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Introduction to the Nervous System, Part 1

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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 as a professional organization.
ABSTRACT
This article, the first in a two-part series on the nervous system, discusses the basics of nervous system communication, sensory nervous systems, and motor neurophysiology. Neurons are the nervous system cells that conduct electrical signals. Most neural functions in the body are carried out by the coordinated action of several neurons. Action potentials are the electrical signals generated by a neuron and propagated along the neuron. Most neurons release neurotransmitters, which are molecules that enable communication with neighboring neurons. Although the neuron action potential is preserved as the means of communication across most of the nervous system, there is tremendous variety in the functional result, which can be seen in specialized subsystems. Sensory nervous systems are responsible for hearing, sight, touch, pain, taste, and smell. In each sensory system, highly specialized receptors act to transduce the stimulus (eg, light, sound, food) into a perceptible event. Before body movement occurs, a muscle fiber receives a neural signal from an innervating motor neuron. This neural signal causes the contraction of a skeletal muscle, which causes movement of a joint. With a basic understanding of how a neuron generates and propagates a signal, medical communicators can delve into topics that deal with signal alterations, such as pharmaceuticals that influence neurotransmitters. The second article in this series will discuss the autonomic nervous system and the central nervous system (CNS).

INTRODUCTION
The purpose of this two-part series is to introduce medical communicators to the anatomy and physiology of the human nervous system. The content is especially useful for individuals who do not have a background in biology or neuroscience. Since the nervous system controls many bodily functions and influences other functions, knowledge of the nervous system will aid medical communicators who work in fields such as endocrinology, cardiovascular medicine, and gastroenterology, to name a few. Clinical applications are discussed to highlight how certain disorders, traumas, and pharmaceuticals affect the nervous system. Part 1 provides basic information about nervous system communication, sensory nervous systems, and motor neurophysiology. Part 2, to be published in a future issue of the AMWA Journal, will discuss the autonomic nervous system and the central nervous system (CNS).

NEURAL BASICS
At the most fundamental level, the human nervous system communicates. It relays information between a source and a target, which can be separated by distances ranging from a few micrometers to nearly a meter. The nervous system simultaneously integrates information from many sources and responds by generating appropriate signals. Neurons are the nerve cells that conduct electrical signals. There are estimated to be more than 100 billion neurons of various form and function in the human body. Glial cells are the other main type of cell found in the nervous system. They primarily support the function of neurons by making a myelin sheath that covers the outer surface of neuron axons. Additionally, glial cells deliver nutrients to neurons and scavenge dead neuron sections.

In general, a neuron is composed of a cell body, which contains the nucleus and other essential organelles; an axon, which transmits the electrical signal away from the cell body toward the next neuron in the circuit; and dendrites, which accept a signal from a neighboring neuron and transmit the signal to the cell body. Glial cells contain a cell body and many extensions, referred to as processes, that extend from the cell body; however, these processes are not categorized as axons or dendrites.

Neurons do not act in isolation. It takes the coordinated communication of several neurons to perform even the most basic function. This coordinated action is achieved by a neural
circuit, which is the assembly of neurons required to carry out a particular function. Afferent neurons carry neural signals toward the CNS. Efferent neurons carry neural signals away from the CNS. Interneurons form local connections between two other neurons in a neural circuit.

Neurons innervate most locations in the body, and they are involved in a wide variety of physiologic functions. The brain and spinal cord, which compose the CNS, are probably the most obvious anatomical components of the nervous system. The sensory nervous system comprises the eyes (visual), the ears (auditory and vestibular), the nose and tongue (chemical), and the skin receptors for pain, heat, and touch. Nerves that innervate skeletal muscles are part of the motor nervous system. Less obvious, but no less important, is the autonomic nervous system, which controls involuntary functions, such as breathing, heart rate, digestion, and sweating.

Basics of Communication
How do neurons communicate? They relay an electrical signal, called an action potential. The action potential originates at the cell body of a neuron and propagates along the axon. The action potential arises when channels in the neuron cell membrane open and allow electrically charged atoms, also known as ions, to flow into or out of the neuron. This ion flow causes a change in the electrical properties of the neuron. If the electrical change is large enough, an action potential can be triggered at the cell body and travel along the axon. Because most neurons in humans are myelinated (ie, covered with a myelin sheath from glial cells), action potentials propagate rapidly.

