ONLINE EXCLUSIVE

Preface to the Online-Only Supplement to the 2017 Postconference Issue

By Jim Cozzarin, ELS, MWC®

When I chose to devote this issue of the *AMWA Journal* to showcasing our AMWA Medical Writing & Communication Conference content, I knew that we would not be able to contain everything we wanted to share in the print issue alone. So we have developed this online-only supplement to the Spring 2018 issue. Herein you will find presentations by Helen Osborne, recipient of the Walter C. Alvarez Award, and Steven Woloshin, MD, MS, and Lisa M. Schwartz, MD, MS, recipients of the John P. McGovern Award, as well as information from many of our exhibitors and reproductions of our conference posters.

We also are pleased to present the remaining open session reports. Let me again express my thanks to the cadre of volunteer reporters who attended and have provided brief reports on most of the open sessions presented at the conference. These brief reports are designed to share some basic information from each session so that those who could not attend this year might nevertheless be informed of topics and trends of interest among our colleagues in the industry. If you see something particularly interesting, please feel free to reach out to the individual presenter.

As you can see, if you missed the annual Medical Writing & Communication Conference, you missed a lot! I hope to see you at the next conference in Washington, DC, later this year!

Yours in AMWA,

~Jim

Walter C. Alvarez Award

The Walter C. Alvarez Award is named in honor of Walter C. Alvarez, MD, a pioneer in the field of medical communication. The award is presented to either a member or nonmember of AMWA to honor excellence in communicating health care developments and concepts to the public. The Alvarez Award is presented during AMWA's Medical Writing & Communication Conference.

Helen Osborne Highlights Health Literacy Awareness, Action, and Advocacy

By Liz Kuney, MS, CCRP

AMWA & The Sturdy Group LLC

Helen Osborne, MEd OTR/L,[a] shines as this year's recipient of the AMWA Walter C. Alvarez Award. Dr Alvarez was a beloved and well-known 20th century American pioneer in medical communication. He pulled medicine down from high dusty shelves and delivered health information directly to the public with compassion and insight through his widely syndicated column and popular texts. In the spirit of his legacy, Helen Osborne's work is at the very core of effective health care communication for the public.

For more than 2 decades, Helen has advocated for health literacy and has motivated medical professionals and others to "communicate about health in ways that patients and the public can understand." She is author of the award-winning book *Health Literacy from A to Z: Practical Ways to Communicate Your Health Message*, as well as other publications. Helen works as a plain language writer and editor on a wide range of topics, several of which have earned Gold Plain Language Awards from the National Institutes for Health. Helen can also be credited with inaugurating October as "Health Literacy Month" nearly 20 years ago as an annual reminder to promote better health communication. In addition, Helen produces and hosts the podcast interview series **Health Literacy Out Loud**. Helen

contributed to the Fall 2017 issue of the *AMWA Journal* in an article highlighting social media as a powerful tool for health literacy. An esteemed member of AMWA, Helen has been a featured speaker at regional and national AMWA events as well as for her local chapter in New England.

Despite these well-earned accolades and successes, Helen, in her Alvarez Award acceptance speech, was quick to shed the spotlight and shine it on the efforts of a beloved colleague she considers to be her "Health Literacy Hero," Archie Willard. Although he attended school just like other kids his age, Archie did not really learn to read until after being diagnosed with severe dyslexia at the age of 54. In the years that followed, Archie became an "ardent and articulate advocate" for health literacy by leading seminars, speaking at conferences, sitting on expert panels, and serving as a reviewer of patient educational materials. Although Archie Willard has recently passed on, his commitment to health literacy from the perspective of a "new reader" (an adult who recently learned to read) lives on.

To improve health understanding, the onus is primarily on the communicator to design and deliver effective messages that align with the needs of the audience. Helen's working definition is that "health literacy happens when patients (or anyone receiving health messages) and providers (or anyone communicating these messages) truly understand one another."

From the start of her stirring presentation, Helen set each of us in the audience squarely into the mindset of someone with poor health literacy. What would it be like if you were unable to adequately read and write? Or understand basic medical terminology? The first demand on many patients at the doctor's office is to read and then answer a series of health history questions. How vulnerable a person must feel when already under the stress of illness to be confronted with this daunting task! This simple scenario focused the audience on the realization of what can be an enormous hurdle and seared into our hearts the essence of health literacy—which most AMWA members (including myself) undoubtedly take for granted. Clear communication is essential to adequate health care and, to be effective, must fundamentally conform to the capacity of the receiver. To improve health understanding, the onus is primarily on the communicator to design and deliver effective messages that align with the needs of the audience. Helen's working definition is that "Health literacy happens when patients (or anyone receiving health messages) and providers (or anyone communicating these messages) truly understand one another."

Health Literacy—When Patients and Providers Truly Understand One Another

Mark Tatro of Rotate Graphics

Being true to her mission and delivering a presentation with empathy and generosity, Helen employed the very methods she was teaching to the awards ceremony audience:

- Create a welcoming and warm environment. Beyond the physical environment, this includes a tone in which people can think, disagree, and ask questions.
- Communicate in ways people can understand. That includes using modalities such as images, storytelling, written words, interaction, and humor.
- Confirm that the intended audience understands health messages. Strategies include getting feedback on written materials and using "teach-back" when talking with others.

Helen's presentation was rich with tools that medical communicators can use. She reinforced the basic principle of "know your audience." One way to do this is by asking, "as a result of communicating this message, what do I hope or expect that the intended audience will know, do, and feel?" Helen stressed that good writing takes a team. Members should include a content expert who is responsible for the accuracy of information, along with a writer who uses plain language strategies and is an unceasing advocate for readers. Equally important on the writing team are reviewers representing health literacy needs of the audience. Each membership role is critical to the whole.

Helen added that the writer has added responsibilities of managing the modes of expression, developing plain language (not as simple as it sounds), and "weighing the ethics of simplicity." She offered examples of the skill and nuance necessary to translate complex scientific information into clear and simple directions. Helen gave a simple illustration: instructions for taking medicine may include the word "once" (as in "take one tablet once a day"). In English, "once" means "one time"; in Spanish, however, "*once*" means "eleven." Misunderstanding this everyday word could be the cause of serious medical consequences.

Most importantly, Helen invited the audience to apply our unique abilities as medical communicators. She urged everyone to get involved—our skills have the power to benefit so many.[b] "Writers can make a huge difference!" In the spirit of

Walter C. Alvarez, who went above and beyond instead of donning his slippers at retirement, Helen spurred AMWA members to be Health Literacy Heroes, always remembering that our words matter.

Notes

[a]Helen Osborne holds a Master of Education and is an Occupational Therapist Registered/Licensed. She is President of Health Literacy Consulting (www.healthliteracy.com) and producer and host of the podcast series "Health Literacy Out Loud" (www.healthliteracyoutloud.com). She can be reached at: helen@healthliteracy.com

[b]According to the US Department of Education, Institute of Education Sciences, 2003 National Assessment of Adult Literacy, roughly a third of adults have only very basic or below basic health literacy, with nearly 15% having entirely inadequate comprehension. US Department of Health and Human Services, Office of Disease Prevention and Health Promotion. America's Health Literacy: Why We Need Accessible Health Information. https://health.gov/communication/literacy/issuebrief/. Published 2008. Accessed December 2, 2017.

Warm thanks go to Marjorie Winters for her essential collaboration.

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John P. McGovern Award

The award, named in honor of John P. McGovern, is presented to a member or non-member of AMWA to recognize a preeminent contribution to any of the various modes of medical communication. The McGovern Award is presented during AMWA's Medical Writing & Communication Conference. The 2017 recipients are Steven Woloshin, MD, MS, and Lisa M. Schwartz, MD, MS.

Communicating Benefit and Harm: Avoiding the NNE (Numbers Needed to Exaggerate)

By Steven Woloshin, MD, MS[1]; Lisa M. Schwartz, MD, MS[1]; Emma Woloshin[2]

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The McGovern Award is especially meaningful because it comes from a group of writers committed to fairly and effectively communicating complex medical information to the people who need it. We know how hard that can be.

Our work has focused on helping people make good decisions.[1] What we have learned over the past 20 years boils down to this simple model: people need the facts and clarity about their values to make good decisions. This model falls apart without the facts. Unfortunately, there are a lot of bad facts.

Consider a Sloan-Kettering Cancer Center ad that says, "The early warning signs of colon cancer: You feel great. You have a healthy appetite. You're only 50." The message is meant to persuade people to get screened—not to inform them. This kind of scary message undermines peoples' resilience. Don't trust how you feel. If you feel healthy, you are probably sick. Yet most people who feel great, have a healthy appetite, and are 50 do not have colon cancer and will not get it. This ad—like many exaggerated messages—uses hype to generate fear to encourage some action.

Exaggerated messages also use hype to generate hope. For example, the president of one of the country's major cancer centers told CNBC, "It's actually plausible that in 10 years we will have curative therapies for most if not all human cancers."[2] That was in 2015. While it hasn't happened yet, maybe it will in the next 8 years. But that seems pretty unlikely. Hopefully the cancer center president is more accurate than *U.S. News and World Report*. It predicted the end of heart disease back in 2003; as we all know, it's still here.

Many exaggerated messages use both hope and fear to promote their product. Mount Sinai Medical Center advertises "An aneurysm is a death sentence. We have the power to grant you a pardon." But in fact, most aneurysms are not a death sentence; the typical aneurysm found by screening is small and unlikely to cause problems, let alone death. Unfortunately, a small number of people who go for surgery will be hurt, and some may die, so that is hardly a pardon.

Given this state of exaggeration, consumers, clinicians, journalists, and medical writers need to develop a healthy skepticism to help their readers see through and push back

against hype.[3-5] This includes a commitment to clearer, more complete, and transparent communication. Many messages like the foregoing examples could be improved by presenting numbers. But the numbers need to be presented fairly. All too often, numbers are used to amplify exaggeration—sometimes deliberately, but often inadvertently, because writers and editors may not understand basics statistics or the principles of how to communicate them.

Most people have heard of the NNT—the number needed to treat. Our talk is about another concept, NNE—numbers needed to exaggerate. That is, how common statistics, when misunderstood and misused (or intentionally manipulated), exaggerate the magnitude of a difference to make treatments seem better or safer than they really are. Unlike many problems in medicine, this is pretty easy to fix. With just a little background, you can see through misleading statistics and help your readers see through them. In this paper, we review 3 NNEs: changes in risk, odds ratios, and survival statistics and cancer screening.

Changes in Risk

Figure 1 is a medical journal advertisement for Evista (raloxifene), an osteoporosis drug, which claims that "Evista significantly reduces clinical vertebral fracture risk at one year—68% reduction risk versus placebo."

While it's easy to criticize drug ads, you can actually learn a lot from them. This one does some things right. It is clear about the outcome that the drug affects: clinical vertebral fractures, or broken bones in the spine. Some vertebral fractures are silent—a person doesn't feel anything and they only know about the fractures because of an x-ray (or might notice a gradual loss in height). Clinical fractures are different. They hurt. Preventing painful fractures is important. The ad is also clear about the time frame: this is the benefit of the drug at 1 year.

The ad, however, is not clear about the most prominent element—the 68%. That's a big number. It invites people to assume the drug works very well. How big is the benefit of Evista? You can't tell from the ad. The impressive "68% reduction" is meaningless unless you know 68% lower than what. It's like a sale. Imagine a store advertises a 68%-off sale on selected items. Would you drive hours to go to the store? Yes—if Ferraris were on sale. Not if packs of gum were on sale. A sale on a Ferrari saves you tens of thousands of dollars. A sale on a pack of gum saves you pennies. To decide how good a sale is, you need to know the regular price of the selected items. 68% of *what* matters.

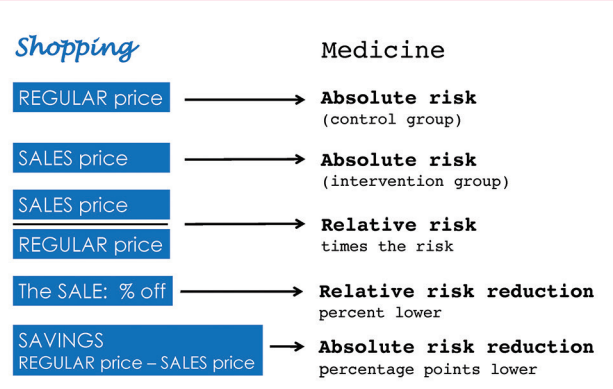
The math behind the benefit of the drug is the same as a sale. The difference is the units. For a sale, you save dollars. For example, if the regular price is $100 and the sales price is $90, how much do you save? The savings is just the regular price minus the sales price: $100 – $90 = $10. For a drug, you save percentage points of risk. Let's take a look at the science behind the Evista ad. In the trial, about 4500 postmenopausal women with osteoporosis at high risk for fractures were randomized to receive either Evista or a placebo. The primary outcome was the percentage of women who had a clinical vertebral fracture at 1 year. In the placebo group, 19 out of 2290 women had a fracture, which divides out to be 0.83%. This is called the absolute risk in control group (or base rate or event rate). That's the regular price. In the Evista group, 6 out of 2259 women, or 0.27%, had a fracture. That's the sales price. How much do you save? The savings is the regular price minus the sales price: 0.82% – 0.27% = 0.56%. The savings is called the absolute risk reduction. Evista lowered the risk of a vertebral fracture by 0.56% percentage points compared to placebo over 1 year. In other words, if a thousand women with osteoporosis at high risk for a fracture took Evista instead of placebo for 1 year, about 6 fewer would have a vertebral fracture.

Figure 1. Evista advertisement as it appeared in the medical journal (panel A). Panels B–D are altered to highlight the absolute risk reduction, the benefit of Evista at 3 years (the prespecified time frame), and Evista's major serious harm, increased risk of thromboembolic events.

The same data is more typically presented as a relative, not absolute, difference. The relative risk is a ratio: the absolute risk in the drug group divided by the absolute risk in the control group. The relative risk for Evista is 0.27% ÷ 0.83% = 0.32. The risk of vertebral fracture for women taking Evista was 0.32 times that of women taking placebo. Because of the clunky language, we usually talk about "percent lower" (the sale). The "percent lower" or "percent off"

(like a sale) rather than "times the risk" (have you ever heard a sales clerk say, this tie is on sale, it's only 90% of the regular price?). equals 1 minus the relative risk. For Evista, that's 1–0.32 = 0.68. That's why the ad says "68% lower." It's a "68% off sale" on your vertebral fracture risk. Evista lowered the risk of vertebral fracture at 1 year by 68% compared to placebo: 0.27% vs 0.83%. The analogy between a sale and the medical risk reduction jargon is shown in the Box.

Box. Shopping-to-Medicine Analogy Glossary.



The foregoing example shows that the same data can be expressed in many different ways. Different formats have different psychological impact, a phenomenon called framing.[6-8] It is a well-described finding that the relative risk reduction feels much more impressive than corresponding absolute risk reduction, especially when the outcome is uncommon, as illustrated in Table 1. The Evista ad agency knew what they were doing. Compare 68% lower versus 0.56% lower (Figure 1). Which will sell more Evista? It is now widely accepted that showing the absolute risks for both groups is the fairest way to present the data.

Table 1. Comparison of relative and absolute risk reductions illustrating how the relative reduction increasingly overstates the difference as the events become rarer.

