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The AMWA Journal expresses the interests, concerns, and expertise of members. Its purpose is to inspire, motivate, inform, and educate them. The Journal furthers dialog among all members and communicates the purposes, goals, advantages, and benefits of the American Medical Writers Association (AMWA) as a professional organization. Specifically, it functions to

➢ Publish articles on issues, practices, research theories, solutions to problems, ethics, and opportunities related to effective medical communication

➢ Enhance theoretical knowledge as well as applied skills of medical communicators in the health sciences, government, and industry

➢ Address the membership’s professional development needs by publishing the research results of educators and trainers of communications skills and by disseminating information about relevant technologies and their applications

➢ Inform members of important medical topics, ethical issues, emerging professional trends, and career opportunities

➢ Report news about AMWA activities and the professional accomplishments of its departments, sections, chapters, and members

The opinions expressed by authors contributing to the Journal do not necessarily reflect the opinions of AMWA or the institutions with which the authors are affiliated. The association accepts no responsibility for the opinions expressed by contributors to the Journal.

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41 ERRATUM
A funny thing happens when you are named editor of a publication whose audience is made up entirely of writers and editors. You begin to doubt your understanding of words and sentence structure. You race to the dictionary to look up words whose meaning you have never once pondered and whose spelling you could have rattled off easily by sixth grade. (Or is it 6th grade? Make a note to check the style. And can the words “publication” and “words” take a “whose”? Of course they can. Can’t they? Yes! No? Pretty sure.)

That, at least, is what has happened to me, in this ongoing n of 1 study that is my life. I mention these obsessions, knowing the risk involved. It practically screams out an invitation to all to carefully scrutinize each sentence of the Journal to find where the editing has gone astray. Yes, read every word! I have obligingly planted mistakes for you to discover, although at this particular moment I may not recognize exactly where they are.

I hope my obsessions will yield positive results for the AMWA Journal, as I want this publication to showcase the crystal clear communication of AMWA members, as well as that of authors beyond our organization who have something to say of interest to our field. If individual sentences aren’t clear, the big picture can easily be lost, and the big picture of health and medicine is of vital importance.

As I write this column, there are more than 5,000 members of the American Medical Writers Association. And there are 7 billion people on the planet. It stands to reason, then, that most of the medical writing and editing going on out there is being done by people who are not members of AMWA.

I mention this because it seems significant to me that we work in an environment in which most people glean their information of health and medicine from sources well beyond the materials our members create. Most articles, publications, and communication vehicles are created by people who may not have not had the benefit of the training offered by AMWA or organizations with related educational missions. That is not to say such information sources must therefore be bad, but we have all experienced the ambiguity, lack of essential context, and mistakes in too much of what we read, hear, or view.

What does all of that mean for AMWA and the AMWA Journal? Enormous opportunities and daunting challenges as we try to expand our reach, an important goal because the world has an insatiable demand for health and medical information and it ought to be reliable. AMWA educational programs and publications provide medical writers and editors with ongoing lessons in clearly communicating biomedical information and living up to the ethical standards that organizations such as ours have established.

Back when I was a newspaper reporter, I used to say that journalists were only as good as their sources. Now I recognize that statement was 75% excuse, 25% explanation, but in essence I was trying to say that if the people I interviewed either didn’t have relevant information or couldn’t explain it well to me, the story that appeared in the next day’s paper would reflect the limitations of the sources.

Medical writers and editors face a similar predicament. In creating content, we rely on the content of others, flawed though it sometimes may be. For health care consumers, if the population of the planet, the much more important predicament is making health decisions based on too shaky a foundation. We must therefore continue to improve writing quality: in the words that many of us obsess over, and the sentences, paragraphs, articles, and books—and the images, audio, and video as well. At the same time, we need to do what we can to make sure we understand what high quality communication really is. The answers from carefully conducted research, after all, can be substantially different from what is expected at the outset.

The AMWA Journal is an interesting hybrid of a publication—research journal, news magazine, and association newsletter. Each part, I hope, will continue to help medical writers and editors become better at what they do. It will, however, only be as good as its contributors. I say that not as an excuse but as a challenge to make sure I am reaching out far and wide to find the best possible contributors and sources of information, and a challenge to you to send me ideas for articles that either you can write or that you wish someone would write.

I am fortunate to be taking over as editor after Lori Alexander, who did a great job of reaching out to find writers, reviewers, section editors, manuscript editors, and proofreaders. She made it all look easy, and I am grateful to her for leaving me with a publication in such good shape and for her ongoing help in seeing me through the transition. My job will be to build upon her efforts. Please join me in this endeavor.

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ABSTRACT
This article provides medical writers with an introduction to the topic of language translation and provides an overview of what translators do when producing texts in other languages. Translation is becoming an important aspect of medical communication as medical industries increasingly seek out market share in a global context. Success in such an international sphere often becomes a matter of access, and in many cases, this access is connected to one key factor: translation, which allows speakers of other languages to access key information needed to understand/access ideas or operate devices (ie, access information on how to use a particular item).

Within this context, documents that are easy to translate (ie, allow translators to convey meaning across languages easily) contribute to this idea of access. This context requires medical writers to review their writing practices to consider how they might create texts that can be translated easily and effectively.

To engage successfully in such practices, writers need to understand what translation is and what translators do. Translation, however, is a complicated process involving a specialized skill set relating to language and meaning. For the medical writer, the challenge becomes viewing the translator as one of the many audiences that will read his or her work. This perspective of translator as reader can help medical writers produce texts that better meet the informational needs of translators. Moreover, such a perspective can be coupled with certain writing strategies that can improve the readability of texts in general as well as facilitate the translation process.

The international nature of modern business has changed how medical writers think about their audiences. Traditionally, patients and health care professionals read medical documentation to learn how to perform a given process or use a particular product. Today, however, companies operate in a wider global context and seek to attract readers from many nations and cultures. As a result, medical writers are increasingly expected to consider a new audience—translators—when producing documentation for overseas markets. This article presents an overview of the translation process and suggests strategies that medical writers can use when working with or writing for translators.

TRANSLATION AND INTERNATIONAL MARKETS
In the past decade, the global demand for medical products has grown greatly. The international market for medical devices, for example, currently represents more than $300 billion in sales. Some organizations expect worldwide sales in the pharmaceuticals market to top the trillion dollar mark in the next few years, with rapid growth in emerging economies such as those of Brazil, Russia, India, and China. In addition, with the aging of the world’s population, global demand for such products—and related documentation—will only increase. As one report has noted, the global population of persons 60 years of age or older is projected to grow from 688 million in 2006 to almost 2 billion by 2050. This number would represent 32% of the planet’s inhabitants, many of whom will need some sort of medical care. For these reasons, today’s medical companies need to think in terms of global consumer bases.

Within this context, translation is essential to international business success, and its importance relates to the concept of access in overseas markets. Specifically, people will buy only those products that are physically available for purchase (actual access) and that they can use or consider worth using (cognitive access). Translation makes both kinds of access possible and enhances product success in global settings.

In the case of actual access, laws relating to language affect whether a product can be sold in a particular market. Canadian regulations, for example, require certain packaging information to be provided in both English and French for products such as medical devices that are to be marketed to a general Canadian consumer base. Similarly, the highly lucrative European Union market (just over 500 million persons in 27 nations) generally requires that product documentation be translated into the various official languages of member states. These language requirements can be particularly complex in situations in which various regulatory agencies must review documentation and provide approval for a product to be marketed and sold in different nations. Moreover, the implementation of US directives such as Executive Order 13166 (Improving Access to Services for Persons with Limited English Proficiency), which affects how medical information is conveyed to patients,
could mean that translation also becomes a requirement when producing medical documentation for different audiences within the United States.11 (See www.justice.gov/crt/about/cor/Pubs/eolep.php for the text of this Executive Order.) Thus, in almost all medical industries, translation is essential to international competitiveness.

The quality of a translated document can also affect how prospective buyers view a product. Some cultures, for example, view manuals as sales tools, and the quality of documentation is taken as a reflection of the quality of the related product;12 if the manual is poorly translated, then it is assumed that the related product is of poor quality. Furthermore, ineffective translations make information and instructions difficult to understand, thereby making the related product difficult to use (ie, restricting cognitive access). Finally, if a manual is not translated at all (ie, presented only in the original language), the failure to translate could be viewed as a slight. Failure to translate could even render a product useless, as prospective consumers might not be able to read foreign-language instructions (another example of restriction of cognitive access). Medical writers, therefore, need to understand the translation process if they wish to help their organizations succeed in the global marketplace.10

THE TRANSLATION PROCESS
Translation is not a simple process of converting individual words from one language to another. That is, it is not a process that anyone can do, with the aid of a bilingual dictionary and enough time. Rather, translation is a specialized skill for which the translator must know two things:

1. what wording to use to convey the same idea correctly and effectively in another language1,13
2. the rhetorical expectations of both cultures, in terms of how to present information credibly to their respective members.1,13

This knowledge enables translators to convert the original version of a document (known as the source text) into another language (known as the target language).

In essence, just because something is stated in a particular way in one language does not mean that the idea should or can be conveyed the same way in another language.1,13 In English, for example, one can ask, “Can you come here?” For the translator who needs to convert that sentence into French, a key question would be, “What is the relationship between the speaker and the listener?” The important cultural issue in this case is that French has two words for the pronoun vous: The pronoun vous indicates a level of formality, distance, respect, and difference in position between speaker and listener. In contrast, the pronoun tu indicates informality, intimacy, and a lack of status difference. The translator who uses the wrong version of vous could inadvertently insult the reader, either by making it appear as if the writer is “talking down to the reader” (the tone being too informal) or by making it appear that the writer wishes to appear aloof and detached from the reader (the tone being too formal).

Thus, translation is not about converting words from one language to another; rather, it is about effectively conveying meaning from one language and cultural system to another.14,15 As such, the translator must first determine what the text means, or what the writer wishes to convey, in the original language. Next, the translator must select the best way to convey that meaning in the target language. In the case of medical writing and medical translation, the translator must often be familiar with the specialized vocabulary of a given industry to produce accurate translations.10 For these reasons, translation is both time consuming and labor intensive. The typical translator, for example, can usually translate 2,000 to 3,000 words a day,16-18 with more time needed for technical documents of greater complexity.19 Any hurrying of this process (ie, requesting a “rush” translation) could result in a loss of meaning or an inaccurate translation14 and will generally also mean higher costs—as much as 30%-50% more.20,21

Moreover, a translated document should ideally be reviewed by a second translator to ensure quality. The second individual compares the source text with the original translation, making revisions or edits, as necessary, so that the correct meaning is transferred across languages. In this respect, translation is like any other form of writing: review by a second pair of eyes can help to catch errors or other problems that the original translator has missed. As for the initial translation process, attempts to rush such a review could affect the quality of the final translated text.

Unfortunately, no licensing process for translators exists in the United States. However, one organization, the American Translators Association (ATA), does provide a certification that can help medical writers assess the qualifications of prospective translators. Such certification is based upon taking and passing an ATA examination that generally requires individuals to translate two passages of text from one language into another. Two graders assess the quality of the translated texts. Those who successfully pass such examinations receive ATA certification in the translation of particular language pairs (eg, from English to French). Such exam-based certification can, in turn, provide medical writers with a mechanism for determining the skills of a particular translator. ATA certification, however, does not exist for all language pairs (see www.atanet.org/onlinedirectories/individuals.php for a list of the languages and areas for
which the ATA does offer certification tests). Individuals considering hiring or working with translators might wish to review the ATA’s website (www.atanet.org) to learn more about the skills and abilities to expect from an effective translator. Medical writers who need to locate a translator for international projects can start by consulting a variety of directories on the ATA site (see www.atanet.org/onlinedirectories/).

TRANSLATION AND THE PROBLEM OF AMBIGUITY

Within the context of translation, ambiguity is highly problematic, and it often relates to one of two situations. Either the intended meaning of a word is unclear, or the context in which that word appears makes its meaning uncertain. Consider the word *set*, which has multiple, different meanings. If a text contains the sentence “We need a set,” the translator must determine which meaning the writer intends. Similarly, the limited context in which *set* appears in this example does not provide the information necessary to determine the intended meaning.

The result of such situations can be twofold. First, the translator might guess at the intended meaning. Yet such guessing—especially when the translator is unfamiliar with the topic—threatens the quality of the translation. Second, the translator might query the writer to determine the meaning of the word or phrase. In the latter case, a good deal of time could then be spent playing “e-mail tag” as translator and writer attempt to exchange information. For each additional meaning-related question, more time is taken. Moreover, while the translator waits for the writer’s response, he or she may be unable to continue with translation of part or all of the document.

One factor contributing to problems in both these situations is the translator’s own background. Ideally, translators transfer meaning from a second language into their native tongue. As such, the best person to translate from English into French would be a native French speaker who is also fluent in English. The reason for such an arrangement is that native speakers of the target language are more familiar with the linguistic and rhetorical conventions expected by members of their same culture. However, translators might not be familiar with all of the nuances of meaning used by authors writing in the source language, which is the translator’s second language. Medical writers who address translation-related issues as they are creating documents can thus contribute to the quality of translation and to the speed with which translated materials (and their related products) reach an overseas market.

To achieve this end, medical writers can use certain strategies that remove ambiguity and specify meaning to create translation-friendly documents that are easy to convert into other languages. These strategies are based on a two-part process of glossary-building and writing for translation.

GLOSSARY-BUILDING

An essential part of facilitating translation is to create a glossary for each document. The aim is to provide translators with definitions of potentially problematic terms. Glossaries remove much of the guesswork or questioning that can take place during the translation process and can contribute to the quality of a translation, while enhancing the speed with which a document can be translated.

The more information that medical writers provide in a glossary, the better. For this reason, glossary entries should have four parts to help specify the meaning of a term:

1. the term being defined
2. the part of speech of the term (e.g., noun, verb, adjective)
3. the definition (intended meaning) of the term
4. a sentence illustrating how the term is used within the source text.

A sample glossary entry for the word *set* might look like this:

*set* (noun): a collection or a group of items

*Example*: These six scalpels are part of a *set* of tools used by the surgeon when performing this procedure.

This four-part format limits assumptions about what the term could mean. By providing the part of speech, the writer limits the number of meanings that the translator can associate with the term (in this example, informing the translator that *set* is a noun enables the translator to dispense with meanings associated with *set* as a verb). By providing a definition of the term, the writer focuses on a specific meaning for that word. By providing a sample sentence, the writer helps the translator to confirm the meaning and facilitates understanding of how that term is used within the context of the document being translated.

Two types of terms should be defined in a glossary: commonly used words with multiple meanings and technical or industry-specific terms essential to the context of the document. With regard to the first of these types, the word *set* is a common term used in everyday conversation, and its multiple meanings can cause problems as the translator attempts to determine what the writer intended to convey by using that word. A glossary entry for *set* limits the meaning to one and only one definition. Writers must then confine their use of such multi-meaning terms to those indicated by the related glossary definition for the document in question.

Specialized terms essential to the context of the document might relate to specific medical terminology (e.g., *thrombus* instead of *blood clot*) or a particular industry (e.g., *lead* instead of *wire connecting the pacemaker to the*
heart). In such cases, although the term may be uncommon, its use is essential to the overall presentation. Translators, however, might not be familiar with such technical terms, and even translators who are familiar with a given field might not know all of its technical terms.\textsuperscript{1,10,14} For example, whereas many health care professionals recognize the word defibrillator, some of them might not recognize the terms sinus rhythm, P waves, or R waves. In these situations, a glossary becomes essential to correct translation.

Organizing translation glossaries requires forethought. In some cases, the writer might assume that glossary entries should be organized in order of appearance of the terms in the source text. This assumption seems like a logical time saver: by listing the words in order of appearance, the writer cuts down on the time the translator has to spend scanning alphabetic entries looking for the definition. Such an approach, however, makes it difficult to find that same word later, should it appear elsewhere in the text. With no structure other than “first come, first served,” the translator must read through a series of entries to find the correct term upon its second or third mention. Glossary entries should therefore be organized alphabetically so that translators can easily find the definition of a term on its second, third, or any subsequent use.

**WRITING FOR TRANSLATION**

Medical writers can also facilitate translation by writing in a way that reduces ambiguity and removes culture-specific references. Known as writing for translation, this approach creates texts that can be translated more quickly and more effectively than would otherwise be the case. Moreover, this process, which focuses on removing ambiguity, is associated with effective writing in general and can be used to improve the quality of a source text, as well as facilitate its translation.