Clinical Applications
Loss of myelin and myelin dysfunction cause clinically significant impairment within the nervous system. When the myelin is not functional, action potentials slow considerably or do not propagate at all. Multiple sclerosis is the most well-known disease caused by myelin dysfunction. The disease is characterized by damage to myelin in the CNS, which leads to scar formation on the neuron. Neuron demyelination and scarring cause a variety of symptoms, from numbness in the limbs to paralysis.1

Once an action potential has propagated the length of the axon, it reaches the presynaptic terminal of the neuron. It is at the synapse, the junction of the axon of one neuron with the dendrite of a neighboring neuron, where neural signals can pass from one neuron to another. When an action potential reaches the presynaptic terminal of a chemical synapse, a vesicle containing neurotransmitter fuses with the cell membrane facing the synapse. Once the vesicle has fused, neurotransmitter is released into the synaptic cleft (Figure 1).

Glossary

**action potential** – The electrical signal that travels from the cell body of a neuron to the axon and allows a neuron to communicate with neighboring neurons or effector cells.

**axon** – The long process of a neuron that conducts an action potential to the presynaptic terminal.

**dendrite** – A fingerlike process of the neuron that receives information from neighboring neurons.

**glial cell** – A type of neural cell that primarily produces myelin and acts as a support cell for the nervous system.

**ion** – Electrically charged atoms or molecules.

**neuron** – A type of neural cell that is specialized to conduct action potentials and transmit information to other cells.

**neurotransmitter** – A chemical that is released into the synapse by a neuron and can then bind to receptors on other neurons.

**synapse** – The connection between two neurons that allows cell–to–cell communication and into which neurotransmitter is typically released.
The neurotransmitter binds to specific receptors in the postsynaptic terminal, thereby acting as a “switch” for the postsynaptic cell. The switch signal can perform many tasks, including initiating an action potential in the postsynaptic neuron, causing the contraction of a skeletal muscle, or inhibiting neurotransmitter release. Not all neurotransmitter released by the presynaptic neuron is bound by the postsynaptic neuron. Most remaining neurotransmitter is degraded by local enzymes or reabsorbed by the presynaptic neuron to be used for subsequent cell-to-cell communication.

Clinical Applications

Many psychotropic medications (eg, antidepressants, anxiolytics, stimulants) act to disrupt the regular pattern of neurotransmitter action in CNS neurons. Psychotropic drugs may increase neurotransmitter release from the presynaptic terminal, block neurotransmitter binding at the postsynaptic terminal, or enhance neurotransmitter binding to the receptors. For instance, a class of antianxiety drugs, benzodiazepines, increases the efficiency of γ-aminobutyric acid (GABA) binding to receptors. GABA is an inhibitory neurotransmitter that decreases the excitability of neurons. Therefore, if more GABA binds at the postsynaptic neuron, less cell-to-cell communication will take place, slowing or calming many functions.2

SENSORY NERVOUS SYSTEMS

Through the senses, people transduce information from one modality (eg, sound) into another (action potential) to perceive the external and internal environments. The sensory systems contain highly specialized sensory neurons that send signals to the brain about both the type of stimulus and the strength of the stimulus.

Somatosensory System

Information about touch, pain, and temperature is transmitted by the somatosensory nervous system. Located in the skin are touch receptors, also known as mechanoreceptors, that allow people to determine the size, shape, and texture of objects. Specialized classes of mechanoreceptors respond preferentially to light touch, to textured surfaces moving over the skin, and to constant pressure. Different parts of the human body have different sensitivities for discriminating touch. Fingers have the highest sensitivity, as measured by two-point discrimination, a test documenting how well a person can distinguish between two items touching the skin. The trunk and proximal limbs have poor touch discrimination: Two stimuli must be separated by 3 to 4 cm on the trunk to be perceived as distinct.

There are also internal mechanoreceptors, termed proprioceptors, that offer information about where the body and limbs are located in space. Proprioceptors associated with skeletal muscle give information about muscle length, and those associated with tendons give information about muscle tension. Movements that require a high degree of precision (eg, fine manipulation with fingers) correlate with a higher density of proprioceptors in the corresponding muscles.