	Absolute Risk of Death at 1 Year		Risk Reductions		NNT
	Placebo	Drug	Relative 1–(Drug/Placebo)	Absolute Placebo–Drug	1 Placebo–Drug
Trial 1	30%	10%	67%	20%	5
Trial 2	3%	1%	67%	2%	50
Trial 3	0.003%	0.001%	67%	0.002%	50,000

Another commonly used statistic is the NNT—the number needed to treat to prevent 1 outcome. It is simply the reciprocal of the absolute risk reduction. For Evista, the absolute risk reduction was 0.56% (ie, about 6 fewer clinical vertebral fractures over 1 year per 1,000 women). The NNT is just 1 ÷ 0.56%, which works out to 178. That means that 178 women have to take Evista for 1 year to prevent 1 vertebral fracture. Table 1 also includes the NNT to illustrate that as events become less common, the NNT increases.

Unfortunately, reporters often do not follow the recommendation to present absolute risks. Not long ago, all top 10 circulation US newspapers and *Time* magazine's lead story covered the World Health Organization's report linking consumption of processed meats to colon cancer. *USA Today*'s headline ("Hot dogs, bacon, processed meats linked to cancer") and results reporting ("increases the risk of colorectal cancer by 18%") were typical.[9] Just like the Evista ad: giving the sale without the regular price (18% off what?). To their credit, the *USA Today* story translated the type and amount of processed meat that raised risk (e.g., 1 ¼ hot dogs a day), a statistic we call—with apologies to the NNT—the "number needed to eat." But the story did not give the basic information needed to decide whether the risk of eating processed meats was big or small. The story should have reported the absolute risks, such as, "meat consumption increases the risk of colon cancer over your lifetime from 5% to 6%."

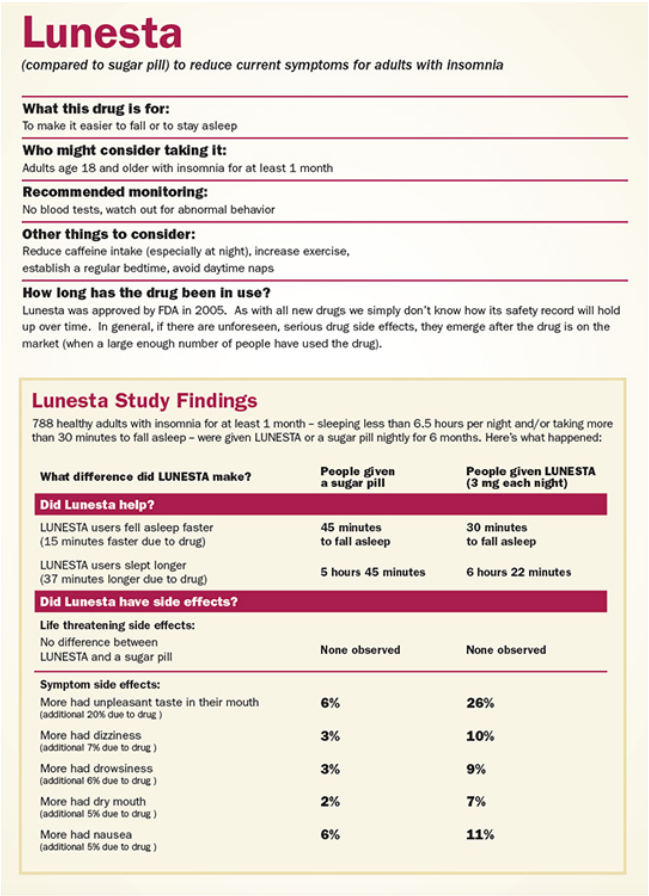
What about harms? While some drugs have benefits, all have harms. Let's return to the Evista ad. Prescription drug ads are required to present side effects. Accordingly, the bottom of the ad reads: "Evista is associated with an increased risk of venous thromboembolic events (potentially fatal blood clots)." The presentation format is unfair because it magnifies the benefit (68% reduction in big font without the small absolute risk reduction) but minimizes the harm (small font, no numbers, buried in a long list readers skip over).

To be fair, benefits and harms should be similarly prominent and quantified. To do this, we read the medical journal article that was the basis for the Evista ad and were surprised to see that the trial lasted 3 years.[10] Why would the ad present data for just 1 year rather than the full 3 years? Figure 1 shows why: the risk reduction was lower (ie, the "sale" got less impressive). The ad should have read "Evista reduced clinical vertebral fractures by 41% at 3 years," not "68% at 1 year." Perhaps the advertising agency wanted to highlight the more impressive 1-year results.

If the ad agency quantified the harms the same way as the benefits, the ad would read "Evista increases thromboembolic events 210% versus placebo." Many women would probably think twice about taking Evista. But wait a minute. Remember the advice: present absolute risks. This is just as true for harm as benefit. You can't know what "210% more"

means unless you know 210% more than what. The risk of thromboembolic events in the placebo group—the "regular price"—was low: 0.35%. Consequently, Evista increased the risk from 0.35% to 1.1%, which is a much less dramatic difference.

To make good decisions about prescription drugs, people need balanced benefit and harm data. One morning over breakfast, the nutrition facts box—the consistent, structured data table required on all food packaging—inspired us. If we can do that for Cocoa Krispies, why can't we do that for Evista? Not give the ingredients, but present the data on how well it works. Thus, we created the Drug Facts Box: a 1-page summary of benefit and harm data (absolute numbers) for each indication of a drug (Figure 2). A series of studies demonstrates that most consumers understand the Drug Facts Box and that it improves decision-making.[11-15] In a nationally representative randomized trial (n = 231), 68% of people randomized to see direct-to-consumer advertisements with drug boxes chose the objectively better of 2 heartburn drugs, compared with 31% of people seeing standard advertisements.[13] Based on our research, the FDA's Risk Communication Advisory Committee voted unanimously in a nonbinding recommendation that the FDA "should adopt the Drug Facts Box format as its standard for communicating essential information about pharmaceuticals" (in the drug label for prescribers, advertisements, and other consumer materials). After *The New York Times* reported on our Advisory Committee presentation, 2 senators drafted a bill that was incorporated into the Affordable Care Act, Section 3507, encouraging the FDA to adopt the Drug Facts Box format. Although the FDA replicated our research findings, they decided not to implement Drug Facts Boxes. Fortunately, *Consumers Reports*,[16] *The New York Times*,[17] and National Public Radio[18] have featured drug boxes. Recently, the UK Academy of Medical Sciences issued a report identifying the Drug Facts Box as an exemplar for the European Union and the European Medicines Agency to draw on to improve the content and accessibility of drug information for the public.[19] So, we're hopeful that at least Europe may adopt Drug Facts Boxes.



Lunesta

(compared to sugar pill) to reduce current symptoms for adults with insomnia

What this drug is for:
To make it easier to fall or to stay asleep

Who might consider taking it:
Adults age 18 and older with insomnia for at least 1 month

Recommended monitoring:
No blood tests, watch out for abnormal behavior

Other things to consider:
Reduce caffeine intake (especially at night), increase exercise, establish a regular bedtime, avoid daytime naps

How long has the drug been in use?
Lunesta was approved by FDA in 2005. As with all new drugs we simply don't know how its safety record will hold up over time. In general, if there are unforeseen, serious drug side effects, they emerge after the drug is on the market (when a large enough number of people have used the drug).

Lunesta Study Findings

788 healthy adults with insomnia for at least 1 month – sleeping less than 6.5 hours per night and/or taking more than 30 minutes to fall asleep – were given LUNESTA or a sugar pill nightly for 6 months. Here's what happened:

What difference did LUNESTA make?	People given a sugar pill	People given LUNESTA (3 mg each night)
Did Lunesta help?		
LUNESTA users fell asleep faster (15 minutes faster due to drug)	45 minutes to fall asleep	30 minutes to fall asleep
LUNESTA users slept longer (37 minutes longer due to drug)	5 hours 45 minutes	6 hours 22 minutes
Did Lunesta have side effects?		
Life threatening side effects: No difference between LUNESTA and a sugar pill	None observed	None observed
Symptom side effects:		
More had unpleasant taste in their mouth (additional 20% due to drug)	6%	26%
More had dizziness (additional 7% due to drug)	3%	10%
More had drowsiness (additional 6% due to drug)	3%	9%
More had dry mouth (additional 5% due to drug)	2%	7%
More had nausea (additional 5% due to drug)	6%	11%

Figure 2. Drug Facts Box for Lunesta (eszopiclone).

Odds Ratios

Our interest in odds ratios began when we heard Ted Koppel say on Nightline: "Last night we told you how the town of Jasper, Texas, is coming to terms with being the place where a black man was dragged to his death behind a truck by an avowed racist. Tonight, we're going to focus on a group of men and women who are, almost by definition, humanitarians, who would be shocked to learn that what they do routinely fits quite easily into the category of racist behavior." Who were these racists? We were shocked when Koppel's guest, the Surgeon General of the United States, said these racists were American physicians. This story was big news, reported by every major media outlet.

We took a close look at the research article behind the news, a *New England Journal of Medicine* article titled "The Effect of Race and Sex on Physicians' Recommendations for Cardiac Catheterization."[20] The article stated that women were referred for catheterization less often than men (odds ratio = 0.6) and that black people were referred less often than white people (odds ratio = 0.6). The typical news story reported "Blacks and women with chest pain are 40% less likely than whites or men to be referred by physicians for cardiac catheterizations." Where does the 40% come from? It's the "percent lower" format, in this case, calculated as 1 – 0.6 = 0.4, or 40% lower. To know what this means, you need to know that the percent of white people or men referred for catheterization was 91% (reported in Table 4 in the article, not in the abstract). To calculate the percent of black people or women referred, you could take "40% off" of 91%, which is 55%. But Table 4 reported that 85% of black people or women were referred. What happened? Odds and odds ratios are not the same as risks and relative risks: 40% lower odds cannot be assumed to be a 40% lower risk.

Risk and odds are different ways to measure chance. A risk is a ratio of occurrence to the whole—a proportion—that ranges from zero to 1. The risk of heads in a flip of a coin is 1 over 2, or 50%. The risk of getting a "1" in a roll of a die is 1 over 6, or 17%. Odds are a ratio of occurrence to non-occurrence. The odds of getting heads in a flip of a coin is 1 over 1, or 1. The odds of getting of getting a "1" in a roll of a die is 1 over 5, or 20%.

In the *New England Journal of Medicine* article, which stimulated the extensive news coverage, including Koppel's show, 85% of black people and 91% of white people were referred for catheterization.[20] The corresponding odds are 5.5 and 9.6. The odds ratio is merely a ratio of odds: 5.5/9.6 = 0.6. The relative risk, however, is 85%/91% = 0.91. It is highly doubtful the finding "blacks were 8% less likely to be referred" would have triggered a special episode of Nightline. One way to correctly report the odds ratio finding is "the odds that black people or women with chest pain were referred for cardiac catheterization are 40% lower than those of white people or men." Most readers are unlikely to recognize the subtle difference between odds and risks, so this rewrite is unlikely to help. The simplest solution is to present the absolute risks in each group. The study shows 85% of black people or women are referred compared with 91% of white people or men.

But even this statement is not right. This study involved 722 physicians attending a primary care meeting. Each physician saw a randomly chosen video of an actor pretending to be a patient with chest pain and was asked "would you refer this patient for cardiac catheterization?" The results are hypothetical answers about actors. The main results looked at white versus black people and women versus men. The results further broken down by actors were: 91% of white men were referred, 91% of black men, 91% of white women, and 79% of black women. How can this be racism or sexism if white and black men are referred at the same rate and white men and women are referred at the same rate? In fact, only 1 of the 8 actors was referred at a markedly different rate—the older black woman. This raises more questions; was it about how she read the script or something else?

The follow-up to this story is that the *New England Journal of Medicine* published our critique as a full article,[21] with an editorial note taking responsibility for the over-interpretation.[22] Many newspapers and the Associated Press printed corrections. Ted Koppel, however, according to the show's producer, stood by his story and did not issue a correction. The take-home message is that odds ratios should be translated into relative risks. As a rule of thumb, odds ratios will only differ importantly from relative risks when the base rate is 20% or higher. But the most important message is to find, and report, absolute risks.

Survival Statistics and Cancer Screening

If there were an academy award for the most misused statistic, the winner would be survival statistics for cancer screening. Sadly, countless examples illustrate how survival statistics are misused. A few years ago, we published a critique[23] of a prototypical example, the Komen Foundation's "breast cancer awareness month" campaign ad, which says, "Early detection saves lives. The 5-year survival rate for breast cancer when caught early is 98%. When it's not? 23%" (Figure 3). The enormous difference—98% versus 23%—makes you feel it would be crazy not to have a mammogram. The idea that early detection saves lives is intuitively obvious. The logic is the more people screened, the more people diagnosed with early cancer, and early cancers have higher survival rates than later-stage cancers; therefore, fewer people are dying from the disease. This is a giant leap of faith.

To understand why, the first step is to understand the difference between survival and mortality.[24,25] Survival is the number of people alive some number of years after diagnosis divided by the number of cancer patients. If 980 out of 1,000 cancer patients are alive 5 years after diagnosis, 5-year survival is 98%. Mortality is the number of people who died some

Figure 3. Komen Foundation breast cancer awareness ad.

years later divided by the entire population (not just cancer patients). If 10 out of 1,000 people died 5 years after the study, mortality is 1%. Mortality typically comes from a randomized trial.

In the context of screening, impressive 5-year survival statistics do not necessarily mean lower mortality—that is, that any lives have been saved. Survival statistics are about what happens after the time of diagnosis, and screening changes when a cancer is diagnosed. Without screening, breast cancers are only detected when a tumor is big enough to feel. With screening, cancers can be detected much earlier, often when the tumor is much too small to feel. Five-year survival is the proportion of women alive 5 years after the cancer is diagnosed. Even if the cancer was untreated, 5-year survival improves with screening just because the clock starts earlier. It is, of course, possible that earlier treatment may help, but that is not the issue here. The issue is that simply comparing survival between screened and unscreened women is inherently misleading.

Figure 4 shows 2 reasons for the confusion.[1] First, imagine 100 women who do not undergo screening and are diagnosed at age 67 when they feel a breast lump (Figure 4A). The black line represents the survival time, or how long they live past the time of diagnosis. Assume the women die of breast cancer at age 70. For this unscreened group, the 5-year survival is 0%: no woman survived 5 years past diagnosis. The second arrow shows what happens to exactly the same women with screening. Because mammograms can pick up cancers earlier, the women are diagnosed at age 63. Again, assume the women still died at age 70, 5-year survival would be 100% because all women lived more than 5 years past diagnosis. Yet none lived even a second longer. This is called lead time bias, and it is a mathematical certainty whenever you diagnose disease earlier.

Dr Barnett Kramer, Director of the National Cancer Institutes' Division of Cancer Prevention, explains lead time bias with an analogy to the old Bullwinkle cartoon.[23] In a recurring segment, Snidely Whiplash ties Nell Fenwick to the railroad tracks to extort money from her family. She will die when the train arrives. Kramer says that lead time bias is like giving Nell binoculars. She'll see the train when it's further away, but it will hit her at exactly the same moment. She just lived longer with the diagnosis of "train." Lead time bias does not mean that screening cannot work. It just means that comparing survival for screened and unscreened populations is inherently misleading.