In essence, writing for translation involves three general principles: avoiding culture-specific expressions, indicating relationships, and focusing on singular meaning.

**Principle 1: Avoid Culture-Specific Expressions**

When converting meaning from one language to another, translators often rely on a literal reading of a text. Thus, expressions that require readers to interpret the nonliteral meaning can be problematic. For this reason, medical writers should not use idioms that have culture-specific meanings (eg, “it’s raining cats and dogs”) but should instead use text that can be interpreted literally (eg, “the rain is falling rapidly and in great quantity”).\textsuperscript{1,14,15}

Similarly, medical writers should avoid metaphoric expressions that rely on a particular cultural understanding to interpret the implied meaning (eg, “it is a bear of a task to complete”). Medical writers should also avoid abbreviations, or should spell out the component terms of each abbreviation upon initial use, for many abbreviations are not recognized outside of certain cultural contexts (eg, the abbreviation “FDA” stands for “Frente por El Derecho a Alimentarse/ Front for the Right to Food” in Mexico and “Fonds de Développement Agricole /Agricultural Development Fund ” in France).\textsuperscript{1,14,15,23}

**Principle 2: Indicate Relationships**

When drafting texts for translators, medical writers should include words that make clear the relationships between items in a sentence or a paragraph.\textsuperscript{1} Every pronoun, for example, should have a clear antecedent to prevent confusion about the item to which it refers. Thus, the expression “This is a problem” leaves the translator wondering “This what? What exactly is the problem in this particular situation?” Because the term this could refer to a number of preceding terms, a noun should be inserted, so the translator will know exactly what it refers to (eg, “This failure to correctly calibrate the device is a problem”).

Similarly, writers should clarify the number of and relationships between items listed in a document. For example, the phrase “You need a pacemaker and lead” could be taken literally as meaning that the user needs a single unit (ie, a combined device made up of a pacemaker and lead, akin to a block and tackle). To address such situations, medical writers should use parallel structure. Since the equipment in this example actually consists of two separate devices, a translation-friendly version of the original sentence would read “You need a pacemaker and a lead.”

**Principle 3: Focus on Singular Meaning**

In addition to providing translators with a glossary, medical writers must write in such a way that each individual word has only a single meaning throughout the text.\textsuperscript{1,10,14} If a writer uses the same word to refer to two or more ideas within a text, then the translator must constantly query the writer to confirm the intended meaning each time the word appears (eg, “Do you intend for the word to mean X, Y, or Z in this passage?”).

Conversely, using different terms to refer to the same concept can cause confusion. For example, here are instructions for a patient, which use three words to refer to the same piece of equipment: “Place the monitor over your pacemaker and hold it there for 10-15 seconds. The device will then beep twice to indicate it has collected the needed information. You can then return the item to its holder.” In such cases, the translator could spend a lot of time trying to find the correct translation of each different term instead of being able to quickly translate the same term repeatedly. In this example, the word monitor could be used three times, instead of monitor, device, and item. Such repetition does not create the most entertaining of texts, but
it produces work that is easy to read, understand, and translate—factors that are foundational to effective medical writing in general.1,10,14

Writing for translation is no easy task. It often requires reflection while writing and requires individuals to be continually conscious and critical of how they write a given text. Both of these factors can initially impede writers’ flow and style as they adapt to the process. Once learned, however, the principles of writing for translation can reduce time and money spent on translation and can also improve the quality of the original source text.1,0,14

CONCLUSION
Global markets are now essential to success in most, if not all, medical industries. Thus, translation has become an essential practice within modern business, for it enables access to prospective overseas consumers. Medical documentation that can be easily translated allows products to enter international markets more quickly and can help businesses to more rapidly gain market share in other countries. By understanding the translation process, by designing glossaries, and by writing for translation, medical writers can facilitate translation and can help their companies or clients succeed internationally.

Author disclosure: The author reports that he has no commercial associations that may pose a conflict of interest in relation to this article.

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References
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ABSTRACT
Most biomedical writers are generally familiar with the quality-enforcement activities of the US Food and Drug Administration (FDA), but few appear to know about the compendial standards in the US Pharmacopeia–National Formulary (USP–NF), which may be enforced by the FDA. This article briefly outlines the history and applications of USP–NF and reports the results of a survey of AMWA members regarding modern applications of these compendia. Although the response rate to the survey was low, respondents’ answers suggest that it may be worthwhile to focus attention on certain concepts in compendial science. Improved familiarity with compendial science will help biomedical writers understand the role of public standards in ensuring the identity, strength, quality, purity, and potency of drug substances, drug ingredients, and drug products.

It is the purpose of a Pharmacopoeia to select from among substances which possess medicinal power, those, the utility of which is most fully established and best understood; and to form from them preparations and compositions, in which their powers may be exerted to the greatest advantage. It should likewise distinguish these articles by convenient and definite names, such as may prevent trouble or uncertainty in the intercourse of physicians and apothecaries.1

It is the purpose of a Pharmacopoeia to select from among substances which possess medicinal power, those, the utility of which is most fully established and best understood; and to form from them preparations and compositions, in which their powers may be exerted to the greatest advantage. It should likewise distinguish these articles by convenient and definite names, such as may prevent trouble or uncertainty in the intercourse of physicians and apothecaries.1

In the United States, compendial requirements for naming and identity were enacted in law as early as the 1848 Drug Import Act and more extensively in the 1906 Food and Drugs Act. The latter established the Food and Drug Administration (FDA) and defined drugs as “all medicines and preparations recognized in the United States Pharmacopoeia [USP] or National Formulary [NF].”4 The 1906 act importantly introduced the concept of adulteration: drugs that differed from “the standard of strength, quality, or purity” in USP or NF were deemed to be adulterated (ie, contaminated by impurities) and thus unfit for human consumption. In 1937, 105 patients died after taking sulfanilamide that had been formulated with toxic ethylene glycol.5 The following year, Congress passed the Food, Drug, and Cosmetic Act (FDCA), which specified that a drug is adulterated “if it purports to be or is represented as a drug the name of which is recognized in an official compendium [USP or NF], and its strength differs from, or its quality or purity falls below, the standards set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium ...” [FDCA §201(b)]. Further, Title 21 of the Code of Federal Regulations refers to compendial standards of “identity, strength, quality, purity, and potency” for drug substances, drug ingredients, and drug products [eg, §601.12(a)(2) and §514.8(1)(2)(i)]. Failure to meet these standards is a violation of current Good Manufacturing Practices.6

During the 19th century, USP was updated at approximately 10-year intervals by volunteers who met as the US Pharmacopeial Convention, which was formally incorporated in 1900 and is a 501(c)(3) nonprofit organization working in the public interest. In 1975, the US Pharmacopeial Convention acquired NF and since then has published the compendia in a combined volume, USP–NF.4

CONTENTS AND APPLICATIONS OF THE COMPENDIA
Biomedical writers generally know about FDA’s activities, but the contents and uses of the compendia are less well known. Manufacturers, purchasers, and regulators rely on compendial tests to
ensure that items in fact comply with their label claims.\textsuperscript{7} Items that fail compendial tests may have been accidentally adulterated (eg, the sulfanilamide tragedy of 1937) or deliberately adulterated for economic gain (eg, the heparin and melamine scandals of recent times).\textsuperscript{5,8,9} Pharmaceutical companies routinely rely on compendial tests to ensure the quality of their raw materials; after their finished products pass compendial tests, the products can be released into commerce with assurance to manufacturers, regulators, and consumers that the products are authentic.\textsuperscript{7} Both of these activities—quality assurance and protection from fraud—involves the compendia and should be well known to biomedical writers who may be called on to explain important concepts related to the identity and quality of pharmaceuticals.

USP reference standards used in compendial testing are highly characterized specimens of drug substances, excipients (ie, ingredients such as bulking or processing agents), impurities, degradation products, reagents, or calibrators.\textsuperscript{10–12} In addition to their use in routine batch release testing, USP reference standards are used to test for counterfeit or substandard medicines (eg, antimalarial, antibiotic, and anti-HIV drugs around the world).\textsuperscript{13,14} Compendial tests and reference standards contribute to public health in other ways: Generic drugs are approved for marketing in the United States after sponsors demonstrate the equivalence of a generic to an innovator product via an approved Abbreviated New Drug Application (21 Code of Federal Regulations 320.21). Here, too, it would be helpful for biomedical writers to know about ways in which the purity of drugs is ensured and how public health officials globally use compendial tests for adulterated and substandard products. Biomedical writers who are called on to discuss generic drugs and bioequivalence will benefit from a firm understanding of the compendia and compendial science.

**COMPENDIAL SCIENCE AND BIO MEDICAL WRITERS**

Broadly speaking, compendial science is the set of skills required to create, apply, and revise or update the compendia. Standard definitions are not available, but compendial science can be described as:

- the application of chemical and biochemical analytical sciences to medicines within the regulatory frameworks used to ensure the quality of medicinal products delivered to patients. Regulatory frameworks can be described as a web of standards, regulations, and guidances that relate to pharmaceutical products (eg, the pharmacopelias, FDA guidances, Code of Federal Regulations requirements, and standards and guidelines from the International Organization for Standardization, the International Conference on Harmonization, the American Society for Testing and Materials, the American National Standards Institute, and others), as well as the science to support the choice of acceptance criteria. (TL Cecil and WW Hauck, written communications, June 2012)

Compendial scientists who use, develop, or revise general chapters that describe tests (eg, Chromatography $<601>$ or Dissolution $<711>$) and monographs (tests for specific drug substances or drug products) in USP–NF often are analytical chemists, but biomedical writers do not require this level of knowledge. Rather, biomedical writers should be aware of the compendia as authoritative sources of drug substance and drug product names and tests that ensure the identity, strength, quality, purity, and potency of both innovator and generic medicines in both domestic and international commerce.

**SURVEY AND RESULTS**

Personal experience suggests that biomedical writers often do not consider compendial science and USP in conjunction with their work in regulatory, biomedical, and other types of writings. To test this hypothesis and to begin to assess the extent to which biomedical writers are familiar with the compendia, I developed and distributed a brief (9-question) survey. After obtaining clearance from the Institutional Review Board at the University of the Sciences in Philadelphia, I included a link to the questionnaire in an e-mail message to the Editing-Writing e-mail list hosted by the American Medical Writers Association (AMWA). Subscribers to the list numbered 2453 (M Rosol, written communication, April 2012). The original invitation to participate was sent on April 16, 2012, a reminder was posted 1 week later, and the survey was closed on April 30, 2012. A total of 66 members responded (absolute response rate = 3%). The small response rate did not achieve statistical significance (with a 95% confidence interval, this would have required 333 responses), which limits the inferences that can be drawn. Nonetheless, the results suggest areas in which biomedical writers may be able to improve their knowledge about and use of compendial science.

Question 1 asked respondents to identify whether they were regulatory writers, nonregulatory writers, or both. In this survey, 52% reported that they work in nonregulatory writing, 29% are regulatory writers, and 19% work in both areas (Figure 1). This distribution may be important for interpretation of responses to survey questions because one might hypothesize that regulatory writers, especially those who prepare materials that must comply with FDA requirements, may have greater familiarity with the compendia than do nonregulatory AMWA members.

To assess the range of biomedical writers’ opinions about the compendia, questions 2 and 3 allowed respondents to select more than one answer, and thus totals for these questions do not sum to 100%. Question 2 asked respondents to characterize the compendia (Figure 2). Most respondents (82%) correctly identified USP–NF as compendia,
and nearly two-thirds (65%) correctly associated the compendia with drug standards. Only 47% correctly associated the compendia with tests for authentic drugs, even though these are important applications of modern compendia. Nearly one-quarter of respondents thought the compendia contained recipes for making drugs (26%) or were textbooks for pharmacists (24%). Historically, both were uses of the compendia, but neither is a function of modern compendia. Contrary to responses from 12% of respondents, the compendia are not historical artifacts or old medical books but instead are updated and used regularly.

Question 3 asked about the contents of USP–NF, and responses highlight important misconceptions about the compendia (Figure 3). NF does include excipients that are used in pharmaceutical manufacturing and USP includes drug substances (65% chose “drug ingredients”), but the best answer to this question is tests for drug substances, ingredients, and products (60% of respondents). A widespread misconception among survey respondents (62%) is that the compendia contain a list of all drugs approved by the FDA, but sponsors are not legally required to submit monographs for all new drugs to USP, and USP continuously works to add new monographs and update the compendia.7,15 Innovator companies tend to submit new monograph proposals to USP shortly before their product’s patent expires, and generic drug manufacturers rely on compendial monographs and the tests in general chapters when they prepare their Abbreviated New Drug Applications.7,16 This may help to explain why 43% of respondents associated the compendia with generic drug information. Another misconception for 35% of respondents is that compendial science involves dispensing; USP began publishing USP Dispensing Information in 1980. Technically, this was a dispensatory or list of approved drugs—not a compendium; in 1998 USP sold it to The Thompson Company.6 Seventeen percent of respondents said the compendia contain master recipes for drugs. Again, this reflects historical but not modern uses of the compendia.

Figure 4 shows the true–false responses to survey questions 4 through 8. Contrary to the answers of 32% of respondents, neither the US federal government nor FDA publishes the compendia. As noted earlier, the nongovernmental nature of USP–NF...
arises in part because the first USP was published in 1820, but the government agency charged with enforcing drug standards, the FDA, was established in 1906 with a remit to enforce USP and NF standards. A slim majority of respondents (55%) knew that drugs named in the compendia must pass USP–NF tests. Nearly equal percentages (52%) misidentified the usual sources of tests for adulteration. Again, an important use of compendial standards is testing, with reference standards, for identity and other quality attributes. Compendial tests also are useful because they can be used in many locations and are independent of either a manufacturer’s or the US government’s participation. Even though respondents may not have known about the origins of compendial tests, 79% knew both that USP–NF contains tests for dissolution, chromatography, and spectroscopy, and these tests can be used, eg, to support batch release and stability testing. Respondents were nearly evenly split about the provenance of tests for adulteration.

Overall, biomedical writers who responded to the survey have some sense of compendial science and the characteristics of the sample (regulatory compared with nonregulatory writers) rather than biomedical writers at large, and the small sample size limits conclusions that can be drawn.

**DISCUSSION**

The results identify several misperceptions among biomedical writers who participated in the survey regarding USP–NF and applications of the compendia. Some of these misunderstandings may arise from historical developments that do not reflect modern uses of the compendia (eg, the association of compendia with old texts, lists of drugs, recipes for making pharmaceuticals, and dispensing information). Some respondents (60%) accurately associated the compendia with tests for the components of pharmaceuticals (Question 3). Still, only half of respondents said that the compendia contain tests for authentic drugs (Question 2), more than half did not know that medicines must pass compendial tests (Question 5), and respondents were nearly evenly split about the provenance of tests for adulteration (Question 6).

**Figure 4.** True or false. Question 4: The US government, via the Food and Drug Administration, publishes and revises USP–NF. Question 5: All medicines sold in the United States must pass the tests in USP–NF. Question 6: When analysts test medicines for adulteration, contamination, or potency, they must rely on information from the drug’s manufacturer or information the manufacturer authorizes the Food and Drug Administration to use. Question 7: USP–NF includes instructions for drug tests such as dissolution, chromatography, and spectroscopy, and these tests can be used, eg, to support batch release and stability testing. Question 8: When analysts investigate potential instances of adulteration (eg, heparin, melamine, or diethylene glycol), they rely on information in USP–NF. (Note: Because of rounding, totals do not always equal 100%.)

**Figure 5.** Question 9: In your biomedical writing and editing how often do you use USP–NF: regularly; not often; I’ve seen it but haven’t really used it; I’ve neither seen nor used USP–NF. Two respondents did not answer this question.
current compendia, but this understanding seems to be colored by historical precedents rather than current applications. Again, the survey results are limited and do not achieve statistical significance for the group questioned. Even so, the findings presented here suggest that biomedical writers often do not understand or consider compendial science and USP in conjunction with their work. The survey was distributed to AMWA members and did not specifically assess the understanding of compendial science among biomedical writers in other parts of the world, although some AMWA members do live outside North America. Findings from surveys of writers in other continents would be of interest and perhaps would further highlight the importance of compendial science for biomedical writers globally.

