, hepatitis B, meningitis, rotavirus, and HPV infections that lead to cervical cancer. Vaccines save up to 3 million lives yearly. Every USD$1 spent on childhood immunization returns up to USD$44 in benefits.

These data are based on decades of peer-reviewed scientific studies that unequivocally support the safety, efficacy and positive benefit-risk ratios of childhood vaccines.
• Measles once killed 2 million people globally every year.
• Measles can have serious consequences, with 30% of cases having complications especially in those who are undernourished and immune compromised, including pneumonia, encephalitis, and hearing loss.
• Following the discovery of a measles vaccine in the mid-1960s, deaths plummeted to 110,000 globally in 2017. In 2000, there were no reported cases of measles in the United States.
• Today, only 85% of the world’s infants receive the first vaccine for measles, and even fewer get the second dose.*

Today, just as we are making tremendous gains toward increasing access to immunization globally, a completely different outbreak has occurred. Rampant misinformation spread by a powerful worldwide “anti-vax” movement threatens to undermine the hard-fought public health victories that comprehensive vaccine coverage represent. Vaccine coverage has waned in many populations. New measles outbreaks are making news while placing children and those without vaccination at risk of an entirely preventable and potentially life-threatening disease.

In the case of highly-communicable diseases such as measles, “herd immunity” requires a 95% immunization rate to protect the group. Even then there is never full immunity. Exposure to the virus from outside the herd puts every non-immunized person at risk. Many children under the age of 12 months, and any child who is immunosuppressed, are at risk of disabilities or death if vaccination rates fall too low.

The re-emergence of measles can be predictably replicated in other childhood illnesses, like rubella, which not only threatens children but also pregnant women and their unborn babies with well-documented consequences that include heart disease, deafness, and brain damage.

In 2019, the United States and 34 countries in the WHO European region no longer have sufficient numbers of people who have received two doses of measles vaccine to provide the “herd immunity” necessary for community protection.

These latest events underscore why the WHO has recognized “vaccine hesitancy” as one of the world’s top 10 global health threats in 2019, placing it on the same threat level as antimicrobial resistance, Ebola, air pollution and climate change. Novel approaches are needed to reverse this troubling trend, a decline that is just one aspect of what experts warn is a broader erosion of public trust in scientific and governmental efforts to sustain public health.

While the overwhelming majority of parents and physicians continue to support and use childhood vaccines each year, the sustained, global campaign of vaccine misinformation, driven substantially through the social media, has shaken the confidence of increasingly large numbers of parents concerned about their children’s well-being. Misinformation threatens the personal and community protection these vaccines offer.

Priorities for Action

We call upon major search engines and social media organizations to:

• Develop principles that distinguish “levels of evidence” in the vaccine information they provide so that they can improve identification of disproven/inaccurate false claims about vaccine safety for their users that have led to the return of childhood diseases, just as they do for sexually explicit, violent and threatening messages.
• Include information from robust scientific sources, particularly as unscientific misinformation puts vulnerable babies, cancer patients of all ages and immune compromised individuals at unnecessary and avoidable risk of serious complications, long term disability and potentially of death.

We call upon governments, policymakers, advocacy groups, educators, and philanthropists to:

• Support laws that mandate childhood vaccination, when they are likely to improve the public’s health, and to support more systematic qualitative and quantitative research on behavioral and social determinants of vaccination integrated with long-term, evidence-based communication programs that will build vaccine literacy in support of these laws.
• Widely disseminate reliable, accurate vaccine information in plain language through mass and social media, and delivered by trusted sources at all levels of society, including celebrities, faith-based leaders and parents.
• Promote “community protection” in public health law and communications to reinforce the equivalence of vaccination with other essential public services like law enforcement, firefighting and sanitation and restore broad societal trust in vaccination as a foundation of public health progress.

We call upon health professionals and educators across society to:

• Join forces to correct misleading information on social media and in community settings.
• Counsel parents and children and reassure them about vaccine safety.
• Commit to listening to and understanding the barriers and concerns of parents so that vaccinations and health services can be more health literate, accessible and user-friendly.

We call upon parents to:

• Seek information about vaccines from sources that have documented scientific and medical expertise, without agendas based on misinformation and unproven alternatives.

The intent of this Statement is to improve childhood vaccine coverage through expanded public dialogue that will enable individuals, communities and government leaders to better understand the role of vaccines, make more informed choices about their use, and sustain investment in expanded access to these vaccines globally.

Notes

The Salzburg Statement on Vaccination Acceptance

jamanetwork.com/journals/jama/fullarticle/2731738 April 19, 2019 (online version).

Conflicts of interest
No Conflicts of Interest Reported by the Authors

Supplementary material
Supplemental data for this article can be accessed here.

AMWA – EMWA – ISMPP Joint Position Statement on Predatory Publishing

The American Medical Writers Association (AMWA), the European Medical Writers Association (EMWA), and the International Society for Medical Publication Professionals (ISMPP) recognize the challenges to scientific publishing being posed by predatory journals and their publishers, which employ practices undermining the quality, integrity, and reliability of published scientific research. This joint position statement complements several other sets of guidelines that have helped define the characteristics of a predatory journal.1-5

Predatory journals pose a serious threat both to researchers publishing the results of their work and to the peer-reviewed medical literature itself. These publications differ from legitimate open-access journals6 in that predatory journals subvert the peer-review publication system for the sole purpose of financial gain with little evident concern for ethical behavior.7

Organizations such as the World Association of Medical Editors (WAME), the Committee on Publication Ethics (COPE), the International Committee of Medical Journal Editors (ICMJE), and the Council of Science Editors (CSE) support good publication practices that are now widely recognized.6,8-10 Predatory journals do not adhere to these practices but instead exploit the Gold Open Access publishing model (for which authors pay a publication fee).11 To generate revenue, these journals intentionally misrepresent practices of editorial and peer review, methods of journal operation, article process charging, dissemination, indexing, and archiving.1

Harm to the scientific literature will be the ultimate result if predatory publishing proliferates. Legitimate research carried out with the best of intentions might be lost if it is not recorded, cited, or made accessible in the long term, and the scientific record is at risk of being corrupted.1 But dangers to authors also exist in that their reputations can be damaged as a result of having their work published in predatory journals or being unknowingly “appointed” to their editorial boards. Furthermore, authors may find themselves trapped after they realize they have submitted an article to a predatory journal.

There is a potential risk that some journals might not return submitted manuscripts or will publish a submitted paper even after an author has protested.

The large increase in scientific journals, including those that are predatory,12 over the past 15 years can make the task of distinguishing predatory or “pseudo” journals difficult. However, online tools are available to help authors in this effort,1,8 and certain characteristics have been identified as being typical of predatory journals and their publishers:

- publishers or journals sending emails that aggressively solicit researchers
- a journal name that sounds somewhat familiar—but is actually a devious permutation of a legitimate journal name
- a website that appears unprofessional, with poor graphics, misused language, dead links, and aggressive advertising
- no street address or in-country telephone number noted on the journal or publisher’s website, or a fake address/phone number provided
- a lack of journal indexing in a recognized citation system such as PubMed13 or within a legitimate online directory such as the Directory of Open Access Journals (DOAJ)14
- promises of unrealistically quick peer review, or no information provided about a journal’s peer-review process
- article processing charges that are not transparent (and may be either very high or very low) or are payable on submission (that is, not dependent on the outcome of peer review)
- claims made of broad coverage across multiple specialties in medicine or across multiple subspecialties in a particular discipline
- a large stable of journals that have been started very recently and/or that contain no or few published articles, are inaccessible, or are of obviously poor quality
- an editorial board consisting of members from outside the specialty or outside the country in which the journal is published, or board members who are unknown to someone experienced in publishing in the field
- a submission system that is overly simple with few questions
asked and no conflict-of-interest or authorship qualification information requested.

Authors should not purposely choose to submit manuscripts to predatory journals to augment their own record of publication, as has been seen more recently.15,16 The conscious and deliberate submission of manuscripts to predatory journals is not ethical. Medical writers and editors, as well as researchers, have a responsibility to evaluate the integrity, history, practices, and reputation of the journals to which their research is submitted.8 We encourage all authors to carry out due diligence by examining the reputation of the publications to which they submit, and send their work only to those journals that provide proper peer review and that genuinely seek to contribute to the scientific literature.

The scientific community must be made fully aware of the harm that publishing in predatory journals poses and understand how to avoid it. AMWA, EMWA, and ISMPP are committed to educating our members about predatory publishing and the responsibilities of medical writers and publication professionals in addressing this significant issue.

References


Acknowledgements

This joint position statement was reviewed and approved by representatives of AMWA, EMWA, and ISMPP. Preparation of this statement was possible thanks to the efforts of the members of the Writing Committee (Barbara Good and Mary Kemper, AMWA; Slavka Baronikova and Julia Donnelly, EMWA; Jan Seal-Roberts and Donna Simcoe, ISMPP), and the organizational reviewers (Shari Rager, AMWA; Tiziana von Bruchhausen and Beatrix Doerr, EMWA; Anna Geraci and Al Weigel, ISMPP).
In early September 2018, the New York Times (NYT) and ProPublica shared results of a joint investigation in which Memorial Sloan Kettering (MSK) researcher Jose Baselga, an international thought leader on breast cancer, had extensively failed to disclose financial ties to industry in such lauded journals as The New England Journal of Medicine (NEJM) and The Lancet. At the time, Baselga was serving as the chief medical officer (CMO) at MSK and was associated with numerous companies, serving on their boards of directors, advisory boards, or as a paid consultant, and was a full or part owner of several start-ups. He was president of the American Association for Cancer Research and editor-in-chief of their primary publication, Cancer Discovery.1

From 2014 to 2017, Baselga did not provide complete disclosure in >60% of his >100 publications, with greater rates of omission in successive years (87% in 2017). Baselga described the finding as an “unintentional lapse.” As CMO, Baselga had input into the drugs and equipment purchased by MSK, though steps had reportedly been taken to ensure that his relationships didn’t influence business decisions. In addition, the interpretation of study results that he offered at speaking engagements appeared biased. For example, when a Roche compound increased disease-free survival by 1% rather than the anticipated 20%, Baselga told investors the results were “very meaningful, on par with many other cancer therapies,” that the data were “far from mature,” and that he was “confident—based on the experience with HER2+ trials—that the benefit will get better.”4

Under pressure, Baselga resigned as CMO of MSK and editor-in-chief of Cancer Discovery.1 He was hired in January 2019 as the head of research and development in oncology for AstraZeneca.2

Conflicts of Interest: Definition and Importance
Conflicts of interest (COI) are any relationships or activities, financial or otherwise, that readers could perceive to influence or potentially influence what is written. In the author instructions for The Journal of the American Medical Association (JAMA), COI are defined as relationships that include but are not limited to “employment, affiliation, funding and grants received or pending, consultancies, honoraria or payment, speakers’ bureaus, stock ownership or options, expert testimony, royalties, donation of medical equipment, or patents planned, pending, or issued.”3 Presently, journals vary in their definition of COI and often also include relationships that exist for a spouse or first degree relative.

Researchers rarely provide blatantly false data in exchange for financial gain. More often, relationships to industry have more subtle effects: researchers may allow industry to determine what is and is not studied or how it is studied and analyzed, authors may be biased in their choice of which data to include or exclude, or researchers may honestly believe in the superiority of an intervention such that he or she is blind to a balanced review of alternatives.

Conflicts of interest are an important topic. In May of 2017, JAMA devoted an entire issue to COI that included 23 articles “that represent[ed] the multifaceted aspects and complexity of COI from numerous perspectives, ranging from academic medical centers and industry to patients and the public.”4 Transparent disclosure of COI help editors to reliably publish scholarly and objective findings that keep the scientific literature credible, allow readers to better evaluate possible bias in an article, and permit clinicians to determine if the findings are valid and applicable to the patients they serve. Ultimately, the lives and well-being of patients depend on rigorously good science.
Conflicts of Interest in Publications

In the late 1990s, many publications contained clinical trials in which authors had selectively included or excluded data and their conclusions underplayed the harm and oversold the benefit of an intervention (Table 1). Multiple studies of bias in the literature suggested that financial relationships between authors and industry were at least partially responsible. These included a 2003 systematic review published in JAMA that comprehensively evaluated the body of evidence relating to financial COI. In it, the literature search retrieved 144 articles, 37 of which met inclusion criteria, and 8 of which accounted for 140 individual studies. Aggregation of the results showed that industry-sponsored studies were 3.6 times more likely to have pro-industry conclusions than non–industry-sponsored studies. The investigators summarized, “financial relationships among industry, scientific investigators, and academic institutions are widespread. Conflicts of interest arising from these ties can influence biomedical research in important ways.”

In response to such studies, educational efforts and the drafting of statements regarding ethical behavior around COI were offered by the American Medical Association, the Pharmaceutical Research and Manufacturers of America (PhRMA), and the Office of the Inspector General. Still, participation in ethical reform was voluntary, adherence was not regulated, and there were no consequences when guidelines were not followed. Compliance was repeatedly poor.