Pain information is transmitted by a different class of skin receptors, the nociceptors. Various subtypes of nociceptors transmit pain information that originates from different sources, such as noxious heat, chemicals, or touch. The brain interprets neural signals that originate in the nociceptors to form a more complete experience and response to the painful stimulus. Similar to the sensitivities for discriminating touch, different parts of the body have different sensitivities to painful stimuli. Interestingly, very few nociceptors are solely responsible for transmitting information about pain from internal organs (ie, the viscera). Usually visceral pain information is transmitted by neurons that also carry information from skin nociceptors. The location of both types of pain information results in referred pain—for example, pain signals originating from the heart are perceived as pain in the arm.

Visual System

Humans rely most heavily on vision to transmit information about their surroundings. The eye and the visual system are very intricate and have a complex function, which can be distilled down to a few key steps. Light passes through the cornea and lens of the eye and is absorbed by photoreceptors (cones and rods) that are located in the retina at the back of the eye. The photoreceptors send electrical signals to retinal neurons, which, in turn, connect to the visual centers in the brain. Rods are very sensitive photoreceptors that are responsible for seeing in low-light conditions (eg, at night). Cones allow humans to see detailed images and color, with three types of cones that are each most sensitive to a particular color (red, green, and blue). Rods and cones generate a graded neural potential that is proportional in size to the amount of light that is absorbed. This response pattern is different from the traditional all-or-none action potential described above.

The density of photoreceptors is greatest in the central part of the retina, called the fovea. This is also the area on the retina where incoming light is focused by the lens. It is not surprising, then, that the fovea is crucial for seeing detail in images. Images are formed, in part, by the amount of light that is focused on a particular photoreceptor and the amount of light that is focused on neighboring photoreceptors. Brain structures for the visual system take information from reti-
nal neurons about the quantity of light absorbed and process the signals to extract information about shape, movement, and color.

**Clinical Applications**

Age-related macular degeneration (AMD) is the most common cause of vision impairment in adults older than 50 years. Vision loss occurs when the retinal pigment epithelium (the nonneuronal layer of the retina) begins to degenerate, which leads to degeneration of the neighboring layer of rods and cones. The epithelium and photoreceptor degeneration occurs only in the macula region, which is near the center of the retina and includes the fovea. Therefore, AMD results in the loss of detailed central vision and the preservation of peripheral vision (Figure 2). Although there is no cure for AMD, therapies exist for “wet” AMD, in which abnormal blood vessels growing behind the epithelium leak blood or fluid that damages the photoreceptors.3

**Auditory and Vestibular Systems**

Hearing and balance are very important senses that can be underappreciated until they are not functioning normally. The auditory system facilitates communication with the world by allowing humans to perceive sounds and interpret their significance. Sound waves enter the ear canal and vibrate a thin membrane, called the tympanic membrane. The vibrations of the tympanic membrane cause movement in a series of bones, which, in turn, move another thin membrane, the oval window. Movement at the oval window causes movement of the fluid contained in the snail shell–shaped cochlea, which is where sound energy is converted into neural signals. The cochlear sensory receptors, the hair cells, transmit electrical signals to cochlear neurons in response to the fluid movement.

The cochlea has been described as a frequency analyzer because it is organized such that neurons at different locations along the length of the cochlea (imagine the snail shell unwound) respond maximally to different sound frequencies (ie, pitches). This frequency organization is maintained throughout many of the auditory brain structures. Cochlear neurons transmit information about the intensity (loudness) of the sound to central auditory regions in part by the number of action potentials that are generated.

**Clinical Applications**

Individuals with sensorineural hearing loss (SNHL) have lost the function of most cochlear hair cells, although some of the cochlear neurons remain and are functional. Patients with SNHL have severe hearing impairments that are not helped by hearing aids, which amplify sound and rely on a complete sensory pathway in the cochlea. However, cochlear implants (devices surgically implanted into the cochlea) can restore sound perception to most patients with SNHL. Cochlear implants deliver electrical impulses directly to the remaining cochlear neurons. The goal is to mimic the input that would have been received by the dysfunctional hair cells.4

The vestibular system has a primary role in the senses of balance and body position. Similar to the auditory system, the vestibular system relies on fluid movement to initiate action potentials. In fact, the vestibular system and the auditory system share a fluid connection, which is evident when vertigo (a vestibular disorder) accompanies an ear infection (an auditory disorder). There are two main components of the vestibular system, the semicircular canals and the otolith organs. The three semicircular canals are responsible for detecting rotations of the head (in three dimensions). The vestibular neurons that innervate the semicircular canals generate a constant rate of action potentials when the body is stationary. Thus, the neurons transmit information about the speed and direction of rotation by either increasing or decreasing