Certainly it seems worthwhile to expand the education of biomedical writers so they better understand the importance and applications of compendial tests to ensure that medicines are correctly named and are uniformly prepared with acceptable quality. Specifically, biomedical writers should have a firm grasp of the importance of establishing and maintaining the identity of drug substances and drug products from preclinical discovery through clinical trials and into public distribution in global markets. These processes involve scale-up and manufacturing at multiple sites around the world, and compendial tests (eg, dissolution, chromatography, and many others) are important tools that help ensure the identity, strength, quality, purity, and potency of pharmaceutical ingredients and products.17,18 Biomedical writers also should understand the processes by which generic drugs are developed and how their equivalence to innovator products can be assessed by the use of compendial tests, and ingredient and product monographs in the compendia.16 Further, compendial monographs increasingly are useful to help detect and, one hopes, to deter economically motivated adulteration both in developing nations (eg, antimalarial drugs) and in developed countries (eg, heparin and melamine). Compendial science may improve biomedical writers’ understanding of public standards and the roles of the latter in ensuring the quality of pharmaceuticals, thereby improving biomedical writers’ ability to communicate such information.

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References


The University of Florida College of Medicine Department of Anesthesiology (Gainesville, FL) seeks an Information/Publications Services Coordinator to join us following the retirement of our current coordinator. This individual will work very closely with the department faculty, residents, and graduate students preparing internal and external documents. The coordinator will be responsible for maintaining, editing, developing, and creating various communication materials: abstracts for research posters and conferences, book publications (both chapters and whole), medical journal articles, other scientific manuscripts, grant applications, department quarterly newsletters, conference pamphlets, fundraising materials, recruiting documents, etc. This editor will also maintain a high level of departmental compliance with ethical aspects of publication and communicate with journal editors and publishers on behalf of departmental faculty.

The coordinator will be responsible for the management of the curriculum vitae, educational portfolios, and clinical portfolios for approximately 70 department faculty along with coordinating the submission of faculty promotion and tenure and mid-career review packets, ensuring accuracy of the documentation and that formatting guidelines set forth by the University and College of Medicine are scrupulously followed. This position also will be involved in coordinating the department’s annual research day. This position ensures timely and accurate dissemination of information to internal and external audiences through a variety of channels.

Applicants must have a master’s degree in an appropriate area of specialization; or a bachelor’s degree in an appropriate area of specialization and at least two years of appropriate experience – science or medical editing is favorable. Preferred qualifications: highly skilled medical editing, excellent communications skills with individuals of diverse backgrounds and cultures, ability to make minor modifications to graphs provided by faculty, knowledge of index services for publications (PubMed, Web crawler, & JCI), ability to use iThenticate, etc. High level of proficiency in Microsoft Office with edits/merge from multiple authors. Knowledge of website development and PhotoShop desirable.

Salary range commensurate to $40,000-$50,842 plus fringe benefits negotiable with education and experience. The University of Florida is an Equal Opportunity Institution dedicated to building a culturally diverse and inclusive faculty and staff. The selection process will be conducted in accord with the provisions of Florida’s “Government in the Sunshine” and Public Records Laws. Search committee meetings and interviews will be open to the public, and all applications, resumes, and other documents related to the search will be available for public inspection.

Interested applicants should apply to UF’s employer’s web site requisition number 0902239 https://jobs.ufl.edu/postings/36275. Deadline for applications is March 31, 2013.
Wednesday Programming

One of the most important new aspects of the conference is that programming begins earlier. Workshops are the primary reason most members attend the conference, and this year, workshops will be offered on Wednesday afternoon. Expanding workshops over 4 days adds flexibility to the schedule, giving you a better chance to take advantage of other conference sessions and activities. You can also pace yourself to avoid “conference fatigue.”

We know that not all of you can stay from Wednesday to Saturday, but all of you will have the
same potential for a rich conference experience—whether you come early and leave early or come later and stay later. If you think a workshop requires too much “brain power” for a Saturday afternoon, you can opt for one of several sessions focused on “lighter” topics that will be planned for that last afternoon. We’re expecting such topics as productivity, organization, creative writing, and so on.

**NETWORKING EVENTS**

Networking is the second reason most of you attend the AMWA Annual Conference, and we are continuing the outstanding networking opportunities that debuted last year. Just look at the networking events—all of which come with free food—and most of which take place in the Exhibit Hall, where you can meet with a variety of vendors.

**Wednesday:** Welcome Reception in the Exhibit Hall
**Thursday:** Boxed Lunch in the Exhibit Hall  
Networking Reception in the Exhibit Hall
**Saturday:** Business Meeting Lunch

In addition to these networking events, the popular Speed Networking session returns, and other special networking sessions are being planned.

**CONFERENCE PROGRAMMING**

With the deadline for proposals just behind us, the AC Committee is currently reviewing proposals from members and nonmembers alike. We cast a wide net this year soliciting proposals so that we could bring you speakers with expertise in diverse areas. We’ll update you on specific sessions when the review process is complete.

In the meantime, we are inviting speakers for some special sessions. Our contacts at the Food and Drug Administration are planning to provide speakers on topics of most interest to writers in the pharmaceutical industry. An editor’s panel will discuss ways for you to become a published author and contribute to the medical writing literature, which is crucial for our industry. And we are pursuing outstanding AMWA award recipients who are sure to delight us with their talks.

The 2013 program will feature new and innovative session formats, such as pro/con debates and hands-on demonstrations. Our goal is to enhance interactivity in sessions so you are better engaged in the learning experience.

**WE HEAR YOU**

Your thoughts about the conference do matter! We have carefully reviewed the responses from the 2012 conference survey and are working to ensure that the 2013 conference meets your needs. For example, breakfast roundtables are popular, but many of you commented on challenges associated with the early time of the sessions and with juggling materials and the meal. We also recognize that morning is not the best time of the day for everyone. So, those of you who work best later in the day can now participate in a lunch roundtable session on Friday. If the morning is your best time, you still have the Thursday roundtable discussion over breakfast. Also, back by popular demand is the Chapter Greet & Go. Mingle with your chapter members at this event and then head out for a chapter dinner. More than 40 restaurants are within walking distance of the conference hotel, so you’ll have plenty of choices. We’ll bring you more information about restaurants in a future issue of the Journal and on the AMWA website (www.amwa.org).

It’s never too early to plan for the AMWA Annual Conference. And it’s never too late to offer a suggestion. Send your thoughts to lori@editorialrx.com. Watch for routine posts on LinkedIn, Facebook, and Twitter to learn more details about the outstanding opportunities at the 2013 AMWA Annual Conference.

**HOTEL RESERVATIONS**

We’ll also bring you details about the conference hotel soon. We urge you to reserve a room in the Hyatt, the primary conference hotel, or in one of the other two conference hotels. Special room rates at the conference hotels make the stay cost-effective for attendees, and a filled room block saves AMWA money, which can be invested into member resources.

**CHAPTER RESOURCE AT THE ANNUAL CONFERENCE**

A special room at the Hyatt will be available as a resource for chapters at specific times during the conference. The room offers space for chapter leaders to meet with their officers or members or where leaders across chapters can share common concerns and best practices.

**COUNT ON THE AMWA WEBSITE FOR THE MOST UP-TO-DATE INFORMATION**

The AMWA website will promote all the milestones on the way to the conference, such as posting of:

- Conference Schedule at a Glance
- Registration Brochure
- Hotel Reservations
- Registration

This year’s registration brochure will be posted a couple of weeks before registration opens so you have time to review and plan your registration strategy.
CONTINUED COVERAGE OF 2012 CONFERENCE

> SESSION SUMMARIES

AMWA’s 2012 Annual Conference in Sacramento, CA, featured more than 30 open sessions with topics of potential interest to biomedical communicators. Here are reports on five sessions.

PERSPECTIVES ON THE CHALLENGES AND PROMISE OF PERSONALIZED MEDICINE

Moderator
Cynthia Carr, PhD
Senior Medical Writer, Ventana Medical Systems, Inc, Oro Valley, AZ

Speakers
Cindy van Dijk
Principal, Scientific Communications, Havelock, NC
Eric Walk, MD, FCAP
Senior Vice President and Chief Medical Officer, Ventana Systems, Inc, Tuscon, AZ
Julie Ann Sakowski, PhD
Associate Adjunct Professor, University of California, San Francisco (UCSF)
Executive Director, UCSF Center for Translational and Policy Research on Personalized Medicine, San Francisco, CA

By Michelle Eby, PharmD, CCRP

In the current “one size fits all” health care model used in most areas of medicine today, each patient with a given diagnosis receives a standard treatment. The advent of personalized medicine (PM) fundamentally alters the traditional health care paradigm. According to Dr Cynthia Carr, “personalized medicine is happening here and now, and is soon to be a household term.” Defined, “PM is the customization of health care, with decisions and practices being tailored to the individual patient by the use of genetic or other information.”

Cindy van Dijk identified the key drivers of change in conventional medicine that seek to maximize the benefit-to-risk ratio and the benefit-to-cost ratio. A significant percentage of patients try several agents before finding a successful therapy. This trial-and-error process incurs added time and expense. The benefit-to-cost and benefit-to-risk ratios can be improved by transitioning to PM, which targets therapy based on each patient’s unique genetic profile. With PM, patients are more likely to receive the right drug the first time.

The PM process begins with tests that analyze blood, other bodily fluids, or tissues to identify biomarkers that guide selection of an optimal treatment for a particular patient. There are several types of biomarkers. Diagnostic biomarkers reveal baseline characteristics that indicate the likelihood a specific patient will respond to a given therapeutic regimen. Detection biomarkers identify disease at early stages. Other biomarkers indicate the propensity for someone to acquire a particular disease. With the use of biomarkers for individual patients, PM changes the way health problems are diagnosed and managed. A particular biomarker may signify a drug is likely to be more effective or may be used to help tailor the dosage to the individual patient.

PM is already available for many cancer treatments. For example, companion diagnostic tests that measure HER2 protein expression are used to identify breast cancers likely to respond to treatment with Herceptin. Approximately 40 companion diagnostics are currently in use. Predictive biomarkers have been validated in large cohorts of patients, leading to greater application of companion diagnostics. According to Dr van Dijk, this is a “game changer” in the way drugs are developed, regulated, prescribed, and used. Various stakeholders have different interests in the transition to personalized medicine (Figure 1).

PM may result in fewer drugs failing to emerge from the clinical trial and regulatory approval process. However, the potential number of patients on any given treatment is expected to be smaller. Consequently, the blockbuster model for drug development, in which pharmaceutical companies aim to create one product to be sold to millions, will likely become rare. Nonetheless, because PM offers greater value for payers and patients, it ultimately may result in higher reimbursement rates for the drugs and companion diagnostic tests.

Pharmacy giants, including Roche, Pfizer, Novartis, and Lilly, are geared up to capitalize on this fast-moving, dynamic business. More than 90% of the agents in Lilly’s pipeline have a corresponding companion diagnostic, van Dijk said. The overall value of the global biomarker industry could reach $25.79 billion by 2016, she said, which would create opportunities for medical writers in a variety of venues, including newsletters, training and education, business proposals, presentations, journal articles, white papers, press releases, website content, webinar summaries, and marketing communications.

To illustrate the progress to date, Dr Eric Walk identified several recent successes in oncology. In 2011, the US Food and Drug Administration (FDA) approved two anticancer drugs that use a companion diagnostic to identify responders: vemurafenib (Xelroban) for metastatic melanoma and crizotinib (Xalkori) for non–small cell lung cancer (NSCLC).

Approximately 40% to 60% of melanomas harbor mutations of the BRAF gene, which manufactures the B-RAF protein involved in cell signaling and cell growth. Vemurafenib is a potent inhibitor of the BRAF V600E mutation, which represents 90% of the V600E mutations in these cancers. In a phase III trial called BRIM3, only patients with BRAF V600E–positive tumors were enrolled. In this trial, which was used to gain FDA approval, there was a 48% response rate, including two patients with a complete response and 104 patients with a partial response. These
rates contrast with the 15% to 20% response rates seen with traditional chemotherapeutic agents, such as dacarbazine, in metastatic melanoma.

About 3% of NSCLC patients express the ALK fusion gene. Only patients with ALK-positive tumors were enrolled in PROFILE 1005, a phase II trial in which the overall response rate was 57%, including one complete response and 46 partial responses. A substantial proportion (63 of 76, or 83%, of patients) had tumor shrinkage. These response rates contrast with the very low response rates seen with traditional chemotherapy in NSCLC.

Dr Walk cautioned that the term “personalized medicine” in oncology is conceptually useful (Figure 2) but does not speak to the biologic complexity confounding efforts to predict response to targeted therapy regimens. Although companion diagnostics can predict responders, these in vitro tests may not identify all responders. Furthermore, Dr Walk said, “Cancer cells are smart” and have primary and secondary resistance mechanisms. It may take more than one companion diagnostic test combined with multiple targeted therapies to cure cancer. Dr Walk predicted pathologists will play a central role in tumor profiling for future therapy decisions. Cancers will begin to be classified on the basis of genes promoting the tumor’s growth rather than the anatomical location.

Dr Julie Sakowski remarked, “new personalized medication technologies are being realized faster than we can gather full information on their most beneficial and appropriate uses.” Utility and economic values of the information offered by biomarkers must be considered. The Centers for Disease Control and Prevention has established a three-tier system for classifying biomarkers on the basis of their recognized clinical utility. To fully implement PM into medical practice, there must be sufficient incentives for both providers and industry.

Personalized medicine is the strategic focus of many drug developers and diagnostic device companies. The ultimate goal of PM is to reduce trial-and-error based treatment, improve medical outcomes, and decrease health care costs. Strong interest in PM from both public and private sectors will continue to generate exciting writing opportunities for medical communicators.

Michelle Eby is a Consumer Safety Officer for the Food and Drug Administration, Silver Spring, MD.

**WHO ARE THE STAKEHOLDERS?**

**PATIENTS**
- Is the drug working?
- Is it safe for me?

**PHYSICIANS**
- What is the best treatment option for this patient?
- What are the potential side effects?

**PAYERS**
- How do we know the treatment is beneficial to the patient?
- What is the evidence for a positive outcome?
- What are the economic health benefits for the payer?

**REGULATORS**
- Is the drug safe for patients?
- Is this the right drug for the right patient at the right dose?
- Is the diagnostic properly assessed and clinically validated?

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**Figure 1.** Various stakeholders with different interests in the transition to personalized medicine. (Figure created by Cindy van Dijk and published with her permission.)

**Figure 2.** The concept of personalized medicine. (Figure created by Eric Walk and published with his permission.)

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**RESOURCES**
- Center for Disease Control: [www.cdc.gov/genomics](http://www.cdc.gov/genomics)
- Food and Drug Administration: [www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/default.htm](http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/default.htm)
- National Coalition for Health Professional Education in Genetics: [www.nchpeg.org](http://www.nchpeg.org)
- National Pharmaceutical Council: [www.npcnow.org](http://www.npcnow.org)
- Personalized Medicine Coalition: [www.PersonalizedMedicineCoalition.org](http://www.PersonalizedMedicineCoalition.org)
THE FDA AS AUDIENCE

Speaker
Debra Hathaway
THinc, Los Angeles, CA

By Mark R. Bowlby, PhD

The first rule of writing that many of us learned in our first writing course is that we need to know our audience, but if your audience is the US Food and Drug Administration (FDA), what does this mean? Many medical writers who prepare documents for the FDA will never meet their reviewers, and it can be a struggle to learn who your audience is at the FDA. Debra Hathaway, however, has not only written and assembled many documents for the FDA, she has attended many FDA review meetings. This gives her an insider’s view of the process, which she shared during this session.

The FDA is first and foremost an agency driven and bound by the Code of Federal Regulations and its own guidances. The regulations are the rules governing the agency, whereas the guidances represent the FDA’s current thinking on particular topics, and as such they are not legally binding. Although many medical writers are likely to be familiar with these documents, they may not be aware of the FDA’s Manual on Policy and Procedures (MAPP), which is a document of standards used for the regulatory documents that the FDA prepares. The MAPP details how the FDA structures its summary reports and decisions on drugs it reviews. In fact, comparing sponsor-submitted documents to the MAPP can reveal sections from the former cut and pasted into the latter, along with the reviewer’s comments. All these documents, and many more, are available at www.FDA.gov.