In light of ongoing problems, Senator Charles “Chuck” Grassley (R, Iowa), chairman of the House Ways and Means Committee, investigated unreported payments to physicians by pharmaceutical companies. This congressional

<table>
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<th>Example</th>
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<tr>
<td>In a pivotal trial of celecoxib for treatment of arthritis, only data on outcomes at 6 months were presented, even though the original protocol called for the trial to be of a longer duration and the outcomes at 12 months were available when the manuscript was submitted. The outcomes at 6 months showed an advantage for the study drug, but the outcomes at 12 months showed no advantage compared with the use of the control drug.</td>
<td>Hrachovec JB, et al. Reporting of 6-month vs 12-month data in a clinical trial of celecoxib. JAMA. 2001;286(19):2398-2400.</td>
</tr>
<tr>
<td>Published clinical trials suggest that selective serotonin reuptake inhibitors have a favorable benefit-risk profile in children with depression. When unpublished data were considered, the evidence indicated that the risks appeared to outweigh the benefits for all but 1 drug in this class.</td>
<td>Whittington CJ, et al. Selective serotonin reuptake inhibitors in childhood depression: systematic review of published versus unpublished data. Lancet. 2004;363(9418):1341-1345.</td>
</tr>
<tr>
<td>The results of trials of paroxetine that demonstrated an increased risk of teenage suicide or a lack of efficacy were not published. The data were revealed only after a lawsuit was brought against the manufacturer.</td>
<td>Gibson L. GlaxoSmithKline to publish clinical trials after US lawsuit. BMJ. 2004;328(7455):1513.</td>
</tr>
<tr>
<td>The manufacturer of aprotinin, an antifibrinolytic drug used in cardiac surgery to decrease bleeding, withheld data that use of the drug increased the risk of renal failure, heart attack, and congestive heart failure.</td>
<td>Avorn J. Dangerous deception—hiding the evidence of adverse drug effects. NEJM. 2006;355(21):2169–2171.</td>
</tr>
<tr>
<td>Results of a clinical trial comparing use of ezetimibe plus a statin with use of a statin alone in individuals with familial hypercholesterolemia were not published until 2 years after the conclusion of the trial. No difference in carotid artery wall thickness was seen between the 2 cohorts.</td>
<td>Kastelein JJ, et al. Simvastatin with or without ezetimibe in familial hypercholesterolemia. NEJM. 2008;358(14):1431-1443.</td>
</tr>
<tr>
<td>Results of a pivotal clinical trial of a blood substitute (PolyHeme) in patients undergoing elective vascular surgery were not released for 5 years after the trial was stopped by the sponsor. There had been significant increases in rates of mortality and heart attack in the group receiving the experimental intervention.</td>
<td>Burton TM. Amid alarm bells, a blood substitute keeps pumping; ten in trial have heart attacks, but data aren’t published; FDA allows a new study. Wall Street Journal. February 22, 2006. <a href="https://www.wsj.com/articles/SB114057765651379801">https://www.wsj.com/articles/SB114057765651379801</a>. Accessed April 4, 2019.</td>
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<td>The manufacturer of a brand name thyroid hormone attempted to block the publication of an article showing that a generic thyroid replacement therapy had bioavailability similar to that of the brand name preparation.</td>
<td>Rennie D. Thyroid storm. JAMA. 1997;277(15):1238-1243.</td>
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*Based on a table from an Institute of Medicine report.*
investigation exposed several widely published, widely admired psychiatric leaders, including Dr Charles Nemeroff (Emory University School of Medicine [SOM]), Dr Joseph Biedrman (Harvard University SOM), and Dr Alan Schatzberg (University of California, Los Angeles SOM), each of whom hid gifts of between $1 and 6 million by manufacturers of psychiatric pharmaceuticals, and each of whom was pushed to resign as head of their respective departments. Grassley’s findings were reported in a 2008 NYT article7 that squarely focused the attention of scientists, universities, pharmaceutical companies, and the lay public on undisclosed COI.

In 2007, Grassley sponsored the Physician Payment Sunshine Act, which required drug and device companies to publicly list all payments to doctors that exceeded $500. The legislation did not become law until 2010 when it was introduced as a part of the Affordable Care Act. The Centers for Medicare and Medicaid Services (CMS) implemented the law by developing the Open Payments Program, which became available to the public in 2014.8 The Sunshine Act revealed how widespread (and in some cases lucrative) speaking fees and consulting fees were for key opinion leaders.

Some have suggested developing a consistent requirement and uniform format for reporting disclosure, but this may be impractical given that many journals have different readerships and contain articles on varied topics, and so what represents a “relevant” COI statement will differ.

The cooperation of medical journals would be key to transparent reporting of COI. In retrospect, they had been complacent about how unacknowledged COI might imperil the perceived, if not genuine, integrity of the scientific literature. In 1997, only 16% of 1,396 highly ranked scientific and biomedical journals had COI policies, with <1% of individual articles in those journals having mention of COI for any author. Two thirds of the journals with COI policies had zero COI listed for that year.9 The situation rapidly improved following the highly publicized “disclosure scandal.” By the end of 2008, 89% of 256 highly ranked journals from 35 medical disciplines had COI policies and, of those with policies, 77% provided definitions for COIs and 54% requested that authors sign disclosure statements. Still, not all COI routinely appeared in print and definitions for COI varied considerably.10

Problems with COI reporting by authors in medical publications persist today, including failure to disclose, incomplete disclosure, inconsistent disclosure, and misunderstanding of what signifies a relevant COI.4 Recently, there has been a trend toward providing transparency around the COI of peer reviewers and journal editors.11 Pharmaceutical companies keep journals profitable through advertising dollars and large purchases of reprints, and there is evidence suggesting that they can influence journal content and layout and will “play hardball” if displeased.12

As for future developments, time-consuming detailed disclosures, each one slightly different, occur throughout the year for most researchers. Some have suggested developing a consistent requirement and uniform format for reporting disclosure, but this may be impractical given that many journals have different readerships and contain articles on varied topics, and so what represents a “relevant” COI statement will differ. In 2012, the Institute of Medicine (now known as the Academies of Medicine) asked the Association of American Medical Colleges (AAMC) to simplify the process. Four years later, the AAMC introduced CONVEY, a secure, global database where researchers and universities can list and modify their data at no charge and to which those needing access to the information can subscribe. Each potential conflict would have attached metadata (eg, type of relationship, subject matter, applicable dates) that would allow for targeted retrieval. As of September 2018, pilot programs were underway at NEJM and the University of Wisconsin. Growth has been slow thus far, but CONVEY may be the disclosure system of the future.13

Mastering COI disclosure is important to many stakeholders. Editors responsible for upholding trust in the literature must accurately get disclosure information from every contributor, no matter their contribution. But when asked, they readily admit that they do not have the resources to devote to the task and instead depend on the professionalism of their authors.1 Universities have COI training as a prerequisite for receiving National Institutes of Health (NIH) grants but also see it as a defense against reputational damage. Physician colleagues who serve as coauthors or peer reviewers should value appropriate disclosure; after all, a COI-related scandal for one author reflects badly on all participants. No individual—no matter how brilliant, no matter how esteemed—is more valuable than the scientific foundation upon which future progress depends.

Conflicts of Interest: Other Applications in Medical Communication

Although COI in publications is the most commonly discussed topic, discussion of COI disclosure is no less relevant to AMWA members working in other areas. Since 1999, regulatory writers submitting marketing applications to the US Food and Drug Administration (FDA) have been required to disclose relationships between industry and investigators for studies showing
the efficacy or safety of all drugs and devices. If the application does not contain appropriate disclosure, filing may be withheld. In addition, FDA employees and any spouse or minor child cannot hold financial interest in any company in which >10% of its income is regulated by the FDA.14

Most grant applications have extensive COI disclosure requirements. The NIH grants $39 million annually through almost 50,000 competitive grants,15 and they are obliged to both advance medical science and responsibly steward taxpayer dollars. Guidelines for reporting COI were introduced in 1995, but the system was restructured in 2011 to better define what constitutes significant financial COI, instruct researchers on the elements of an appropriate disclosure to their institution, guide institutions in management of their COI database, and provide an outline of appropriate investigator training. Universities must monitor the COI of their research staff and work hand-in-hand with the NIH by providing information at the time of application and yearly for the duration of the grant and as needed for any change in status. Through dialogue, discrepancies are clarified.16 Reporting failure can result in withdrawal of all NIH grants awarded to an institution (although this has never happened).1

In perhaps no area of medical communication is COI disclosure more critical than in continuing medical education (CME). Physicians need fresh information, updates, clarifications, and corrections to be taught in an environment free from commercial bias. The Accreditation Council for Continuing Medical Education (AACME) was founded in 1981 to independently determine whether programming is unbiased, safe, effective, cost conscious, and evidence based or consistent with best practices. Industry support of CME must be acknowledged, resolved (if possible), and disclosed to attendees. Use of a peer reviewer who can vouch that CME material is balanced and does not unjustly focus on a sponsored product is one means of resolution. Peers must have similar training to the presenting faculty, be involved in the medical environment, and fully understand the content being presented.17 Completing accredited CME credits allows physicians to maintain licensure and specialty certification, to be credentialed in health care environments, and to attain membership in professional societies.

In 2007, commercial subsidies to CME totaled $1.2 billion. For-profit contributions fell to $659 million by 2013 but have increased over the past 4 years despite a downward trend in US provider numbers. Spending reached $740 million in 2017, accounting for 28% of all monies spent on CME.18 Industry has increasingly sought to influence program content and speaker choice. As stated in an article in the Journal of Continuing Education of Health Professionals, “Leaders in medicine and in government are asking about the effectiveness of CME, the influence of commercial support, and the value of CME credit and accreditation in assuring CME courses offer valid content, free of commercial bias.”19

Health care journalism is an area of medical communication in which writers may have direct responsibility for final content and approval. Therefore, writers must exercise extreme caution when interacting with pharmaceutical and biotech companies. In a 3-part series titled, “Conflicts of Interest in Health Care Journalism. Who’s Watching the Watchdogs? We Are,”20,21 veteran journalist Gary Schwitzer noted a disturbing increase in “questionable alliances” between news organizations and industry sponsors. Until recently, the National Press Foundation offered all-expense paid trips for health care journalism workshops sponsored by drug and device companies and, as seen with CME programming, sponsors often had influence over the agenda and presenters.21 At the 2017 World Conference of Science Journalists, gifts from the top 2 sponsors totaled just under a half million dollars. It does not strain the imagination to presume there was some advantage to such generous backing.21 At times, industry pressure, real or perceived, may guide editorial decision-making around content or ad layout. At the University of Colorado, a significant nondrug sponsor (Coca-Cola) may have had delayed influence. Shortly after the conference, a reporter from CNN contributed to a story on the obesity epidemic that identified lack of exercise as a causative factor but failed to mention the consumption of sugary soft drinks.20 If health journalism is to remain more than a vehicle for advertising, it will be imperative to remove conflicted money. Foundational support or advertisements for products without health claims (eg, Fitbit, a body weight scale, or the Calm app) could serve as ethical alternatives.20

The Role of Medical Writers
Publication, regulatory, CME, and grant writers and editors are strongly urged to take as much care with COI statements as they do with data. Whether working for themselves or for a pharmaceutical or biotech company, CME developer, university, government agency, or another entity, medical communicators should take extra care around disclosures to protect the profit and reputation of both themselves and the individuals for whom they work.

The following recommendations are aimed at publication writers but could be modified to suit most types of medical communication. First, even though our study leads may not realize the importance of accurate and complete disclosure, as a professional medical communicator, you (now) do. As in nature, knowledge sharing can be the difference between survival and extinction. As medical communicators, we work in the shadows to protect the scientists with whom we work and show them in their best light. Authors may be highly respected,
incredibly busy, and slow to respond, and these obstacles can make us hesitant to gather the COI information that we need. However, these interruptions could be career saving. If an author refers you to an assistant to obtain their COI disclosures, promptly gather the information and compare it to recently published COI disclosures, making sure to take note of any discrepancies.

Second, carefully read the instructions for authors for the target journal to determine if they have a specific disclosure form or specify a format in which COI statements are crafted. Many depend on use of the International Committee of Medical Journal Editors (ICMJE) disclosure form (http://www.icmje.org/conflicts-of-interest/), and the ICMJE maintains a list of journal participants. If the target journal doesn’t use a specific form, it may be helpful to create one (Figure 1). Ideally, your COI form will be painless and easy to complete. Useful elements include the name of the target journal; requirements copied directly from the instructions to authors; a table with the required COI components and persons to whom they apply (researcher, spouse, minor children, etc.); a request for clarification if you’ve found discrepancies compared to recent publications; a preliminary COI statement draft; request for subtractions and additions; and the researcher’s signature and date. Requiring a final signature and date can help focus your author’s attention. If questions arise as to whether a COI is relevant or not, contact the editor directly for clarification.

Most importantly, plan ahead. We live in a world of deadlines, and the number of details that demand our attention is inversely proportional to the time remaining to complete the task. Therefore, time is most fleeting toward the end of any endeavor. Whether completing a specific COI form supplied by the journal or creating one, the process is best accomplished within several weeks of the deadline, rather than several days prior to submission.

Figure 1. Example of created COI form.
tion, or interprets health in political, socioeconomic, or medical contexts, you must be wary of support that undermines the power of your words. Likewise, you must be cognizant of the commercial drivers of content and layout and minimize their influence whenever possible. As the eminent journalist and Professor Ben Bagdikian, winner of both the Pulitzer and Peabody awards, told his students, "Never forget that your obligation is to the people. It is not, at heart, to those who pay you, or to your editor, or to your sources, or to your friends, or to the advancement of your career. It is to the public."^{22}

### Conclusion

Many medical researchers have ties to the for-profit health care industry. These financial relationships can be productive and advance the development of beneficial drugs, devices, and tests. Researchers who have COI are not fundamentally greedy or unethical and can handle COI in a professional manner. A few, however, honestly believe that they can “take the money, allow industry to control the agenda, and still conduct unbiased research.”^{23} Regardless, full disclosure is key—disclose everything and allow the reader to decide what may/may not be of interest. As the ICMJE recommendations state, “Public trust in the scientific process and the credibility of published articles depend in part on how transparently conflicts of interest are handled during the planning, implementation, writing, peer review, editing, and publication of scientific work.”^{24} In the introduction of the AMWA Code of Ethics, we are reminded that ethical behavior also strengthens the integrity of the medical literature.^{25} It is therefore not at all surprising that appropriate handling of COI disclosure is just one more task in which we demonstrate our competency.