Figure 4B shows the second reason why comparing survival for screened and unscreened groups is misleading. Imagine a large city where no one undergoes screening. Say there are 1,000 women with breast cancers diagnosed because they felt a lump. After 5 years, 200 women are alive and 800 are dead. The 5-year survival is 20%: 200 women alive 5 years after diagnosis divided by 1,000 with breast cancer. Imagine exactly the same city, except women undergo screening. But now an additional 4,000 women are diagnosed because a mammogram found a cancer—none of which were destined to progress. That means all 4,000 will still be alive 5 years later. What would this do to 5-year survival? The number of women alive 5 years after diagnosis is 4,200 (4,000 found by screening + 200) out of 5,000: Five-year survival increased from 20% to 84%, but the same number of women died (800). This scenario is "overdiagnosis"—the detection of cancer that would never progress to cause symptoms or death. Overdiagnosis does not mean screening cannot work or that screen-detected cancers are never dangerous. It just means that comparing survival for screened and unscreened populations is inherently misleading.

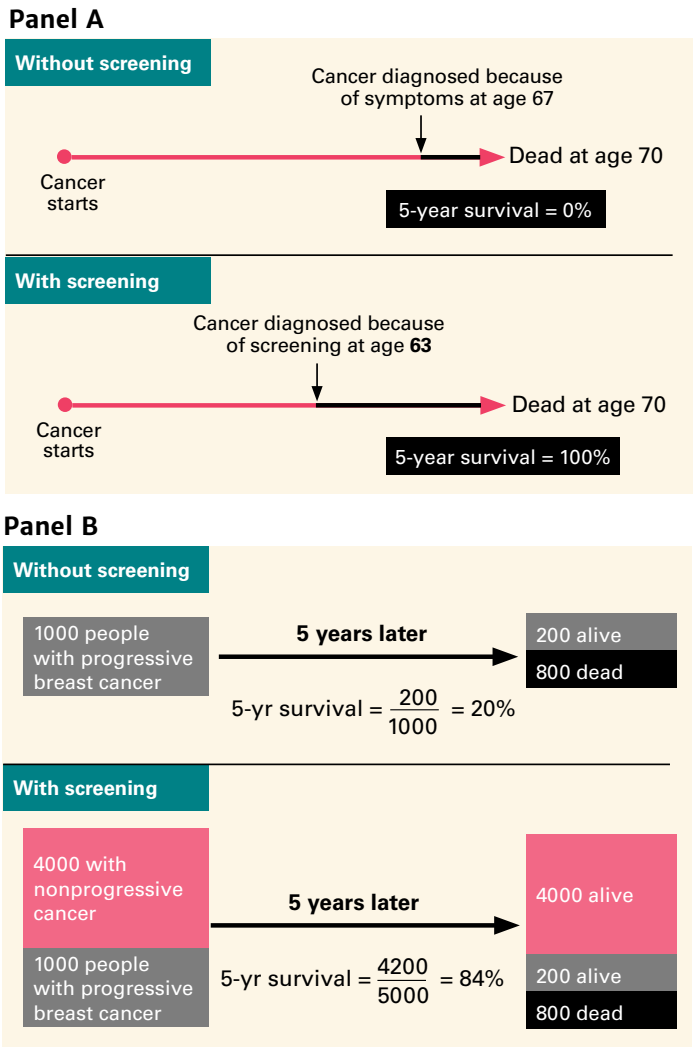


Figure 4. How early detection can result in higher 5-year survival but no real improvement. Panel A illustrates lead time bias. Panel B illustrates overdiagnosis.

Because lead time and overdiagnosis biases cannot be disentangled, experts have long pointed out that, in the context of screening, survival statistics are meaningless. What is meaningful—and what matters a lot—is whether screening changes how many people die from the cancer. The benefit of breast cancer screening looks more like this. Imagine 1,000 50-year old women over 10 years. Five will die from breast cancer without screening versus 4 with screening. So, 1 out of 1,000 women avoids a breast cancer death because of screening.

Conclusion

Medical writers have a very important but very hard job. Effectively communicating complex medical information to the public is crucial. An uninformed public is especially vulnerable to misleading information, which can lead to bad decisions, wasted resources, and harm. Remembering the numbers needed to exaggerate will help you do the opposite: present fair and transparent facts that lead to informed decisions.

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Conflict of Interest Statement: Drs Schwartz and Woloshin have served as medical experts in testosterone litigation and were the cofounders of Informulary, Inc, a company that provided data about the benefits and harms of prescription drugs, which ceased operations in December 2016. Ms Woloshin has no conflicts to report.

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TECH TOOLS TO HELP YOU RUN YOUR FREELANCE BUSINESS

Speaker
Monica Nicosia, PhD
Nicosia Medical Writer LLC, Bryn Mawr, PA

By Mia DeFino, MS

This session sought to help freelances identify what tech tools are available that can help them with routine tasks in their business, how to research potential tech tools, and how to decide which tools are the best for them.

Monica Nicosia is a freelance medical writer in Bryn Mawr, Pennsylvania, who works from her home office and focuses on writing scientific manuscripts, continuing medical education and patient education materials, and health technology assessments. She previously collected data on the tech tools that freelances use via a survey administered in 2016 and published the results in the **Fall 2017** issue of the *AMWA Journal*. Additional details on different software types are in the slides from this session, which are available at **https://c.ymcdn.com/sites/www.amwa.org/resource/resmgr/Conference/2017/SessionRoundtableHandouts/TechToolstoHelpyouRunYourFre.pdf**.

The basic functions in Nicosia's business are shown in Figure 1. She said that these functions need to be optimized for efficiency so that one can reduce time spent on nonbillable tasks.

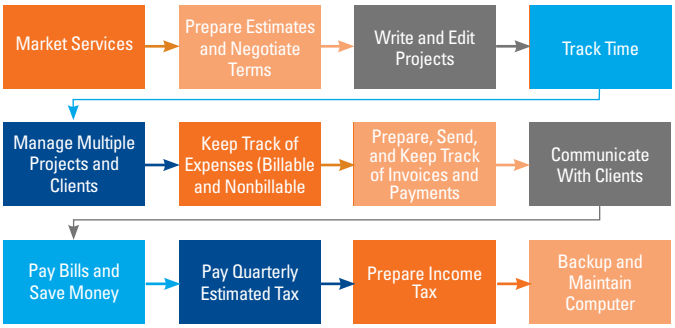

Figure 1. Basic Freelance Business Functions

At different times in her freelance business, Nicosia has needed to re-evaluate the tech tools her business needed and used; she used the following 4 criteria to narrow down which tools were the best fit for her: price, ease of use, features (eg, auto bank/credit card feeds, easy reports, summaries), and interconnected functions (eg, time tracking, invoicing, estimates). She encouraged anyone evaluating tech tools for their freelance business to take advantage of free trials before signing up and paying for extraneous services; you could find that you do not need the most elaborate version and can do fine with a basic subscription or even a free version if one is offered.

Nicosia offered several considerations for deciding to incorporate new tools into a business practice:

- Which tasks could be made more efficient?
- What are your "must-have" and "nice-to-have" features?
  - Ease of use
  - Potential time saving
  - Ease of integration into work routines
- Should you use computer-based software or a web-based application?
  - Do you need to be able to access it via mobile app?
  - Accessibility for your accountant, if you use one
  - Don't splurge for extra features you won't use
  - Take advantage of free trials
- What are the system requirements (for computer-based software)?
- What is the cost?

She recommended that freelances interested in researching tech tool options should perform Google searches for product reviews and look at blogs, computing magazines (eg, PCmag.org), and online resources targeted at small businesses and/or freelances. She also suggested taking advantage of an AMWA member benefit by asking on AMWA Engage about the tool in which you are interested. Recommendations from colleagues and friends may also be helpful. "It is a balance between being thorough and being time conscious. Do not take forever to decide as your time is valuable and, if you find something better later on, you can always switch."

Surprisingly, Nicosia found that many freelances do not use technology to help them run their businesses; they instead use paper-based systems. Some reasons for this may include a lack of comfort with using new software/apps, satisfaction with their non-tech system, lack of trust of cloud-based applications, and a lack of awareness of time-saving, low-cost tools. However, "as freelances and medical writers we have to be computer literate; we don't have to be on the cutting edge, but we also shouldn't lag too far behind," she pointed out. Nicosia encouraged freelances to go for the middle ground and, when it is affordable and convenient, take advantage of well-tested tech to help you be more efficient.

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WHAT YOU SHOULD KNOW ABOUT PR AND MARKETING

Speakers

Hilary Graham, MA

Senior Manager, Scientific Marketing, Luminex Corporation, Austin, TX

Erin L. Boyle

Senior Editor, Remedy Health Media, Arlington, VA

Katrina Burton, BA

Senior Communications Specialist at The University of Texas MD Anderson Cancer Center, Houston, TX

By Rajalaxmi Natarajan, PhD

This session sought to provide insights into how marketing and public relations (PR) in the sciences operate and to offer career guidance for medical writers interested in transitioning to these fields. The presenters were a marketer with a biotech company and 2 PR professionals employed with a media agency and cancer research center.

A Marketer's Perspective

Hilary Graham launched the session with a basic definition of marketing as an activity that creates awareness about a product or a service with the goal of either selling a product or a service or changing behavioral patterns of the consumer. She said that marketing refers to paid advertising such as billboards, TV, radio, magazines, newspaper or digital ads, and exhibits at conferences and trade shows. She added this is a rapidly evolving field and that marketers need to constantly experiment with different formats, styles, and types of content collaterals. Nowadays, marketers have a treasure trove of real-time analytics data to identify website and social media trends that help them customize future marketing campaigns.

Graham mentioned social media monitoring as one of the latest trends to track and improve the consumer's perception of a product, service, or organization. Concise and visual content such as infographics and videos are being increasingly preferred. Finally, she advised marketers to shift the focus from the organization, product, or service to the consumer and to leverage the power of storytelling.

Insights from a PR Professional

Erin Boyle initiated the discussion on PR by defining it as strategic communications that mutually benefit an organization, individual, product, or service and its audience by creating brand awareness and shaping public perception.

She explained that, unlike marketing, PR is "earned" media—an organization, individual, product, or service has to accomplish something impressive or outstanding to receive attention from media organizations in the form of press releases, press briefings, media stories, or on-air coverage.

These days, digital storytelling platforms such as blogs, videos, and social media are also being used increasingly in the PR arena. Boyle explained that the trend in PR is toward cultivating closer relationships with journalists, journal editors, and social media influencers by sharing personalized pitches in lieu of press releases.

Advice on Executing an Effective PR Strategy

Katrina Burton shared her insights on how to build relationships with key stakeholders to execute an effective PR strategy. She said that PR is a fast-paced enterprise wherein potential crisis situations can occur unexpectedly. Thus, the key to a PR professional's success is to continually invest time and effort to build trusting relationships with key internal and external stakeholders and collaborators who can help source the best newsworthy stories and work with you when a story is breaking.

For medical or scientific organizations, external stakeholders may include local and national media reporters, producers, consumers, patient families, disease associations, peer-reviewed journals, and bloggers. Some large organizations work collaboratively with external PR agencies to maximize their reach to national media outlets. Internal stakeholders would be physicians, surgeons, clinical staff, researchers, social workers, and administrative and fundraising staff members who help source potential stories or are content experts. Burton considers other internal marketing teams that handle social media, websites, video production, and other creative services as her collaborators.

Websites

- Content Marketing Institute
- Hubspot Academy
- Lynda.com
- Life Science Marketing Radio
- Cision—a global media database
- EurekAlert!—online science news service

Conferences

- Content Marketing for Life Sciences
- Science Marketing Lab

Associations

- Life Science Marketing Society
- Public Relations Society of America

Books

- *Persuading Scientists* by Hamid Ghanadan
- *Catalytic Experiences* by Hamid Ghanadan

She said that, when done correctly, PR builds respect and trust among consumers such that they eventually become ambassadors of your brand.

Conclusion

All the presenters noted that while the audience, presentation format, and goal of scientific marketing or PR collaterals may appear to be entirely different from typical documents prepared by a medical writer (eg, a scientific manuscript, a grant, or an FDA regulatory application), they all need to be persuasive in style and have a compelling message.

Their parting advice to medical writers interested to transitioning to scientific marketing and PR was to learn the best practices, volunteer for assignments outside of their normal job duties, and leverage their current network of contacts.

Dr Rajalaxmi Natarajan is a Scientific Research Web Writer at Texas Children's Hospital and Baylor College of Medicine in Houston, TX. Her role is to translate the latest scientific advances for the lay public.

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THE TICKING CLOCK: MAINTAINING SANITY FOR QC

Speakers

Amanda Pennington, BS
Quality Reviewer and Medical Editor, Whitsell Innovations, Inc.
Oxford, PA
Ashley Khan, PharmD
Medical Writer and Consultant, Whitsell Innovations, Inc.
Pittsboro, NC

By Katelyn Le, MS

Quality control (QC) is an important step to finalizing regulatory documents, but to perform an efficient QC review, the document writer and QC specialist must coordinate carefully.

Quality reviewer Amanda Pennington and medical writer Ashley Khan discussed how both parties can work together to save time and meet deadlines without threatening sanity or office relationships. Whether your QC process involves an in-house department, an outside company, or the editor in the next cubical, these tips can help you maintain sanity.

What Is QC?

Pennington was quick to say that QC is not proofreading or grading. Rather, QC is a "100% data check," focusing on consistency within and across documents and on accuracy. Do the data in the document match the data in the source? QC may also involve ensuring consistency with a style guide and the use of clear and consistent wording.

Among many reasons to perform QC are to maintain credibility with clients, promote efficiency through an accurate, streamlined document, and avoid rejection. ("Who thinks the FDA is picky?" Pennington asked. The entire room raised hands.)

Tips for Writers

How can writers keep QC specialists from ripping their hair out? Khan suggested several tips for optimizing workflow.

The Writer "Do's"

1. Give QC specialists notice before sending a project their way, and update them immediately whenever timelines change.
2. Proofread the documents before you send them to QC. Also, annotate your documents. Flagging problem areas, hand calculations, or issues unique to the project ensures that QC specialists have all the information they need without having to hunt for it, saving them time and stress.
3. Have a formal handoff, and double-check that you send the QC specialists every source they may need.
4. Keep open communication, and reply to questions quickly.
5. Give feedback to improve future collaborations.

The Writer "Don'ts"

1. Don't whine, vent, or bash clients or coworkers. The QC specialist is not your therapist. Khan added, "Medical writing is a small world. You'll be amazed that you'll cross paths again."
2. Don't send sloppy documents, and don't just say, "They'll catch it in QC!" If some sections still need work but QC can't wait, the writer should explain this to the QC specialist.

Tips for QC Specialists

Pennington described the steps of her own QC process while emphasizing how to best support the writers.

The QC Specialist "Do's"

1. First, skim the document to find problem areas. Are any pieces missing? Did the writer leave annotations to point out any issues? Now is the time to ask the writer for any extra sources or information.
2. Invest in time-saving editorial software such as PerfectIt.
3. Start with the data check, both the numbers and their interpretation.
4. Ensure the summaries, synopses, and conclusions all agree.
5. Read the entire document thoroughly.
6. Check the "extras" such as links, lists of abbreviations, and references.