The best method for beginning to get to know the FDA is from the myriad documents available online. Starting with the most relevant codes and guidances for your individual work is a well-known beginning point, but it’s only the tip of the regulatory iceberg. If you need to write an Integrated Summary of Efficacy (ISE), searching the FDA Guidance, Compliance and Regulatory information section of the website for a closely related ISE from a marketed product should uncover useful examples to study. Indeed, once new drugs are approved, the ISE is available for the public (ie, you) to review. An ISE is required by law for all drugs, with the exception of those whose sponsors negotiated an ISE waiver. A draft guidance for writing an ISE is also available, as is its European counterpart, the Common Technical Document (CTD) M4E Revision 1 (R1); search in the “Guidance (Drugs)” section of the website for this information.

Another great source of more general information on competitor drugs and their approval dossiers is the Drugs@FDA section of the FDA’s website. Search this area for many documents that were included in the approval documentation of a drug and to find out how arguments for approval were constructed. In addition to the expected documents, there are minutes from any pre–new drug application (pre-NDA) meeting, comments from discussions, and administrative review, and advisory committee documents.

These documents can provide unique insight into the thinking of the FDA and the sponsor regarding efficacy and safety testing. Because the pre-NDA meeting is designed to aid in the resolution of outstanding questions and issues that have arisen during clinical evaluation of a new drug, the minutes of this meeting can be especially informative.

During the question and answer period of the open session, Hathaway painted a verbal picture of what it’s like to attend a pre-NDA meeting. First, there’s the security screening, then the inevitable wait (with other presenting companies), and, finally, the reveal: Is the committee lying in wait to pounce, or is it a friendly review? The odds of obtaining the latter can be improved with a well-written dossier, but also by providing a full, clear disclosure of the drug’s strengths and weaknesses. It’s not a good idea to try to minimize the weak points of a potential drug, as the FDA is expert at ferreting out the deficiencies in applications. A trusted reputation will also help you and your clients obtain a fair review the next time around.

So be above board and transparent with your documents to the FDA; burying or hiding information will only hurt you and your client. Bring your key issues and questions to a pre-NDA meeting; that’s what it is for. And read about your audience in the documents that they make available. Your time will be well spent building a top-notch reputation for you and your clients.

Mark R. Bowlby is Principal Medical Writer at Allergan Inc in Bridgewater, NJ.

DIAL 911: EMERGENCIES IN MEDICAL WRITING

Speakers
Anne R. Jacobson, MPH, CCMEP
Freelance Medical Writer, Cocoa Beach, FL
Scott Kober, MBA, CCMEP
Director, Content Development, Institute for Continuing Healthcare Education, Philadelphia, PA

By Amy Karon, DVM, MPH, MA

Nearly every seasoned medical writer at some point faces clients and contracts that become the stuff of nightmares. Maybe endless requests for revisions are eating into your sleep time. Or perhaps you realize you’re plagiarizing.

Stay in the profession long enough and scenarios like these are bound to make you hold your head. But there’s help. At the 2012 AMWA conference, Scott Kober, MBA, CCMEP, and Anne Jacobson, MPH, CCMEP, reprised their popular open session on emergencies in medical writing.
Using digital keypads, attendees anonymously chose responses to a variety of hypothetical problems. Lively discussion followed. Here is a summary of those debates and dilemmas.

**Scenario 1:** Your work from long-term clients is drying up after more than 20 years of freelancing. Do you really need a Web presence?

You do need a consistent and varied online presence, said Kober and Jacobson. But there are two ways to go about it—by dipping your toes in, or going all out.

More cautious medical writers might start by creating their own simple website and LinkedIn profile. Others might hire a marketing and social media consultant to help develop a brand, website, detailed LinkedIn page, and professional Twitter account. Whichever way you go, said Jacobsen and Kober, your website should include a résumé and some sample writing or editing projects. If you’re under a nondisclosure agreement, keep that in mind. Some writers create pieces specifically for their online portfolios.

**Scenario 2:** Your last client burned you. How do you vet a new one to prevent this from happening again?

“My first-line approach is to e-mail people whom I trust,” Jacobson said. “Luckily, I know a lot of freelance medical writers whom I can vet clients through.” She said she tends to avoid asking for feedback from members of AMWA’s online discussion groups.

Kober and Jacobson also suggested crafting a checklist of the kinds of clients and projects you want. This will help you develop a broader perspective on whether prospective clients fit your business goals.

**Scenario 3:** You discover an author whose review article you’re editing is recycling chunks of text from a previous article. Whom do you tell, and how?

Make your client aware of this taboo practice and consider proposing a solution, said Jacobson and Kober. But don’t approach the faculty member yourself. Let the client handle it.

Be aware, too, that copyright infractions can return to haunt writers. “Some faculty don’t even realize that self-plagiarism is a problem,” Jacobson said. “When this has happened to me, usually the remedy is just to rewrite (a piece) because it obviously can’t go out as it is.”

If a client tries to say self-plagiarizing is all right, rewrite the piece anyway and then don’t take any more work from the client, Kober recommended. Participants also suggested ensuring that clients understand that journals use software to detect plagiarism and copyright infringements, and that infractions can result in being blacklisted.

Medical writers also should note red flags that could signal plagiarism. For example, watch out if the first draft of a manuscript is clean, with perfect punctuation, Kober said. “Plug it into Google and see what comes up.”

**Scenario 4:** You have a major deadline in 3 days and your father has been rushed to the emergency department. His physician thinks he’ll be okay, but has to run some more tests.

Do you go and bring your work? Tell your client you can’t make the deadline? “Mild emergencies come up all the time and you find yourself schlepping your work all sorts of places,” Jacobson said. “The real question is whether to alert your client that there could be a problem. It depends on the client and the relationship.” But from a client’s perspective, Kober said, “I would want to know as soon as possible. There is nothing worse than hearing on the day of the deadline, ‘Oh, I’m sorry, my dad has been in the hospital for a week and a half.’ I’m sympathetic, but I also wonder why you didn’t tell me before.”

Others recommended giving clients the names of three people they trust to get the work done. Communication is critical, they agreed; let the hiring manager or the client know right away that you are working at a hospital. Most will appreciate the information and adjust their expectations accordingly.

**Scenario 5:** A client asks you to cover the cost of purchasing full-text references, which is not the norm. Do you renegotiate your contract?

Kober retrieves needed references for freelances, but encourages them to get what they can on their own. “Ideally, from a client’s perspective, it would be great if we didn’t have to dig up references for you.”

Jacobson said, “When a client is nickel and diming you about project costs, they are unlikely to be willing to renegotiate a project fee.” She suggested searching on PubMed and restricting access to free, full-text articles. “Open access sources are now pretty good,” she added. “Every once in a while, I spring at the last minute for a $30 reference for a big project.”

Participants noted that AMWA membership includes access to the MD Consult database. Alumni organizations also sometimes offer limited journal access. Writers can also try entering an article title into an online search engine—sometimes a PDF will pop up.

DeepDyve, at www.deepdyve.com, lets you “rent” full-text articles for small amounts of money, members added, although you can’t print or save them to your computer.

Participants also cautioned their peers about downloading PDFs and giving them to clients; that can be seen as illegally selling them, they said.

**Scenario 6:** A client is asking for many more revisions than expected. You are being paid for the extra time, but you’ve taken on other scheduled projects and this one is now keeping you up nights and weekends.

Think about how much you want to keep this client, Kober and Jacobson advised. If you don’t want to work with him or her again, consider politely extracting yourself by explaining that your contract does not include project management. You can also try renegotiate for more money per hour.
Another approach: Say that you have taken on other projects because the plan did not include this much extra time.

Attendees also suggested building milestone payments into bigger projects. Otherwise, at the end of 6 months, you could be crossing your fingers and hoping the client doesn’t refuse to pay you because the company went bankrupt or you finally drew the line at further revisions.

Scenario 7: You are writing multiple needs assessments for the same client on the same topic. Can you reuse your work?

In short, no. “If you’re not willing to turn a blind eye to a faculty self-plagiarizing his own work, how are you willing to turn a blind eye to yourself?” Kober said.

Added Jacobson, “Once you have already done the mental work of understanding the same disease states, it is easier to crank [pieces] out. You do have an obligation to submit original material.”

But try for a bit of wiggle room when working with the same client on certain projects, Jacobson suggested. For example, agree to write updated needs assessments for the same client, rather than reinventing the wheel each time.

Scenario 8: After 5 years of full-time freelancing, you’ve decided to take a job. You just interviewed for what seemed like a terrific position, but half the interviewers did not show and no one explained why or followed up. Do you give the company the benefit of the doubt?

That scenario certainly should raise a red flag, said Jacobson, noting that she is working on noticing such signs and steering clear of clients and companies who raise them.

“There are far too many employers who think they are doing an employee a favor by giving them the time to talk to them,” Kober added. “It’s a slap in the face. It’s rude and disrespectful.”

One option: Write a courteous letter to human resources, explaining what happened and expressing your disappointment. HR departments often appreciate hearing this, participants said. But don’t address your letter to the people who didn’t show up to the interview!

Scenario 9: You (in a client’s role) hire a freelance who checks out and has great references and clips, but turns in awful work. What do you say?

Session attendees said they definitely want to hear feedback. Kober said he makes it a personal rule to give it. In addition, Jacobson recommended asking clients for an edited version of a document. If a client constantly changes a certain word, for example, you can modify your writing style for that client accordingly.

When hiring and applying for work, require and send raw copy, suggested participant Debra Gordon. She added that she plans to send her clients an anonymous SurveyMonkey questionnaire so they can provide honest feedback on her work without worrying about jeopardizing their business relationship.

Amy Karon is a freelance medical writer who operates Karon Medical Writing, LLC, in Madison, WI.

A version of this article appeared first on the AMWA Annual Conference Blog.

90-MINUTE MBA FOR FREELANCES

Moderator
Debra Gordon, MS
President, Gordon Squared, Inc, Williamsburg, VA

Speakers
Scott Kober, MBA, CCMEP
Director, Content Development, Institute for Continuing Healthcare Education, Philadelphia, PA
Roger T. Smith, CFP, CPWA
Financial Advisor, Planned Solutions, Inc, Sacramento, CA

By Whitney Smalley-Freed, PhD

A n entrepreneur is “a person who organizes and operates a business, or businesses, taking on financial risk to do so,” Scott Kober, MBA, CCMEP explained. Most freelance medical writers do not have a business background, yet they are trying to run a business on their own. Kober, who recently completed an MBA, recommended reading Good Strategy, Bad Strategy: The Difference and Why it Matters, a book on business strategy.1

Measuring Success Versus Failure

Kober pointed out that “you can’t manage what you don’t measure,” and suggests keeping a spreadsheet of different aspects of your business.

Examples of what to record

• How many jobs did you work on this year?
• How much did you make per client?
• Who are your most profitable clients? What are you doing to keep them happy?
• Who are your least profitable clients, and is it worth keeping them happy?

It is important to evaluate who your good and bad clients are. This also relates to “opportunity cost.” For every decision you make, there is a tradeoff, so if you take job A, you may not be able to take job B. Therefore, you want

Download Open Session Handouts from the 2012 Conference at the AMWA Website
www.amwa.org
to take the jobs that are going to be most beneficial to you, and say no to the least beneficial jobs.

Kober also recommended looking at what is going on around you and taking the current overall environment into account. Two ways to do this commonly used in businesses are SWOT (strengths, weaknesses, opportunities, threats) (Figure 1) and PEST (political factors, economic factors, social factors, technological factors) analyses.

“You are running a business,” Kober said. “Be very careful, look around you, see what’s happening, and make smart decisions.”

Kober’s slides are available at prezi.com/oczbdhharf/-amwa-2012-mba-presentation.

### Planning Your Retirement

Roger T. Smith, CFP, CWPA, pointed out that “the sooner you start saving, the longer your money can work for you.”

For freelances, the two main retirement fund options are a Simple Employee Pension (SEP) or IRA. The one that is best for you depends mainly on your income level and should be discussed with a financial planner.

Smith noted that saving earlier for retirement is easier than waiting. If you save $154 per month for 30 years, with an 8% return rate, you will have $229,388. However, that same $229,388 will take $663 per month with an 8% return rate if you only have only 15 years to save, or $3,122 per month if you have only 5 years to save.

Contributions to either a SEP or IRA are tax deductible or pre-tax, although contribution limits exist for both.

Smith concluded “Pay yourself first; it’s critical,” referring to saving money; for retirement before making other purchases with the money you earn.

### Tales from the Trenches

Debra Gordon, MS, warned that freelances should never put all their eggs in one basket. Gordon updates her SWOT analysis yearly and is always looking for new writing opportunities that result from changes in the government and economy. Gordon recommended the book *Who Moved My Cheese?*, a business parable about dealing with change. “You should never get comfortable where you are—you have to look down the road to where you need to be tomorrow,” Gordon advised.

Freelances frequently debate the merits of an hourly fee compared to a project fee. Benefits of a project fee pointed out by Gordon include:
- Fee is based on value added and experience and does not penalize a writer for working efficiently.
- Both parties know the final amount ahead of time.
- Unlimited income potential.

If a client is resistant to paying a project fee instead of an hourly rate, it may help to point out that the risk lies with the writer, not the company, if the writer underestimates the number of hours required.

As far as finances are concerned, Gordon has always taken 50% of what she makes each month and put it into a checking account to pay herself. The other 50% goes into a money market that she uses to pay her estimated taxes throughout the year and SEP and taxes at the end of the year.

Gordon suggests getting an accountant, lawyer, and virtual assistant if it will cost the same or less than your hourly rate would be for doing the work they will be doing. “Run your business like a business,” Gordon concluded.

Whitney Smalley-Freed, principal of Precise Medical Writing, LLC, is a freelance medical writer in Nashville, TN.

### Figure 1. Examples from Scott Kober of what to include in a SWOT (strengths, weaknesses, opportunities, threats) analysis.

<table>
<thead>
<tr>
<th><strong>Strengths</strong></th>
<th><strong>Weaknesses</strong></th>
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<tbody>
<tr>
<td>- What do you do better than your competitors?</td>
<td>- What do your competitors do better than you do?</td>
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<tr>
<td>- What intellectual property do you own?</td>
<td>- What do you need to compete more effectively?</td>
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<tr>
<td>- Does your company have a clear, communicable vision or direction?</td>
<td>- Does your company have the financial resources to withstand downturns or unforeseen negative circumstances?</td>
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</table>

<table>
<thead>
<tr>
<th><strong>Opportunities</strong></th>
<th><strong>Threats</strong></th>
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</thead>
<tbody>
<tr>
<td>- What changes are occurring in the industry or in customer demands that you can take advantage of?</td>
<td>- What changes are occurring that your competitor can take advantage of better than you?</td>
</tr>
<tr>
<td>- What weaknesses of your competitors can you take advantage of?</td>
<td>- What are your competitors doing to attract your customers?</td>
</tr>
<tr>
<td>- Can you improve your use of the Internet for marketing or customer relations?</td>
<td>- Are regulatory requirements or customer demands forcing a change in your products or services?</td>
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References
BEYOND BELLY ACHEs: IDENTIFYING AND DIFFERENTIATING FOOD ALLERGIES AND INTOLERANCES

Moderator
Karen Kafer, RD
Vice President, Health Partnerships, National Dairy Council, Washington, DC

Speakers
Jeanette N. Keith, MD
Director, Gastroenterology and Bariatric Medicine, Cooper Green Mercy Hospital, Birmingham, AL

Roberta L. Duyff, MS, RD
Food and Nutrition Consultant, St. Louis, MO

By Alysson Troffer, MA

A n increased awareness of food allergies and intolerances has been accompanied by misconceptions that can lead to adverse health outcomes, according to Karen Kafer, RD. This session provided science-based information about these concerns and recommended strategies for identifying and managing food allergies and intolerances.

Food Allergies and Intolerances Defined
Jeanette N. Keith, MD, described food sensitivity as a blanket term for all reactions to food and then defined the three types of food reactions:

- **Food allergy**—An immune response that occurs reproducibly upon repeat exposure to a particular food, specifically the protein in the food. IgE antibodies are produced during initial exposure to fend off the “foreign” protein during any repeat exposure. With a food allergy, anaphylaxis is possible.

- **Food intolerance**—An adverse physiologic effect that also occurs reproducibly upon repeat exposure to a food; however, no IgE antibodies are produced.

- **Adverse reaction**—An abnormal response to food because of the presence of infectious (bacterial, viral, or parasitic), food-borne, or water-borne contaminants.