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Strategies for Building a Successful Medical Writing and Editing Business: Results from a Survey of 175 Freelances

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ABSTRACT
To learn more about the strategies that freelance medical writers and editors find most helpful in building their businesses, we created a 10-item survey and posted it on several popular forums (LinkedIn, Freelance Success, AMWA Engage). A total of 175 respondents took our survey. Their responses suggest 1) many freelances are here to stay (most respondents reported at least 10 years of experience); 2) many freelances are making a good income (most reported an effective hourly rate between $51 and $150); and 3) the top freelance problems relate to getting enough business (eg, finding clients, making enough money, marketing, getting steady clients). We identified several trends that suggest many freelances could secure more work by making simple changes. For example, although referrals are a great source of new business, many freelances do not rely on them: about 40% of respondents reported that less than 25% of their new business comes from referrals. Similarly, networking is a great source for new clients, as well as new colleagues, but most respondents reported attending networking events fewer than 5 times a year. Finally, many freelances reported that by consistently being professional, checking their work, being on time, and integrating with the team, they become invaluable to their clients. Our survey data are roughly consistent with data from other surveys in the field related to income, types of medical writing, and years in business, suggesting the surveys have drawn from a similar pool of respondents. As a supplement, we include a list of resources that freelances reported are helpful for running their businesses (https://tinyurl.com/y6m38ev5).

METHODS
Survey
We developed a survey in Google Forms consisting of 10 questions, which took 5 to 10 minutes to complete. Response options were open ended, multiple choice, or a combination of both (ie, multiple choices were presented but respondents could also write in answers). The questions were as follows:
• How long have you been a freelance writer/editor?
• What is your effective hourly rate?
• What accounts for the majority of your work?
• What percentage of your current business comes from repeat clients?
• What percentage of your new business comes from referrals?
• What types of things do you do to make yourself an invaluable part of your clients’ teams? For example, help clients develop communication strategy or XXX.
• What is your work-life balance like?
• What are your biggest challenges as a freelancer?
• Are there any resources you would recommend to other freelancers in terms of improving their business practices?
• How often do you go to networking events?

Survey Administration
We advertised the survey in several forums (LinkedIn, Freelance Success, AMWA Engage) and gathered responses from April 23, 2018, until May 31, 2018.

RESULTS
A total of 175 individuals responded to the survey, though some questions had fewer responses (i.e., respondents skipped questions).

Respondents
The majority of respondents were not new to the field of medical writing. Over 40% (73 of 175) reported having worked as freelance medical writers or editors for more than 10 years, and less than 20% (30 of 175) reported less than 2 years of experience (Figure 1).

When respondents were asked what their effective hourly rate was, the most common response (39%; 67 of 174) was between $51 and $100 (Figure 2). Fewer than 10% of respondents (15 of 174) reported an effective hourly rate greater than $150, and 16% (27 of 174) reported an hourly rate of $25 to $50.

The most commonly reported specializations were publications (26%; 44 of 173) and regulatory writing (15%; 25 of 173), closely followed by continuing medical education (12%; 21 of 173) (Figure 3). Some respondents selected more than one category of work or wrote in a more specific description of the type of work they do; a total of 53 different types of medical writing were reported.

Common Problems With Building a Freelance Business
When respondents were asked about the biggest challenges they encountered as freelancers (respondents could choose more than one response as well as add in their own), the top 3 problems were related to getting enough business:
• Finding clients, 32% (54 of 171)
• Making enough money, 20% (35 of 171)
• Marketing, 19% (33 of 171)

In addition, 16% of freelances (28 of 171) reported that taxes were a major challenge. Although other challenges were reported, none accounted for more than 1% of responses.
Business Practices

When asked how much of their work came from repeat business, 60% of freelances (105 of 175) reported that repeat business accounted for more than 75% of their work. Another 24% (42 of 175) reported that repeat business accounted for 51% to 75% of their work.

When asked how much of their work comes from referrals, a quarter of respondents (42 of 173) reported that referrals account for more than 75% of their work. However, the largest group of respondents (39%, 68 of 173) reported that referrals account for less than 25% of their business.

When asked about how frequently they attend networking events, roughly 50% (89 of 172) of respondents said they only go to such events several times a year (Figure 4). Another quarter (26%; 45 of 172) reported that they only go to networking events once a year. More than 10% of freelances reported that they never go to networking events; some of the reasons given were extreme introversion, living in an area with few networking opportunities, and no time.

In response to a question about how freelances become invaluable to their clients, many survey respondents reported they do so by following basic best practices (eg, being professional, checking their work, being on time, integrating with the team). In particular, some of the responses to this open-ended query included

“Being reliable, good at what I do, and easy to work with.”
“Meeting my deadlines, doing good work, being pleasant to work with.”
“Providing quality work in a timely manner.”
“Participate in team meetings/strategy sessions, contribute to/critique project plans, serve as ‘on-call’ writer for multiple clients.”
“Project management assistance as well as writing.”

When asked what statement best encapsulated their work-life balance, 58% of respondents (101 of 174) selected: “I take vacation and have a social life outside of freelancing; my balance is always changing.” Only 5% (9 of 174) selected the statement “I am always working; freelancing does not allow for free time.” Some freelances are also making the most of their flexible schedules; 10% (18 of 174) reported working most weekends to make up for the time they enjoyed spending with friends and family during the week.

Helpful Resources

Finally, in response to our question about resources that have helped freelances improve their business practices, frequent recommendations included EndNote and Zotero for reference management; Harvest, Pomodoro timer, Rescue Time, and Toggl for time tracking; and QuickBooks and FreshBooks for bookkeeping and invoicing. A summary of the resources recommended in the survey can be found in a supplemental resources sheet located at https://tinyurl.com/y6m38ev5.

DISCUSSION

We conducted this survey to learn more about the strategies that freelance medical writers and editors use to build successful businesses. The responses we obtained provide a valuable window into both common achievements and challenges in the field.

Comparison to Previous Surveys of Medical Writers and Editors

Other surveys conducted among medical writers and editors over the past 5 years provide insight into how representative our results are. First, in terms of experience, the 2016 Freelance Medical Communicator Tools of the Trade survey found that of 323 respondents, about 30% had worked more than 10 years as a freelance medical communicator. This percentage is smaller than the one we found in our survey, in which 42% of respondents reported having worked as freelance medical writers or editors for more than 10 years. This could indicate that we advertised our survey to a pool of more experienced freelances or that more experienced freelances were more likely to respond to our survey. Second, in terms of income, roughly 75% of our respondents reported an hourly rate between $51 and $150. This is consistent with the 2015 AMWA Salary Survey, which reported average hourly rates of $111 for freelance writers and $73 for freelance editors.1

Third, in terms of specialization, the Tools of the Trade survey asked about participants’ top 1 to 3 areas of work; 60% reported scientific publications, 39% continuing education, 23% regulatory documents, 22% patient education materials, and 14% sales training materials.2 Our question was phrased...
differently (“What accounts for the majority of your work?”), which resulted in most respondents picking only one specialty (those who picked “other” were allowed to write in multiple specialties, however). Nevertheless, the order of specialties by popularity was similar to that in the Tools of the Trade survey (publications, regulatory documents, continuing education, patient education, medical news, and sales training), suggesting that the pool of writers and editors surveyed did similar types of work.

Finally, our respondents’ recommendations for favorite software were similar to those recorded in the Tools of the Trade survey. Overall, the relatively consistent results obtained across multiple studies underscore the robustness of our results.

Hourly Rates Indicate That Medical Writing and Editing Is a Lucrative Field

In this survey, over 45% of respondents reported an effective hourly rate greater than $100—and 9% reported an effective hourly rate greater than $150—demonstrating that freelance medical writers often command high rates for their work. However, the fact that 16% of respondents reported making $50 or less an hour suggests that a substantial fraction of freelances have the potential to increase their rates.

Nurturing Repeat Business Is a Popular Strategy

In this survey, respondents reported that they relied heavily on repeat clients to stay busy. Indeed, 60% of freelances reported that repeat clients account for more than 75% of their business. This strategy is highly efficient, as freelances who retain quality clients need not spend time marketing to new clients. Moreover, as freelances get to know their clients well, they can deliver work that better meets their needs, improving client satisfaction.

Referrals and Networking: Neglected Opportunities?

One of the enduring challenges reported by respondents to our survey was getting enough business. Therefore, we were surprised that many freelances reported seldom employing two strategies that have yielded a great deal of new business for each of us: relying on referrals and engaging in professional networking.

In this survey, nearly 40% of respondents reported that referrals accounted for less than 25% of their business. However, whether from colleagues or clients, referrals are a great source of new work. Because prospective clients come to the freelance, the freelance gets to concentrate on completing paying projects rather than on marketing. Referred clients are also typically already familiar with a freelance’s scope of work and fees, making it less likely that the freelance and client will waste time figuring out whether they are a good match. Finally, referred clients are usually excited about the prospect of working with a successful freelance writer/editor. This is a role reversal from the typical situation, in which freelances are approaching clients for jobs.

Similarly, 52% of respondents reported attending networking events only several times a year, 26% went only once a year, and many didn’t go at all. This suggests that lack of networking may represent a major missed opportunity for many freelances. In particular, in marketing surveys conducted by Lori De Millo and colleagues during the past several years, networking was listed as one of the best ways to find clients—and it was also a topic that survey respondents wanted to learn more about. Reasons that survey respondents listed for not attending more events included introversion, a lack of events to attend, not seeing the importance of networking as a business growth opportunity, and lack of time. Although we can certainly relate to some of these reasons, we encourage any freelances who would like to boost their client list to try adding just a few networking events to their calendars this year, to see whether they prove beneficial.

We have both had good luck with a variety of networking opportunities. In addition to its annual conference, which is full of networking opportunities, AMWA encourages its local chapters to host networking events. Even regions without a formal chapter often host such events informally, and attending a gathering nearby involves relatively little time and expense. These are great opportunities to meet fellow medical writers and editors who may be happy to refer work to other freelances. Attending events where potential clients congregate is also a great way to obtain new work. We have met new clients by attending scientific and medical conferences, industry meetings, and gender-specific meetings (such as those organized by Women in Bio or the Association of Women in Science).

Of course, networking does not have to be restricted to formal events. It can also consist of meeting a local colleague for lunch to talk about common professional interests. We both consistently schedule calls with colleagues to ask questions, help each other brainstorm ideas for our businesses, and think through different business issues. The trust and respect that accumulates through these conversations has resulted in a great deal of work being referred back and forth. Networking can also happen online through forums, such as AMWA Engage or Freelance Success.

Although our survey did not ask about volunteering directly, we have found that volunteering for organizations that we are passionate about can be a great way to network with other like-minded professionals. Volunteering provides...
an opportunity for a freelance to show others that she or he can deliver high-quality work, is responsible, and is pleasant to spend time with. These are three key things that help build trust in a freelance’s ability to do other kinds of work, and they often lead to word-of-mouth referrals to potential clients or to other freelancers who need help. In particular, volunteering can be a great way to find a niche in an organization that does not have a large representation of writers or editors; in this way, a freelance stands out from the crowd and can quickly become the go-to person when someone is looking for a medical writer or editor.

We realize that many medical writers and editors are introverts, and networking may be the last thing on earth they want to spend their time doing. However, there are special guides written for people like us (Alaina Levine’s Networking for Nerds, for example), and we both find that as soon as we actually get to an event, it quickly becomes fun. Taking the pressure off networking by focusing on meeting new and interesting people, sharing your talents, and helping other people—rather than on immediately identifying new career opportunities, which can seem intimidating—can be one great way to motivate yourself to attend a conference where you don’t know anyone or to send an email to a colleague you’d like to get to know better.

Limitations of Our Survey
This study has several important limitations. First, our findings are likely to have been affected by response bias. We collected responses, in part, by advertising our survey on forums, some of which required membership fees. The fact that our respondents were able to pay these fees likely indicates that they have achieved a certain level of income, introducing bias into who took part. In addition, evidence from prior research suggests that both struggling and extremely successful freelances may have been less likely to participate in a survey about their businesses than moderately successful freelances, especially a survey that included questions about income.8 Once a person decides to participate in a survey, social desirability bias might lead them to overreport their income and the frequency of behaviors perceived as pro-social, such as networking and volunteering.7,8 Finally, after completing the survey, we noticed that the response categories for years of experience overlapped slightly (ie, 2–5 years and 5–10 years). Thus, some people with about 5 years of experience could have chosen either response, muddying the division between these two categories.

CONCLUSION
In this study, we set out to learn more about the strategies that freelance medical writers find most helpful in building businesses that are both lucrative and satisfying. Our survey results reveal that freelances commonly count on repeat clients in order to stay busy and that they focus on maintaining a healthy work-life balance. However, finding enough clients is a common concern, even for the relatively experienced population surveyed, and business-boosting strategies, such as networking and promoting referrals, appear underused. In the future, it might be useful to approach some of these topics in a more systematic way to learn, for example, more about correlations between certain freelance habits and outcomes such as repeat business and income. At present, however, our results may help freelancers who want to compare their habits with those of their peers. Our findings may also help identify professional development topics to focus on at upcoming conferences, such as the annual AMWA conference.

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Art of Writing Effective Response Letters to Editors and Peer Reviewers

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Brief Background on the Peer Review Process
Medical writers follow the authors’ guidance to substantively edit or craft a manuscript that highlights the data’s story; the authors’ interpretations, conclusions, and revisions; and its limitations and significance in the field in accordance with International Committee of Medical Journal Editors (ICMJE) and Good Publication Practice 3 guidelines.¹,² The corresponding author or designee submits the manuscript and cover letter. The multistep peer review process occurs between manuscript submission and receipt of a decision letter from a journal editor. Top tier journals receive 10 to 20 times and specialty journals receive 2.5 to 8 times more manuscripts each month than space allows.³,⁴ Thus, rejection rates range from about 60% to 95% of submitted manuscripts.³,⁴,⁵ This article describes an overview of this stage, lists common reasons for rejection, and provides suggestions for writing effective response letters.