7. Do a final read-through and ensure your comments are clear, descriptive, and specific.
8. Return documents to the writer with feedback, and keep notes on the writer's feedback for you to use in future projects.

QC checklists or standard operating procedures are very helpful to frame your QC, Pennington added. Many companies have their own, or QC specialists can make their own. It may even be helpful to have a separate checklist for each client, especially if the client's preferences are unique or particular.

The QC Specialist "Don'ts"

1. Don't break timelines, and don't let timelines of different projects escape the time you budgeted them.
2. Don't marathon. "Powering through" a QC with a stressed, tired mind won't do anyone favors.
3. Don't be afraid to negotiate. If you're running up on a deadline, offer to return what you have reviewed so far so the writer can get started.

Tips for Working Together

Khan and Pennington also reminded both parties of how to communicate when working together:

- Leave concise, actionable comments. Don't be wordy or ambiguous. No one should lose time reading editorials or hieroglyphs to understand what changes to make.
- Be tactful and considerate, not offensive or offended! All parties are working under pressure.

"A message you are trying to send can be valuable," said Khan, "but the way it's framed makes the difference."

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CORE REFERENCE: A YEAR OF EXPERIENCE PREPARING CSRS FOR MULTIPLE AUDIENCES

Speaker
Aaron B. Bernstein, PhD
Principal Regulatory Writing Consultant, Aaron Bernstein Consulting, LLC, Millburn, NJ

By Hazel O'Connor, PhD

Aaron Bernstein has more than 25 years of experience in the pharmaceutical industry and was a principal in the development of the CORE Reference tool. CORE (Clarity and Openness in Reporting: E3-based) Reference was developed as a guide to assist medical writers in navigating relevant guidelines in creating content for Clinical Study Reports (CSRs) appropriate to today's studies. It was developed by the Budapest Working Group (BWG), a group of 9 authors, including both AMWA and EMWA members, to ensure representation in the United States and the European Union, with a collective 200 years' industry experience. The group was composed of 6 authors who had headed 1 or more Medical Writing departments, a statistician, a clinical pharmacologist, and an overall regulatory and strategic advisor.

The BWG recognized that the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E3 had not been updated since 1995; thus, they developed a users' guide explaining how to implement ICH E3 requirements as well as addressing some of the changes that have occurred in recent times with respect to technology, transparency, and privacy. CORE provides value-added enhancements to ICH E3 guidance. The separate mapping tool comparing ICH E3 sectional structure and CORE Reference sectional structure is provided in spreadsheet format and supports the utility of the CORE Reference. Stakeholders (representatives from Health Canada, a DIA CORE Review Task Force, an academic and principal investigator, and a patient advocate) provided comprehensive reviews, and the methods were published in a peer-reviewed journal in 2016.

Clarity

CORE Reference provides many suggestions intended to help make CSRs more clear and unambiguous. Suggestions to improve clarity include proper differentiation between removal of subjects from treatment versus the withdrawal of subjects from a study in Section 9.3.3. In some studies, subjects can discontinue treatment but remain in the study. In such cases, subjects may continue to contribute to safety analyses and analyses of long-term outcome, while subjects withdrawn from the study do not. CORE suggests that patients should be referred to as subjects, as it is easier to compare subjects between different trials. A table in Section 9.5 (Efficacy and Safety Variables) is provided to help differentiate between commonly confused statistical terms (eg, measurement, variable, end point). The table provides examples to illustrate the differences in these terms and is supplemented with references.

Openness

There have been numerous calls for transparency in recent years to foster trust and understanding of the data and to potentially improve the design of future trials; CORE encour-

ages transparency. This includes the suggestion that CSRs include references to posters and abstracts based on the study, as well as provide data cutoff dates for long-duration trials, trial registry information, and changes to analyses after unblinding (post-hoc analyses).

In 2015, the European Medicines Agency (EMA) released EMA policy 0070, which mandates clinical report disclosure (including CSRs). CORE Reference goes a long way in assisting the production of CSRs that protect the identity of trial participants as well as prevent the disclosure of commercially confidential information. Publicly disclosed CSRs are available online (**https://clinicaldata.ema.europa.eu/web/cdp/home**).

CORE Reference suggests that a CSR be considered as a single document with 2 uses. The primary-use CSR is for regulatory review; the review process must not be constrained. The secondary-use CSR comprises redacted CSR text and redacted selected appendices. Throughout CORE Reference are comments to indicate individual text portions that may potentially impact the secondary-use CSR and therefore should be considered for redaction.

In the spirit of openness, CORE Reference makes transparent the source of its text descriptions. An example page from CORE Reference is provided in Figure 1. Original ICH E3 text is identified by grey shade highlight, ICH E3 2012 Q&A text is identified by grey shade within a black box, and the newly added CORE Reference text is in plain text. The right margin comments section includes any background rationale, clarifications, and comments to supplement the CORE Reference text. Hyperlinked text provides links to approximately 100 source references (authoritative source documents, policy documents, guidelines, regulations, and peer-reviewed journal articles).

Reporting E3-based

Reporting E3-based refers to the fact that the CORE Reference remains consistent with the ICH E3 guidelines. Examples of how CORE makes suggestions for reorganizing sections are given for Sections 10 and 11, with the differences between ICH E3 guidelines and CORE reference highlighted in purple (Figure 2).

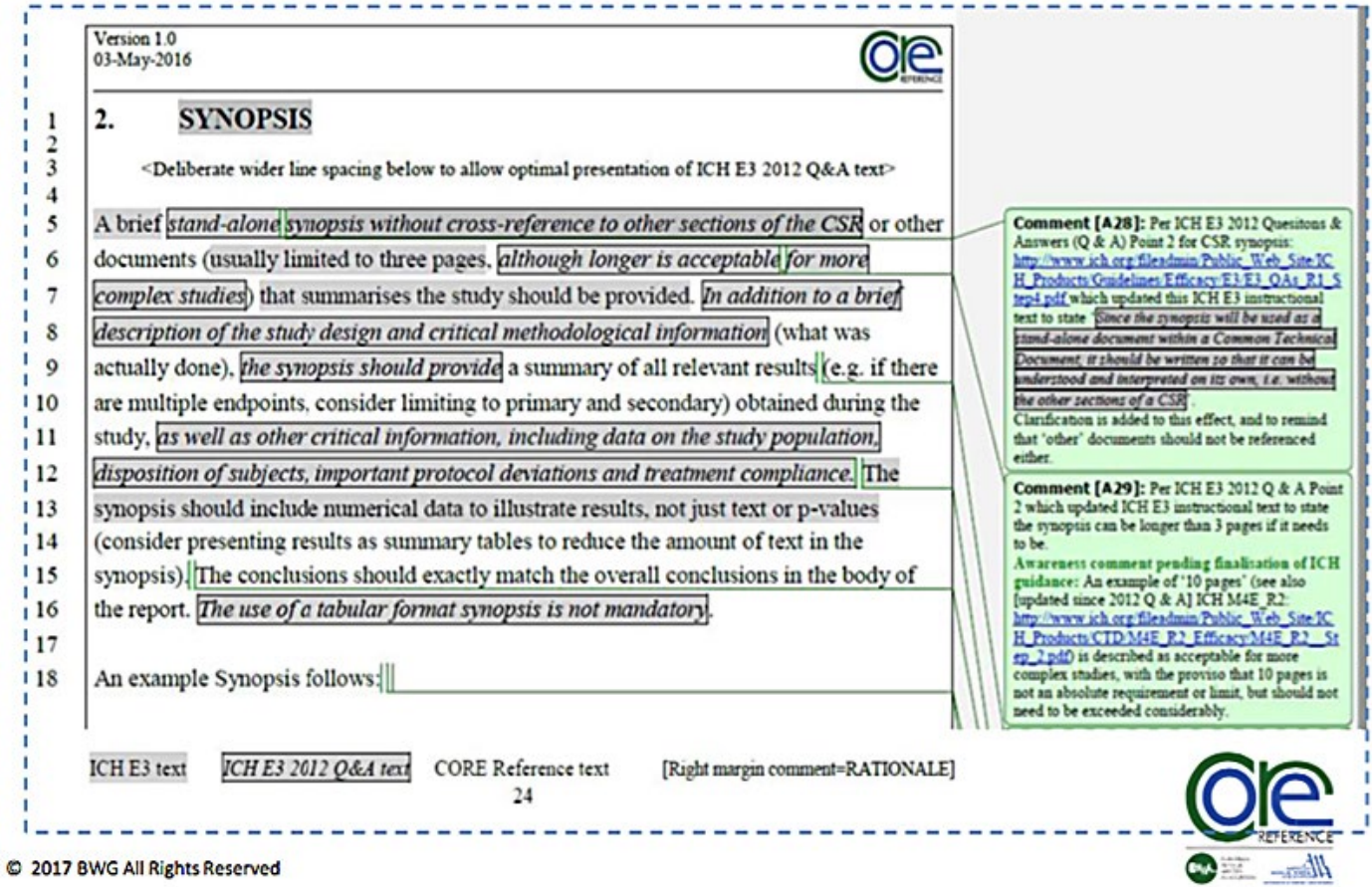
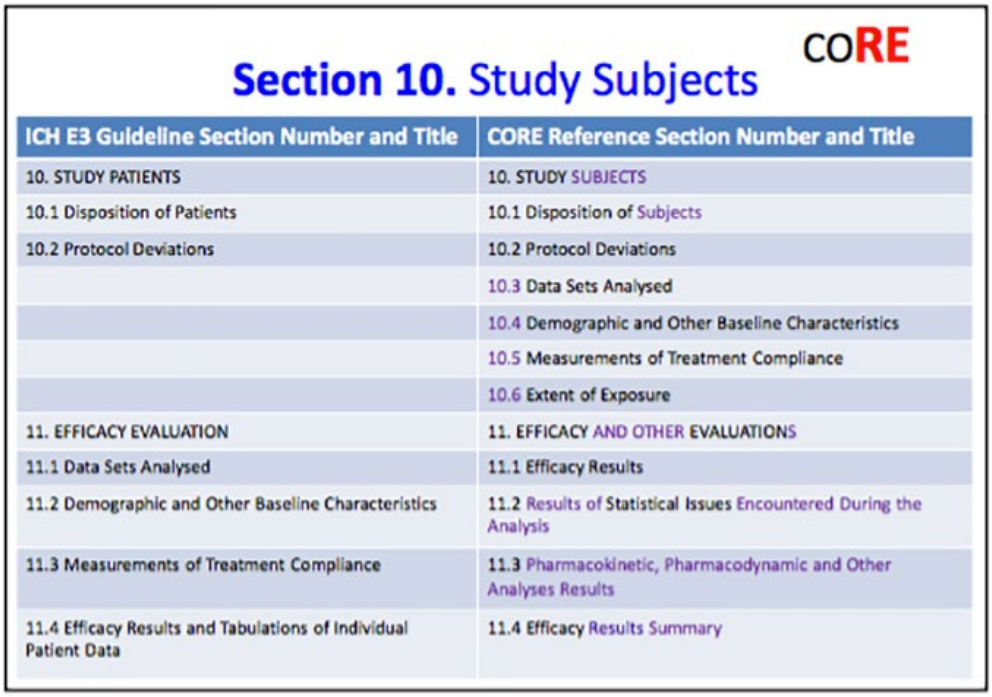


Figure 1. Example page from CORE Reference.



Section 10. Study Subjects

CORE

ICH E3 Guideline Section Number and Title	CORE Reference Section Number and Title
10. STUDY PATIENTS	10. STUDY SUBJECTS
10.1 Disposition of Patients	10.1 Disposition of Subjects
10.2 Protocol Deviations	10.2 Protocol Deviations
	10.3 Data Sets Analysed
	10.4 Demographic and Other Baseline Characteristics
	10.5 Measurements of Treatment Compliance
	10.6 Extent of Exposure
11. EFFICACY EVALUATION	11. EFFICACY AND OTHER EVALUATIONS
11.1 Data Sets Analysed	11.1 Efficacy Results
11.2 Demographic and Other Baseline Characteristics	11.2 Results of Statistical Issues Encountered During the Analysis
11.3 Measurements of Treatment Compliance	11.3 Pharmacokinetic, Pharmacodynamic and Other Analyses Results
11.4 Efficacy Results and Tabulations of Individual Patient Data	11.4 Efficacy Results Summary

Figure 2. Representative examples of changes suggested in CORE Reference. Structural changes to Section 10 and 11 as suggested by CORE Reference (right) in comparison to ICH E3 guidelines (left) are shown. Suggested section title changes are given in purple.

CORE Reference has been downloaded over 10,000 times and has received excellent end-user feedback. For further information and to download CORE Reference, visit http://www.core-reference.org/.

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A SURVEY TO DETERMINE THE METHODS WRITERS USE TO CREATE CONTENT FOR THE SUMMARY OF CLINICAL EFFICACY (SECTION 2.7.3 OF THE COMMON TECHNICAL DOCUMENT)

Speaker

Nancy R. Katz, PhD, MWC

President, Illyria Consulting Group, Inc., Soda Springs, CA

By Linda F. Wood, MPH

Drug applications submitted in Common Technical Document (CTD) format must contain Section 2.7.3, the Summary of Clinical Efficacy (SCE), which provides a high-level summary of efficacy data. Thus, the SCE is a critical document that supports the rationale for approval of the drug. Drug applications submitted in CTD format are now required by many regulatory authorities (eg, the Food and Drug Administration and the Medicines and Healthcare Products Regulatory Agency); therefore, the SCE is a frequently written document. Despite this fact, little research has been conducted regarding the scope and complexity of the work required to create an SCE.

Nancy Katz and Linda Wood addressed this gap by developing a survey that assessed the methods used to create content for the SCE. Methods of content creation were characterized (writing *de novo*, repurposing, or receiving from another team member) and used to investigate the challenges involved in writing this document. Questions were sent to potential survey participants via Survey Monkey. A total of 107 participants opened the survey invitation, and 74 responded, for a response rate of 69.2%. A qualified respondent was one who had been a lead writer (determined the content of the document and created at least 50% of the content for it) or a substantive contributor (created at least 30% of the document in conjunction with the lead writer). Forty-four respondents were qualified respondents. Most were from the United States (87.5%), and most were full- or part-time employees of either a pharma/biotech company or a contract research organization (57.5%).

The results showed that for almost all subsections of an SCE, most qualified respondents used a combination of *de novo* and repurposed content. Very rarely did respondents incorporate content with minimal or no change. This trend was noted for an SCE that summarized both pooled and unpooled data.

Most respondents reported that creating an SCE was akin to tracking a moving target; many respondents started an SCE well before finalization of the Clinical Study Reports on which the document was based (in some cases, the Clinical Study Reports had not even been started). In addition, respondents reported finding errors in final tables and listings. Most respondents multitasked; many who wrote the SCE were also responsible for writing the Integrated Summary of Efficacy

(ISE). Several developed an alignment plan with their colleague so as to ensure consistency of data, tone, and messaging.

In contrast with the perception that creating an SCE is primarily a "copy and paste" exercise, these results suggested that creation of an SCE requires a writer who creates substantial *de novo* content and judiciously repurposes existing content—in other words, a successful SCE requires a writer who is highly creative and at the same time well-grounded in the science and regulations underpinning the document. Such skills allow a writer of an SCE to create a novel core document that contributes to the integrity of a drug application.