Dr Keith explained that the clinical features of these different types of food sensitivities can be similar, so she recommends diagnostic evaluation to determine which mechanism is at work. Otherwise, many people self-diagnose and unnecessarily avoid entire categories of foods, which can cause nutritional deficiencies and other health problems.

Lactose Intolerance
Symptoms of lactose intolerance include abdominal pain, cramping, bloating, and diarrhea that occur when an insufficient amount of the enzyme lactase is produced by the villi in the small bowel to break down the milk sugar lactose. Without sufficient lactase, the excess sugar escapes to the colon where gut bacteria break it down for absorption, causing symptoms in some people.

According to a 2009 study in *Nutrition Today* that Dr Keith cited, 12% of adults in the United States reported being lactose intolerant. The prevalence of lactose intolerance varies by ethnic group: European Americans, 7.72%; Hispanic Americans, 10.05%; and African Americans, 19.50%.

Dr Keith also cited a 2011 study in the *American Journal of Clinical Nutrition* in which participants with self-perceived lactose intolerance opted for a restriction in dairy intake without increasing their consumption of nondairy calcium. Dr Keith explained, however, that it is important to maintain sufficient intake of calcium and dairy foods. For those who do, the risk of developing hypertension and diabetes is reduced by a third. She noted that most Americans do not consume enough calcium and that even patients diagnosed with lactose intolerance do not need to exclude all traces of dairy products from their diet.

In discussing the importance of diagnostic evaluation, Dr Keith emphasized that “All that rumbles is not lactose intolerance.” She explained the importance of recognizing the “masqueraders,” which include:

- Milk allergy
- Irritable bowel syndrome
- Celiac disease
- Non-celiac gluten sensitivity
- Inflammatory bowel disease, such as Crohn’s disease and ulcerative colitis
- Small intestinal bacterial overgrowth
- Bowel injury due to non-steroidal anti-inflammatory drugs

According to Dr Keith, the gold standard for diagnosing lactose intolerance is the hydrogen breath test, which is the least expensive, least invasive, and most available method.

Gluten Intolerance
Gluten intolerance is also known as “gluten sensitivity.” Dr Keith described gluten as a protein present in many grains, although wheat, rye, and barley are the grains that are typically associated with gluten intolerance. The portion of this protein called gliadin causes the most inflammation in gluten-sensitive people. According to Dr Keith, gluten intolerance includes:

- Non-celiac gluten sensitivity—An immune response, which is not autoimmune, that results from ingesting gluten. Although gut inflammation is present, the villi in the small bowel are normal.
- Celiac disease—An autoimmune disease that occurs in response to ingesting gluten, which damages the villi in the small bowel. Because of villi damage, celiac disease can coexist with lactose intolerance.

Dr Keith stated that in people with non-celiac gluten sensitivity, symptoms improve on a gluten-free diet. For those with celiac disease, a gluten-free diet is required to stop progression of the disease. Dr Keith provided these statistics about celiac disease: In the general population, the prevalence of celiac disease is 1 in 100. For those with gastrointestinal symptoms present,
the prevalence increases to 1 in 56. For those with a first-degree relative with celiac disease, the prevalence increases further to 1 in 22. Dr Keith recommends screening for this disease in any patient who has been diagnosed with diarrhea-predominant irritable bowel syndrome. However, a fifth of patients with celiac disease initially have no symptoms, she stated.

In addition to the nonspecific gastrointestinal symptoms common to all the “masqueraders,” Dr Keith explained, other indicators of possible celiac disease can include anemia, osteoporosis, constipation, and abnormal liver tests. The diagnosis of celiac disease requires compatible clinical symptoms and serologic testing. In most cases, she recommends the immunoglobulin A tissue transglutaminase (IgA tTG) blood test. For the 2% to 3% of the population with an IgA deficiency, she recommends the IgG tTG test. If serologic testing is positive, the gold standard is to confirm the diagnosis with a small-bowel biopsy. If the diagnosis is unclear, genetic testing can be performed.

If a patient has already begun a gluten-free diet, serologic testing might be negative, even if the patient has celiac disease. However, Dr Keith noted, a gluten-challenge diet is no longer recommended for such patients. Unfortunately, no medical tests can confirm non-celiac gluten sensitivity, but an elimination diet can prove useful.

Even with diagnostic confirmation of gluten intolerance, patients can typically eat other grains and starchy foods, Roberta L. Duyff, MS, RD, explained. Alternatives include amaranth, arrowroot, beans, buckwheat, millet, potato, quinoa, rice, and sorghum. She noted that the unintended consequences of grain avoidance (particularly whole grains fortified with nutrients) include the loss of complex carbohydrates as an energy source, and deficiencies in fiber, magnesium, selenium, iron, the B vitamins, and folic acid.

The health benefits of consuming whole grains, Duyff noted, include a reduction in constipation and heart disease risk, and assistance with weight control. In addition, grains fortified with folic acid consumed before and during pregnancy can help reduce neural tube defects in the fetus.

**Food Allergies**

Duyff described a case study of an 8-year-old boy named Daren who suffered from itchy eyes, swollen lips and tongue, sneezing, and nausea. On the basis of his medical history, food diary, physical exam, and experiences with an elimination diet, lab testing was performed. He underwent a skin prick test, RAST (radioallergosorbent) blood test, and food challenge test. Daren was diagnosed with allergies to wheat and dairy, which are common allergies in children (as are allergies to eggs, peanuts, soy, and tree nuts).

Duyff explained that with wheat, the food allergy reaction is to the proteins albumin and globulin fractions. With dairy, the reaction is to a milk protein, for example, casein. For Daren, all milk and milk products must be avoided, and all wheat products and foods made with wheat must be avoided; however, wheat substitutes, including rye and barley, can be safely consumed.

Daren’s family should apply the following strategies to keep him safe:

- Learn which foods contain the allergens Daren must avoid and which foods are risky. For example, most soy sauces contain wheat. Note that Food and Drug Administration labeling regulations require a “contains wheat” or “contains milk” statement on product labels, when applicable.
- Diligently read food labels, and contact food manufacturers with questions.
- In the kitchen and at the table, avoid cross-contamination of food allergens into allergy-safe food. For example, use separate containers and utensils for foods prepared without food allergens.
- Make recipe substitutions. For example, one cup of wheat flour can be replaced with ¾ cup of rice flour plus ¼ cup of cornstarch. Also, fruit juice or coconut milk can serve as substitutes for regular milk.
- Be just as vigilant when away from home, reviewing menus ahead of time if possible.
- Develop a plan with school personnel. Address food substitutes with the food service staff or have Daren eat home-prepared food. Make sure that Daren knows the symptoms of an allergic reaction and what he should do about them, such as how to signal for help. Also, educate him about why “food swapping” with friends must be avoided, and equip him with a personal emergency card and his parents’ phone number(s). Plan with the health care provider, other responsible adults, and Daren himself for giving medication, if needed.

Duyff concluded her talk by challenging the audience to correct misconceptions about food sensitivities, encourage diagnostic evaluations for gastrointestinal symptoms, and communicate strategies that help people with food sensitivities manage them “without compromising good nutrition, health, or the enjoyment of eating.”

Alysson Troffer, a technical communicator in the information technology industry for 16 years, recently left her position to pursue a career in medical writing and editing in Golden, CO.

**References**

The online Thesaurus defines retirement as “departure, giving up work, withdrawal, retreat, sequestration.” Certainly, those terms aren't very appealing unless one seeks hermit-hood. However, many workers look forward to retirement as leaving daily work to relax, travel, or change occupations from industry to hobbies, charities, or pleasurable pastimes. The reality is that each individual defines retirement in uniquely personal terms.

Those who like working and need/want monetary income have the options of self-employment, part-time work, making a hobby pay, etc. The once common practice of remaining employed full time until a predetermined age, then moving on with a pension, may be history. Additionally, those blessed with long life and good health may require the stimulus of productivity. As a medical writer/editor fortunate enough to maintain a freelance career after years in a large research institution, I continually meet physicians who want to write and hope to publish but don’t know how. I even work for some of them.

My first hitch after retiring (I simply could not produce one more annual report with 300+ authors) was Social Security. The IRS agent said, “You can start receiving checks now,” but I continued to work as a freelance. Only at the year’s end did I learn that income is limited after those Social Security checks begin, and higher earnings are taxed at an increased rate. So an accountant’s advice is worth the cost whenever income changes, and freelance charges must cover tax fees. Also think about health care insurance, which rarely comes with freelance work. For retirees of Medicare age, an insurance supplement is essential. Younger freelances must calculate insurance costs in their fees.

Here are some retirement options that have served me and other (so-called) retirees I know. Obviously, the best way of easing into retirement is to negotiate a part-time or temporary medical writing/editing consultancy at the place of former full-time work. Then there’s time to build contacts for other opportunities. Ideally, at least a year before retiring voluntarily, carefully plan/research your budget, activities, and goals. Repeatedly, ask for advice.

During a pre-retirement year, learning new skills in a college course or evening job is worthwhile, both for the knowledge and the contacts. A co-worker of mine joined several civic organizations and later acquired a year-long book editing project with another member. If travel is the reason for retiring, while booking an exotic destination, arrange an interview with local people, write/photograph the story, and sell your work (eg, to a travel publication). As AMWA members, all of us have an open book of contacts abroad. Use the Internet to access foreign medical institutions open to salesmanship—give an AMWA workshop, write a brochure, prepare a news story, investigate a unique health care technique. How often have you seen a travel guide in need of improvement? Market your skill to fix it! Publication Departments in foreign hospitals are a fascinating source of writing material, especially if you have information to share about a similar department where you’ve worked.

I’ve known several sports fanciers who, upon retiring, soon connected with part time work as, in different instances, a SCUBA instructor, food shop purveyor, gift buyer in foreign markets, or fishing guide. Find out what’s new in your travel country of choice; for example, China is rapidly building hospitals to care for the elderly who formerly remained with the family clan. However, the one-child birth policy now leaves more elders than younger relatives and no insurance for institutional care—a big subject for writers.

When retirement comes unexpectedly, enjoy the free time while you can, because the options for friends, play, and work can be overwhelming. I hasten to add, retirement can be the most creative time of life.

—Phyllis Minick

A – This is an interesting question, especially as it relates to freelances. Individuals who work full time for a corporation or other entity traditionally retire when they reach the age of 65 and are eligible for full Social Security. Some do it sooner and some do it later; some do it willingly; others have to be “encouraged” to retire. For freelance writers/editors, it’s not that cut and dried. Although we certainly have plenty of stresses, many of which are of our own making, we don’t have the kind of stress that comes with working for someone
else and we’re not bound by any formal retirement policy. That really leaves the decision to retire completely up to us; and we can easily continue to work as much or as little as we choose and still collect money through Social Security.

From a personal perspective, I’ve preferred to ease into retirement. I started thinking of myself as “semi-retired” 12 years ago, when my husband officially retired and we moved to Florida. I continued to work for long-time clients and occasionally took on a new client, but I became more particular about accepting assignments, often passing on projects that didn’t interest me or that had unrealistic deadlines. When my husband became ill, I began accepting even fewer assignments and now, 3 years after his death, I officially refer to myself as “retired.” However, that doesn’t mean I’ve lost interest in medical writing, or writing in general. I can be tempted by a freelance project that really interests me and has a reasonable deadline, but I no longer feel the need to be out there competing for assignments with much younger people who really need the work. Although I’m part of a generation with a strong work ethic, I’m learning there is more to life than work. I write a blog, I belong to a book club, I go to lunch and movies with friends, I travel, I work as a volunteer—often using my research, writing, and editing skills—and I remain an interested, active member of AMWA.

—Donna Miceli

A - When I “retire,” I won’t be shutting my office door one day and never working again. As a freelance, I plan to taper off work over time, fully retiring only when I don’t want to work anymore (after giving my clients sufficient notice, of course). I’d like to start by getting down to 35-40 hours a week of work over the next few years, and taper off to about 20-25 hours a week when I hit my 60s. As I work less, I’d like to spend more time doing things that are important to me, like practicing yoga and exploring the United States and the world. I’ll probably look into some type of volunteer work, but I think I’ll want to do something different—outside of writing and medicine. Then again, I may decide to work on that novel I’ve been thinking about since college.

Whatever the future brings, I’m grateful that being a freelance medical writer gives me many options for a fulfilling semi or full retirement.

—Lori De Milto

Do you have questions for the AMWA Freelance Forum panelists? Send them to JournalEditor@amwa.org.
The fundamental tenet underlying the creation of all accredited continuing medical education (CME) is that the activities and programs we develop must improve how clinicians practice medicine and, consequently, improve patient health. To accomplish this goal, medical writers must identify where clinicians’ professional ability fails to meet best practice standards, then design CME that helps elevate their competency. This three-part series will provide an introduction to the process CME writers use to ensure the programs we develop are relevant and effective.

In the Beginning There Was Educational Linkage
When we develop CME, a process called educational linkage guides us through the creation of a series of interdependent products. If done correctly, each element in the process informs the one that follows next, thus creating a logical flow (Figure 1). Through educational linkage, direct connections can be made between (a) an identified deficiency in physician performance, (b) the educational intervention, (c) some change in way clinicians practice, and (d) an improvement in patient health outcomes.

The needs assessment is the foundation of all development of CME. The needs assessment demonstrates that there is a definite need to improve clinician competency through education. The first step in writing a needs assessment is to conduct a gap analysis.

Step 1: Identifying the Practice Gap
The first element in the creation of CME is a process called discrepancy or gap analysis. At its essence, gap analysis is the study of differences between two competency points in which current practice behavior is compared with an ideal or accepted standard of performance. The Accreditation Council for Continuing Medical Education (ACCME), the organization that accredits CME providers, defines a clinical practice gap as the “...difference between health care processes or outcomes observed in practice, and those potentially achievable on the basis of current professional knowledge.”

Providers of CME must create programs that correct the discrepancy so clinicians attain the desired level of competency—that combination of knowledge, skills, and attitudes that embody proficiency. Gap analyses provide direction for the development of content by identifying the gap between what is and what should be, by identifying where clinicians have an insufficient level of knowledge or skill, or where their practice performance is substandard. Gap analyses also clarify what measurable outcomes educational programs should achieve by determining what our learners ought to be able to do differently in the clinical setting after participating in the CME activity (Figure 2).

To be accredited by ACCME, CME programs must address relevant competency gaps. Medical educators must “…incorporate into CME activities the educational needs (knowledge, competence, or performance) that underlie the professional practice gaps of their own learners.”

Identifying a gap in practice performance involves a proven association between two factors: (1) a lack of...
clinician proficiency in a specific area, and (2) the poor health outcome caused by it. How CME providers pinpoint the gap depends on which of these two factors we know and which we need to discover. There are three situations typically encountered. In the first situation, a known gap in physician competency is associated with a known poor health outcome(s) (Figure 3A). This is the most common situation and the simplest to document. In the other two cases, one element is unknown and must be identified through reliable sources of information. Either we know that a particular poor health outcome exists and a search is made to identify the gap in competency that causes it (Figure 3B), or the gap in competency is known and its effect on patient outcomes must be verified (Figure 3C).

**Step 2: Documenting the Educational Need**

Once an association between the gap in clinician practice and a poor health outcome(s) has been determined, the next step in the educational linkage process is to document the need for medical education that will help clinicians improve their competence and close the gap. Educators must demonstrate that there is a real necessity for the training. Accredited CME must be directly related to the work clinicians do and help them practice more effectively or efficiently. According to ACCME, CME must “… serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.” There are many programs created for clinicians that are interesting and beneficial, but unless there is a direct correlation between the characteristic(s) the program seeks to improve and some aspect of patient care, it can’t be CME. For example, a course in investment finance, while beneficial to the clinician, has no direct relevance to patient care, and therefore can’t offer CME credit.