**Figure 2.** The human eye. A: In a healthy human eye, light enters through the cornea, passes through the lens and vitreous gel, and is absorbed by photoreceptors in the retina. The density of photoreceptors is highest in the fovea, which is responsible for central vision. B: This image depicts how a scene might appear to a person who has age–related macular degeneration. Note the loss of central vision and the remaining blurred peripheral vision. The images are courtesy of the National Eye Institute, National Institutes of Health, US Department of Health and Human Services.
the rate of action potentials. The otolith organs detect head tilt and linear movement (imagine the sensation of riding an elevator).

Chemical Senses
The senses of taste and smell are closely related and are responsible for most human interaction with chemicals in the environment. The olfactory system detects odors when an odorant (i.e., an odor molecule) comes in contact with a sheet of cells lining the inside of the nose, the olfactory epithelium. Sensory cells housed within the olfactory epithelium have receptors that, when bound by certain odorants, will cause a neural response. The particular pattern of neural responses arising from different olfactory cells provides a neural signature that is unique for each odorant. Exposure to certain odorants can cause physiologic responses, such as salivation and hormonal fluctuations. The olfactory system is one of the least studied sensory systems in humans; therefore, much less is known about its organization and function.

Taste sensations begin at the taste buds, located on papillae on the tongue. It is estimated that each person has 5,000 to 10,000 taste buds. When a tastant (i.e., a chemical in food) interacts with taste buds, neural signals are transmitted along the gustatory neuron to the brainstem. Human taste sensation primarily detects flavors such as salt, sweet, bitter, and sour, although humans can perceive other tastes such as fatty, umami, and pungent. A much larger range of chemicals can be detected through smelling than through tasting. Different locations on the tongue have higher sensitivities to different tastant classes, but it is a common misconception that certain areas of the tongue are exclusively used to perceive certain tastes.

MOTOR NEUROPHYSIOLOGY
Skeletal muscles are the large muscles most commonly associated with movement. These muscles, composed of individual muscle fibers, attach to bones and facilitate joint movement. To accomplish joint movement, a muscle fiber receives a neural signal from an innervating alpha motor neuron. This neural signal causes contraction of the skeletal muscle, which typically causes movement of a joint. Each muscle fiber is innervated by one alpha motor neuron, but each alpha motor neuron innervates many muscle fibers. Therefore, with a signal originating from one alpha motor neuron, the coordinated contraction of many muscle fibers occurs. Each alpha motor neuron and its associated muscle fibers is considered one motor unit. The force with which a particular muscle contracts is variable and regulated by the number of motor units that are recruited.

For most movements, a pair of muscles evokes opposite actions on a joint. When the flexor muscle contracts, the joint closes; when the extensor muscle contracts, the joint opens. To achieve any particular joint movement, one muscle must contract and the other must lengthen in a coordinated fashion.

Clinical Applications
Amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig disease, is a disease marked by progressive degeneration of the alpha motor neurons and motor neurons that originate in the brain. The disease affects 1 to 3 people per 100,000, and the cause of the disease is unknown in almost all cases. When the motor neurons degenerate, they no longer transmit signals to the innervating muscles; the result is muscle weakness, muscle atrophy, and eventually the inability to initiate voluntary movement. Most patients with ALS are affected in their limbs first, showing muscle weakness or stiffness. Currently, there is no cure, but one US Food and Drug Administration–approved drug, riluzole, slows the progression of ALS.

Reflex Pathways
Reflex movements are automatic movements that occur in response to certain stimuli. Take, for instance, the leg extension reflex that occurs when the knee is tapped with a small rubber reflex hammer. To execute this leg extension, a muscle stretch receptor in the extensor muscle, which is stretched in response to the knee tap, sends a signal through a sensory neuron to the spinal cord. In the spinal cord, the sensory neuron activates a motor neuron innervating the stretched extensor muscle, causing the extensor muscle to contract. At the same time, the sensory neuron signal inactivates the flexor muscle in the back of the leg, causing the flexor muscle to relax.