Linda F. Wood, MPH, is President of MedWrite, Inc. in Orleans, MA.

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WHAT CAN INSTRUCTIONAL DESIGN DO FOR YOU?*

Speaker
Deborah Anderson, PhD, MS, MT(ASCP)SH
DGA Medical Communications, Bristol, PA

By Brian G. Bass, MWC, and Cyndy L. Kryder, MS
The Accidental Medical Writer

At AMWA's 2017 Medical Writing & Communication Conference, one of the many great educational opportunities we attended was the open session "What instructional design skills do you need to learn to develop effective educational communications?" The session was led by Deborah Anderson, PhD, MS, MT(ASCP)SH. Boy did we learn a lot from her!

Attending this session was a great reminder that no matter how much experience you have in a certain area, there's always more to learn. We've been writing educational materials for health care professionals, pharmaceutical sales representatives, medical science liaisons (MSLs), and patients for many years. And like many medical writers, we've often learned by the seat of our pants, then honed our skills through experience. Instructional design, or ID, is a specialty we've never dug deeply into. Deadlines press us to get things done and leave little time to study what we're doing.

Debbie did a great job of breaking down the steps that true ID specialists use to develop dynamic and effective educational communications. She began by describing ID as a 360-degree process that looks at learning from every possible angle. That makes sense, but doesn't it sound exhausting? We thought so at first, until Debbie explained how taking the time to consider all aspects of the learning experience really makes a difference.

While there are apparently quite a lot of ID models out there to follow (who knew?), Debbie identified the following steps that are integral to all of them:

1. **Gain information.** Ask questions about everything, including the learner, the learner's goals, the instructor, the instructor's goals, the learning environment, and the content.
2. **Analyze.** What does your research tell you? (Be prepared to be surprised!)
3. **Use.** Put what you've learned to use by developing educational content that not only takes into account but also leverages the myriad dynamics you've identified.
4. **Manage.** Keep communications open among all stakeholders throughout the development process and beyond.
5. **Evaluate.** Without metrics there's no way to confirm that you've achieved your objectives, and no way to improve.

What really impressed us from this open session is how clearly Debbie enabled us to see that taking a more systematic approach to developing educational content can actually make the work more fun and more rewarding! When you consider more than just the message you need to communicate—such as the environment in which the learning will take place; the expectations, limitations, and diversity of the learners; and the desired outcome—you can actually expand your creativity in the process. Going this extra mile is a great way to stand out from the crowd of medical writers, which is a fantastic way to market your freelance business!

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AN OVERVIEW OF PEDIATRIC PLANS: MEDICAL WRITING FOR THE EVOLVING PEDIATRIC LANDSCAPE

Speaker
Jennifer Rilstone, MD, PhD
Principal Regulatory Documentation Scientist, Hoffmann-La Roche Ltd, Mississauga, Ontario, Canada

By Anita Sebastian

"Over the past 20 years we have evolved from a view that we must protect children from research, to a view that we must protect children through research, in order to assure their access to new and effective medications."

Keynote Speech, Alexandria Summit on Oncology 2013
Margaret A. Hamburg, MD
Commissioner of Food and Drugs
New York, NY

This session provides an overview in regulatory writing for pediatric medications. It outlines why pediatric plans evolved, what components make them effective, and how medical writers play a strategic role in their preparation and implementation.

Why Did Pediatric Plans Evolve?

- Children are not little adults; small children have a completely different physiology from that of adults.
- Historically, there has been a dearth of pediatric research, which has led to inappropriate pharmaceutical formulations, extensive use of off-label medications, and exposure of children to unwanted side effects or under-dosing.
- Children were thus labeled as therapeutic orphans because they were deprived of the full benefits of pharmacotherapy available to other populations.

Beginning in 1997, there have been new pediatric regulations introduced in both the United States and Europe, starting with the Best Pharmaceuticals for Children Act (BPCA) and continuing with the Pediatric Research Equity Act (PREA), the European Pediatric Regulation, and, more recently, the Research to Accelerate Cures and Equity (RACE) for Children Act (2017). All of these legislations require pediatric plans to be an integral part in the development and approval process for new drugs and their indications. Ultimately, the mission of a pediatric plan is to improve product labeling for the pediatric population.

There are different pediatric plan documents globally, primarily the PIP (pediatric investigation plan) and PSP (pediatric study plan). The PIP is used in Europe whereas the PSP is implemented in the United States. Global drug development often requires the approval of both plans.

What Are the Critical Components of a Pediatric Plan?

1. **Position the drug among therapeutic options for the intended indication.** To best align the drug, you need to look at the clinical landscape for the disease in children and how the drug best fits within that context. For example, could the drug fulfill any unmet needs of the disease? One strategy is to compare and contrast the adult and pediatric indications of the drug by discussing the pathophysiology and disease course in all the different pediatric age groups. The other is to address the drug's potential therapeutic benefits over existing options by evaluating the drug's mechanism of action and its pharmacology.
2. **Provide a rationale to support drug entry into the pediatric population.** A safety profile for the drug can be established through nonclinical and clinical studies. By obtaining data from animal studies in the framework of growth, development, and fertility, you can identify any potential drug safety signals that would be relevant to pediatric patients.
3. **Provide a strategy and plan for pediatric development.** Providing a strategy for pediatric development is important to ensure all pediatric ages are considered for development and to address certain dilemmas, such as small children who are unable to swallow large pills. By evaluating the pharmacokinetics of the drug in children, you can determine its specific pediatric formulation: dosing, pharmaceutical form, strength, and route of administration. Your plan should also address the feasibility of conducting clinical trials in all age groups. In some cases, you can extrapolate existing clinical data from adult patients to assess the drug's efficacy in the pediatric population.
4. **Develop timelines.** Timelines for pediatric development are binding and must be agreed to with the agency. Deferrals can be requested to ensure that studies in children are safe to conduct.

How Do Medical Writers Play a Strategic Role in the Preparation of a Pediatric Plan?

Strategic medical writers need many skills to succeed in regulatory writing, including the ability to lead and manage a team. Preparing pediatric plans is not a solo effort but instead requires input from many functions within the company, including regulatory, clinical, nonclinical, and technical colleagues. A strategic medical writer can guide the provision of the content and then ensure the completeness of the proposal, the consistency among sections, the clarity of the key binding elements, and the overall coherence of the plan. The estimated time to prepare a pediatric plan for submission is at least 4 months.

Some of the challenges that medical writers encounter in preparing pediatric plans are (1) team experience with pediatrics, (2) a clear strategy at the start of drafting, (3) focusing content on supporting pediatric development (ie, no extraneous data), (4) complete justifications for supporting pediatric development, and (5) anticipation for short timelines and backup plans.

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TIME-SAVING TECHNIQUES FOR MICROSOFT WORD: BEST TIPS, SHORTCUTS, IDEAS, AND GUIDES

Speaker
Zoe Wright
Product Manager, Ideagen PLC, Nottingham, United Kingdom

By Kelly Schrank

Zoe Wright works for Ideagen, one of the exhibitors at this year's conference. Every year, she offers a session on Microsoft Word, and the PDFs of the MasterClasses are all gathered on the company's website: **https://www.ideagen.com/word-masterclass/**. Despite the fact that the material would all be available on the website, the room was standing room only (with many attendees sitting on the floor).

Though there are about 350 commands in Microsoft Word, most people only use about 10% of them. This session covered the following commands and functions: selection of text, random text filler, extended clipboard, keyboard shortcuts, calculations, object linking and embedding, and document map.

Selection of Text

The first "tips, tricks, and shortcuts" showed easy ways to select text:

- To select a *word*, double-click in the middle of it
- To select a *line of text*, put cursor at start of line, then press **Shift + down arrow**
- To select a *sentence*, put cursor within sentence, then press **Ctrl** and click in sentence
- To select a *paragraph*, put cursor within paragraph, then click three times
- To select a *section*, put cursor within section, then press **Shift** and click once

Random Text Generator

For those who need to show the layout of a document before they have complete or approved text, Wright explained how to use the random/filler text feature. Place your cursor where you need the text, then type **=lorem (x,y)** or **=rand (x,y)**, with the number of paragraphs as **x** and the number of sentences as **y**, then press **Enter**. Word will fill in the requested number of paragraphs and sentences with Lorem Ipsum dummy text or random text generated by Word. The Lorem Ipsum text is dummy Latin text that has been used for centuries in printing. The random text appears to be random English text from Microsoft instructions.

Extended Clipboard

If you find yourself doing a lot of copying and pasting, you might find the extended clipboard helpful. It allows you to copy and paste lots of text at one time (up to 24 snippets). Any text or graphics you copy will be placed in the **Clipboard** task pane. When you are ready to paste a snippet into your text, perform the following steps: (1) click the **Home** tab; (2) click the **Clipboard** dialog box launcher; (3) the **Clipboard** task pane will open, showing all of the snippets available; (4) click the **Paste All** button to paste all of the snippets at once in the order they are presented in the **Clipboard** task pane or choose which snippets you want to paste individually. Note: You cannot use the **Paste Special** command with items you are pasting from the **Clipboard** task pane. When you are done with the snippets and ready to save and close your document, press the **Clear All** button, or these paste options will be in the next Word document you open.

Keyboard Shortcuts

There is a whole page of keyboard shortcuts in the MasterClass online, but several are popular:

- Press **Ctrl + I** for italics
- Press **Ctrl + F** to open the Find command
- Press **Ctrl + Enter** to insert a page break
- Select text, then press **Alt + Ctrl + 1** to give it the Heading 1 style (works for default Headings 1, 2, and 3)

You can also see keyboard shortcuts in ScreenTips by hovering over the menu or buttons. If you are not seeing the keyboard shortcuts, then perform the following: press **Word Options > Advanced > Display > Show shortcut keys in ScreenTips**. Note: Not all buttons and menus have keyboard shortcuts.

In response to a question, Wright informed us that there was a way to have Word flag when you have 2 spaces after a period and when the Oxford comma is not being used. Each is flagged during your Spelling and Grammar check. To set up these options, perform the following: press **Word Options > Proofing > Settings** (next to **Writing Style**). Then choose the following under **Require**: whether you want the Oxford comma, (never, always, don't check) and how many spaces should be between sentences (1, 2, or don't check).

Calculations

While Word is certainly not as robust as Excel, you can do some simple calculations in a Word table. Go to **Table Tools > Layout > Formula** to see your options. One thing to keep in mind is that choosing which cells to put in the calculation is a little trickier in Word than Excel. For example, since the cells are not numbered, you must say whether the cells are above, below, or to the right and/or left. For example, you could put the **=SUM (above)** formula in the cell at the bottom of a row, and Word will add up the numbers in the cells above it. Other options

are **=SUM (below)**, **=SUM (left)**, **=SUM (right)**. If Word's calculation features are not robust enough, you can also link or embed the Excel file in the Word document.

Object Linking and Embedding

Linking and embedding objects allows you to include materials such as a graphic, spreadsheet, PowerPoint presentation, or PDF in your Word document. The fundamental differences between linking and embedding are whether the object will continue to stand on its own in another location (linking) or whether it will be incorporated into the document wholly (embedding). The advantages of linking are a reduced file size and the ability to keep up with changes in the separate file, but it does require that those receiving the Word document also have access to the separate source file. Embedding an object eliminates the requirement for access to the separate source file, but it will not be updated if the separate source file is changed, and file sizes can get burdensome with Word documents containing embedded objects.

To link an object, place your cursor where you want the object (or an icon for the object), then press I**nsert > Object > Create from file > Browse**…. Find the object, then click the **Link to file** box. If you would like to display an icon instead of the object, click the **Display icon** box. You can change the icon or its text to be something more helpful than a file name; for example, "Trial Data—Click Here." When you're done, press **OK**. If the source file is updated, your link will need to be updated. This is done automatically when you open and close your document, or you can do it manually.

To embed an object, place your cursor where you want the object, then press **Insert > Object > Create from file > Browse**…. Find the object, then press **OK**.

Document Map

The document map function allows you to use the power of the **Navigation** pane to reorganize sections of your document quickly and without a lot of cutting and pasting. Wright explained this as taking the Outline View one step further. It does require that you use the Headings styles in your document. When you are looking at the Headings in your document in the **Navigation** pane, you can move the headings around, and the text that falls within each section will move with the headings. Word will also renumber your headings if you have numbered headings.

All of these topics are covered, some in much more detail, in the Part Three MasterClass online: **https://www.ideagen.com/word-masterclass/**.

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BEST PRACTICES FOR WRITING AND EDITING CME NEEDS ASSESSMENTS

Speakers

Donald Harting, MA, ELS, CHCP

Manager, CE Grant Writing and Outcomes, National Comprehensive Cancer Network, Fort Washington, PA

Katherine Molnar-Kimber, PhD

President, KMK Consulting Services of Kimnar Group LLC, Worcester, PA

Nathalie Turner, MS, ELS

Senior Grant Developer, Medscape Education, Newtown, PA

By Liz Kuney, MS, CCRP

In this well-attended open session, only 2 or 3 in the audience had any experience preparing needs assessments for continuing medical education (CME) credits. I was barely familiar with the topic when the session began, yet by the end, my team and I had prepared a feasible needs assessment that reflected current best practices!

What Is a Needs Assessment?

Whether they are physicians, nurse practitioners, or pharmacists, all licensed health care providers must maintain a high level of practice by earning CME credits to keep their knowledge and effectiveness current. Needs assessments determine what health care professionals need to learn (and thereby help determine CME offerings) by identifying and analyzing the gaps that exist between what is customary (actual practice) and what the standard should be (optimal practice). In a 2016 *AMWA Journal* scholarly article that surveyed current methods for preparing needs assessments, authors Don Harting and Nathalie Turner explained that the activity of clearly identifying the actual practice gaps is essential. Also known as gap analyses, needs assessments "guide the development of educational interventions, with the ultimate goal of improving patient care."

To develop an accredited CME program, several other ingredients, in addition to the needs assessment, make up a typical request. These include a budget, a schedule, an audience generation plan, and an outcomes measurement plan. Although the needs assessment may be only 1 small piece of the entire pie, it plays an essential role in the planning process. For a CME offering to be approved by the governing body (such as the Accreditation Council for Continuing Medical Education, the organization that regulates CME for physicians), the education provider must be able to demonstrate that the offering was based upon an assessment of need (ie, knowledge, competence, or performance) that underlies a substantive gap in clinical practice.

A Needs Assessment of Needs Assessments

In 2010, Harting partnered with fellow AMWA member Sandra

Binford, MAEd, to investigate the state of needs assessments that were prepared to obtain commercial support for accredited CME. In this investigation, the 2 identified a high level of variability in format and style. They also identified perhaps more crucial variability in the wide-ranging types of evidence used to support the analysis of need. These included practitioner surveys, interviews with key opinion leaders, medical literature reviews, and supportive charts or graphs.

In 2014, Harting partnered with another fellow AMWA member, Ruwaida Vakil, MS, to develop the first formal survey of best practices for writing CME needs assessments. The survey was dispersed to a range of medical writers and communicators, primarily those experienced in preparing needs assessments for accredited education. Four successive annual surveys have now been collected, with considerable data amassed, including the number of projects authored, timelines for publishing, number of revisions, document length, age of references, author's contractual status, types of data preferred by clients/employers and their priorities, barriers to success, inclusion of patient perspectives, and identifying quality indicators, among others.