Furthermore, every gap in clinician competency and every need for education must be objectively demonstrated. It is not enough for a program director to simply decide it would be a good idea to develop a program on geriatric diabetes. There has to be some way to prove the need exists. There are three broad categories of sources that provide information about existing educational needs: documented needs, presumed needs, and expressed needs (Box 1).
Box 1. Sources of Information on Educational Need

<table>
<thead>
<tr>
<th>DOCUMENTED NEEDS</th>
<th>PRESUMED NEEDS</th>
<th>EXPRESSED NEEDS</th>
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<tbody>
<tr>
<td>Objective external data sources</td>
<td>New methods of diagnosis or treatment</td>
<td>Evaluations of past CME activities</td>
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<tr>
<td>Epidemiologic data</td>
<td>Availability of new medications</td>
<td>Patient inventories</td>
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<tr>
<td>Morbidity and mortality data</td>
<td>Development of new technology</td>
<td>Consensus reports</td>
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<tr>
<td>Quality assurance and audit data</td>
<td>Changes in healthcare legislation or regulations</td>
<td>Clinician surveys</td>
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<tr>
<td>Evidence-based literature</td>
<td>New guidelines</td>
<td>Expert opinion</td>
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Documented needs, the most common category used to substantiate the need for CME, are proven through objective, external data sources and are typically evidence-based. Examples of documented needs include published literature and epidemiologic data. Using our example of geriatric diabetes, valid sources of documented need might be prevalence and incidence rates of type 2 diabetes published by the Center for Disease Control or any other secondary source literature, which show that adults ≥ 65 years age are disproportionately burdened by diabetes and its acute and chronic complications.

Presumed needs can be inferred from a variety of sources, such as changes in diagnostic criteria or emergence of new treatments, innovations in technology, or new regulations. From these developments, it can be surmised that clinicians will need training to master and incorporate the new information or skill into their practice. The recently published consensus statement by the American Diabetes Association, which provides a framework for consideration of treatment goals for glycemia, blood pressure, and dyslipidemia in older diabetic adults, is a good verification of presumed need for CME.4

Expressed needs are conveyed directly by clinicians. In keeping with the current effort by CME professionals to make medical education more learner-centered and connected to clinician practice, we frequently seek evidence of educational need from clinicians who are familiar with the subject of a particular CME program. This information is collected a variety of ways, including use of targeted surveys and interviews with medical experts and clinical administrators to obtain the clinician’s perspective and recommendations for improving patient care. When my students write their needs assessment, I require that one source of information about the need for education come from a live interview. There is so much we can learn about the challenges clinicians face by talking to them directly that isn’t written in meta-analyses or review papers.

In an upcoming issue of the AMWA Journal, Part 2 of this series will describe how to pull together information from the gap analysis and information we’ve gathered to verified the need for medical education to create a formal document, the CME Needs Assessment. I will discuss how, through educational linkage, this document is used to inform the educational objectives of the program, the content, activity evaluation, and outcome studies we conduct to demonstrate the effectiveness of our CME.

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References

I don't know enough about foreign languages (or is it non-English languages?) to determine whether any of them are flexible enough to generate some of the interesting—and humorous—results that the English language can produce.

I do know that there are puns in some other languages but maybe not the variety of confusion we have in our language. Perhaps that is why English is so difficult to learn as a second language.

Fortunately, many of these “crazies” give us a good laugh (what's a bad laugh?) even when repeated often.

We have puns
A pun, the dictionary tells us, is the humorous use of a word to suggest two or more of its meanings or the meaning of another word similar in sound.

How about:
Atheism is a non-prophet organization
Do infants enjoy infancy as much as adults enjoy adultery?
If two physicians get together, do you have a paradox?

We have paradoxes
Why is the man who you trust to invest your money called a broker?
Why is the slowest traffic time called the rush hour?
If a vegetarian eats vegetables, what does a humanitarian eat?
Why is bra singular and panties plural?

We have opposites that are not opposite
Why is it that rain drops but snow falls?
Why is a boxing ring square?
Doesn't quicksand work slowly?
Sweetmeats are candies, but sweetbreads, which are not sweet, are meat.

We have opposites that have the same meaning
A house burns down as it burns up.
You fill in a form by filling it out.
An alarm goes on by going off.
Slow down and slow up.
You have a slim chance and a fat chance.

We have opposite uses
We recite at a play but play at a recital.
We have noses that run and feet that smell.
We drive on parkways but park on driveways.
Athletic events have stands but they are made for sitting.

We have words and expressions with no opposites
Filthy lucre—clean lucre?
High jinks—low jinks?
Short shift—long shift?
Out of whack—in whack?
Pre-cut—what is post-cut?

We have unanswered questions
If the plural of tooth is teeth, why isn't the plural of booth beeth?
If teachers taught, why didn't preachers praught?
What if there were no hypothetical questions?
What was the best thing before sliced bread? (This has got to be absolutely an English—or American—usage)
How is it possible to have a civil war?

And we always have those unintended double entendres
(These are actual newspaper headlines. Wow!)
_Panda Mating Fails; Veterinarian Takes Over_  
A doctor dedicated to his profession!  
_Hospitals are Sued by 7 Foot Doctor_  
A tall tale  
_Man Kills Self Before Shooting Wife and Daughter_  
I'm still trying to visualize this one.  
_Juvenile Court To Try Shooting Defendant_  
A better approach to kids in trouble?

As I wrote once before: Follow my lead and get the lead out.

(With thanks to various anonymous e-mail authors)
Don’t Lead Readers Down the Garden Path!

By Laurie Thomas, MA, ELS

To lead someone “down the garden path” means to mislead them. A garden path sentence is a grammatically correct sentence that initially lures people into an incorrect interpretation. Here’s a classic example, from Steven Pinker’s *The Language Instinct: How the Mind Creates Language*:

\[ \text{The horse raced past the barn fell.} \]

The first three words in the sentence lead you down the garden path. They make you think that *raced* is the main verb in the sentence. Then, when you see “fell” at the end of the sentence, you realize that your initial interpretation of the sentence makes no sense. You have to go back to the beginning of the sentence and reinterpret the whole thing. Only then do you realize that the sentence means the following:

\[ \text{The horse that was raced past the barn fell.} \]

By definition, a garden path sentence is grammatically correct. However, it still qualifies as bad writing because it annoys the reader. People don’t like being led down the garden path, and they don’t like having to backtrack to figure out what the writer really meant.

Causes of the Garden Path Effect

Garden path sentences are a common problem in written English because English is an analytic language and therefore relies heavily on word order to establish what role each word plays within the sentence. It’s far more difficult to find examples of garden path sentences in a highly inflected language such as Latin, which uses word endings to indicate parts of speech, case, and so on.

Garden path sentences are a far more common problem in written English than in spoken English because English speakers use prosody (ie, rhythm, intonation, or stress) to clarify meaning. These clues are lost when a sentence is written down.

Although a garden path sentence is grammatically correct, it is still badly written. Careful attention to some simple grammatical principles can help you avoid sending your readers down the garden path.

Reduced Relative Clauses

The garden path effect often results from the use of a reduced relative clause. In an overzealous attempt to “omit needless words,” many people end up omitting relative pronouns: the *wh* words (*which*, *who*, etc.) or *that*. Using a reduced relative clause will shorten the sentence but may nevertheless end up wasting readers’ time by leading them down the garden path.

\[ \text{The cotton clothing is made of is grown in Mississippi.} \]
\[ \text{The cotton that clothing is made of is grown in Mississippi.} \]
\[ \text{Fat people eat accumulates.} \]
\[ \text{The fat that people eat accumulates.} \]

Careless Punctuation

If your house style permits, use close punctuation, which means using all of the punctuation that the grammatical structure of the material suggests. Some people kvetch that all those extra commas make the writing seem “choppy,” but close punctuation sometimes prevents the garden path effect:

\[ \text{I kissed Joan and Mary laughed.} \]
\[ \text{I kissed Joan, and Mary laughed.} \]

GRAMMAR REVIEW

**Clause**—the smallest grammatical unit that can express a complete proposition (ie, it contains a subject and a predicate).

**Subordinate clause**—Also called a dependent clause, a subordinate clause cannot stand on its own as a sentence. Instead, it modifies an independent clause or serves as a component of it.

**Independent clause**—a clause that can stand on its own as a sentence.

**Relative clause**—a subordinate clause that modifies a noun or noun phrase. In English, a relative clause is usually introduced by a relative pronoun: *who, whom, whose, whoever, whomever, which, what, whatever, or that*.

**Reduced relative clause**—a relative clause that is not marked by an overt complementizer, such as that or who. In English, relative pronouns are used as complementizers; dropping them can lead to the garden path effect because it becomes difficult to parse the sentence until you have finished reading it.
Words That Straddle Word Classes

Garden path sentences are common in English because English words can serve as different parts of speech without being marked as such. Adjectives can serve as nouns, nouns can become verbs, and verbs can become nouns.

- The man who hunts ducks out on weekends.
- The hunter ducks out on weekends.
- The old man the boat.
- The elderly people man the boat.

To detect this kind of garden path sentence before it gets published, watch out for adjectives that are being used as nouns and verbs that look like nouns.

Block Off the Garden Path

When viewed as a whole, a garden path sentence is grammatically correct. However, readers do not view sentences as a whole. They read them one word or phrase at a time. For that reason, garden path sentences should be corrected so that readers will be led in the direction where the writer really wants them to go.

It’s easy to find garden path sentences in someone else’s work. They make you stop in confusion and then backtrack to figure out what the writer really meant. It’s harder to find garden path sentences in your own writing because you know what you meant!

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Reference
The Forever Fix
Ricki Lewis, PhD

Ricki Lewis, PhD, is a masterful storyteller. Her book *The Forever Fix* not only explains the complicated science of genetics but also takes us into the human stories of children, parents, and researchers who show unimaginable courage. In this account, which reads like a science fiction novel, she describes how each gene therapy trial has taken us one step closer to the promise of a “forever fix” to attack the most challenging medical conditions at their genetics roots.

The hero of the book is 8-year-old Corey Haas. Corey was going blind from a rare hereditary disorder called Leber congenital amaurosis or LCA2. Lewis recounts how Corey’s parents endured years of trying to identify the cause of their son’s disappearing vision and became advocates for their son. Like most people, Ethan and Nancy Haas had never heard of gene therapy. They soon learned.

In 20 compelling chapters, Lewis leads the reader through the parade of researchers, doctors, parents, and children who have had hopes for curing “incurable” conditions. She describes both successes and failures. Jesse Gelsinger was a young man with an inborn error of metabolism called ornithine transcarbamylase deficiency or OTC. Although his condition was controlled by more than 50 pills a day, he volunteered for a gene therapy procedure. On September 29, 1999, headlines in the *Washington Post* rang out “Teen Dies Undergoing Experimental Gene Therapy.” A firestorm erupted with questions of ethics, improprieties, and informed consent, and ending with sanctions and apologies. A shadow was cast, threatening the progress of gene therapy. However, parents who had hope for gene therapy persisted in encouraging research and continued to fight to raise money and form support groups.

Before Gelsinger, many other gene therapy trials had received acclamation. The very first gene therapy trial for an inherited disease took place on September 14, 1990. Ashanti (Ashi) DeSilva had a condition called adenosine deaminase deficiency or ADA, a disorder caused by an enzyme deficiency. Gene therapy replaced the genes that create the enzymes, leaving a healthy young woman who no longer needs to be treated. Lewis recounts the idea of the evolution of gene therapy through children with severe combined immune deficiency, known as the SCID Kids, including David Vetter, the Bubble Boy. Lewis also explores gene therapy experiments with children born with other genetic diseases such as giant axonal neuropathy (GAN) and Canavan disease. The parents who fought for their children who had “orphan” diseases—now called rare diseases—revealed the indomitable spirit and courage of individuals whose lives were committed to getting funding for disorders that no one was interested in because they were so rare.

Corey’s story is told through the eyes of the parents and the researchers who were determined that gene therapy was the answer to LCA2. The parents found “how getting a clinical trial for a gene therapy up and running was more complicated than doing so for a conventional drug. Gene transfer is risker and there is a lot more to consider. You have to determine which vector to use, how much, where it goes, if you can direct where it goes, the time course, the level of gene expression, what happens if something goes awry, and toxicity,” wrote Lewis. And dealing with the alphabet soup of government—FDA’s CBER, NIH’s RAC, independent DSMBs, local ethics boards, and finally IRBs—was like traveling blindly through a complicated maze. Corey received his therapy in September 2008; he and the Briard sheepdog Lancelot, whose breed also has the gene for LCA2, were big hits at the American Society of Gene and Cell Therapy in Washington in 2010. They could both now see.

*The Forever Fix* is the first book detailing the fascinating story of gene therapy, how it works, the science behind it, and how scientists learned from each trial. I highly recommend it as “must” reading for medical writers who desire an overview of this important “fix” of the future.

— Evelyn B. Kelly, PhD

Evelyn Kelly is a freelance writer in Ocala, FL.
I have always been a little vague about numbers. One result of this vagueness is a peculiar amnesia about how much time I spend on any activity, including work activities. With such a dysfunctional view of time, it is a miracle that I have survived as a freelance as long as I have.

After I read AMWA member Laurie Lewis’ *What to Charge* recently, I understood that my ignorance is costing me money when bidding for work on a project basis. Lewis suggests that as a general practice, we should log every activity on every project and then mine those logs to understand more clearly how long the tasks of a prospective project might take. You can see how to do this in Chapter 3, where she explains how to use these logs to estimate any new project. Laurie argues: “For 6 months, keep task-oriented logs on every project you do, whether you are paid by the hour, the day, the job, or whatever. After you’ve used the information in your logs to price other jobs and to manage your business better, you will be convinced that the little bit of record-keeping effort was totally worthwhile” (p. 34).

I’m convinced! Before I had read this book, I had estimated and bid a training customization at 3 hours but it actually took 13 hours. Of course, I couldn’t charge for the 10 extra hours. You can bet that I will use this painful experience to bid more realistically next time.

Chapter 8 shares some excellent negotiating tactics. One that I have used with success appears on page 96: “Call your suggested project rate a cap, and say you will try to make the final bill less.” Another strategic suggestion is not to suggest your price right away; continue to ask questions and maybe they will reveal their budget for the project. In any case, you’ll get more insight into the project before you commit to a price. I was also fascinated with her triple-scenario, multiple-rate, task-based estimating method. She suggests that you prepare three time-estimate scenarios, which she refers to by descriptive nicknames:
1. Everything goes exceptionally smoothly (Cream Puff).
2. The job is fairly typical (Average).
3. Every task is more complicated than usual (Job From Hell).

By projecting different rates and possible scenarios, you provide yourself with room to negotiate on the basis of what you understand about the project and your client’s budget. You will be able to more accurately bid jobs so that you get paid a fair rate.

Lewis’s book can help three audiences: new freelances, experienced freelances, and employees. New freelances will get a glimpse into a rational method of setting rates and negotiating. Experienced freelances will understand the value of keeping detailed task logs. (This practice had always seemed so compulsive to me, but now I am a convert). Employees will learn how (and why) to keep a task log that can help them justify time estimates for projects that management may be underestimating; they will also learn some negotiating tips and tactics for their next raise or job negotiation.

I recommended *What to Charge* to fellow AMWA member William Brown, MD, who recently launched his editing business. Here is his brief review: “Establishing a medical editing service is a daunting proposition. I have written and edited medical research articles for over 40 years, but when I recently began to set up a for-profit editing service, I encountered many unanticipated hurdles. *What to Charge* has given me sound advice on several issues, with clarity and directness. The book’s figures, illustrating essential items such as records of income/expenses, time expenditure, and sample contracts, are particularly useful.”

— Elizabeth Frick, PhD, ELS

*Bette Frick is president of The Text Doctor LLC in Boulder, CO.*

Are there books you are interested in reviewing or think should be reviewed? Write to JournalEditor@amwa.org.
New social networking sites seem to pop up constantly, and the influence of social media grows daily. Consider these statistics: In a 2012 survey, 92% of US companies said they use social networks to find employees.\(^1\) This is a marked increase from the 78% of companies that relied on social media to recruit employees 5 years ago.

And what was the most popular platform for social recruitment? LinkedIn, with nearly all businesses (93%) leveraging it at some point during the recruiting process. These figures suggest that social media is not a gimmick. It represents a shift in the way we are doing business today—and will do business in the future.

The social networking sites with the most traffic are Facebook, Twitter, and LinkedIn.\(^2\) But traffic is only part of the story. Keep in mind that social media are fluid. Some sites are designed for very selective audiences; the membership of others evolves over time. The site that meets your networking purposes today may be obsolete for you tomorrow.

If you’re looking for a new platform from which you can build more personal connections with colleagues, clients, and prospective customers, then here are a few other social networks to consider.