Complex Movements
Many usual body movements involve groups of sensory and motor neurons that form circuits through the spinal cord. Research in paralyzed animals has shown that walking movements can be completely restored by controlled stimulation in the spinal cord alone. Several “higher” areas of motor control in the CNS are involved in coordinating, adjusting, and deciding about movements. They will be discussed in Part 2 of this series.

CONCLUSION
With a basic understanding of how a neuron generates and propagates a signal, medical communicators can delve into topics that deal with signal alterations, such as pharmaceuticals that influence neurotransmitters. Although each sensory system is specialized to respond to a particular stimulus, the systems have much in common, such as how
Peripheral information is transmitted and how stimuli are discriminated.

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

Author contact: agnella@aimbiomedical.com

References


RESOURCES

Training a Novice to Edit Documents in the Pharmaceutical Industry

By Kelly F. Horn, PhD, ELS, and Patricia A. Ennis, ELS / Associate Director, Medical Writing; Manager, Medical Writing; PPD, Wilmington, NC

It takes time to find the right person to edit. To be a successful full-time editor, a person needs a special attitude and aptitude. PPD is a global contract research organization that provides comprehensive services for the pharmaceutical industry, and this article describes our methods for identifying and training a person to edit regulatory documents, including clinical study reports, protocols, and investigator’s brochures, in the pharmaceutical industry. We consider editing to be the same as quality control because in addition to checking grammar, spelling, and punctuation, our editors also verify data and the consistency of the text against source documents.

Identifying the Best Candidate to be an Editor
Education, experience, and personality are standard elements used to evaluate candidates. At PPD, a candidate must have a 4-year degree, preferably in a biological or physical science. This ensures that the candidate is familiar with looking at data. Copyediting is teachable, but understanding how the data are organized and interpreted in a document comes with experience. This background is needed at the very beginning of the training period.

We ask all candidates to take an assessment consisting of a page of text from a clinical study report, a sample table with an accompanying source table to verify data, and a series of questions regarding editing examples. The assessment provides us with a baseline for what candidates know about editing and gives them an idea of what the daily work will be like.

After receiving the edits from the candidates, we review their work, send it back with our revisions, and then make a follow-up call to discuss the edits. One part of the assessment is to determine whether the candidates have the ability to see inconsistencies such as punctuation differences and different terms used for the same concept (eg, clinical study and clinical trial). Some people seem to have an innate ability to see such differences, and this trait is especially important in the work we do.

Once a person is selected to join our team of editors, training begins on the specifics of how we review documents.

Training the New Editor
During the training period, the new editor reviews a variety of documents (eg, clinical study reports, protocols, and narratives) together with an experienced editor to become more familiar with the different aspects of reviewing documents. However, before new editors begin to review any document, we find it useful to have them study examples of edited versions of various documents to learn what is expected from a review. From these edited examples, the new editor learns the kinds of copyedits to make (eg, American Medical Association [AMA] style is to use serial commas) and how to address comments to the writer. The edited versions also have examples of edits for consistency regarding terminology and style.

Training materials, including standard operating procedures, working practice documents, and self-guided step-by-step training modules, explain the processes for reviewing clinical study reports and protocols. These materials are to be read before an actual review assignment is given to the new editor, so the person knows what is expected in reviewing different sections of these documents.

The new editor reviews current documents at the same time as an experienced editor. Although it is not expected that the new editor’s review will be complete in time to meet the deadline, this real-time experience gives the novice a perspective on how to meet deadlines. The new editor also gains a sense of accomplishment, as he or she is contributing to a document that will be going to a client. Oftentimes, edits from a new editor will make it into the second draft that goes to a client.
A review is done electronically, with the changes tracked, and a hard copy of the document is kept to be sure all of the text has been verified. Experienced editors use pens or markers to check off sections and data that have been reviewed. Most new editors are not familiar with the *AMA Manual of Style*, our default style. New editors should study the sections on punctuation, capitalization, and numbers and percentages. Most of the other information in the style manual is learned on the job as the new editor encounters instances of questionable style. We also have an in-house style guide that addresses issues not covered by AMA style (eg, how to punctuate bulleted lists and how to format tables). Often, clients will provide their own style as well.

At PPD, the set instructions that the new editor must learn include the following.

• **Editing rule #1**: Do not change anything you cannot support with a source.