Recipes for Best Practices

The project's ultimate aim is to improve the quality of needs assessments. From careful analysis, Harting et al have distilled the cumulative results into a menu of 3 "recipes":

- *Basic*—a single scoop of plain vanilla ice cream on a simple cone;
- *Better*—a large soft-serve chocolate cone slathered in sprinkles; and,
- *Deluxe*—an elegant dessert sundae served in a crystal goblet complete with caramel syrup and a cherry on top!

Which "recipe" to follow would generally depend upon the level of funding available, yet the essential ingredients for a *Basic* needs assessment would best include the following:

1. Medical literature review,
2. Practitioner survey,
3. Reference to clinical practice guidelines,
4. Key opinion leader interview(s), and
5. Alignment chart with columns labeled Learning Objective, Practice Gap, and Desired Outcome

The *Better* and *Deluxe* recipes assume more resources are possible for production. A *Better* needs assessment would add perspective from a patient or patient advocacy group regarding patient-level gaps, texts or charts showing outcomes data, and evaluation reports from participants in previous activities. The *Deluxe* needs assessment enhances the cumulative elements with reference(s) to national health care quality standards and evidence of change measured against a validated quality benchmark. Note, however, that some practitioners consider most of the *Better* and *Deluxe* ingredients to be standard.

Team Exercise

After the initial presentation, session attendees broke into smaller teams and reviewed provided materials. Each small team assembled an outline for a needs assessment by following the *Basic*, *Better*, or *Deluxe* recipe. The audience relished the interactive portion of the open session almost as much as a real ice cream dessert!

What a Good Needs Assessment Needs

After reminding attendees that any writer's foremost responsibility is to consider the target audience—the fundamental rule of any good communication—the speakers presented final tips for preparing a good needs assessment:

- Set the stage of a problem: "Indicate what isn't being done (knowledge, competence, performance)."
- Give background: "Describe why it's not being done (evidence)."
- Tender a resolution: "Describe what needs to be done or known (solution)."
- Point to the wisdom that results: "Indicate expected outcomes from closing the gap(s)."
- And…"Keep it concise!"

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STRATEGIC GRANTSMANSHIP PRINCIPLES FOR ACADEMIC AND SCIENTIFIC WRITERS

Speaker
J. Kelly Byram, MS, MBA, ELS
CEO & Scientific and Medical Communications Lead at Duke City Consulting, LLC, Albuquerque, NM

By Julie A. Daymut, MA, CCC-SLP

The first rule of thumb to strategic grant writing is "DON'T PANIC." In order to not panic, you can implement different tools and strategies to mitigate issues that might arise during the process. In this session, J. Kelly Byram, an expert in the field of grantsmanship, shared some doable and necessary tips for effectively and efficiently navigating the grant-writing waters.

Work Backwards

Plan your grant proposal project schedule by working back-

wards from the deadline. Start with the end point in mind and try to anticipate any questions or issues that may occur. This strategy allows for enough time to make modifications along the way.

Define Your Value Proposition

Develop a value proposition for your work. Be sure your proposition and work align with the funder's mission and vision. Make clear what you are bringing to the field that is innovative and how that work will complement the grantor's portfolio. This is crucial in a hypercompetitive environment where grant funding is decreasing and institutions' indirect, negotiated rates are increasing.

View Your Grant Submission as a Business Proposal

View your grant submission as a separate entity—as a business proposal. Your job is to show how you will be successful with their money and how you will maximize their dollars with minimal risk. As well, reviewers are looking for a paradigm shift. How will your work move the needle?

Ways to Make Your Grant Proposal Shine

You want a polished proposal. The goals are to make your grant submission stand out. Allow enough time for an internal peer review before submission to the funder. Also have individuals outside of your discipline review the proposal; this external review can help to identify and bridge any knowledge gaps.

Gain firsthand experience as a peer reviewer in your research area and for an outside organization, such as a not-for-profit. These exercises teach you about targeting specific audiences and the different proposal formats and processes.

Ask questions of the grant's program contact. This person can be a wonderful resource to help determine if your work is a good fit and to let you know if funding is still available. Byram suggests asking for permission to submit a 1-page summary to the program contact prior to a phone consultation to help make this assessment.

Writing Style

An effective grant-writing tool is to discuss the members of the research team throughout the proposal and, for some funding opportunities, to use personal pronouns and team members' first names. The funders want to see your team's backgrounds, management skills, and overall collaboration.

Appeal to both the deep reader and the skimmer. Use active voice and have only 1 editor review the proposal for tone. Also be sure to mirror the funding opportunity's language. For example, in the field of clinical psychology, "clients" is the preferred terminology. Funders love data sets and a robust research design, so determine what you can share in the proposal and highlight measurable outcomes.
Stay focused and within the boundaries of the scoring criteria. Read the funding announcement several times—know it inside and out. Read the funding website for submission tips.

Tips for Managing the Project Team

- Have a budget for both time and money.
- Create a detailed schedule with timeframes. Send calendar invites.
- Set an internal proposal completion date for the team in advance of the actual due date.
- Designate a backup person to answer questions in case someone is out of town or unavailable.
- Use Microsoft Project, a Word document, a spreadsheet, or whatever means works for your team to help them stay focused, connected, and on schedule.

Resources

Check out the National Institutes of Health website for tips, including blog postings and a video, on what has worked and has not worked to win grant funding.
Go to FBO.gov, SBA.gov, Grants.gov, or the funding foundation's website.

Summary for Strategic Grant Writing

Be unique. Be innovative. Be prepared and polished. And… don't panic.

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FDA EXPEDITED REGULATORY APPROVAL PROGRAMS

Speaker
Monique Pond, PhD
Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

By Priyanka Ingle, MD, PhD

This session sought to help participants understand the similarities and differences between the Food and Drug Administration (FDA) expedited regulatory approval programs and learn strategies for requesting expedited review by the FDA.

Drug discovery and development can be a very long and risky road. Traditionally, this process can encompass 3 to 6 years for drug discovery and preclinical development, 6 to 7 years for clinical trials, and 6 months to 2 years for regulatory agency review and optimization of manufacturing pro-

cesses. The FDA offers 4 expedited approval programs as alternatives to the standard process (Table 1). These programs are intended to facilitate and expedite development and review of new drugs that address unmet medical needs in the treatment of serious or life-threatening conditions. The Accelerated Approval pathway and Priority Review designation were initiated in 1992, followed by the Fast Track Designation in 1997 and, most recently, the Breakthrough Therapy Designation (BTD) in 2012.

Like the BTD, the Accelerated Approval pathway is for a drug candidate that addresses a serious condition and may offer a meaningful advantage over available therapies, with the distinction that the accelerated approval pathway allows for the use of a surrogate end point as the basis for approval (Table 1). The use of a surrogate end point can result in a shorter time until approval of a drug; however, the sponsor must provide evidence supporting clinical benefit after approval is granted, usually by conducting a confirmatory trial. The priority review designation is for a submission that addresses a very serious condition and is used if a significant improvement in safety or efficacy has been demonstrated. Under a priority review designation, the FDA review time is reduced from a standard 10 months to 6 months. The Fast Track designation is designed for drug candidates intended to treat a serious condition and that have demonstrated the potential to address an unmet medical need during nonclinical studies.

Oncology is one of the therapeutic spaces where both the BTD and Priority Review designation are used extensively. A growing percentage of oncology drugs are utilizing both of these programs, from 11% of all novel approved oncology drugs in 2013 to 32% in 2016. Another program that can decrease drug development time for a drug candidate intended for rare or orphan diseases is the Orphan Drug Designation. This designation qualifies the Sponsors for various development incentives, including tax credits for qualified clinical testing. For example, a marketing application for a prescription drug product that has received Orphan Drug Designation status is not subject to a prescription drug user fee unless the application includes an additional indication other than the rare disease or condition for which the drug was designated.

Table 1. FDA Expedited Approval Programs: Main Components

	Accelerated Approval	Priority Review	Fast Track	Breakthrough Therapy
Nature of Program	Approval Pathway	Designation	Designation	Designation
Qualifying Criteria	Benefit over current therapy with surrogate end point to predict clinical benefits	Significant improvement in safety or efficacy	Nonclinical or clinical data for unmet medical need	Clinical data show significant improvement over available therapy
Submit Request to FDA	Discuss surrogate end point used during development and planned confirmatory trials	With original BLA, NDA, or efficacy supplement	With IND or after No later than pre-BLA/NDA meeting	With IND or after No later than end-of-phase-2 meeting
FDA Response to Sponsor	Not specified	Within 60 days of receipt of documents	Within 60 days of receipt of request	Within 60 days of receipt of request
Features	Approval based on surrogate endpoint	Shortened review time (10 to 6 months)	Rolling review of application	Fast Track features plus extra guidance
Additional Considerations	Subject to expedited withdrawal	Assigned at NDA or BLA submission	Designation can be withdrawn	Designation can be withdrawn

BLA, Biologics License Application; IND, Investigational New Drug Application ; NDA, New Drug Application.

The expedited programs are utilized by sponsors, and the use of some programs appears to be on the rise (Figure 1). Use of BTD and possibly Priority Review is growing more common, while use of the Fast Track designation has decreased among approved drugs. Similarly, BTD requests per year are on the rise; the current estimated BTD request acceptance rate is 38% for all requests submitted from 2012 through 2016. The FDA recommends that sponsors initiate conversation with the Agency regarding a prospective BTD application as early as possible during clinical drug development. The applicanited

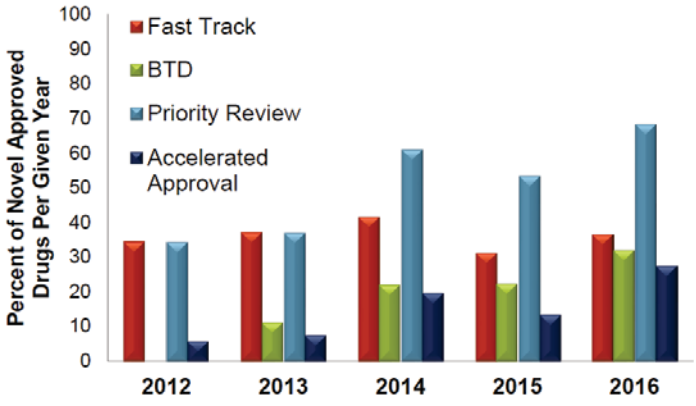

Figure 1. FDA Expedited Approval Programs: Use Among Novel Approved Drugs in the United States

tion should be filed no later than the end-of-phase-2 meeting but can be filed as early as the Investigational New Drug or Biologics License Application submission. A medical writer will usually work with a team composed of members from several functional areas, including clinical, pharmacokinetics, regulatory, safety, and statistics, to write a BTD application.

Similar to the FDA's expedited programs, the European Medicines Agency grants Conditional Marketing Authorizations (CMAs) for early access for medicines that fulfil an unmet medical need. The CMAs are valid for 1 year, are renewable, and require postauthorization data.

Toward the conclusion of the session, Monique Pond referred to a *BMJ* article[1] published recently that explored the rate of safety-related label changes for new drugs approved through expedited programs versus the traditional pathway. Pond suggested that care be taken when assessing the effects of expedited programs on patient safety and that overall patient health be considered when attempting to understand underlying factors that contribute to safety.

Reference

1. Mostaghim SR, Gagne JJ, Kesselheim AS. Safety related label changes for new drugs after approval in the US through expedited regulatory pathways: retrospective cohort study. *BMJ*. 2017;358:j3837.

Additional Reading

US-FDA Guidance for Industry, Expedited Programs for Serious Conditions—Drugs and Biologics; September 2017.
US-FDA Draft Guidance for Industry, Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; November 2017.

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DESIGNING YOUR REGULATORY CONTENT FOR MULTICHANNEL TARGETS: NEW MEDIA CHANNELS, WRITING, TECHNOLOGY, AND SOFTWARE

Speaker
Susan Bairnsfather, BSc
Manager, Medical Writing, Indivior, Shreveport, LA

By Laurie Endicott Thomas, MA, ELS

In the old days, regulatory applications were typed on paper. Subsequently, the applications were written in word processing programs but still submitted on paper. Then regulatory writers began submitting the word-processed documents for drug applications on small personal computers. Finally, electronic submissions were submitted to regulatory agencies via the Internet, through electronic portals such as the Food and Drug Administration's Electronic Submissions Gateway. Currently, the growing use of mobile devices for reading electronic documents has made it necessary for regulatory writers to make these documents readable on various electronic platforms. Fortunately, responsive Web design software can be used to automatically adjust the formatting of HTML5 output to fit the screen size of the reading device. Besides creating media for various mobile device screens, regulatory writers must also submit regulatory documents to regulatory agencies with differing submission requirements as well as submitting documents in multiple languages.

To meet the varying media and submission requirements, writers have a choice of software programs that can export to various formats and outputs. Microsoft Word macros and cascading style sheets (paired with XML elements) establish page sizes, font styles, and other formatting templates for the different outputs. Thanks to the implementation of the Common Technical Document specifications, regulatory writers who are preparing regulatory documents now use methods that allow product topics to be authored and archived separately, tagged as metadata, and reused, thus allowing important cost savings when preparing submissions to agencies with different submission requirements and also preparing output in different languages.

In her presentation, Susan Bairnsfather provided an overview of what the channels are, what kind of software enables you to output documents in different channels, and how to use software for archiving, reuse, and version control. Additionally, she explained how to plan the overall project workflow. For example, a master project is a repository for template files, and these template files are linked to child topics. Her presentation used the Madcap Flare software to demonstrate the strategies for storage, repurposing, and output. Other software, such as Framemaker and DITA, can allow you to use similar strategies to provide deliverables through various channels of device platforms and/or to meet the requirements of a particular regulatory agency. The use of these software tools enables efficiencies in topic authoring, document creation, and document output that are not possible through today's commonly used Microsoft Word software.

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HELPING NON-NATIVE ENGLISH-SPEAKING INVESTIGATORS GET THEIR RESEARCH PUBLISHED IN QUALITY JOURNALS

Speaker
William R. Brown, MD
Director, International Medical Editing Service, Denver, CO

By Kirby Snell

Preparing a manuscript for submission to a journal can be a daunting task for any researcher. But for non-native English speakers hoping to publish in quality English-language journals, it can be a monumental endeavor, and not just because of the challenges of writing in a foreign language. In this session, Dr William R. Brown offered a wealth of information for medical editors working with non-native English speakers in preparing their work for submission.

The Needs of Non-Native English-Speaking Authors

The session began with an overview of some of the unique editorial needs faced by non-native English speakers and how an editor might prepare when approaching such work.

As an editor, you may have to do a lot of actual rewriting for non-native English speakers. Dr Brown noted that authors may be eager for help and willing to accept sweeping changes from an editor. When you do have to rewrite or make extensive edits, do so with respect. Major changes should be introduced as suggestions, with the author being invited to approve your proposed revisions.