**Google+ [plus.google.com]**: Google Buzz, the first attempt by Google to create a social networking site, went the way of the dinosaurs. It has morphed into Google+, Google's latest social networking attempt. By September 2012, Google already had more than 400 million members.\(^3\) These aren't all active users, just members who have joined the network. At first glance, Google+ appears to do everything that other social networks do: facilitate connections and sharing between people. Whether it's actually better than other sites is debatable. If you have a Gmail account, which now also requires you to create a Google profile, then you're automatically joined into Google+. Interestingly, in global and US traffic rankings, Google+ was the sixth most popular social networking website as of early February 2013.\(^2\)

**NetParty [www.netparty.com]**: A combination of business and social networking, NetParty is designed for young professionals in their 20s and 30s. NetParty sponsors live face-to-face events in cities throughout the United States, Canada, Europe, and South America. In addition, NetParty members have access to webinars, job postings, speed networking, and social events. Browse events by city, or join the young professionals’ group in the city where you live via Facebook. If you're young and looking to build your professional network, NetParty is designed for you.

**Sermo (www.sermo.com)**: Sermo is a social-media site reserved exclusively for licensed physicians. You must be an MD or DO in the United States to join. More than 125,000 physicians already are members. Some of Sermo's features include an iPhone app that enables doctors on the go to stay connected to the Sermo community; the iConsult feature, which allows doctors to collaborate with other physicians by sharing photos, laboratory and imaging results, and other patient data (all confidentially, of course); and resources that deliver the latest clinical trial data, drug and product updates, and prescribing and safety information straight to a computer or smartphone. According to Sermo's website, doctor members spend 40,000 hours on Sermo each month.

**Goodreads [www.goodreads.com]**: Goodreads, which has been described as Facebook for people who love reading books, is designed for readers around the world to share their book recommendations. At last count, Goodreads had more than 13 million members who have added more than 430 million books to their shelves. If you’re an author, Goodreads is another platform from which you can...
promote your book to readers through book reviews and other promotions you might want to run, such as book giveaways. Be sure to check out the Goodreads Choice Awards 2012; Goodreads’ members voted for the best books of 2012 in multiple categories. The winning book in the nonfiction category was *Quiet: The Power of Introverts in a World That Can’t Stop Talking*.

**Introducing the New Endorsements Feature on LinkedIn**

*By Mali R. Schantz-Feld, MA*

*Freelance Medical Writer, Seminole, FL*

The recently added “Endorsements” feature is causing some controversy among LinkedIn users. Introduced on September 24, 2012, this feature is a quick, one-click way to recommend someone without taking the time to write a recommendation. In the LinkedIn blog, David Breger, the company’s senior product manager, explained how the endorsement feature works:

1. On the top of a connection’s profile, you’ll see recommended endorsements for them. You can suggest additional skills as well.
2. You can also endorse them from the new Skills & Expertise section that now showcases these endorsements.

He notes that LinkedIn will notify you by e-mail message and on LinkedIn whenever you are endorsed. You can scroll to the bottom of your profile page under “Skills and Expertise” to see the faces of people who have endorsed you, and you can also accept any new skills recommended by your peers that you may not have thought to include on your profile. Or you can also add a new skill by clicking on “add a skill” on your profile page.

This sounds like an efficient, time-saving way to give kudos to your connections, and it can be; however, some LinkedIn users are discounting the new feature because they are receiving endorsements from people with whom they have never worked. Although you can only receive endorsements from first-degree connections, many LinkedIn users also connect with friends, colleagues’ friends, and acquaintances. Some are trying to be nice by endorsing their friends, or hope to gain endorsements of their own through reciprocation.

Do endorsements mean anything? Yes, if they come from someone who knows your work and skill level. What can you do if you receive an endorsement from someone who does not know your skill sets? Go to “edit profile,” then, go to the “skills and expertise” section of your profile, and on the right of the pictures of those who endorsed you, you will see a pencil. Click that, and you will see options for hiding some or all of your endorsements.

Julie Inouye, spokesperson for LinkedIn, said in a *Forbes* article in December 2012 that since the launch, more than 200 million endorsements had been issued, and users were making roughly 10 million endorsements a day. Time will tell if these endorsements make an impression on potential employers, or if the race to collect and give endorsements renders the application less valuable.

Here’s hoping that all of your recommendations and endorsements lead to new opportunities! Until next time, I’m looking forward to connecting with you on LinkedIn!

**References**


www.facebook.com/amwa.org

www.linkedin.com/groups?gid=55526&trk=myg_ugrp_ovr

twitter.com/AmMedWriters
The lengthening days and fresh air of spring make it a nice time of year to clear accumulated clutter out of your life. While you’re busy beating the dust from the curtains and sorting through outdated magazines, don’t forget about an insidious hideout for clutter: your computer.

Although more physically compact than that overflowing basket of old newspapers, the digital clutter clogging up your hard drive can be insidious in its own way and can create a huge drag on your physical and psychological resources. Organizing your computer’s files and folders and freeing up storage space and RAM can be as liberating as clearing your desk.

If I’ve convinced you to break out the virtual feather duster, here are some clutter-prone areas to consider addressing.

**Change Your Passwords**
Using weak passwords (such as short words found in the dictionary, names of children or pets, or even the word password), using the same login and password combination across multiple sites, and never changing passwords are practices that can put your financial security and personal/professional privacy at serious risk. If you don’t already manage this routinely, now would be a great time to systematically change the passwords for all sites where you perform financial transactions or store confidential information, and any other site you use on a frequent basis.

**Trim Bookmarks**
Bookmarks can be handy, but only if they’re not so numerous and jumbled that you can’t quickly find what you need. Take a day to set up a bookmark folder system and organize them. In the process, you may come across useful links you’d marked but forgotten about.

**Clean Out Your Inbox**
Cleaning out your inbox can be daunting, and not everyone subscribes to the “inbox zero” philosophy. Instead, why not at least sort your e-mails by sender as an easy way to find and delete groups of unread newsletters, expired commercial offers, and old statement notifications? While you’re at it, unsubscribe to some of those commercial solicitations and reconsider how many newsletter subscriptions you can actually consume. If you’re warming to the task, set up a few folders and filters to make it easier to stay on top of your e-mail.

**Prune Autosuggest Lists**
If your e-mail program auto-fills the recipient field for you as you type, it probably also suggests obsolete addresses or people you haven’t contacted in ages. Pull up the “previous recipients” list and delete old names. This saves time and the headache of accidentally sending messages to the wrong person.

**Archive and Upgrade-Proof Financial Records**
If you use software to track business or personal finances, program obsolescence can be a huge concern. To help guard against data loss, close your books and create an archive every year. That means: reconcile all accounts from the previous year, back up the files digitally, and create a year-end copy. Then, run year-end reports (profit and loss, balance sheets, trial balances, transaction reports, etc). Store these as PDFs and also export them to a text format, such as CSV (comma-separated values). You might even consider printing hard copies to be stored in a safe location. Once this is done, it’s safe to delete mid-year backups and working files from that year.

**Clear Out Files, Old Backups, Caches, and Deleted Files**
Remember that stack of outdated magazines? It’s time to tackle the digital equivalent—all those memory-hogging files you’ve hung on to but really don’t need any more.
• Dig through your desktop and subfolders for projects or other work completed in the last year. Delete initial drafts, working files, outdated source materials, and anything else that you’ll never need again now that the project is done.
• Review your contacts and delete or archive ones you’re truly no longer in touch with.
• Do a quick sweep of last year’s photos and toss near-duplicates and poor or blurry images.
• Uninstall or delete programs you no longer use.
• Clear your computer’s cache of temporary files. Instructions can be found in the June 2012 issue of the AMWA Journal.¹
• If you keep static file backups anywhere, now would be a great time to make new ones and delete old ones.
• Finally, empty your deleted items/trash/recycling folder. Don’t forget the trash bins on your desktop and in your e-mail program, and program-specific ones as well.

Give Your Hard Drive Some TLC
Since you’re on a cleaning roll anyway, take a few moments to run your computer’s disk utilities to verify that your hard drive is in good working order. Mac users can verify the disk and permissions, while Windows users should consider defragmenting the hard drive and cleaning the registry. For instructions, refer to your operating system’s help files.

Last but Not Least: Create a Plan for Regular Maintenance
You’ve taken some important first steps, but for best results maintenance should be performed regularly. Consider setting up automatic reminders to revisit this task at least once per quarter, and the serenity of a clutter-free digital life can be yours!

References
At last year’s Annual Conference in Sacramento, we solved a dilemma that had long troubled us: how to attract members to the Annual Business Meeting, where much important information about AMWA is discussed. By combining the meeting with a networking lunch, we attracted 250 people, not the typical 50 to 60. A group this size inspires a speaker, so I opted for a message that emphasized confidence in the face of challenges, optimism that problems contain hidden opportunities, and an invitation to all members to join in the effort to make AMWA as relevant to the medical writers of the future as it has been to current members. As an accompaniment to this address, I included in a handout available at the tables the plans for 2012-2013 that AMWA’s Executive Committee had formulated when we met in Nashville in July 2012. The address and plans were published in the most recent issue of the AMWA Journal.1

These plans, set out in in five related areas, had as a common theme the goals of continuing to meet the needs of members, to be the voice that speaks for medical writing, and to be “the resource for medical communicators.” When you kick off your program year with a proclamation of your goals and plans, then you’ve set up a challenge for yourself, because members will want to know how you’re doing.

And that’s what this column is about—a mid-journey report on how AMWA is doing in accomplishing its goals and plans for 2012-2013. As preparation for the Executive Committee meeting in January, I asked the officers and department administrators to identify some steps they had taken to meet our program goals. Here are some highlights:

1. The AMWA headquarters staff, in an initiative led by Deputy Director Shari Rager, is working with vendors and member volunteers to implement a new AMWA association management system and website.

2. The Publications Committee, reports administrator Anne Marie Weber-Main, is working with headquarters staff to make decisions about the organization of and content for a planned AMWA Amazon storefront.

3. The Publications Committee is also at work on steps that will lead to two new volumes of the AMWA Collections: subjects are (1) The Best of Dear Edie, (2) Freelance Medical Writing and Editing.

4. The Publications Committee is also exploring potential reprinting by AMWA of two seminal books on document design (guidelines, research) as evidence-based resources for the profession.

5. Awards Administrator Deborah Whippen reports that a review of AMWA’s Awards program is underway, with the goal of enhancing its value as a member resource.

6. As part of the effort to reach out to sister organizations, Annual Conference (AC) Administrator Lori Alexander invited the Editorial Freelancers Association (EFA) to develop an AC session that includes highlights of EFA and education based on EFA’s core expertise.

7. The AMWA Journal has successfully made the transition to new Journal editor Victoria White. AC poster session presenters are being encouraged to develop their posters into articles. Finally, the methods of e-journal delivery are being reviewed so that members who opt for “green” subscriptions are receiving the content in its optimal form.

8. To improve communications with internal and external stakeholders, I have initiated regular communication with AMWA past presidents; Treasurer Christine Wogan and headquarters staff are reviewing and implementing guidelines governing the dissemination of financial information; AC Administrator Lori Alexander has engaged chapter leaders in promoting the AC Call for Proposals with e-mail messages outlining how to help and requesting that they post information on their chapter LinkedIn pages; and Chapter Relations Administrator Katharyn Spiegel is continuing chapter leadership teleconferences, scheduled monthly throughout 2013.

9. Online Community Administrator Kristina Wasson-Blader has established a social media committee. Already, the committee has prepared policy and guidelines statements for AMWA’s social media engagement. Now that the Executive Committee has approved them, the policy and guidelines were mentioned in the
January member update distributed by e-mail and have been posted on our website at www.amwa.org/default/AMWASocialMediaPolicyandGuidelines.pdf.

10. In the area of promoting AMWA programs and services, AC Administrator Lori Alexander has sent customized Calls for Program Proposals to 16 related organizations and developed a social media campaign to promote the Call for Proposals within and outside of AMWA.

11. In the area of the certification initiative, Commission Chair Karen Potvin Klein has been invited to present at the Delaware Valley Conference in March. In addition, she has prepared articles and letters on certification for the AMWA Journal. Karen is also attending the Drug Information Association Medical Writing & Scientific Communications meeting March 19-21, where the Sacramento AC AMWA Open Session will be reprised by David Clemow, a member of the commission. Finally, a training session for writing certification exam items is planned for this spring.

That’s a snapshot of our progress toward our 2012-2013 plans and goals. I hope that what jumps out at you is the variety and multiplicity of our activities. These qualities typify medical communication and AMWA itself: dynamic, rapidly changing, and made possible by the efforts of dedicated AMWA members.

Please write me with any question or opinion you have about AMWA; I love hearing from members. My e-mail address is hanelind@ferris.edu.

References
1. Haneline D. Inaugural presidential address. AMWA J. 2012;27(4);183.

Erratum: The expansion for the abbreviation ISMPP was incorrect in a recent issue of the Journal (Volume 27, No. 4, page 184). The correct expansion is the International Society for Medical Publication Professionals.

Quarterly Update from the Medical Writing Certification Commission

By Karen Potvin Klein, MA, ELS, GPC
2012-2014 Chair, AMWA Medical Writing Certification Commission

The Medical Writing Certification Commission was established to initiate, evaluate, maintain, and oversee the credentialing program for medical writers. The commission seeks to represent the diversity that exists within the profession and serve as a voice for stakeholders who have an interest in maintaining high standards in medical writing.

Commission members: Karen Klein is now the Certification Commission Chair (2012-2014); former Chair Thomas P. Gegeny remains on the commission. Our other members, who have agreed to another year of service, are David Clemow, Barbara Gastel, Sue Hudson, and Marianne Mallia.

Plans: Our plans for the next year include short-term and long-term activities.

A key way in which an AMWA member can be part of this project is to share his or her expertise as an item writer, to help develop a bank of material for use in a future exam. We want the exam to reflect the diversity of our profession—and for that, we need many different contributors. For example, anyone with experience in writing test questions for adult learners would be particularly helpful in this project. Contact AMWA Executive Director Susan Krug, CAE, if you’re interested. The first item-writing session is planned for this spring at the office of our test vendor, Schroeder Measurement Technologies, Inc, in Clearwater, FL. Stay tuned!

Outreach to other organizations: Thanks to David Clemow, we were invited to reprise our 2012 annual conference talk on the progress of the certification initiative at the Medical and Scientific Communications forum of the Drug Information Association in March.

We will continue to pursue opportunities to involve sister professional organizations, such as the International Society for Medical Publication Professionals and the Society for Technical Communication, in the planning and development of the certification program. We’ll have more to tell you about in the next update.
The Global Alliance of Publication Professionals: Update on a Small Group with a Big Mission

By Art Gertel, MS, Cindy Hamilton, PharmD, ELS, Adam Jacobs, PhD, MSc, Gene Snyder, MBA, CMPP, and Karen L. Woolley, PhD, CMPP

The Global Alliance of Publication Professionals (GAPP) is a group of five volunteers from Europe, North America, and the Asia-Pacific region (Figure 1).

We are experienced and passionate medical publication professionals who have held or do hold leadership positions in the American Medical Writers Association (AMWA), the European Medical Writers Association (EMWA), or the International Society for Medical Publication Professionals (ISMPM). GAPP is not an association, but seeks to complement the work done by our professional associations.

Why did GAPP start and how does it operate?

GAPP started in January 2012, but the idea originated several years earlier. During her keynote address at the 2009 AMWA Annual Conference, Karen L. Woolley, PhD, CMPP, challenged our profession to speak up, more quickly and with a more unified voice, when influential reports appeared (eg, in journals, mainstrean media, and social media) that affected (and often denigrated) medical publication professionals. Rejoiners from poorly informed critics, particularly those who confuse ghostwriters with professional medical writers, often dominated the responses to such reports (Figure 2).

Although rebuttals that supported our profession may have been given initially by individuals and later by associations, such comments were often limited in their representativeness or their speed (Figure 2). A gap existed and GAPP was established to fill this gap!

GAPP developed a unique volunteer model. As we are all senior managers or owners of our companies and have existing voluntary commitments to our respective associations, we realized that time for GAPP could be quite limited. To help ensure we could sustain our energy throughout the year, we divided the year into 10- to 12-week blocks and assigned a "lead responder" to each block. The lead responder was responsible for drafting the response, incorporating feedback from fellow GAPPers, and submitting the response. To help ensure credible and timely communications, we developed a list of communication points that we all agreed upon and a list of references that could be used to provide evidence-based support for these points. These lists were developed before our first response and have proved quite useful. We also set up a website, a LinkedIn account, and a Twitter account to help ensure our supporters and critics could find out more about GAPP and to allow us to leverage social media to alert our networks (and their networks) to what GAPP was doing.