  Our editors do not change words because one sounds better than another word. Changes must be supported with a grammatical or logical explanation. If wording is not clear, we will rewrite a sentence and ask the writer whether this is what he or she meant. The new editor must learn to recognize when text needs to be revised and when it doesn’t, which is learned as part of our company’s style.

  While the new editor is learning what styles are appropriate for a particular client, he or she also must edit for consistency to help the reader stay focused on what is in the text, rather than wondering whether the text means something else because similar terms are used to describe the same idea.

  Through our experience, we have identified specific terms that we use to train the new editor on what is meant by consistency. For example, do “end of treatment” and “end of study” refer to the same time point?

• **Editing rule #2**: Provide comments to the writer in complete sentences, which follow AMA style, and do not use personal pronouns.

  New editors tend to add more comments than experienced editors, perhaps because they may feel the need to establish their credibility with the writers. We do not discourage the comments because they help the novice editor become more familiar with the function of a reviewer.

  Embedded comments should be clear and in complete sentences. The comments should be written in AMA style to allow the novice editor and the writer to become more familiar with this style.

  To avoid the subtle confrontation of “I” versus “you,” personal pronouns should not be used in comments. For example, we discourage writing, “I think this should be...because...” or “You wrote this, but it should have been....” The finished document is the result of collaboration, and all parts of the project should be completed through teamwork. Therefore, any form of conflict should be avoided. The examples of the comments could be rewritten as, “This should be...because...” and “Should this be...?”

  During training, accuracy is more important than requiring the new editor to meet a deadline. The experienced reviewer working with the new editor will finish reviewing the document by the deadline. The new editor’s review speed increases with experience.

**Becoming More Comfortable with the Process**

Before the review is completed, the new editor reviews a checklist of items that should have been completed during the editing process (eg, headers were checked, hyperlinks were verified). There is much to confirm during the editing of a document, and the checklist is a reminder of what needs to be done.

While going over the review with the novice editor, the experienced editor should build the new editor’s confidence. This can be done by noting the helpful corrections the novice editor has made. At the same time, the experienced editor should gently explain any points that were missed and provide guidance on how to avoid the oversights.

All documents must be read for content consistency, grammar, and style, but documents that have data to verify require an additional level of review. When switching from reviewing words to verifying numbers, an editor must adjust his or her thinking. The source documents are different, and the text in which the information is presented is different.

The novice editor is instructed on where to find the source to verify the information in a document, but the order in which the novice verifies the information is a personal choice. Does one check all of the data first and then check the text, or should one check the data while reviewing the text in each section? We have found that editors have varying comfort levels regarding ways to review a document, so we leave it up to them. We all must complete a thorough review within a limited time, but how we accomplish this is up to each editor.

After a client returns the document with changes and the writer incorporates them, the editor reviews the document in what we call a check-of-changes review. Because we are only interested in the changes, the entire document does not have to be reviewed. A comparison document is generated to identify the changes between the last edited version and the current version. It takes a bit of experience to get used to interpreting the comparison document, so the points of the comparison document are explained to the novice editor.

In the check-of-changes review, it is important not only to verify that the client’s comments have been addressed but also to determine that each occurrence of a term or passage requir-
ing correction has been changed throughout the document. The new editor is taught to search for key terms that have been changed to determine that the text around these key terms is consistent throughout the document.

**Editing Independently**

The time needed for a new editor to review documents with an experienced editor varies from 1 to 3 months. Some people understand the process and learn editing skills more quickly than others. We determine when a new editor can work independently by gauging how closely a review by the new editor matches the review of the experienced editor and how long it took for the new editor to complete the review.

Reviewing a document independently of the experienced editor is an anxious time for new editors because they may be uncertain as to whether or not they have found all of the points necessary for a complete review. Returning the edited document to the writer is the moment of judgment as to how well the new editor has reviewed a document. Acceptance of the review as complete by the writer is a point of satisfaction for a new editor because it represents fully billable time rather than partial training time.

The first independent review by a new editor is still read by an experienced reviewer to determine how well the process for reviewing a document was followed and to note any obvious oversights. If an obvious gap in the quality of the review is noted, then some additional training is done.

**Continuing Education of an Editor**

Even after an editor is able to review documents with minimal support, there is more to learn. Once established, the editor broadens his or her review of deliverables to include manuscripts and current awareness documents, begins mentoring new editors, takes on managing large projects involving multiple editors and writers, and is encouraged to take the Board of Editors in the Life Sciences certification examination.