While some manuscripts may need significant help with grammar and language usage, a paper being prepared for submission to a journal needs more than English "polishment," and as a dedicated medical editor, you should be prepared to offer more. Authors may need assistance in the logical and systematic construction of a research article according to English-language medical journal requirements. You may need to help with composing a proper title, constructing an abstract, describing statistical methods, and so on. Larger structural guidance may be necessary, such as making sure each section of the paper includes the correct information and the appropriate level of detail. Dr Brown mentioned that papers by non-native English speakers often have issues with the topics of sample sizes and randomization, so the editor should be familiar with the relevant requirements and be able to identify when something may have been done incorrectly. Authors may also need help in following journal instructions and navigating submission requirements.

Mentorship

When working with non-native English speakers, the editor's roles should be as an advocate and teacher, not as a harsh critic. "Let the author know you're working with them," encouraged Dr Brown. They may need some tough love; don't be afraid to tell an author, for example, that although their research paper is interesting and important, it is poorly designed and likely to be rejected by a high-tier journal—but that you will help them. If your authors' paper is accepted to a journal with a request for revisions, let them know that this is common and that they should be encouraged—and then offer your help through the revision and response process.

Plagiarism

One major issue that cannot be overlooked when working with international authors is plagiarism—a topic that inspired a good deal of discussion among the session's audience. The understanding of what constitutes plagiarism varies from culture to culture; in some countries, it may be considered a sign of respect to directly repeat a more senior researcher's work. Often, it is simply a lack of understanding about what needs to be cited and how. Regardless, because plagiarism is a serious problem with potentially severe repercussions, editors must keep an eye out for this and be prepared to alert and instruct authors.

The Rewards

Dr Brown noted that although editing in the international research arena comes with its own host of challenges, it also offers many rewards. For authors, there is the pride in seeing their work published in a high-quality journal and in being able to make a contribution to the medical field. For the editor, in addition to earning the author's gratitude, a broader view of the world and a greater appreciation for the important research being conducted worldwide may be gained. Long-term benefits also include the development of new friendships and professional relationships with individuals across the globe.

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

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A REVIEW OF PROCESSES AND SOME BEST PRACTICES FOR NARRATIVE WRITING

Speaker
Karen L. Campbell, MS
Manager, Medical Writer & Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

In the world of clinical regulatory documents, there are 2 kinds of nonfiction stories to tell: that of the drug and its path to approval (or abandonment) and that of the subject. For most documents (protocols, investigator brochures, clinical study reports), the story of the drug takes center stage. Narratives, however, tell the story of individual subjects. They are informative documents that can provide Health Authority reviewers with the necessary details to understand an adverse event or other predefined situation within the context of the subject's study participation.

In addition to understanding the overall scope of work, including narrative criteria for the project, number of narratives needed, and project timelines, key components of a successful narrative writing project include

- Understanding the nuances of the source data (eg, final data or a data cutoff, listings or patient profiles, availability of safety data)
- Creating a detailed and thoughtful process (eg, assessing and customizing the narrative template, understanding the review process, ensuring compliance with the style guide)

The variety of data sources can add complexity. Typically, source data for narrative writing include data from a clinical database (eg, listings, patient profiles) and data from a safety database (eg, CIOMS, MedWatch). Determination of the appropriate source in case of a discrepancy between the source data ensures consistency of the narratives.

Creating a template allows for consistency between narratives in the study as well as across studies within the same overall project. Whether a template is provided by the sponsor or one is developed for a specific project, annotating the template provides several advantages it (1) confirms that all source data have been provided to complete the narrative, (2) allows sponsor preferences and style guide requirements to be built in, (3) ensures consistency with the data used (especially if there are multiple writers on the project), and (4) helps the quality-control (QC) reviewer know where to find the data used.

Once the writing has started, tracking the progress of each narrative supports the successful on-time completion of the project. A spreadsheet noting the author and the dates of completion of the draft, medical review, QC review, and finalization helps ensure that the project has been completed and can be modified to become a table of contents for the narratives in the project. Additionally, with multiple narrative projects, spreadsheets can be used to generate metrics on "average time to complete." Similar organization of email or computer folders can facilitate tracking of a narrative project.

Narratives can provide a sole source of information about specific subjects' events. They represent a consolidation of information from various sources to provide details about an event of importance–whether serious adverse events or other types of events. Understanding the scope of the project, using an annotated template, and following a process will lead to the successful completion of the narrative project.

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FREELANCE MEDICAL EDITING, WRITING, OR BOTH: WHICH PATH IS RIGHT FOR ME?

Speakers
Julie Munden
Medical Editor & Copywriter, Blue Ink Communications, Souderton, PA
Lori De Milto, MJ
Writer for Rent LLC, Sicklerville, NJ

By Mia DeFino, MS

Both medical editors and medical writers have many interesting freelance opportunities. But choosing whether to be an editor, writer, or both can be challenging. This session focused on helping freelances decide whether they should market themselves as a medical editor, a medical writer, or both. Even if attendees were not currently freelances, the session was intended to be helpful for thinking through how to decide what you can do or would enjoy doing the most. Both Julie Munden and Lori De Milto presented their own paths to deciding what type of work best suited them and their freelance business.

Munden tried editing first and enjoyed it, then had some experience with copywriting, and ultimately found she liked medical editing much more. Today, she is a senior medical editor and content manager with one of her favorite long-time freelance clients. She is happy with her focus on editing because she likes to use her strengths of being detail-oriented, factual, and consistency-based.

De Milto has been a writer since she was a kid and has completed a master's degree in journalism. She started out by writing for a physician newsletter and then happened to do some medical editing work when she started her freelance business, which led to multiple connections and long-term clients. Today, her business is all medical writing. When clients are looking for a freelance editor, she refers them to a colleague who is an editor because she enjoys writing more.

Both speakers emphasized that it is important for branding and marketing of your freelance business to decide which type of work you enjoy the most and what you are good at (ie, do you have the skills and qualifications to do the type of work you enjoy?).

The types of clients and projects that medical editors and writers work for and on are very similar, and the targeted audiences are the same as well, said Munden (Table 1). However, said De Milto, there are 2 skills that writers need that editors do not: the ability to analyze vast amounts of data and information and the ability to write.

De Milto helped the audience understand the money-making potential of both paths: "Both medical editing and writing are well-paid careers. Editing tends to pay slightly less, but it is important not to choose writing just because it pays more." It is important to do the work that is a better fit for you because you will be happier and more satisfied in your career choice.

Ultimately, there are some freelances who do well as both writers and editors, and there are other freelances who are satisfied to focus their efforts on one path, both speakers concluded. "It is important to think about how clients perceive you. They want to hire a specialist, and sometimes if you do both they may not think that you're good enough at one or the other," warned De Milto. She also cautioned that doing both makes it harder to attract great clients, because effective marketing focuses on what clients need and how you can meet their needs.

As an example, De Milto said that if the prospective client is looking for a particular skill set, they may be more interested in you if you do only what they are looking for, rather than if you do both. However, if existing clients only know you as an editor, for example, sometimes they will ask if you are interested in writing. If you are, this is an opportunity to do both. But if you are not interested, it is okay to say so and direct your client to writers you may know who can help, suggested De Milto. Often, even if we brand ourselves one way, we can sometimes be open to trying new types of projects to see if we like other types of writing or editing, she concluded.

Munden finished the session by providing criteria on which attendees could base their career path decisions: preferences, skills, credentials, and experience. Please see the handout from this session on the next page to help you determine the best path for you.

Table 1. Choosing Your Path: Skills, Credentials, and Experience

Skills	Freelance Editors	Freelance Writers
Editing	Definitely	Somewhat
Knowledge of style guides	Definitely	Somewhat
Literature searching and fact-checking	Definitely	Usually
Knowledge of instructional design	Definitely	Maybe
Analyze data and information	Not applicable	Definitely
Writing	Not applicable	Definitely
Software proficiency	Definitely	Definitely
Organization	Definitely	Definitely
Time management	Definitely	Definitely
Communication	Definitely	Definitely
Education level		
Bachelor's degree	Minimum	Minimum
Advanced degree	Not applicable	Likely
Degree field		
Science or medicine	Not applicable	Likely
English	Likely	Not likely
Journalism or communications	Possible	Likely
Public health	Possible	Likely
Certification		
Board of Editors in the Life Sciences (BELS)	Likely	Not applicable
MWC®	Not applicable	Possible

› For a copy of the slides and all handouts, email Munden at julie@blueinkcommunications.net or De Milto at loriwriter@comcast.net.

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Checklist For Choosing Your Path: Freelance Medical Editing, Writing, or Both

Use this checklist to help decide whether freelance medical editing, writing, or both is right for you. The checklist, however, is a guideline. Many successful freelance medical editors and writers might not seem more clearly suited to one career path over the other.

My Preferences and Skills

- ❑ I like editing more than writing. **(E)**
- ❑ I like writing more than editing. **(W)**
- ❑ I enjoy fact-checking content. **(E)**
- ❑ I know style guides. **(E)**
- ❑ I can't resist the urge to correct mistakes and always notice illogical arguments, inaccurate statistics, inconsistent writing, and poorly constructed sentences. **(E)**
- ❑ I have an extreme passion for details, accuracy, and correct grammar. **(E)**
- ❑ I'm detailed-oriented and focus on accuracy but prefer for someone else to make sure everything is consistent and grammatically perfect. **(W)**
- ❑ I love to learn about new topics in medicine, health, and health care. **(W)**
- ❑ I love to organize data and information into clear and interesting writing. **(W)**
- ❑ I can analyze large amounts of data and information. **(W)**

My Credentials

- ❑ I have a bachelor's degree. **(E, most likely)**
- ❑ I have an advanced degree. **(W, most likely)**
- ❑ My degree is in English, journalism, or communications. **(E, most likely)**
- ❑ My degree is in science, medicine, or public health. **(W, most likely)**

My Experience

- ❑ I have experience in editing and/or medical editing. **(E)**
- ❑ I have experience in writing and/or medical writing. **(W)**

Calculate Your Path

Count up the number of **E**s and **W**s.

Number of **E**s: _____

Number of **W**s: _____

If you have:

Many more **E**s than **W**s:
Freelance medical editing is the best path you.

Many more **W**s than **E**s:
Freelance medical writing is the best path for you.

About an equal number of **E**s and **W**s:
Both freelance medical editing and writing, or writing and editing, is a good path for you.

More **E**s than **W**s: Editing should probably be your primary work.

More **W**s than **E**s: Writing should probably be your primary work.

My choice is:

_____

THE ELEMENTS OF A GREAT MULTIPLE-CHOICE TEST QUESTION

Speaker
Nathalie Turner, MS, ELS
Senior Grant Writer, Medscape Education, Newtown, PA

By Heather Gorby, PhD

There is an art to creating effective multiple-choice questions that test knowledge. Sometimes with poorly constructed questions, the test taker can guess the correct answer instead of applying their knowledge of the material. Nathalie Turner provided suggestions for writing effective multiple-choice test questions.

The Purpose of Testing

Testing is a key component of providing continuing medical education (CME) credit to clinicians. Testing is done to ensure that a participant understands the content and to reinforce the learning of key concepts, skills, and clinical practice habits. It can also help participants identify individual knowledge gaps. Knowledge gaps can also be used by organizations to design future learning activities.

Elements of Good Multiple-Choice Test Questions

Turner stated that a good testing strategy is the "one-best-answer" format, with a lead-in question that uses language that clearly asks for 1 best answer, followed by 4 (sometimes 5) options. Clinical scenarios/vignettes can also be added. Providing a rationale to describe the reasoning for correct/incorrect answers is an option, and many CME providers ask for a rationale.

If added, clinical vignettes/scenarios should be brief and precise without providing superfluous information. Turner suggested that, in general, writers generally should avoid using personalization or names (eg, "John came to the office…"). However, there are instances when using names is appropriate. If, for example, the testing module refers to multiple patients, first names can help make it clear which patient is being discussed in a particular question. Personalization could also help to add social, ethnic, or religious information if crucial to answering the questions.

Additionally, to avoid subconscious patterns in correct answer placement, items are best listed in alphabetical order. When referring to body regions, items instead can be listed in order from head to toe. Turner suggested avoiding opposites (eg, hyperthyroidism and hypothyroidism) or items that are too closely related (eg, MRI with contrast and MRI without contrast), as this can eliminate 2 options right from the start if the test taker knows that the issue is not related to the thyroid or that an MRI isn't appropriate.

Examples of good question lead-in phrases:

- The most likely test result is…
- The most appropriate management is…
- Which of the following is the most appropriate next step?
- The most likely diagnosis is…
- Which of the following is the most likely cause of the patient's symptoms?

Common Errors of Multiple-Choice Test Questions

Writers should avoid cueing the test-taker to the correct answer. As the goal is to reinforce learning, overly complicated and difficult questions are unnecessary. Some common flaws are not using parallel structure in the correct answer, using absolute terms such as "always" and "never," and having a longer or otherwise unique correct answer. Sometimes a word or part of a word will repeat in the lead-in and the correct answer, leading the test-taker to the right answer. Avoid negatively phrased questions such as "…all of the following *except*…" or "Diagnostic testing should *not* include…," because this creates an unnecessary element of complexity. Avoid vague terms like "sometimes" or "rarely," as these terms can add too much uncertainty. Do not use "all of the above" or "none of the above," because these options are almost always the correct answer, and test takers will likely choose this option without needing to read the question.

Turner also advised writers to avoid "hinging," which occurs when several questions in a row will depend on the answer to previous question. This can lead to the test taker incorrectly answering several questions in a row based on a single incorrect response.

Turner suggested some strategies to evaluate your own questions:

- Is the clinical scenario necessary to answer the questions(s)?
- Are all the options plausible?
- Are the options homogeneous?
- Is the correct answer the best choice given?

Ideally, you want to construct easy-to-understand questions that are clear to the test taker. Avoid frustrating the test taker with overly complicated and confusing questions.

Further Resources

Turner also suggested some resources for further learning:

- National Board of Medical Examiners: **http://www.nbme.org/publications/item-writing-manual.html**
- National Board of Osteopathic Medical Examiners: **http://www.aobpr.org/wp-content/uploads/2016/02/IW-guide-2006.pdf**

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EXHIBITORS

Trilogy Writing & Consulting

At Trilogy, medical writing is our passion. As specialists in clinical regulatory documentation, we provide a service that is more than just writing. Our writers are integral parts of our clients' teams: they are engaged in proactively planning, coordinating, and writing their clinical documents to meet timelines, with a readability that reduces the time for review and approval. We have been helping pharmaceutical companies and clinical research organizations of all sizes, worldwide, to streamline their documentation processes for over 15 years—either as support on a one-off document or the entire clinical development program.

We provide our clients with constructive advice on their projects: we guide our clients' teams through the writing process and ask them the right questions in order to produce documents that communicate effectively. Our writers are trained to understand that our job is not to produce a data dump: it is to think about the data available and work with the team to pull out the messages and present them as clearly as possible, so that a reviewer can quickly find the information they are looking for and easily understand the story to be told. Our approach to writing clinical documentation ideally results in a minimum of clarifying questions from reviewers, speeding the process of review and ultimately leading to faster approval.

Trilogy currently has more than 40 writers, who are located in Trilogy's 3 offices: Frankfurt in Germany (HQ), Cambridge in the United Kingdom, and Durham, North Carolina, in the United States. We pride ourselves on our "dedicated team" approach when developing documents, which greatly reduces the time needed for production and ensures much greater levels of continuity throughout an entire development program.