What has GAPP done to help our profession?

GAPP has helped members of our profession by standing up for our profession, often when nobody else has. Even though there are only five people in GAPP, we have managed to publish articles in high-ranking, international, peer-reviewed journals (including The American Journal of Medicine, Current Medical Research & Opinion, and Trials), and provided responses to contentious articles or inquiries from mainstream media (eg, Forbes) and web-based media.
(eg, the blog Retraction Watch). Although most of our activities have been reactive, we have started to be proactive, with a provocative editorial recently published in Current Medical Research & Opinion. We have witnessed critics changing their minds (or at least their words) in how they refer to professional medical writers—yes, they now accept that we should not be called ghostwriters! (Figure 3).

Differentiating professional medical writers from ghostwriters has been a frequent theme of GAPP's responses (Table 1). We might think this is an “old” issue, but it isn’t for those outside our profession. We all need to realize how others view our profession; if they don’t understand us or value us, whose fault is it? The irony of communicators not communicating well is rather evident and rather harsh.

On a more philosophical and perhaps strategic level, we’d like to think that GAPP has emerged as a role model for interassociation collaboration. We do not represent any of our associations as part of our role in GAPP; however, we have shown how volunteers from different associations can work together in a practical, positive, and productive manner. GAPP has shown that such collaboration can occur across the world, leveraging technology and bridging time zones to deliver results in a cost-effective manner. We hope GAPP serves as a catalyst for more formal interassociation collaborations in the future.

What can AMWA members do to help GAPP?
There are at least three ways you could help GAPP:

1. Be a scout: We would be very grateful to have “scouts” from around the world who could alert us to articles that demand a timely and credible response. We have

Table 1. Summary of the Key Points in Articles and Comments from GAPP*

<table>
<thead>
<tr>
<th>Article / comment</th>
<th>Key point</th>
</tr>
</thead>
<tbody>
<tr>
<td>GAPP review of medical writing issues in Ben Goldacre’s book, Bad Pharma; posted on Amazon.</td>
<td>GAPP agrees with Ben Goldacre on condemning ghostwriting, but rebuts assertion that AMWA, EMWA, and ISMP are “ghostwriters’ associations.”</td>
</tr>
<tr>
<td>GAPP editorial in Current Medical Research &amp; Opinion.</td>
<td>GAPP’s editorial quickly makes “top 5 most read” articles in Current Medical Research &amp; Opinion. GAPP provides the first financial model to show how professional medical writers could fix poor compliance with results reporting.</td>
</tr>
<tr>
<td>GAPP comment on the Lacasse et al article published in BMC Research Notes.</td>
<td>GAPP critiques article purporting to study only ghostwriting when it actually studied ghostwriting, guest-authorship, and possibly, ghost-authorship.</td>
</tr>
<tr>
<td>GAPP comment on the Lundh et al article published in Trials.</td>
<td>GAPP challenges assertion that medical writers strive to please marketing departments—ghostwriters might, but professional medical writers do not!</td>
</tr>
<tr>
<td>GAPP letter to the editor in response to article by Bosch et al published in the American Journal of Medicine.</td>
<td>GAPP’s letter to the editor accepted for publication in the American Journal of Medicine. GAPP cites evidence on the benefits of using professional medical writers.</td>
</tr>
<tr>
<td>GAPP comments sent to editorial office of Ophthalmology: comments received and to be considered at annual review of Instructions to Authors</td>
<td>GAPP requests that Ophthalmology’s Instructions to Authors clarify that ghost authoring, guest authoring, and ghostwriting are all unacceptable practices. The current Instructions equate ghost-authorship with ghostwriting. Further, there is no clarification that professional medical writing assistance is acceptable.</td>
</tr>
<tr>
<td>GAPP correspondence with Ivan Oransky (co-founder of the blog Retraction Watch).</td>
<td>GAPP reinforces statements from the International Federation of Pharmaceutical Manufacturers and Associations on the need for industry to publish clinical trial results and cites evidence that lack of time is a major factor for why authors fail to publish results. GAPP highlights how professional medical writers can help address the problem of nonpublication.</td>
</tr>
<tr>
<td>GAPP comment series in response to article about industry-supported editorial assistance published in Forbes business magazine.</td>
<td>GAPP clarifies the roles of professional medical writers, authors, and sponsors. GAPP asserts that disclosure of medical writing support is necessary, but not sufficient; ethical publication practices have to be followed!</td>
</tr>
<tr>
<td>GAPP comment on University of North Carolina Medical School's ghostwriting policy.</td>
<td>GAPP agrees that medical schools should ban ghostwriting. GAPP clarifies difference between ghostwriters and professional medical writers.</td>
</tr>
</tbody>
</table>

* For a list of GAPP responses, with hyperlinks to items included here, please visit: www.gappteam.org/news/index.html.

Figure 3. Extract from the reply from Xavier Bosch (author of “Ghostwriting: research misconduct, plagiarism, or fool’s gold?”) to GAPP’s letter to the editor published in the American Journal of Medicine. In his original article, he had implied professional medical writers were ghostwriters; after GAPP’s response, he acknowledged the difference.
some scouts already but would welcome more. A quick e-mail message to contact@gappteam.org or a tweet to @GAPPTeam is all it takes. We aim to respond within 2 working days.

2. **Request an author testimonial:** GAPP would like to help build a database of testimonials from well-respected authors indicating why they use professional medical writers (not ghostwriters). We know that all types of authors use medical writers and do so for a variety of reasons. Nevertheless, some authors can confuse professional medical writers with ghostwriters and may refuse professional medical writing support on the basis of this conflation. The irony is that evidence to date suggests that papers prepared with professional medical writing support are less likely to be retracted for misconduct, more likely to adhere to best practice reporting guidelines, and more likely to be published more quickly. Also, in the Asia-Pacific region, some authors fear that using a medical writer is a sign of weakness. Directing apprehensive authors to a website that displays numerous testimonials could help reassure these and other authors that leading researchers from around the world recognize professional medical writing support as a legitimate, ethical, and valuable service. There is nothing wrong or weak about using professional medical writers—indeed, there is lot of good that comes from using us.

3. **Refer a journalist:** If you meet a journalist or become aware of a journalist with an interest in the medical writing world, please refer them to GAPP (www.gapp-team.org). We would be happy to be a trusted and timely source of information for them. The Statement of Principles of the Association of Health Care Journalists indicates that journalists’ gaining information from a variety of sources is a key principle. Too many stories focus just on ghostwriting; the perspectives from professional medical writers would help provide fair balance to such articles. However, if journalists don’t know whom to contact and they are facing a pressing deadline, is it any wonder that critics of writers, who are more than willing to make time for journalists, get their views published?

**What’s next for GAPP?**

GAPP was started as a 1-year pilot project. We did not know if the GAPP model would work. We did not know if GAPP would get anything published. We think we have established a model to successfully support our profession and effectively engage its critics. We are convincing critics that professional medical writers are not ghostwriters. This may seem banal to us, but we’re not the ones confusing the two. We still have more to do to reach out to and build mutually respectful relationships with journalists. We are continuing in 2013, but we also recognize the need to create a succession plan to ensure the work continues.

**Where can I find out more about GAPP?**

Follow GAPP on Twitter or go to our website or LinkedIn group (at www.linkedin.com/groups/Global-Alliance-Publication-Professionals-4289870). We also are delighted that conference organizers around the world are starting to approach GAPP to provide their attendees with an update on GAPP’s activities. We can alert their attendees to GAPP publications in peer-reviewed journals that they can then use to highlight the value and ethics of professional medical writers. In addition, journal editors, journalists, and critics who may attend these conferences will see that our profession, quite rightly, is starting to stand up for itself.

**What do our associations and GAPP members think of GAPP?**

When GAPP was still at the concept stage, we were pleased to receive in-principle support from the American Medical Writers Association, the European Medical Writers Association, and the International Society for Medical Publication Professionals. These associations could see that GAPP aimed to complement, not compete against, our associations. As GAPP speaks on behalf of five members, rather than thousands, we can respond quickly. Nevertheless, when GAPP’s responses are complemented by official statements from our associations, our profession gains a stronger voice.

**Acknowledgments**

The authors acknowledge funding from ISMPP to support the GAPP website and technical expertise from Tim Bacon (Medicine in Practice) to develop the GAPP website. We are also grateful for AMWA, EMWA, and ISMPP for giving the GAPP concept in-principle support. We hope you’re pleased with our progress! Finally, we want to thank our supporters (eg, existing scouts, re-tweeters, followers) for helping GAPP do what it does and thank our critics for making GAPP do what it does.

**References**


*continued on page 47*
In her last issue as editor of the AMWA Journal (2012;27[4]), Lori Alexander, MTPW, ELS, quoted herself, saying, “Ten years is enough time for doing almost anything.” Her arrival at the Journal in 2003 ended a stretch of issues somehow produced without a permanent editor in place. By the time she departed at the end of 2012, Alexander was directing a fleet of more than 50 volunteers, each playing important roles in the development of each volume.

To recognize her outstanding leadership of the AMWA Journal—one of AMWA’s most valued member resources—the Executive Committee granted Alexander the honorific title “editor emeritus” at the October 2012 annual meeting. After 10 years atop the Journal masthead, she is back on it for countless more.

To earn the editor emeritus distinction, Alexander established the Journal’s first Editorial Board to guide the publication’s direction. She championed the development of new sections in the Journal for enrichment of different segments of the AWMA membership and the field of medical communications. She engaged and managed dozens of volunteer section editors, columnists, peer reviewers, copyeditors, and proofreaders. Supporting the volunteers and maintaining the Journal’s high standards, Alexander developed and implemented online training sessions on peer review and copyediting.

The Journal received external honors during Alexander’s tenure as editor. In 2009, the Journal received an Apex award for general excellence and an EXCEL Award, also for general excellence, in the category of scholarly journals. And last year, the Journal’s special green theme issue from 2011 won an Apex award for publication excellence in the category of “green magazines and journals.”

Perhaps remembering all too well how she was flung into deep waters at the start of her time as AMWA Journal editor, Alexander took the time to lead the new editor, Victoria White, and herself through a safe and orderly transition in the second half of 2012. She did so “with a quiet humor and grace that endears her to many,” to borrow words from the October presentation by Anne Marie Weber-Main, AMWA Publications Administrator.

Such contributions of innovation, excellence, and service are what the American Medical Writers Association has come to expect of Lori Alexander, Editor Emeritus.
The most recent edition of the Journal includes an update on AMWA’s certification program, to which we are clearly committed. However, despite several decisions, board votes, and articles with optimistic generalities, several key questions remain unanswered.

Why certification? Below is the sum of what I received when I requested information on the data justifying the program:

On a survey of AMWA members:
*Is professional certification with a competency examination desirable for the medical communication profession?* Of 1,483 responders, 878 (59%) said yes and 605 (41%) said no or skipped the question. The difference is 273 responses, or only 5% of our 5600 members.

*Would you pursue certification with a competency examination for medical communicators if it were available?* Of 1,483 responders, 737 (49.7%) said yes and 746 (50.3%) said no or skipped the question.

A general question on certification posed to about 400 employers and recruiters: Of 65 who responded, 26 supported certification; 39 did not or skipped the question. “Certification or professional membership” was identified by 22 as the most important job requirement, after experience, and 31 would give extra consideration to candidates passing a validated (emphasis added) certification examination.

By themselves, do these data justify developing a $200,000 program? If a formal needs assessment was done, I propose that it be published. If not, shouldn’t one be done before we continue?

Why a single examination? We are apparently developing a one-size-fits-all, multiple-choice, pass-fail exam—an absurd approach, given the diversity of the profession. Testing for the “lowest common denominator” across all areas of the profession can only result in an exam too general to mean much. Can we be assured that more meaningful and less-costly alternatives were considered? If not, shouldn’t they be considered now?

Which study materials? A key aspect of any certification exam is how one prepares for it: what do candidates study? Not identifying appropriate study materials creates the “Stump–the–Student” problem, in which the test-taker has to guess what’s important. Have specific source materials been identified? Medical writing is a poorly documented profession, so identifying sources with anything but general information, such as style manuals, may be difficult. Shouldn’t these materials be identified before we continue?

What meaning? The most important aspect of the program remains unclear: what does passing the test mean? We are told that candidates who pass will meet the minimum requirements for the job. For which job? How will we know what these requirements are? *Will the exam be validated?*; that is, will it differentiate between medical writers, good writers, and non-medical writers? If the meaning of passing the test has not been identified, shouldn’t we identify it before continuing?

I think these are reasonable questions that should have been asked and answered before the development process was begun. If so, I propose their answers be published. If not, shouldn’t they be answered before we continue? Without compelling answers to these questions, isn’t certification premature?

— Tom Lang, MA

Tom Lang Communications and Training International, Kirkland, WA

References
We appreciate the concerns that Tom Lang has raised, both in this letter and in his article in last year’s AMWA Journal. It is important to stress that the Certification Commission, and AMWA’s leaders, value transparency highly. Thus, for some of the issues raised, if details have not been readily available, it is because the work is in progress. For example, we are in the process of identifying source materials (to cover core content and to use in exam preparation), which we agree is a necessary step.

We’d like to clarify the allocation of $200,000 for the certification program. The Board of Directors, the body that oversees the AMWA budget, voted to allocate funds up to that amount to support certification activities for 3 years. If there are funds left over at the end of that period, they can be reallocated to support AMWA activities. We arrived at this figure with the guidance of our previous Executive Director, Donna Munari, and following best practices described by the Institute for Credentialing Excellence.2

Where we disagree with Tom is that a “one-size-fits-all” exam, to use his term, is meaningless. The Commission’s research into how other certification programs are structured, and our own personal experiences with other certification programs, both suggest that a broadly based exam, with multiple-choice and other components, can indeed provide meaningful indications of a candidate’s knowledge and experience. Tom’s question of exam validation among those who are not medical writers has considerable merit, as does his earlier suggestions of self-testing modules (which could be developed and used as one means for preparing for certification).

The format of our exam itself is still under consideration; we have not ruled out a short essay or writing exercise as part of the test, for example. The portfolio model, which we have considered, has not worked well for other organizations we consulted, and is both subjective and overreaches (who are usually volunteers). As exam development progresses, content coverage will be guided by the recent survey data from 1,177 medical writing professionals who ranked the importance of various tasks requiring certain knowledge, skills, and abilities.

What is important to emphasize is that this certification program—from its inception and through its evolution—is ours to shape as medical communication professionals. At any point in time, the architecture and organization of the medical writing certification program will reveal to others the core aspects of what we do and what we consider centrally important for competence in our profession. Setting a “lowest common denominator” is not the same as establishing standards for essential proficiency, the latter of which is at the heart of AMWA’s current initiative and the focus of examination development.

Will additional examinations or more specialized certifications eventually be developed? Will the exam and process be substantially different after 10 or 20 years from launch? What will our profession be like after medical writing certification becomes a well-established option for those who wish to become professional medical writers? We cannot predict the future, but we can lay a foundation now for our own and future generations to build upon.

Communicating to members about all of AMWA’s activities is important, and this letter attests to our ongoing commitment to keep members informed about the certification initiative. We will submit a quarterly update on Certification Commission activities for each issue of the AMWA Journal and briefer items in the monthly “AMWA Update.” We also are planning conference calls and webinars at the chapter level. Most importantly, we will be involving many more members in the certification program development process, to ensure that the ensuing examination achieves the rigor and high quality that we all desire and captures the essence and breadth of our profession.

—Thomas P. Gegeny, MS, ELS, CMPP, 2011-2012 Chair, AMWA Medical Writing Certification Commission
—Karen Potvin Klein, MA, ELS, GPC, 2012-2014 Chair

References
1. Lang TA. Doing certification right: avoiding the one-test, one-score, one-time, one-size-fits-all examination trap. AMWA J. 2011; 26(3): 101-105.

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American Society for Indexing
April 17-19, 2013
San Antonio, TX
www.asindexing.org

International Society for Medical Publication Professionals
April 29-May 1, 2013
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International Association of Scientific, Technical & Medical Publishers
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American Medical Writers Association
November 6-9, 2013
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