Figure 1 shows an overview of the multistep peer review process. Editors read and reject approximately 20% to 60% of submitted manuscripts (called a “desk reject”) (Figure 1A). Desk reject occurs rapidly, usually within 3 days to 2 weeks.³,⁴,⁶ If a submission passes this initial screening, editors send the title and abstract to multiple potential peer reviewers and maybe a statistician. Some don’t accept the task. Peer reviewers often are provided 10 to 21 days to critique the manuscript (Figure 1B). The editor reflects on the reviewers’ comments for authors and editor, the reviewers’ comments solely for the editor, and reviewers’ recommended outcome. The editor makes a decision for immediate acceptance (very rare), opportunity to resubmit after minor or major revisions, or rejection. The decision letter is sent to the corresponding author (Figure 1B). Authors then decide how to address the editorial and reviewers’ comments and revise the manuscript. A medical writer may coordinate the responses and manuscript revisions under the direction of the authors, keep records for compliance, and format the point-by-point response letter (Figure 1C). The editor examines the authors’ responses and the revised manuscript to determine whether the authors have

Figure 1. Overview of the editorial and peer review process. A. Initial review by editor (prominent scientist or clinician) culminates in decision to send for peer review or rejection (called “desk reject”). B. Editor reflects on peer reviews, confidential comments from peer reviewers, and writes decision letter to corresponding author. C. Editor examines the authors’ revisions in the manuscript (MS) and explanation in response letter, reflects on comments from possible 2nd peer review, and issues a decision letter for acceptance or rejection. MS, manuscript.
sufficiently addressed the editor’s and the peer reviewers’ issues. In cases of major revision, the editor may send the revised manuscript again to the same peer reviewers for their opinions. After review, the editor sends the corresponding author a decision letter with either acceptance for publication or rejection.

**Editorial Review**
The initial editorial review assesses the manuscript from different perspectives than the peer review (Table 1). The editor’s initial screening of the manuscript assesses the suitability of the manuscript for the journal (type of article) and its readiness for peer review. Editors also attempt to assess whether the topic and novel findings in the manuscript may justify publication in their highly competitive journal. Although modeling the article’s potential effect on the journal’s future Impact Factor (IF) is challenging, editors may estimate its likelihood of being cited (i.e., citeability) at least as much as their average article. The editors often attempt to increase the journal’s IF each year by publishing manuscripts describing prestigious research by prominent authors. In addition, the editors may balance the number of manuscripts sent for peer review on a specific topic so that a variety of topics are published in each issue.

Common reasons for a desk reject include lack of sufficient novelty, out of scope, ethical problems, and poor English and/or manuscript structure (Table 2).

**Tip:** Thus, the abstract and manuscript should clearly and concisely explain the rationale, methods, and novel significant findings followed by fully supported conclusions. Professional medical writers often use reporting guidelines for describing specific types of human trials and methods to ensure the abstract and manuscript body include the salient points.

**Peer Reviews**
In comparison, peer reviews assess the scientific and clinical rigor of the manuscript: the explanation of the rationale and significance of the research, completeness of the methods, appropriate analyses, clear presentation of results, fair balance of scientific (and clinical) discussion, and accurate summary in the conclusions (Table 1, right column).

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**Table 1. Functions of Editorial and Peer Review**

<table>
<thead>
<tr>
<th>Initial Editorial Review</th>
<th>Peer Reviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>Scientific accuracy</td>
</tr>
<tr>
<td>Adherence to journal guidelines</td>
<td>Novelty, timeliness</td>
</tr>
<tr>
<td>Gatekeeper role (citeability, balance topics)</td>
<td>Rigor of experimental design and analyses</td>
</tr>
<tr>
<td>Readable for peer reviewers</td>
<td>Clarity of presentation of results</td>
</tr>
<tr>
<td>Compliance with ethical guidelines</td>
<td>Completeness, fair balance of discussion, supported conclusions</td>
</tr>
<tr>
<td>Choose and contact peer reviewers; confirm acceptance and follow-up</td>
<td>Provide comments and ask questions that guide authors to improve manuscript</td>
</tr>
</tbody>
</table>

**Table 2. Common Reasons for Editorial Rejection and Underlying Meaning**

<table>
<thead>
<tr>
<th>Common Reasons for Editorial Rejection</th>
<th>Potential Underlying Meanings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Out of scope</td>
<td>• Incongruent topic for readership</td>
</tr>
<tr>
<td></td>
<td>• Type of article (eg, case series) not published by journal</td>
</tr>
<tr>
<td></td>
<td>• Type of article (eg, review) usually written by invited author</td>
</tr>
<tr>
<td>Insufficient novelty or impact</td>
<td>• Novelty below journal expectations, no novelty</td>
</tr>
<tr>
<td></td>
<td>• Confirmation of previous results or incremental advance</td>
</tr>
<tr>
<td></td>
<td>• Insufficient estimate of online reads/downloads for top-tier journal</td>
</tr>
<tr>
<td></td>
<td>• Accepted sufficient number of manuscripts on topic for upcoming issues; recently published articles with similar findings</td>
</tr>
<tr>
<td></td>
<td>• Duplicate publication</td>
</tr>
<tr>
<td></td>
<td>• Topic priority is low</td>
</tr>
<tr>
<td>Limited clinical relevance</td>
<td>• Restricted to geographical area outside of journal expectations</td>
</tr>
<tr>
<td></td>
<td>• Minimal effect on standard-of-care</td>
</tr>
<tr>
<td>Poor writing and/or manuscript structure</td>
<td>• English too difficult to understand for sending for peer review</td>
</tr>
<tr>
<td></td>
<td>• Information placed in wrong section (eg, results in Methods section, essential background in Discussion)</td>
</tr>
<tr>
<td>Obvious bias</td>
<td>• One-sided descriptions and/or discussion (eg, only advantages for new medication and only adverse events for competitors)</td>
</tr>
<tr>
<td>Lack of ethical compliance</td>
<td>• No description(s) of approval of animal experiments, protocols for human clinical trials, nor informed consent</td>
</tr>
<tr>
<td>Lack of trial registration</td>
<td>• Clinical trial not registered in acceptable registry</td>
</tr>
</tbody>
</table>
Editors choose potential peer reviewers who are well-recognized authors of high-quality articles with sufficient expertise in the therapeutic area or scientific field. Peer reviewers may be assistants to full professors, researchers, clinicians, policy makers, and sometimes industrial scientists. Most peer reviewers adhere to the Ethical Guidelines for Peer Reviewers published by the Committee on Publication Ethics (COPE) and follow the guidelines of the publisher and journal. For example, the PLOS series of journals provide guidelines found under the individual journal names, which include questions for evaluating the validity and quality of the manuscript. Less-detailed checklists are common. On average, volunteer peer reviewers spend 5 hours/manuscript to read, critique the manuscript, and write a review. If a peer reviewer has concerns on ethical behavior, s/he sends a confidential note to the editor who can address the ethical concern with the corresponding author and, if necessary, contact the author’s institution.

**Tip:** Because it’s a common ethical mistake, writers are urged to verify that the images pasted into figures are correct and not a “placeholder image” from a prior manuscript.

### Types of Decision Letters
After the peer review, editors will send 1 of the 4 main types of decision letters:
- Acceptance as is (very rare, rejoice),
- Rejection with suggestion to submit to sister or cascading journal (same publisher),
- Rejection, or
- Conditional rejection with opportunity to submit a revised manuscript (minor or major revisions).

### Rejection and Disclosure of Prior Peer Review
Common causes of rejection after peer review (Table 3) included flaws in methodology and study design; inadequate description of methods; poor statistical analysis; problems with control, case groups, covariates, or outcomes; overstatement of conclusions, no new information; and major flaws in interpretation of results.

If the manuscript is rejected, consider that most manuscripts can be revised to address many of the peer reviewers’ points and may be accepted by another journal. Approximately 65% of manuscripts rejected by the *British Journal of Surgery* were published in another of 198 journals within 3 years; average delay was 13.8 months. This fact can spur writers and authors to provide the relevant revisions and sufficient supporting evidence in the response letter to the editor.

Many authors are reluctant to admit that their manuscript has had prior peer review. Some authors actively deny prior peer review. However, we always recommend disclosing prior peer review for the following reasons. First, it demonstrates transparency and honesty of the authors. Second, it can eliminate the need for a new peer review in some instances. Third, in some specialties, the reviewer pool is small. Nothing is worse for an editor than sending a “new manuscript” to a peer reviewer who writes back that they reviewed this manuscript for journal A and the authors made no attempt to address any of the issues. The editor then doubts the honesty of the authors about other aspects of the manuscript.

**Tip:** If the manuscript is rejected, identify a different target journal with scope that encompasses the research and its article type. Revise it for the new target journal and address as many of the reviewers’ issues as possible.

**Tip:** When the editor suggests submitting to a sister or cascading journal, authors should address any editorial and peer reviewers’ comments and refocus the manuscript to the scope of the target journal. Consider submitting a cover letter with a response that details the revisions made to address the prior peer reviews by using the suggestions outlined below.

### General Strategies for Responding to Peer Review Comments
Very few manuscripts are “accepted as is,” so authors should expect to revise their manuscript to address the editorial and reviewers’ comments. Most authors believe that revisions spurred by peer review improved the manuscript. The tone of the response letter and the completeness of the authors’ reply to each issue raised by the peer reviewers can influence the decision of the editor.

### Mindset
Many authors and professional medical writers still consider the peer review process as a major hurdle to overcome on the path to publication. After reading extensive peer review comments, some authors may need to progress through the 5 stages of grief described by the Kübler-Ross model—denial, anger, bargaining, depression, and acceptance—before they can actively explore options and provide strategies for writing the response letter. In some cases, a writer may help maintain the revision schedule by listening to and collating the thoughts of the corresponding author and co-authors as they process the review. In addition, consider coaching your authors to adjust their mindset so they consider the peer reviews as free consultations with 2 to 4 subject matter experts.

### Writing Major and Minor Revisions
Editors may classify the manuscript as needing only minor revisions: it usually needs only changes in the text with no additional peer review before acceptance. In comparison, manuscripts needing major revisions often require additional experimentation and may undergo a second round of peer review with the same peer reviewers.
Table 4 lists our main recommendations for developing and writing effective response letters. Effective response letters include a summary for the editor, and an authors’ point-to-point response document showing each comment from each peer reviewer immediately followed by the authors’ reply to that issue. Although a table for the comments and authors’ replies may be suitable for straightforward responses, a sequential format for questions needing longer responses is easier for editors to review. The response letter format should not require the editor to continuously flip from the authors’ reply to the revised manuscript.

**Tip:** Consider including the revised text from the revised manuscript in the response letter (with page and line numbers). Effective authors’ replies provide sufficient information to the editor so s/he agrees that the authors’ replies and the corresponding revisions in the manuscript have adequately addressed each of the reviewers’ comments, and the publication is ready for acceptance.

Although authors agree with some reviewers’ comments and can easily write their respective responses, authors usually will disagree with some reviewers’ suggestions. Table 5 provides suggestions on how to handle the more common disagreements between authors and peer reviewers. Some reviewer comments may indicate a misunderstanding, a different interpretation of the text, or briefly discussed information missed by the reviewer (“missed information”). Indicating to the editor that the original manuscript contained the “missed information” is a pitfall of response writing. The authors’ reply to this unclear point or insufficiently discussed point should involve revised text with possibly a table, figure, and/or added citations in the revised manuscript to satisfy the reviewer’s issue and ensure readers can absorb the perspective.

Table 3. Common Reasons for Rejection After Peer Review

<table>
<thead>
<tr>
<th>Common Reasons for Rejection After Peer Review</th>
<th>Potential Underlying Meanings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low novelty</td>
<td>• Specific to geographic area</td>
</tr>
<tr>
<td></td>
<td>• Similar findings for separate populations</td>
</tr>
<tr>
<td>Bias/lack of neutrality</td>
<td>• Missing discussion of alternate interpretations</td>
</tr>
<tr>
<td></td>
<td>• Industrial bias towards sponsor’s compound (need both efficacy data and safety profile)</td>
</tr>
<tr>
<td>Ethical considerations</td>
<td>• Plagiarism</td>
</tr>
<tr>
<td></td>
<td>• Evident self-plagiarism in Introduction, Results, Discussion</td>
</tr>
<tr>
<td></td>
<td>• Failure to disclose conflict of interest, or other conflict</td>
</tr>
<tr>
<td></td>
<td>• Manuscript reviewed by same reviewer at prior journal but had no revisions to address prior peer review</td>
</tr>
<tr>
<td>Missing citation of important articles</td>
<td>• One-sided discussion, rambling discussion</td>
</tr>
<tr>
<td></td>
<td>• Missing citations of opposing views</td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td></td>
</tr>
<tr>
<td>Flaws in study design</td>
<td>• No power analysis</td>
</tr>
<tr>
<td></td>
<td>• Group sizes too small</td>
</tr>
<tr>
<td></td>
<td>• Inadequate controls</td>
</tr>
<tr>
<td></td>
<td>• Ignored important covariates</td>
</tr>
<tr>
<td></td>
<td>• Unsound science</td>
</tr>
<tr>
<td>Flaws in methodology</td>
<td>• Inadequate description</td>
</tr>
<tr>
<td></td>
<td>• Inadequate outcome measures</td>
</tr>
<tr>
<td></td>
<td>• “Old” assays where more detailed assays readily available</td>
</tr>
<tr>
<td></td>
<td>• Unusual or inappropriate analyses, resulting in significant bias</td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td></td>
</tr>
<tr>
<td>Nothing new</td>
<td>• Subtle novelty that was not highlighted</td>
</tr>
<tr>
<td>Data not supportive of conclusion</td>
<td>• Speculation belongs in Discussion</td>
</tr>
<tr>
<td></td>
<td>• Overstated significance (statistical significance vs clinical significance)</td>
</tr>
<tr>
<td></td>
<td>• Major flaws in interpretation of results</td>
</tr>
<tr>
<td></td>
<td>• Figure quality unacceptable</td>
</tr>
<tr>
<td>Too few outcomes</td>
<td>• Outcomes from clinical trial or research split among too many manuscripts (attempt of “salami science“)</td>
</tr>
<tr>
<td><strong>Discussion</strong></td>
<td></td>
</tr>
<tr>
<td>Vague or overreaching statements of conclusions</td>
<td>• Potential bias</td>
</tr>
<tr>
<td></td>
<td>• Extended conclusions to additional populations not tested</td>
</tr>
<tr>
<td></td>
<td>• Unjustified superlatives (eg, robust, rapid, dramatic)</td>
</tr>
<tr>
<td>No meaningful conclusions</td>
<td>• Significance in field not evident, rambling discussion</td>
</tr>
</tbody>
</table>
Table 4. Eight Recommendations for Writing Effective Response Letters