It takes a certain personality to become an editor—a person dedicated to a career of ensuring consistency and accuracy. Careful nurturing at the beginning of the editor’s career results in an established collaborator who assists writers in creating professionally crafted documents.

**Author disclosure**: The authors note that they have no commercial associations that may pose a conflict of interest in relation to this article.

**Author contact**: Kelly.Horn@ppdi.com

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**Getting a Foot in the Door, Then Making Yourself at Home: Additional Thoughts on Learning to Edit Pharmaceutical Documents**

*By Peggy Boe, RN / Principal Consultant, Nightingale Medical Writing, LLC, Hampstead, NC*

Whether the goal is to become a medical editor or writer in the pharmaceutical industry, the training processes described by Kelly F. Horn and Patricia A. Ennis in their article are fundamental. Most big pharmaceutical companies are reluctant to hire people who need to be trained; time is money. Self-training and obtaining certificates or degrees are clearly a plus, but hands-on experience is still the ticket to employment.

So the first step really is to find a company willing to provide training and experience. Contract research organizations (CROs) are a great place to look, but don’t rule out pharmaceutical companies (or “sponsors” of clinical investigations) in the search. Some leaders are willing to spend the extra time now to develop the perfect long-term employee. Networking, of course, is imperative, whether it is via social media or by attending annual conferences or other meetings held by professional organizations (eg, AMWA, BELS, RAPS, DIA, and STC). If the ultimate goal is to be a regulatory medical writer (ie, one who writes documents slated for submission to regulatory agencies, related to research, development, and product approval), starting as a quality control (QC) reviewer or editor will provide a lot of the experience and skills needed as a medical writer. (The differences between QC reviews and full editing can be a difficult concept for some but is not our focus here. Jean Hollis Weber has provided a great overview of that topic.)

**ABBREVIATIONS:**

- **BE=Board of Editors in the Life Sciences**
- **RAPS=Regulatory Affairs Professionals Society**
- **STC=The Society for Technical Communication**
The following is a summary of some of the great points in the article by Horn and Ennis, plus some tips of my own.

**Skillsets and Education**
The authors specify that at their company they prefer that candidates have a degree in a biological or physical science. This is very common in the industry. A degree in English or technical writing is not necessarily a deal killer. Many medical writers have started with that background, and skillsets from those areas are a definite plus. But for editing writing scientific and regulatory documents, some background in a medical field or a science is generally expected, so additional education and internships can help.

**Variety**
Editors are exposed to a wide variety of documents, indications, and writing styles. In the clinical regulatory environment, that typically means reviewing protocols and amendments, investigator’s brochures, clinical study reports, and other documents that are the backbone of research and development (R&D). Over time an editor may have the opportunity to review submission summary documents, more complex compilations of the entire R&D story. Consider trying to reach this level before seeking the chance to use acquired editing skills for writing, though it’s not necessary.

While gaining editing (or writing) experience, keep a spreadsheet list of every document type worked on, the sponsor’s name, the indication, and your role as a contributor. This will come in handy later, for example, when writing a résumé. Also, in time, seek opportunities to contribute to some of the actual writing. Hands-on experience is helpful for long-term career development. An appreciation of the writer’s perspective can also improve editing skills.

**Styles**
The authors rightly name the *AMA Manual of Style* as the regulatory editor’s primary source for editing clinical documents; if editing nonclinical or CMC (chemistry, manufacturing, and control) materials, familiarity with other professional manuals, such as the American Chemical Society (ACS) style guide, may be required. However, if the sponsor has a corporate style guide, that document is the primary default for stylistic questions, followed by the professional style manual.

Expect to see a lot of variation in the way writers present data. During the project-planning phase, encourage team members to establish the sponsor’s style preferences on items not mentioned in the corporate or AMA style guides. This approach will help to achieve consistency within and across documents. This can be a crucial step in any writing/editing project, regardless of whether the scope is one document or a full submission.

**Source Verification**
The authors have provided some great tips on how to keep reviews (or writing) objective and focused on clarity and accuracy. Source verification is an important part of the editor’s role, but applicable sources can vary a lot, and they are not always current. Confirm that the writer has provided the most recent source document version, and question whether the sources are final or under revision.