Please contact Mari Welke at mari.welke@trilogywriting.com for more information.

* * *

Microsystems

Microsystems DocXtools for Life Sciences is a software that integrates into Microsoft Word and is designed to find deviations from document standards quickly with features that identify and fix the incorrect usage of abbreviations, symbols, formats, and phrases.

DocXtools was developed with the recognition that a decade of research, thousands of patients, and countless hours of work can go into developing new drugs and therapeutics. After all this investment, a business can't afford to waste time and resources on document formatting and layout during preparation for regulatory submission.

When it comes to the final steps of completing eCTDs in the correct format, accelerating the authoring and review process and automating quality checks are more than important; they are essential. DocXtools helps ensure high-quality documents quickly, permitting companies to accelerate their eCTD creation and quality control processes with the ultimate goal of improving the health of patients.

Microsystems is focused on helping organizations spend more time creating great documents and less time fixing them. Over the years, as we've learned what goes wrong with complex documents, we have proactively sought out our clients' pain points to create solutions for them. We made a simple promise: to solve our clients' document problems and free them up to focus on what matters.

Please contact Matt Miller at mattm@microsystems.com for more information.

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The University of the Sciences Biomedical Writing Programs

The University of the Sciences Biomedical Writing Programs—an MS in Biomedical Writing and 2 certificate programs—are 100% online with admissions on a rolling basis for 3 full 15-week semesters a year. The MS program is geared mostly toward nontraditional students, that is, students who are currently or recently employed, may have some experience in the pharmaceutical/device industries, or have a background in technical writing or journalism and wish to change careers. The program can also be useful to those who have established their basic careers within the industry but are looking to advance to the higher levels, start their own business, or shift career tracks to medical writing. The certificate programs, either regulatory or marketing writing, are suited to those who are well established but need some additional education and credentialing in order to have an easier career-track advance or transition.

The specific structure of the 12 courses in the MS program includes 5 required foundation courses, 4 electives, and 3 required courses in the final research module. All courses are 15 weeks and 3 credit hours, except for Special Topics in Biomedical Writing and Independent Study; these 2 courses vary from 1 to 3 credit hours. The foundation courses include an overview of medical writing, information science and publication database searching, drug development from a medical writing standpoint, foundations of statistics geared toward helping writers work with biostatisticians, and legal and ethical issues, including the ethics of medical writing, human use in research, and intellectual property, along with an introduction to the legal issues in drug promotion. The research 3-course module includes a methods course followed by 2 semesters of individual research.

There is a varied selection of electives, including courses on devices, biologics, chemistry manufacturing and controls, continuing medical education, and special topics that can vary depending on the availability of instructors with specialist knowledge at any given time.

We believe that we offer a deep-background program that helps start medical writing careers on the right track and can boost those careers from midlevel writing to positions of greater responsibility.

As of this writing, there are discounts available for most students enrolling in the MS or certificate programs. In addition, AMWA members who are accepted and enroll in the MS program can receive an additional 15% discount on the first 12 credits for which they enroll.

For more information, please contact Dan Benau at d.benau@usciences.edu or visit https://www.usciences.edu/mayes-college-of-healthcare-business-and-policy/biomedical-writing-ms-certificates/application-process.html.

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National Library of Medicine

The National Library of Medicine (www.nlm.nih.gov), the world's largest medical library, has been involved with AMWA—in particular, exhibiting at annual conferences—for more than a decade. In that time, we have answered many astute (and sometimes challenging!) questions, collaborated with AMWA staff on training and education opportunities for members, done a bit of mentoring and job coaching, benefited *ourselves* from attending educational sessions and hearing guest speakers, and developed many meaningful friendships. (We've also been pleased to receive suggestions for improving our resources, which we've always shared with the appropriate NLM office.) Throughout, it's been gratifying to witness how AMWA has grown, not only in number of members but also in its dedication to education and knowledge-sharing. We look forward to seeing many of you in Washington, DC, for the 2018 conference, and to many more years of fruitful collaboration.

For more information, please contact:
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Deputy Director
Office of Communications and Public Liaison
National Library of Medicine
melanie.modlin@nih.gov

* * *

PubsHub Software Solutions

Increasing speed & efficiency for medical communications teams

Global medical affairs publications teams must communicate scientific and medical information for both pipeline and commercial products in an accurate, transparent, and efficient manner. They must comply with stringent ICMJE and GPP3 guidelines and other global regulatory requirements, often under compressed timelines and with limited resources.

PubsHub brings speed and efficiency to medical teams by delivering easy-to-use, Web-based solutions that bridge process gaps for system harmonization across companies. The solutions are powerful, cost effective, and configurable, yet with an uncomplicated approach that allows for rapid deployment and immediate user traction, resulting in high return on investment.

PubsHub serves pharmaceutical, biotechnology, medical device, and research-based companies. Our intuitive, easy-to-use, Web-based products stand alone as well as integrate with one another to streamline scientific content development and distribution to bring new therapies to market faster.

Our client services team helps clients leverage system advantages to achieve better business results. We offer a full range of industry-leading services, including change management best practices and systems integration.

PubsHub Product Line

PLATFORM: SaaS technology supporting strategic foundations for your communication plan.

Journals & Congresses

PubsHub Journals & Congresses is a time-saving tool that gives researchers and scientists the ability to search and filter across thousands of medical journals and scientific conferences using the criteria that fits their publication needs all in one place.

PMSolution

Manage your entire publication development process with less effort in meeting deadlines, maintaining version control, tracking reviews and approvals, and creating on-demand reports for your medical communications teams.

Knowledge Manager

Use this enterprise-wide document repository for the appropriate and efficient dissemination of scientific materials. Knowledge Manager allows you to organize and search scientific content for quick and easy retrieval.

PubsHub Strengths and Unique Capabilities

We are well-positioned to partner with you. When you choose PubsHub SaaS Software, you are getting a quality system and a team who understands that success depends on excellent execution.

Please contact us at enquiries@iconplc.com for more information.

Bioscript

- Bioscript is an established, **independently owned**, full-service agency group with specialist expertise in medical communications, strategic planning, regulatory writing, digital solutions, and health economics and outcomes research.
- Through close **collaboration**, we build talented, cross-functional teams to provide tailored, high-value **support across the product life cycle**.
- Our culture values hard work and innovation while promoting a **rewarding environment** and a good work/life balance—we believe this is key to our ongoing success, because it allows us to
  - **Attract** a unique blend of highly sought experts who are motivated by a desire to provide quality service and exceed expectations.
  - **Retain** these talented professionals so that we can bring the benefits of continuity and long-term partnerships—experience, efficiency, insight, and added value—to all of our clients.
  - **Promote** the individual responsibility, leadership, and flexibility needed to adapt to client needs and deliver successful, industry-leading solutions.

AMWA members may contact Jackie Richards, Operations Director (Jackie.Richards@bioscriptgroup.com) for additional information about our professional services.

For US medical (regulatory) writing services, please contact Barbara Lombardi by phone (1-609-480-5457) or email (barbara.lombardi@bioscriptgroup.com).

For US medical communications services, please contact Ruth Widmer (ruth.widmer@bioscriptgroup.com).

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The Editorial Freelancers Association

The Editorial Freelancers Association brings together nearly 2500 editors, writers, proofreaders, translators, indexers, and other editorial professionals who are located across the United States and internationally. We are a professional association that serves independent editorial specialists and those who need to hire them. Specialties of members who focus on the health sciences range from copyediting pharmaceutical ad copy to creating abstracts of scientific articles to writing, copyediting, proofreading, and indexing nonfiction trade books. Some hold doctoral degrees in areas such as biochemistry and neurobiology.

Clients can find members whose skills match their goals by searching our free online **Member Directory**. You may mark a specific specialty from our list of search terms, such as "medicine" or "nursing." You can also do a keyword search for a more specific term, such as "oncology" or "public health," to further focus your results. Another great way to find a freelancer is to post an ad on our free online **Job List**. Because of these free services, *Publishers Weekly* has called the EFA "the book publishing industry's most powerful secret weapon."

As an EFA member, you can draw on a wide array of resources to help expand and support your freelance business and to connect socially and professionally with colleagues who share your interests and concerns. The Directory and Job List are sources of new clients for many members. Others join primarily for our online Discussion List. It's active, collegial, and energetic; we discuss language issues, as one might expect, but also share resources and ask for advice on specific business situations. Members can avail themselves of discounts on the reasonably priced **online courses and webinars** we offer throughout the year, designed and taught by other editorial freelancers specifically to address your needs. Networking opportunities abound. We have active chapters in more than 20 locations around the United States that offer their own social and skill-building programming. And because we are volunteer-run, there are many opportunities to get involved and expand your networks of colleagues and potential clients. For a full list of membership benefits, click here.

For more information, please contact us at office@the-efa.org or visit our newly redesigned website at www.the-efa.org.

And don't forget to follow us on Twitter: https://twitter.comEFAFreelancers and Facebook: https://www.facebook.com/editorialfreelancersassociation/.

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Global Medical Writing & Translation

Global Medical Writing & Translation (GMWT) is a rapidly growing boutique regulatory writing company that specializes in a few core areas. We're scientists, researchers, engineers, and prolific writers. We know the business and we hit the ground running. We work in teams, so for every client, a team of our very best writers tackles assignments together to bring decades of experience to each project.

Our Focus

We didn't want to be just "pretty good" at everything; we want to be the best at a handful of really important things. So, our company is organized by team:

1. **Medical Device CER Team:** Preparation of Clinical Evaluation Reports for all devices sold outside the United States.
2. **CMC Team:** Preparation of eCTD manufacturing sections and material.

3. **Biologics and Biosimilars—General Writing:** We have decades of experience supporting Clinical, CMC, and Regulatory Strategy writing in large molecules.

Our Approach

GMWT is entirely remote, with some travel as needed to support our clients on important occasions. We are very different from other medical writing companies.

1. **Team-Based Structure:** We work in teams to share our strengths on each project and enable each other to enjoy a flexible work schedule. We are deliverable-based, so as long as assignments are finished on time and you are available for communication during normal work hours, we don't care where or when you are working.
2. **Specialized Training for All Levels of Writers:** Point-blank, there is more work out there than trained writers, particularly in our niche areas. GMWT has carefully built training infrastructure as well as a mentorship program into each team. We hire at all levels of experience—those with the most experience build out teams and lead them, and those with the least experience are able to jump in and learn the ropes of medical writing. We take great pleasure in finding the most promising writers and teaching them how to become experts in their craft.

We take care of each other. At GMWT, we believe in and practice a healthy work/life balance. We mentor together, learn together, we lead and we follow. We stand by our creed: WE WRITE. YOU CURE.

GMWT is currently looking for go-getters with advanced degrees who have experience in any of the following areas:

- CMC Specialists (biologics, biosimilars, small molecules)
- General Clinical Regulatory Writing (protocols, CSRs, IBs, etc)
- Medical Devices/Cardiology
- Medical Devices—Regulatory Affairs

Please email your CV to Emily Stephens at estephens@globalmwt.com if you are interested in working with us.

* * *

Cardinal Health Regulatory Sciences

Over the past 40 years, Cardinal Health Regulatory Sciences has provided industry-leading expertise and guidance to help pharmaceutical, biotechnology, and medical device companies accelerate their journey to regulatory approval while maintaining high quality and avoiding costly pitfalls. We specialize in the areas of regulatory strategy, lifecycle management, nonclinical and clinical consulting, CMC, compliance, medical writing, regulatory operations, and submission operations, with more than 500 product approvals across more than 175 countries. Our experienced team of more than 200 scientists, regulatory consultants, writers, and document specialists have an average of 18 years of industry and regulatory experience. Our regulatory and product development strategies are designed to reduce risk and maximize value from discovery to commercialization.

With expertise across a wide array of therapeutic areas, the medical writing team at Cardinal Health Regulatory Sciences helps clients prepare clear, concise, and accurate documents to effectively demonstrate their product's potential. Our clinical, nonclinical, and CMC regulatory writers truly operate as an extension of your regulatory team and adhere to ICH and FDA requirements using detailed templates and style guides. In addition to small molecule regulatory writing, Cardinal Health has supported writing efforts for more than 40 orphan products and several 505(b)2 NDA submissions over the past 5 years alone. We have also supported BLA writing and submission processes for nearly 35% of the biosimilar approvals in the United States. Combined with our diverse therapeutic expertise, we have the experience needed to prepare any and all documents along the drug development process from pre-IND, to IND, to NDA regulatory approval and beyond, to post-marketing commitments.

Contact our team today to learn how we can help you reduce cost and risk and accelerate your product's journey to regulatory approval:

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Whitsell Innovations, Inc

Whitsell Innovations, Inc (WI) is a boutique medical and scientific writing and quality control review firm. We are headquartered in Chapel Hill, North Carolina, and have writers in 13 US states. We've written a broad range of documents for the life sciences industry, and we specialize in 5 main areas: clinical regulatory writing, chemistry manufacturing and controls regulatory writing, manuscripts and educational materials, safety/pharmacovigilance, and strategy (high-level process support and project management for document submissions). Our ideal clients are pharmaceutical, biotechnical, or medical device firms that embrace quality as an underlying ethos for medical writing.

What we think differentiates WI is our culture. Although we are remote workers, we emphasize communication, collaboration, and teamwork as the way to create our best product. We embrace our family-friendly and collegial nature. We believe in the scholarship of medical writing as a profession and the importance of professional development in creating high-quality work. For this reason, we consistently participate in AMWA on a regional and national level. Attending and presenting at AMWA meetings is a great opportunity for our staff to grow as writers, presenters, and thought leaders. It gives us a chance to participate in and inform the conversation around best practices in medical writing, which ultimately allows us to have the greatest impact on the lives of the patients we all serve.

WI is a growing organization. We are always interested in adding talented and dynamic scientist-writers to our team. Each person we add helps grow our culture and impact. Adding team members also allows us to serve additional clients while maintaining an appropriate work-life balance.

Interested writers can reach us at: careers@whitsellinnovations.com

POSTERS

To view the following posters from the 2017 AMWA Medical Writing & Communication Conference **click here**.

First Thursdays: Strengthening the FL AMWA Chapter Through Effective Networking
Larry Lynam, Melory Johnson, Barbara Goodheart, Clyde Goodheart, Shara Parry, Irvin Peralta, Stanley Sack, Lynne Schneider

Development and Communication of the AMWA–EMWA–ISMPP Joint Position Statement on the Role of Professional Medical Writers
Art Gertel, Christopher Winchester, Karen Woolley, Yvonne Yarker, on behalf of the American Medical Writers Association, European Medical Writers Association, and International Society for Medical Publication Professionals

Use of Standards and Automation to Deliver Cost-Effective Patient Narratives
Mary E. McKenna, Angela M. Horowitz

Authoring Protocols for Different Phases of Clinical Development: Key Differences and Tips for Preparation
Barbara Orban

Best Practices for Writing CME Needs Assessments 2016
Katherine L. Molnar-Kimber, Donald Harting

Communication in a Virtual Team and Telecommuting
Sharad Wankhade

Write How? Do Writers Have the Instructional Design Skills Necessary to Develop Effective Communications?
Deborah Anderson

Crash Course in Food and Dietary Supplement Regulations
Kelly Kilibarda, Stephen Carlson