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Comments</th>
</tr>
</thead>
</table>
| 1. Consider peer reviews as free consultations with 2 to 3 subject matter experts. | • Provide a collaborative tone of the authors’ reply congruent with a consultant’s suggestions.  
• Revise manuscript text to address each issue.                                                                                             |
| 2. Engage the authors.                                                          | • Provide authors sufficient time to process, accept peer reviews, and respond to the reviewers’ comments.                                                                                               |
| 3. Include all comments from reviewers in numbered list and provide point-to-point response using different styles or colors for easy reading. | • Include both compliments and requests for changes. Including the positive reviewers’ comments reminds editor of the positive aspects of manuscript.  
• If reviewer’s issue #2 contains 3 questions, number them 2a, 2b, 2c and respond to each individually.  
• Use different font styles or colors for reviewer’s comment & authors’ responses (eg, black italics vs regular font).  
• Consider including revised text (with page numbers and line numbers) in authors’ responses. |
| 4. Be grateful for their time and efforts, be respectful and polite to all reviewers and the editor. | • Always thank editors and reviewers for time and efforts.  
• Provide a direct answer to their issue upfront if possible.  
• Use professional tone in responses.  
• Write (or rewrite) authors’ responses in a respectful manner & remove any hints of frustration and sarcasm. |
| 5. Whenever possible, revise as requested by reviewer.                          | • General rule: agree with reviewers at least 75% of time.  
• Support replies with very relevant citations, as needed.                                                                                   |
| 6. If reviewer does not understand a rationale, method, subgroup, or an interpretation, rewrite to clarify it. | • Rewrite that segment/paragraph to clarify the point. As needed, consider adding a diagram or table.  
• Consult with your peers.                                                                                                                  |
| 7. Format revised manuscript as requested by editor and provide a copy with all revisions saved. | • Show changes in manuscript as requested: track changes or highlighted revised text.  
• Include a clean copy of revised manuscript.                                                                                               |
| 8. Summarize revisions at beginning of response letter to editor.               | • If there are disparate reviews or many requests for revisions, consider making a cover letter to editor and a separate document with author responses point by point. |

Tip: In the response letter, the following phrases may help the writer to start a response to a point of misunderstanding or different interpretation and introduce the revision that helps clarify the issue:
• “The referee is right to point out…”
• “Thanks for pointing out the ambiguity or a different interpretation. We have clarified…”
• “We felt that this point is not completely correct…. We agree that…. However, we disagree about…and have clarified....”

The Role of the Medical Writer
Writers or medical communication companies may use software (eg, Datavision, Tableau, Excel, PleaseReview) to track each author's suggested revisions and confirm their ultimate approval of the revised manuscript. Writers may expedite the writing of the response letter by asking authors to focus on developing responses to a subset of the reviewers’ comments: asking for additional experiments and alternative analyses, or on questions about significance of the research, implications, or conclusions. If reviewers request that the conclusions be toned down, the writer may provide several alternative sentences for the authors to revise. If the manuscript entails several specialties, authors (writer or project manager) may suggest that each expert mainly focus on addressing the reviewers’ comments in their own specialty.

In summary, writing effective response letters begins with thanking the editor and reviewers for their time and for the insights that the authors believe have improved the manuscript. Authors’ responses are incorporated with a polite, objective, professional tone in the letter. Each reviewers’ comment is paired with a reply that contains sufficient supporting information (data, citations, and revised text with corresponding page number and line number) to convince the editor that the issue was addressed. If requested, the authors should have revised the text of the manuscript to clarify the novelty or significance of the findings and/or tone down the conclusions before resubmission. The authors’ responses and the revised manuscript should indicate that the authors took the editorial
and reviewers’ comments seriously. If the manuscript has been rejected outright and the manuscript has been revised for a different target journal, the cover letter should include disclosure of the prior peer review with explanations of revisions.

Acknowledgments
We thank Richard W. Davis IV, PhD, for critically reviewing the manuscript.

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Author contacts: kmolnar_kimber@verizon.net and carolinehalford@hotmail.com

References

Table 5. Suggestions for Responding to Disagreements Between Authors and Peer Reviewers

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Suggestions for Responding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delayed receipt of peer review &amp; decision letter</td>
<td>• Request a status update on peer review of manuscript.</td>
</tr>
<tr>
<td></td>
<td>• “As a reviewer myself, I (author) understand the time and efforts needed for a thorough</td>
</tr>
<tr>
<td></td>
<td>review....”</td>
</tr>
<tr>
<td></td>
<td>• If author has published in the target journal, consider: “I understand the shortage of</td>
</tr>
<tr>
<td></td>
<td>reviewers. Although I cannot review my own manuscript, I am offering to review a different</td>
</tr>
<tr>
<td></td>
<td>manuscript to help you with the backlog.”</td>
</tr>
<tr>
<td></td>
<td>• “I enclose suggestions of suitable peer reviewers from within this field....”</td>
</tr>
<tr>
<td>Did not “get it”</td>
<td>• “We thank you for pointing out an alternate interpretation of.... We have clarified....”</td>
</tr>
<tr>
<td>Additional experiments or analyses</td>
<td>• Perform if at all possible.</td>
</tr>
<tr>
<td></td>
<td>• Provide robust rationale for not performing the requested experiment(s) and include</td>
</tr>
<tr>
<td></td>
<td>limitation in Discussion.</td>
</tr>
<tr>
<td></td>
<td>• Suggest them as future experiments.</td>
</tr>
<tr>
<td></td>
<td>• Understand that not supplying requested experiment(s) may result in rejection.</td>
</tr>
<tr>
<td>Request for citation of multiple articles by specific</td>
<td>• Citation of 1 to 2 of the most relevant suggested references usually improves the</td>
</tr>
<tr>
<td>authors</td>
<td>Discussion or Introduction.</td>
</tr>
<tr>
<td></td>
<td>• Refuse citing all suggested references to maintain fair balance.</td>
</tr>
<tr>
<td>Contradicting reviews</td>
<td>• Fair balance: include both positive comments (agree) and negative comments (how</td>
</tr>
<tr>
<td></td>
<td>manuscript has been revised).</td>
</tr>
<tr>
<td></td>
<td>• Consider revising manuscript to address both contradicting reviews on the issue;</td>
</tr>
<tr>
<td></td>
<td>authors’ reply for each reviewer’s comment may be diverse, focusing on each reviewer’s</td>
</tr>
<tr>
<td></td>
<td>perspective.</td>
</tr>
<tr>
<td></td>
<td>• Assume reviewer with negative comments did not understand... and consider clarifying the</td>
</tr>
<tr>
<td></td>
<td>issue.</td>
</tr>
<tr>
<td></td>
<td>• Consider revisions that will help readers the most (eg, revise figure).</td>
</tr>
<tr>
<td></td>
<td>• Ask the editor for guidance/clarity.</td>
</tr>
<tr>
<td>Seeming personal attacks in some comments</td>
<td>• Occurs more often when manuscript presents data that refute accepted paradigm: present</td>
</tr>
<tr>
<td></td>
<td>results using different, well-established experimental and analytical techniques.</td>
</tr>
<tr>
<td></td>
<td>• Consider discrepancy due to different subpopulations (patients meeting classification</td>
</tr>
<tr>
<td></td>
<td>criteria vs real-world evidence).</td>
</tr>
<tr>
<td></td>
<td>• Provide citations (in letter) showing assays were used to determine.... Maybe add</td>
</tr>
<tr>
<td></td>
<td>citation in methods, if needed.</td>
</tr>
<tr>
<td>Glaring personal attacks in most or all comments from</td>
<td>• Maintain a professional objective tone in authors’ replies.</td>
</tr>
<tr>
<td>one reviewer</td>
<td>• Speak to editor confidentially and s/he may provide additional peer reviewer.</td>
</tr>
</tbody>
</table>

and reviewers’ comments seriously. If the manuscript has been rejected outright and the manuscript has been revised for a different target journal, the cover letter should include disclosure of the prior peer review with explanations of revisions.
Do you scope your work/contract using project or hourly rates? What are the advantages and disadvantages of each?

Recognizing that there are times when project pricing is not feasible, I recommend to all freelances to charge by the project rather than by the hour. *Charging by the hour punishes the proficient and rewards the inefficient.*

What do I mean by this? There are 3 indisputable truths to consider before you decide to charge an hourly wage:

**TRUTH #1:** No matter how good you are, how experienced you are, how highly educated you are, where you live, or the type of work you do, there is a finite amount of money a client will agree to pay you per hour.

**TRUTH #2:** Everybody has time. However, since there’s finite value to time (see TRUTH #1), selling your time instead of your value makes you, and what you do, a commodity. Commodities are perceived to have no special value; they’re all the same.

**TRUTH #3:** The more experience you gain, the faster and more efficient you become at what you do.

Let’s look at the financial impact of these truths.

**Charging by the hour:**
When you’re young and inexperienced, you charge $85 per hour and it takes you 100 hours to complete a project. The client pays you $8,500.

$85/hr x 100 hr = $8,500

Several years later, you’re more experienced and charge $100 per hour. You complete the project in 75 hours because you’re better and faster at what you do. The client pays you $7,500.

$100/hr x 75 hr = $7,500

You’ve lost $1,000

Several years later, with even more experience under your belt, you charge $125 per hour. Once again, you take on a similar project, this time completing it in 50 hours. The client pays you $6,250.

$125/hr x 50 hr = $6,250

You’ve lost $2,250

As you’ve become more experienced, you charge more for your time and work more efficiently. However, if you charge by the hour, you make less money than when you started, despite increasing your hourly rate! You might count-ter that by working faster and more efficiently, you get projects finished sooner and can work on more projects in the same time period. That doesn't change the fact that by the project, the better you get, the more you have to work to make the same money you made when you were less experienced and less efficient.

Now let’s look at the financial impact of these same dynamics if you charge by the project.

**Charging by the project:**
When you’re young and inexperienced, you charge the client $8,500 for a project. It takes you 100 hours to complete. The client pays you $8,500.

$8,500/100 hr = $85/hr

Several years later, you take on a project similar to the one you did before and decide to charge the same fee. (You could charge more, right? However, for the sake of example, let’s stick with the original fee.) You complete the project in 75 hours because you’re better and faster at what you do. The client pays you $8,500.

$8,500/75 hr = $113/hr

Several years later, with even more experience under your belt, you take on a similar project again and you charge the same fee again. This time you complete it in just 50 hours. The client pays you $8,500.

$8,500/50 hr = $170/hr

Charging by the project, not only can you make more money than any client would likely agree to pay you if you charged by the hour, as you work faster and more efficiently you have more time to take on other equally more-profitable assignments. Admittedly, it’s harder to provide a project estimate than simply to quote an hourly rate, but your bottom line will really appreciate the extra effort!

— Brian Bass

**Hourly Rate**

**Advantages**

I don’t worry about how long the project takes. Once the client and I agree to an hourly rate, and I tell them how long a project may take me, I keep them apprised of my progress. All I have to do is keep track of time spent on a project to know how much my invoice will be.

For example, if my rate is $50 per hour and the project takes 4 hours, then I am paid $200. If the project takes me 6 hours, then I am paid $300.
I generally alert the client as soon as I know that a project is taking me longer than my time estimate, so they are not surprised by the invoice. I email a status report while I’m working and give them specific examples of any time-consuming elements—e.g., nonworking hyperlinks that I have to look up, more substantive editing than anticipated (such as moving paragraphs or adding heads for parallel structure), formatting issues, and any other unexpected tasks that become necessary.

Periodic status reports help manage client expectations and eliminate uncomfortable conversations at invoice time long after I’ve finished the project and perhaps forgotten about what contributed to the high number of hours. I also include such detail in the description section of my invoice, so the client is reminded of all tasks performed.

**Disadvantages**

My effective hourly rate never goes higher unless I change my hourly rate. I can work only so many hours in a day, week, month, or year, so my effective income has a ceiling.

For example, say my rate is $85 per hour, and I work 1,200 hours in a year. My gross annual income is therefore $85/hr x 1200 hr = $102,000. This gross income seems nice, but it won’t go higher unless I raise my hourly rate or work more.

**Project Rate**

Agreeing to a project rate entails me knowing as many details about the project as possible, so I can calculate how long I think it will take me to complete the project, multiply that by my desired hourly rate, and add about 20% to account for unforeseen time-consuming aspects.

**Advantages**

Once the client and I agree to a project rate, we both know before I start the project how much I will be paid. It doesn’t matter how long I take to complete the project. As with hourly rates, though, I keep close track of my time. Thus, I can determine my effective hourly rate, which has the potential to increase above my desired hourly rate.

A project rate that I negotiate can work to my advantage if I know how long it will take to complete the project so I can negotiate for an acceptable fee.

If I am given a project rate without the possibility of negotiating it, then that rate will work out in my favor if I complete the project quickly.

For example, a client once asked me to proofread page proofs of an article and said she could pay $400 for the project, to which I agreed. I finished the proofreading in 2 hours, so my effective hourly rate for that project was $400/2 hr = $200/hr. I was very happy with that effective hourly rate, a high amount of money to be paid for proofreading. The client probably would not have agreed to pay me $200 per hour to complete the project, but was happy to pay $400 to get the job done.

**Disadvantages**

However, if the project takes longer than anticipated, the effective hourly rate could then decrease below the desired hourly rate.

For example, in 2006, a client offered me $2,500 to write up a short clinical trial for a peer-reviewed journal. I knew at the time that this fee was low, but I agreed to it because I wanted to gain experience writing. The tasks included submitting an outline for approval, writing up the clinical study report into a journal article for submission to a peer-reviewed journal, and annotating the references and the manuscript.

The end result was 38 manuscript pages, 28 references, 3 tables, and 2 figures. This project took me 50 hours—a long time because I hadn’t done much medical writing.

My effective hourly rate was $2,500/50 hr = $50/hr, which was disappointing because that was my rate for editing back in 2006. I had hoped to make closer to $100 per hour for this writing project but hadn’t realized how long it would take me to deliver the final product. You can now find me in PubMed, so I gained valuable experience not only in writing but also in project rates.

**Project Rates and Fact-Checking Are Not a Good Mix**

One task that is ill-designed for project rates is fact-checking. Fact checking entails (1) verifying that every fact and product claim in a manuscript is accurate based on the references; (2) ensuring the reference PDFs are highlighted/annotated accurately to support the facts and claims in the manuscript; (3) ensuring the annotations in the manuscript are accurate and per client style; and (4) providing references as individual highlighted PDFs or compiled into 1 reference binder.

There is no way to know ahead of time what will go wrong or what will need to be fixed during fact-checking. Therefore, estimating the time to complete such a project is challenging. If a client insists on a project rate for fact-checking, you could try estimating 1 hour per reference, but it’s anyone’s guess how accurate that estimate will be.

Here are some examples of unforeseeable time-draining problems that may occur during fact-checking:

- A PDF is not searchable. Solution: You run OCR (optical character recognition) software to enable the PDF to be searched electronically.
- A PDF is “locked,” meaning that highlighting, boxing, and typing cannot be inserted into the PDF for annotation purposes. Solution: You “unlock” the PDF at https://www.sodapdf.com/unlock-pdf/ or a similar website that you find in a Google search of “unlock PDFs.”
- A fact is not supported by a reference citation/annotation. Solution: A best practice in fact-checking is to collaborate with the writer and see if you can quickly find the needed support. Perhaps one of the references supplied can support the fact, but that entails searching for support among the
supplied references. Alternatively, you could search for the fact in another reference that you have to find. To minimize time, you can insert a writer query to ask the writer to find the support.

- A reference PDF was not highlighted or boxed off by the writer. Solution: You highlight or box off the relevant support.
- An annotation inserted by the writer is inaccurate: Perhaps the writer inserted the wrong page, column, or paragraph number by mistake; used the PDF page numbers instead of the articles published page number; or used an annotation style that doesn’t match the client’s preferred style. Solution: You fix any typos or errors to ensure the annotations are accurate and in the client’s preferred style.
- The writer annotated to the abstract. Solution: Annotate to the body of the article. Because abstracts are often written before a study is complete, the data in abstracts may not match the data in the body of an article. Therefore, a best practice in fact-checking—for both writers and editors—is to annotate to the body of an article and never the abstract, unless the support is found only in the abstract.
- The writer did not show math calculations for numbers that were derived from but do not appear in the article. Solution: Insert a text box in the reference showing any calculations. Writers who calculate a number that does not appear directly in the reference should insert a text box in the reference showing their calculations, but some have not been trained to do so. The fact-checker needs to see all calculations, as does any medical-legal review team.

Thus, we have at least these 7 possible areas of unknown variables that can confound time estimates for a fact-checking project. Hourly rates usually cause the fewest fact-checking headaches.

— Melissa L. Bogen

I scope my work using project rates. Project rates have several advantages for both the freelance and the client: freelances are rewarded for their value, which is based on their experience and efficiency; freelances are motivated to work smarter, thereby increasing their effective hourly rate (increasing their income!), enabling them to submit deliverables to the client sooner (pleasing their clients!), and allowing them to move on to the next project sooner (increasing their paying work!); and project rates facilitate the assignment of specific fees to specific deliverables (outline, draft 1, draft 2, etc.), making scope creep (e.g., draft 4 for a project that only had fees assigned to drafts 1-3) obvious. Project rates are disadvantageous when the freelance underestimates the hours they need to spend on a project, or the estimate does not clearly define the scope. Therefore, accurate and specific estimates are critical for making project rates work. Estimates, which are based on clear expectations of what a project entails, are one of the most important things freelances do!

In contrast, hourly rates guarantee that freelances are fully compensated for their time, and they often simplify accounting for the client. However, hourly rates have several disadvantages. The freelance will never earn more than their hourly rate; the only way to increase their income is to increase their hours, so they effectively have to work harder rather than work smarter. Hourly rates punish experienced freelances because our industry has maximum hourly rate caps that clients will accept, and experienced freelances who work at that cap will earn less money than a newer freelance who spends longer completing a project, even if the newer freelance charges a lower hourly rate. Furthermore, clients get hurt when they pay higher fees to less experienced freelances who may deliver lower-quality products. Clients should not care about a freelance’s hourly rate; rather, they should care about a freelance’s cost to deliver a high-quality product by a deadline.

— Gail Flores

I prefer to bill an hourly rate, although I will sometimes do a project for a fixed fee. Some clients accept an hourly rate, while others insist on a fixed-fee bid, so I feel it is prudent to be flexible. The type of project is an important factor, e.g., I will not do a regulatory project for a fixed fee: everything is billed hourly because of the huge number of variables involved in these types of projects. MedCom projects generally are easier to bid as a fixed fee—provided that you actually have hands-on experience!

There are pros and cons to fixed fees and hourly rates. Working by the hour can create more complicated billing because you must detail the time spent—but at least you’re getting paid for all of your time. A disadvantage is that clients might complain about the number of hours; to avoid this, try to discuss the project carefully with the client in advance and provide an approximate estimate of the range of hours you believe, based on experience, the project will require. If the client thinks you’ve estimated high, suggest that you work a specific number of hours and then meet afterward to discuss progress. Alternatively, you can tell him/her that you will work a fixed number of hours and turn it in as complete as it could be in that time. Experienced people are faster, so this “ceiling” idea has never been a problem for me; but if you’re a newbie, I do not advise this strategy. Frankly, if you have been clear in advance and are keeping in touch with the client about unexpected complications and the client complains about the number of hours billed, you should consider letting him/her go and move on to someone who does not complain about your salary: it is demeaning.

Fixed fees can be risky because you may seriously underestimate how long the job will take you—and lose your shirt, as they say. On the other hand, you may complete a job in fewer hours than projected, making your hourly rate far higher for
that project! Experience teaches us when this is more likely. When asked to quote a fixed fee, be sure the client has been specific about what s/he expects and what background material will be supplied compared with what will be obtained by you. Clarify everything so that both of you have the same understanding of the deliverable, timing, revisions, etc. As well, be sure to have a written agreement indicating everything the fee will include—and what it will not include!

Contracts are a subject for another column; they can be complicated and tricky. Nonetheless, whether you work fixed-fee or hourly, get a written contract, please.

— Cathryn D. Evans

**Q** When (if ever) is a retainer a good idea?

**A** When a client has a large, ongoing, and perhaps nebulous project, you might consider establishing a retainer whereby the client secures your talent and expertise for a set amount of time and money per day, week, or month in return for your being committed and available to them for that time. The advantage of a retainer is that it guarantees you a set income for the duration of the contract. However, in my opinion, there are more potential disadvantages associated with retainers.

First, a retainer can become complicated if the client wants to carry over unused time that they’ve clearly paid for. For example, you’re contracted for 20 hours per week, and due to workflow nothing comes through to you one week, so the next week the client wants 40 hours from you. How do you juggle the work you may have from other clients?

Second, a retainer can prevent you from getting other work. If you’re only available a certain number of hours per day, week, or month, other clients may be hesitant to come to you with assignments. After all, projects don’t usually fit neatly into the openings you have available. Every project has a life and makes demands of its own.

Third, if a retainer buys all your time for a specific period of time, you’re not really freelancing, are you? The client “owns” you—that is, until they “fire you” at the completion of the contract. Then you’re out of work and, as seasoned freelances know, the time to look for work is not when you need it.

Fourth, retainers buy your time, not your value. Hopefully, my response to the question about charging by the project versus by the hour has convinced you that charging for your time usually isn’t a good idea.

I don’t like retainers for two reasons: I don’t want my client to “own” me, and I don’t charge by the hour. When I have the opportunity to take on a large, ongoing, and perhaps nebulous project, I break it down into smaller, hopefully, more definable pieces for which I can provide individual project estimates. If the client can’t (or won’t) define what those pieces are, I’ll set the parameters myself and estimate to those parameters. This gives me and the client benchmarks against which we both can monitor the deliverables as they progress and adjust the estimates if necessary as the parameters become clearer.

— Brian Bass

I have had only one retainer agreement in my freelance career, and it was very long ago when I was first starting out, and I didn’t even have many other clients then. I understood that “retainer privileges” meant that this client could command a priority use of my time over other clients, ie, even if I had work for other clients, the retainer client could give me an assignment at any time and it would always take priority. The retainer agreement was for 100 “guaranteed paid” hours of work per month, at a lower hourly rate than my usual rate. Time spent over 100 hours would be paid at my regular hourly rate. In the contract negotiation stages, I specifically told the client that it was up to them to assign the 100 hours of work and that I was not responsible for that. What ultimately transpired was that the client only had about 40 to 60 hours of work monthly for me to do during the term of this retainer agreement (I think it was for a year!). I made a fortune!

Again, this retainer contract was a very long time ago and very early in my career. I would not call it “representative” at all of retainer agreements, and I have not had any client since then even propose such an arrangement. I’m not sure I would agree to that type of retainer situation now anyway. I would have to really love the client and love the work, and all the contract language would have to be very carefully negotiated. With the slippery slope of scope in regulatory writing, it would be hard to commit to anything like “drop that, do this instead.”

— Sherri Bowen

A retainer is a written agreement that you will work for a certain period (or bi-monthly or weekly) amount over a specified period of time—it can be to the completion of a long-term project or simply for the whole year, or even open-ended. It’s up to you and the client. When to select this option depends on the client, your financial and workload situation, the work itself, and perhaps simply your subjective feelings about working with a particular client. **Advantage:** When a retainer is in place, the client pays you the specified amount each month even if they did not actually give you that much work in a particular month. (Thus, the client needs to pay attention to the competence of his/her Project Manager to be sure they are not paying you $$$ each week while you work on another project because someone forgot to send you something essential to enable you to go on.) The guaranteed income for a specified period of time is helpful for the freelance so we can avoid the “feast/famine” syndrome. **Disadvantage:** The other side of this is that you could end up putting in far more hours than you’re being paid for...
because there is much more to do for certain periods of time (sometimes it can be less than half your rate if your contract has not been carefully agreed upon/written). I have experienced both situations.

Retainer fees are usually paid in advance each month (or at an agreed-upon interval). The client pays this advance fee to assure that you will be available for a specified amount of time. Payment terms may vary, depending on your agreement.

Personally, I like the retainer agreement plan and have been willing to discount my hourly rate for the guarantee of $XXX every month. The one time I made significantly less than I should have happened to be a project I loved and enjoyed working on each month, had great relationships with the team, and basically had fun with them for several years. So, I accepted the lower rate because I also had significantly higher-paying freelance projects going on at the same time. Caveat: If you are going to commit a large number of hours per month, I suggest not discounting the fee unless you are desperate or are truly attracted to the client/project/deliverables. And never allow a retainer-client to be the largest percentage of your business if you can avoid it.

— Cathryn D. Evans

Q How do you market your business? Print? Online? Social media? Other?

A The most effective marketing tools for freelance medical writers and editors are networking, LinkedIn, the AMWA Freelance Directory, and direct email. I built my freelance business to 6 figures in 18 months through networking and direct mail (I use direct email now). Networking through professional associations such as AMWA is an easy way to get referrals to clients, and sometimes to meet clients. However, people need to trust you before they’ll be willing to help you. I build trusting relationships with colleagues by volunteering for AMWA and focusing my networking on giving more than I take.

LinkedIn wasn’t around when I started out in 1997, but it’s become increasingly important for freelance medical writers and editors. My client-focused profile, especially the headline and summary, helps the right clients find me. Having a large network of relevant connections and being reasonably active helps me rank higher in search results. I spend about 10 minutes a day on LinkedIn commenting on other people’s posts and doing my own posts about 3 times a week.

The AMWA Freelance Directory is another easy and effective marketing tool if you develop a client-focused listing. You can use a lot of the information from your LinkedIn profile for your Directory listing.

Direct email is a more active way to market your freelance business because you choose the clients you want to work with and reach out to them instead of waiting for clients to find you. I listed direct email last because it takes the most time and effort. However, it’s very effective. After developing a prospect list, you write a customized, targeted email to each client. Each email focuses on helping clients solve their problems, not trying to sell your services.

These days, most of my new business comes from clients finding me through referrals, LinkedIn, and the AMWA Freelance Directory. When I’ve wanted to shift the type of work I do or a few times when I’ve lost big clients, I’ve used direct email to attract new clients quickly.

— Lori De Milto

My marketing strategy consists of
• volunteering and my freelance directory listings in various organizations,
• my LinkedIn profile, and
• word of mouth.

I will be adding a website this year, not so much for advertising but as a space—in addition to LinkedIn—for potential clients to see my portfolio. I haven’t found a website necessary since 1997 when I started my freelance editing business because I do not market to individuals, and I prefer long-standing working relationships gained through referrals to one-off jobs. However, I do recognize the importance of an online presence.

Sometimes potential clients contact me after seeing my presentations on editing or Microsoft Word tips, which I have given for AMWA (at the national conferences and at local chapter meetings) and for the Editorial Freelancers Association (EFA). Giving presentations is probably the most fun and effective way to get to know clients and colleagues and become known as competent and reliable. Potential clients have also found me through freelance directory listings that I have with AMWA, the Board of Editors in the Life Sciences, and the EFA.

My LinkedIn profile is complete with highlights of my accomplishments, free giveaways, PDF links to some of my presentations and PowerPoint tips, a few good recommendations, and many keywords that show up in searches so potential clients can find me. I participate in LinkedIn discussions, which allows people in our industry to get to know me online, and I can take an active role in establishing myself as a knowledgeable editor.

Word of mouth is a powerful way to market. Developing strong relationships with other successful freelances has taken time. I have a solid network of editing colleagues I met through AMWA. We refer work to one another because we have gotten to know one another over the years and have worked directly with one another. We know our work is excellent, and we’ll make each other look good in the process of our referrals. It’s a 2-way street; we each give one another referrals.

— Melissa L. Bogen
I spoke recently with my college roommate’s husband. We chat infrequently, but each time we do, he asks me to please enlarge the font in the prescribing information of the prescription drugs he takes. Every. Single. Time. You see, despite my many attempts to explain to Larry what I actually do, he still doesn’t understand that writing prescribing information has never been part of my job description.

I’m not the only medical communicator who has had this experience. Many of us are familiar with the glassy stares we get when we deliver our elevator speeches to those outside of the industry. We medical communicators are an odd bunch in that we aren’t easily pigeonholed into defined career pathways. As Steve Palmer so aptly put it in his inaugural presidential address, “When each of us was of single-digit age, and an adult asked us what we wanted to be when we grew up, none of us said ‘a medical writer.’”

**Defining Our Value**

Given the many professional areas in which we work—regulatory writing, scientific publications, health communication, continuing medical education, promotional writing, grants—describing what we do isn’t our only challenge. When people ask why they need the expertise of a professional medical communicator, we should be able to give them an evidence-based answer, but can we?

Quantifying the value of professional medical communicators hasn’t been easy. We’re not making widgets, after all. Members of AMWA’s Medical Writing Executives Advisory Council tell us that they struggle with this as well. Consequently, how to define our value will be one of the topics on the agenda at the second annual invitation-only Medical Writing Executives Forum at this year’s annual conference in San Diego. In the long term, we hope to identify metrics that might offer a better perspective of our value beyond adherence to reporting guidelines and good publication practices, metrics that past researchers used to define our contributions in scientific publications. If you have ideas, let me know.

**Three Little Letters. One Big Deal**

Credentialing is part of the value discussion, not just for what it offers to individuals, but for what it provides to membership associations. According to leaders of associations that confer and support credentialing programs, the benefits include elevating associations and increasing their visibility and legitimacy. Association leaders describe several commonalities among credentialed members. They are more likely to be considered leaders in their field, follow standardized practices, serve as officers in the association, continue to renew their association membership, and hold a competitive advantage over their noncredentialed colleagues.

Five years have passed since the initial Medical Writer Certified (MWC) examination was administered in October 2015. Since then, more than 100 people have earned the MWC. Those first individuals who became credentialed in 2015 will soon be going through the recertification process.

The MWC prompts much discussion on Engage and is a source of an enormous amount of “fake news.” We’re trying to correct those misperceptions. Is the MWC exam a regulatory-writing exam? Absolutely not. Is the exam challenging? Of course it is. The easier a credential is to earn, the lower its perceived value. But the 125-question test is by no means insurmountable. I know. I passed it.

And for those of you wondering why someone who is closer to the end of her career than the beginning would bother to pursue credentialing, I’ll tell you. Those 3 letters represent a professional standard that demonstrates to clients and colleagues that I know what I’m doing. It’s part of my value proposition, the promise of the value I deliver to clients. I don’t yet know how much of a competitive advantage it will give me, but that’s not the sole reason I took the exam. I believe that the MWC is one way to elevate the profession and better define our value. I’ve already seen job postings stating “MWC preferred.” That tells me that employers are beginning to use the MWC to gauge our value as well.
See You in San Diego

This is my final column to you as president of the association. In November I hand over the gavel to Ann Winter-Vann. It has been an honor and a privilege to serve with our talented Board of Directors and to work with our exceptional Executive Director, Deputy Director, and staff to accomplish so much this past year. Any successes we’ve experienced have been because of their creativity, integrity, and commitment to this association.

We’ve had a busy and productive year. We engaged employers and learned what they need for their employees from an educational perspective. Moreover, this engagement is ongoing, and we’ll use the input to create more content to further our mission. We introduced new workshops and are developing a resource library for members. We completed the 2019 Compensation Survey and quickly delivered the results (see the summary in this issue). We worked with the European Medical Writers Association (EMWA) and the International Society for Medical Publication Professionals (ISMPP) to create a joint position statement on predatory publishing (also in this issue). We amped up our marketing and…

Are you curious to know more? Join me at the Annual Business Meeting on November 9, 2019, and find out.

One More Thing

The year 2020 marks AMWA’s 80th year in existence. We’ll be celebrating this benchmark throughout the year with special offers and discounts for our members. Stay tuned!

References


Cynthia L. Kryder, MS, MWC® / 2018–2019 AMWA President

2019 President’s Award Recipient: Joanne M. McCandrews

The President’s Award is given by the AMWA president to a member of AMWA who has made distinctive contributions to the association at the chapter or national level. The nominee must have been an AMWA member for 10 years and cannot have served on the Executive Committee.

It is with great pleasure that I present this year’s President’s Award to Joanne M. McCandrews, PhD. Joanne will receive the award this fall at the Medical Writing & Communication Conference.

Joanne is a former research scientist who launched her freelance medical writing career in 2000. She joined AMWA in 2004 and has been an engaged volunteer ever since. At the national level, Joanne codeveloped and teaches 2 AMWA workshops, Effectively Searching Online Databases and Introduction to the Endocrine System, with Tom Gegeny and Jacky Wu, respectively. She frequently leads roundtables and speaks on various topics at the annual Medical Writing & Communication Conference, contributes to the AMWA Journal, and has served on several AMWA committees, including the Nominating Committee, the Fellowship Committee, and the Annual Conference Program Committee.

Joanne also is active within her local chapter, the Mid-America Chapter, having served as chapter president (2008-2010), membership chair (2007-2008), treasurer (2013-2016), and on several chapter conference planning committees. She has been one of the coordinators of a bimonthly luncheon series for freelance medical/technical writers and editors in the St. Louis, Missouri, area for the past 13 years. Joanne was awarded an AMWA Fellowship in 2014.

Please join me in congratulating Joanne on this well-deserved honor.
Medical communicators are a DIVERSE group of professionals. Our interests span a variety of fields, from grantsmanship to regulatory writing, from peer-reviewed publications to sales training manuals, from continuing education materials to clinical protocols. That is what makes AMWA’s annual Medical Writing & Communication Conference so special. It does not focus on just 1 area or demographic; instead it provides critical updates and resources for a variety of fields. It enables writers to expand their horizons into new fields and new writers to explore the possibilities. The 2019 programming is now available and registration is open!

As you peruse the multitude of options, you will be sure to find open sessions, workshops, and roundtables that will meet your specific area of interest, but even more, we hope you find several opportunities that allow you to grow or cultivate a new area of development. You will notice that workshops and open sessions have been organized into several “tracks.” Regulatory and freelance participants will find a specific session for their fields at every time slot. Need help with technology? We have a track that will explore just that and introduce you to new tools as well as optimize the way you are currently using software and social media. In addition, the session “Augmenting Medical Writing with Artificial Intelligence and Natural-Language Generation” will dive into just how software is evolving with strong implications for the medical communicators of today.

The annual conference is not only about technical education—it also focuses on professional and personal development. Multiple sessions will engage participants in soft skills, leadership and management techniques, mentorship, and even investing and retirement planning! Further, this year we are offering a wellness track that will benefit any attendee regardless of focus or workplace.

At the core of medical communicators’ needs are writing and editing competency skills, which are featured in many of the workshop offerings this year. The AMWA workshops are offered with an additional cost; however, their value cannot be overstated. Each workshop is led by a field expert and offers a deeper dive into the ocean of a particular medical communication skill. More than 30 offerings are available, and you are sure to find one that could further your knowledge and your career. In today’s competitive market, we must continue to be at the forefront through continuing education. These workshops meet that need and are excellent elements that can be added to your résumé. Whether you are new to medical writing or have 5+ years of experience, you can find a workshop that will enable you to grow, and many employers encourage attendance based on the skills that attendees come back with. For those seeking the Essential Skills certificate, there are opportunities to take in-person workshops that offer a wealth of knowledge in an interactive and enjoyable space. You get to network while you learn!

Speaking of networking, the conference provides the perfect space to reconnect with colleagues at coffee breaks, lunches, and jam sessions. Jam sessions are held during the open session times and are moderated by AMWA members and targeted for each level of the medical writer (beginner, mid-level, advanced). Roundtables are another opportunity to network and learn in a smaller, more intimate setting. Groups of ~10 participants will gather over breakfast or lunch and discuss a topic of interest. This format allows for a more open and easy dialogue than can be achieved in any other format.

But that’s not all! We also offer poster sessions, new member meet and greet, multiple dinner options—even beachside morning jogging/walking and yoga! In short, we have an incredible program designed specifically to enhance the conference experience for all attendees and to meet the needs of medical communicators across all career levels. Workshops and roundtables will fill up fast, so be sure to make your plans early. No matter your specialty, your workplace, or your role, you will find valuable (and fun) opportunities during these 3 days in sunny San Diego!

A new (and exciting) element of this year’s programming are the MedWrite Talks. Two sessions will be included, and each will contain 3 inspirational and motivational talks. You will not want to miss the inaugural session!
David Clemow, PhD, MWC®, Is Selected for 2019 Swanberg Award

The Harold Swanberg Distinguished Service Award is named in honor of Harold Swanberg, MD, the founder of the American Medical Writers Association. The Swanberg is presented to an active member of AMWA who has made distinguished contributions to medical communication or rendered unusual and distinguished services to the medical profession. The Swanberg Award is presented during AMWA’s Medical Writing & Communication Conference.

This year’s Swanberg Award recipient is David Clemow, PhD, MWC®. For the past 2 decades, David has contributed to the advancement of medical communication as a profession on numerous fronts, including expanding and maintaining its skills and reinforcing its reputation by educating others about its value.

An AMWA member since 1999, David’s most recent contributions have been to the Medical Writing Certification Commission, of which he has been a member since 2010 and has chaired since 2017, and to the Regulatory Education Advisory Group (2015–2016). As a member of the Certification Commission, he was integral in launching the Medical Writing Certified (MWC®), the first credentialing program for the medical writing profession. He has since worked to strengthen and expand the reach and impact of this certification. His service to AMWA also includes 2 articles for AMWA Journal and contributions as an open session speaker and roundtable leader at the annual conference.

David has also been a member of the Drug Information Association since 2003 and has made significant contributions to that organization, which demonstrates his dedication to the profession on a global scale. He has served as a member (since 2003) and chair (2010–2018) of the Global Medical Writing Community, has helped grow its membership and establish regional communities in India and China, and has helped oversee medical writing programming content at the European Union, North America, and Medical Affairs and Scientific Communication Forum annual meetings. He also served as a member (2011–2018) and chair (2016–2018) of the Community Leadership Council. Especially significant is David’s service as chair of the 2009 and 2017 Medical Writing Competency Model Working Group, given the impact this model has had on the profession—including its use as a source document for MWC program development.

Among his several teaching appointments, David has served as an instructor in scientific communications at Purdue University and at Florida A&M University, where he also served as an Adjunct Professor.

Starting in 2008, David has written and presented on medical writing as a profession, including the strategic impact of medical writers on regulatory documents, publications, and promotional activities. Other topics include implementing software to write clinical study protocols, medical communication data visualization, important skills for medical writers, and how medical writers fit into the strategic organization of a pharmaceutical company. He is the author or coauthor of more than 30 articles in such journals as Therapeutic Innovation & Regulatory Science, CNS Neuroscience & Therapeutics, Postgraduate Medicine, and PLoS One, along with more than 50 abstracts, posters, presentations, and white papers.

The Member Recognition Committee was greatly impressed by David’s long-standing commitment to advancing the understanding and cause of medical communicators. He is truly an example of someone who has made “distinguished contributions to medical communication.” AMWA is proud to recognize David as this year’s Swanberg Award recipient.

Dr Clemow will receive the Harold Swanberg Distinguished Service Award and deliver an address at the 2019 Medical Writing & Communication Conference in San Diego, California.

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AMWA Fellowships Awarded to Drs Eller, Ruff, and Winter-Vann

Fellowships are presented to members of AMWA to recognize their significant contributions to the goals and activities of AMWA as well as their other professional accomplishments. Candidates must have been active members in good standing for at least 5 consecutive years immediately before Fellowship nomination.

The Member Recognition Committee is pleased to award AMWA Fellowships to 3 outstanding members this year, each of whom has distinguished records of service at both the chapter and national levels.
Elise Eller, PhD
Elise has been an AMWA member since 2009 and is a member of the Rocky Mountain Chapter. In her chapter, she has served as Colorado Education Director (organizing 2 chapter conferences), as chair of the Nominating Committee, and as chapter president—for 4 terms! She also served as a board delegate several times. At the national level, Elise has chaired the Chapter Handbook Committee and served on the Chapter Advisory Council Task Force and the Chapter Support Committee. She currently serves on the Constitution & Bylaws Committee and is an at-large director on the AMWA Board of Directors. She also has led open sessions at AMWA annual Medical Writing & Communication Conferences and has written for AMWA Journal.

Elise is currently a medical writer and consultant at Whitsell Innovations, where she leads and participates in the preparation of clinical trial protocols, clinical study reports, and manuscripts for publication. She has also been a freelance medical writer specializing in nonregulatory medical writing, including a variety of informational or promotional documents for pharmaceutical companies and preclinical study reports.

Naomi Ruff, PhD
Naomi has been an AMWA member since 2000 and is a member of the North Central Chapter. In her chapter, she has served as secretary, membership chair, board delegate, and as a member of the Bylaws Committee. She was previously a member of the Northern California Chapter, for which she served as secretary, newsletter editor, and president. She also helped organize and direct several of the Pacific Coast Conferences. At the national level, Naomi has served on the Nominating Committee, Freelance Directory Subcommittee, Poster Selection Committee, Constitution & Bylaws Committee, and the Engage Advisory Group. She was also a member of the Science Curriculum Task Force, Elections Task Force, and Chapter Advisory Council Task Force. She developed and led the Introduction to the Nervous System workshop, has been a speaker and roundtable leader at AMWA annual Medical Writing & Communication Conferences, and was the 2014 President’s Award recipient. She currently serves on the Engage Committee.

As the President (and sole member) of RuffDraft Communications LLC, Naomi puts her background in science (BS, Biochemistry; PhD, Neurosciences) and language (BA, Linguistics) to work helping scientists, physicians, and others tell their stories in a clear and compelling way.

Ann Winter-Vann, PhD
Ann has been an AMWA member since 2007 and is a member of the Carolinas Chapter. In her chapter, she has served as president-elect, president, conference coordinator, and board delegate. At the national level, she has served on the Nominating Committee, Constitution & Bylaws Committee, Regulatory Action Advisory Group, and chaired the AC Program Committee. She also served as Awards Administrator and Publications Administrator on the Executive Committee before becoming an at-large director on the AMWA Board of Directors. She has led open sessions at AMWA annual Medical Writing & Communication Conferences and the Carolinas Chapter Conference and has written 3 articles for AMWA Journal. She currently serves on the Nominating Committee, is the board liaison to the Workforce Training Committee, and is the AMWA President-Elect.

Ann earned her PhD in Molecular Cancer Biology from Duke University, where she was a predoctoral fellow of the Howard Hughes Medical Institute. Following a postdoctoral position in the Pharmacology Department at UNC-Chapel Hill, Ann joined Whitsell Innovations, where she is now a senior writer and manager. She has extensive experience in clinical regulatory writing and provides consultations and training in medical writing.

Please join AMWA in congratulating these 2019 award recipients at the Medical Writing & Communication Conference in San Diego, California.

* * *

Michael Schneir, PhD, Receives 2019 Golden Apple Award
The Golden Apple Award is awarded to workshop leaders who have demonstrated excellence in teaching in the AMWA education program.

This year’s Golden Apple recipient is Michael Schneir, PhD. The Member Recognition Committee was impressed with Michael’s long record of accomplishments and contributions.
to AMWA’s education program. An AMWA Workshop leader since 1991, he has taught nearly 50 workshops and consistently receives high evaluation scores. He has also created 5 new workshops, including Taxonomic Analysis of Medical Writing and Semantic Analysis of Medical Writing.

Michael is a professor of Biomedical Sciences at the Ostrow School of Dentistry of the University of Southern California, where he teaches Oral Biochemistry and Systematic Research Writing and facilitates Problem Based Learning. After years of biochemical research on the effect of diabetes on collagen biosynthesis in oral and other connective tissues, his current research is analyzing reasons for why some medical/research writing sounds better than others. His objective is to enhance medical writers’ intuitive writing skills by systematic identification and revision of syntactic distractions. Toward this objective, he has developed a taxonomic analysis in a nearly completed book, Revising Research Writing: Reasons Not Rules.

In his service to AMWA, Michael has written for AMWA Journal, served on the Workshop Subcommittee, and led roundtables at the annual conference. At the 2019 Conference, he will be leading the Sentence Structure and Patterns workshop.

Please join AMWA in congratulating Michael as he receives his award at the 2019 Medical Writing & Communication Conference in San Diego, California.

The Member Recognition Committee members were Noelle Demas (board liaison), Helen Hodgson, Karen P. Klein, Jude Richard, Barbara Snyder, and Christine Wogan (chair). Katie Bergmann from AMWA HQ provided superb guidance and support.

Slate of Candidates for 2019–2020 Election

Ann M. Winter-Vann, PhD / 2018–2019 AMWA President–Elect

Each year, the slate of AMWA officers is chosen by the Nominating Committee, which consists of the President-Elect (who serves as chair of the committee) and 6 voting members (appointed by the President-Elect and approved by the Board of Directors [BOD]). My thanks to the members of this year’s Nominating Committee: Esther Brooks-Asplund, PhD, RAC; Karen Klein, ELS, GPC, MWC®; Jen Minarcik, MS; Jill Roberts, MS; Dikran Toroser, PhD; and Shawn Watson, PharmD, PhD, BCPS. Susan Krug (Executive Director of AMWA) was an ex officio, nonvoting member of the committee.

The Board Interest Form is available upon request following an announcement to the AMWA membership. This form gives candidates an opportunity to express their interest in and qualifications for serving in an elected officer or an at-large director position. Members of the Nominating Committee discuss the potential officer candidates and select 1 qualified candidate for each position. The names of these candidates are then presented to the BOD for approval.

The following candidates were selected by the Nominating Committee and subsequently approved by the BOD in June:

- **President-Elect**: Gail Flores, PhD
- **Secretary**: Katrina Burton, BS
- **Treasurer**: Julie Phelan, MD, MBA

President-Elect

Candidate: Gail Flores, PhD. An AMWA member since 2001, currently serves as Secretary on the BOD and chair of the Constitution and Bylaws Committee. She has served on the BOD since 2016 and previously has been chair of the Membership Committee (2017–2018), a member of the Pacific Coast Conference Committee (2017–2018), chair of the Chapter Transition Task Force (2017–2018), a member of the Engage Advisory Group (2015–2016), and a member of the Workshops Subcommittee (2012–2013). At the chapter level, Gail served as Membership Chair for the Pacific Southwest Chapter from 2007–2016. At the annual conference, she has led roundtables (2016, 2018), workshops (2018), and open sessions (2018), and presented a poster (2018). She has also written articles for AMWA Journal and is a regular contributor for the Freelance Forum (2017–2019). Gail is the Principal Writer of Encore Biomedical Communications LLC.
Secretary

Candidate: Katrina Burton, BS, an AMWA member since 2010, is in her second year on the BOD as chair of the Chapter Advisory Council. She has previously been a member of the Communications and Marketing Committee (2012–2013). At the chapter level, she has served as Communications Director/Chair for the Southwest Chapter since 2013, and previously served as Publications Chair (2017–2018), President (2016–2017), President-Elect (2015–2016), Program Chair (2015–2016), Assistant Program Chair (2014–2015), Director-at-Large (2012–2013), and a Chapter Delegate to the Board (2015–2017). At the annual conference, she has served as a roundtable facilitator (2014) and open session speaker (2013, 2017). Katrina is a program manager at The University of Texas MD Anderson Cancer Center in Houston, Texas, covering Pediatrics. She has more than 15 years of experience in health-care marketing, public relations, brand development, and media relations, working with writers, editors, and producers for local and national media outlets.

Treasurer

Candidate: Julie Phelan, MD, MBA, an AMWA member since 2009, is in her third year as Treasurer on the BOD and as chair of the Budget & Finance Committee (2016–2019). She has previously been a member of the Budget & Finance Committee (2015–2016), the Communications Committee (2014–2015), the 2015 Salary Survey Task Force, and the Online Community and Social Media committees. At the chapter level, she was President of the Greater Chicago Area Chapter (2013–2016), serving previously as President-Elect (2012–2013). She has also served as the Membership Chair for the chapter (2011–2015) and as Chapter Delegate (2013–2016). She has written articles for AMWA Journal and currently serves as AMWA’s Registered Agent. She was previously awarded an AMWA fellowship in 2017. Julie is President of Biomedisys, Inc.

Procedure for Additional Nominations

According to AMWA’s Bylaws (Article IV.2e-f), additional nominations for President-Elect, Secretary, or Treasurer may be made by any member whose dues are current, provided that any such nomination is submitted in writing to the Secretary of AMWA at least 30 days before the annual business meeting (which will take place November 9, 2019, at the AMWA Medical Writing & Communication Conference in San Diego, California). Such nominations must meet the criteria set forth by the Board of Directors, must clearly state the qualifications of the candidate and be signed by 50 members in good standing as of the date of the receipt of the nomination, and must be accompanied by a letter from the candidate stating that he or she is willing to serve if elected. As required by the bylaws, these nominations were announced to the AMWA community by email more than 60 days before the annual business meeting. A nominee who is unopposed for any office is declared automatically elected at the annual business meeting.

The 2019–2020 AMWA Board of Directors

As stated in Article III of the AMWA Bylaws, the BOD manages and controls the property, affairs, and business of AMWA. The BOD approves the budget, the slate of nominees for elected office, and any proposed amendments to the Constitution or Bylaws. It also appoints members of all committees, workgroups, and task forces; authorizes dissolution of AMWA; and fulfills such other duties as are specifically mentioned in the Constitution and Bylaws and as required by law. The BOD also has the power to establish reserve and endowment funds and approves the plans and regulations necessary to administer such funds. The BOD may, by general resolution, delegate to AMWA elected officers or committees such powers as provided for in the Bylaws. The BOD empowers the Executive Committee (comprising the President, President-Elect, Immediate Past President, Secretary, and Treasurer) to act between meetings of the full BOD.

AMWA strives to have a BOD that is representative of the organization’s membership, reflecting characteristics of the member population. Each at-large Director shall be nominated by the President-Elect and approved by a majority of the BOD. The Bylaws specify that the BOD shall be between 12 and 17 voting members, and shall include the elected Officers, chair of the Chapter Advisory Council, and at least 5 appointed at-large Directors.

At its meeting in July 2019, the BOD approved the following individuals to serve as at-large Directors for the 2019–2020 term:

- Brian Bass, MWC
- Loretta Bohn, BA, ELS
- Noelle Demas, MSTC
- Sarah Dobney, MPH
- Elise Eller, PhD
- Melory Johnson, VN
- R. Michelle Sauer, PhD, ELS, CRA
- Laura Sheppard, MBA, MA
- Shawn Watson, PharmD, PhD, BCPS

The BOD also approved the chair of the Chapter Advisory Council (a voting member of the BOD):

- Kimberly Korwek, PhD

The 2019–2020 Board of Directors begins its service on November 9, 2019, at the conclusion of the 2019 Annual Business Meeting.
Frankenstein’s Cat: Cuddling Up to Biotech’s Brave New Beasts

Emily Anthes


Emily Anthes reexamines our age-old relationships with animals in the context of biotechnologies we use to modify them for companionship, food, pharmaceuticals, research, and war. Anthes never shies from the “troubled middle” stance humanity has taken on animals. Increasingly humans demand and legislate animal rights in research and domestic settings, especially for primates and conventional pets, while unceasingly consuming food and medical products from their flesh and bodies.

Anthes immediately delves into the soft power of pets to sway opinions on new animal-modifying technologies. Humans imprecisely bred animals for thousands of years before unraveling the DNA code and finding ways to insert various genes, like green fluorescent protein. Creators of the popular aquarium pet GloFish were aware the red, green, and blue buddies, controversially debuted in 2004, could assuage negative to alarmist public opinion about genetic engineering. Scientists in the cloning world, seeking replicates of disease-resistant animals and animals at risk of extinction, felt similarly. The promise of never having to say goodbye to a family pet can ease the “yuck factor” reaction to unnatural creatures.

The author reports that only 27% of surveyed Americans believe the government should regulate genetic engineering entirely based on science. The majority, 63%, believe regulatory decisions should additionally be based on moral and ethical factors. Anthes explores genetic modification of animals for enhanced nutrition, to produce medication in milk, or to create organs for human transplant through lenses of animal rights philosophies and regulatory and governing bodies’ concerns about safety. Governments opposing the technologies may soon feel pressure from more enthusiastic governments aligned with some scientists’ visions for saving human life from disease and famine.

There is a setting in which modifying animals could make them partners in environmental conservation and climate change research, as opposed to instruments of human interests: tracking devices. Though some argue that the programs advance human control over nature and the environment, the procedure does cause the animals pain and the process of implanting trackers may modify animal behavior. Similarly, animal prosthetics, although altruistic, can also be fertile research ground for human prosthetics in which animals suffer. Animal cyborgs, particularly insects, are already here. Originally conceived for military espionage, their brains and nervous systems are ready to be controlled by any biohacker or interested amateur.

Frankenstein’s Cat is a wonderful read for science news and bioethics enthusiasts curious about the ways current biotechnology may impact our future alongside animals. Anthes lays bare the pace of human inventiveness for use of animals’ bodies, including improved lives for animals, as managed by humans. Inherently, readers are asked about their place in the troubled middle and whether or not the technologies discussed shift their positions on a myriad of animal modifications.

Reviewer: Elizabeth Schiavoni

Elizabeth Schiavoni is a graduate of Georgetown University in Global Health and holds a master’s degree in Genetics, Genomics, and Bioinformatics. She is a freelance writer and project manager in Buffalo, New York, working primarily in the nonprofit sector.


AMWA 2019

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