Writers know that they must supply editors with primary source documents to verify content, but sometimes source material is buried in e-mail messages that contain specific text or directives from the sponsor. The writer may need a reminder that to do a thorough job the editor needs everything the writer needed as a source for writing. Ask the writer as soon as possible if it seems that a source document is missing to avoid leaving several remaining “unable to verify” notes that have to be addressed later.

**Timelines**
As the authors point out, new editors need extra time to complete a project while learning. Even for experienced editors, the amount of time needed to complete a project will vary depending on the document type, complexity of the indication, the scope of the editing tasks, and the writer’s skills. Get in the habit of assessing these items up front before committing to a deadline. Or, if the deadline is nonnegotiable, use the assessment to determine whether a second editor is needed, and if so, plan to divide the tasks by logical topics and also possibly by the editors’ skillsets.

**Electronic Review Techniques**
The authors note that they use Microsoft Word’s tracked changes and comparison document features as their primary review tools. Using Microsoft Word for reviewing is common, but consider also the following review tools.

*Adobe Acrobat*: Comments from individual reviewers can be collated into a single PDF file for easier incorporation into a master version. The writer can respond to each suggested revision in the same PDF file, creating the perfect audit trail for archive, and subtle changes are easier to spot compared to a Microsoft Word tracked-changes document. One drawback is that the team will need to have the professional version of Adobe Acrobat installed, as the free Adobe Reader software will not suffice. Also, some professional team members may be reluctant to learn a new software, though training on this one is simple.

*Workshare Compare*: This software also is an added expense, but if just one person on the team has this software, it could prove invaluable for those times when the best intentions for document version control prove to be inadequate.
Some sponsors may also require using collaboration tools, such as PleaseReview. Adaptability is essential in this business.

Additional Training Needs
The editor must also be familiar with the following resources.

Regulations: In the United States, this means reading the section of the Code of Federal Regulations that is applicable to the assigned document in order to guide the authors regarding potential content for inclusion. Likewise, if assigned a document slated for a non-US submission, at the very least, ask the author whether the project’s regulatory affairs personnel are aware of any special needs unique to the submission region.

Guidances: In addition to regulations, most countries issue guidance documents on various subjects; they could be specific to a document type, an indication, or even a process. In the United States, these are called “guidances” and are must-read as applicable. Adhering to guidances is not mandatory, but is strongly recommended.

Guidelines: International guidelines are also must-read items. These are produced by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (commonly known as ICH). Following ICH guidelines is also not mandatory, and there can be many reasons to deviate from them, as they are not all-inclusive. Just be prepared to give concrete reasons for any deviations if asked, as the ICH guidelines are considered to be primary sources for international content.

I could easily add more, but I hope the extra tips provided here will be helpful to both the novice and the experienced editors and medical writers alike. Best of luck in achieving your goals!

Peggy Boe is coeditor of the AMWA Journal’s Regulatory Insights section.

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

Author contact: peggy.boe@gmail.com

References
Memphis, Here We Come!

By Lori Alexander, MTPW, ELS
2013–2014 Annual Conference Administrator

Memphis, Tennessee, is the birthplace of rock 'n' roll and home of the blues. And for at least 4 days in October, it will be the home of the AMWA’s 74th Annual Conference. In keeping with the lively musical spirit of the city, conference attendees will shake, rattle, and write their way through a variety of sessions, workshops, and networking events. And you’ll have time to enjoy Memphis, an affordable and fun city.

The Annual Conference Committee has been creating an innovative program that meets the needs of our diverse membership. And once again, the committee has reached well beyond AMWA to solicit speakers with unique expertise of value to AMWA members and other medical communicators. The goal is to create 3.5 days of programming that will shake, rattle, and roll your medical writing and editing!

CONFERENCE PROGRAMMING
This year’s program is being built on popular session formats that debuted at the 2013 Annual Conference. Many sessions last year were highly interactive, and we’ve continued that trend by asking speakers to develop sessions that involve attendee participation. We’ve also increased the offering of roundtable discussions, the conference’s most popular event. To encourage more AMWA members to lead roundtable discussions, the committee developed a webinar with tips on how to prepare for and lead an effective roundtable discussion.

The Annual Conference Committee is reviewing proposals for presentations on a wide range of interesting and valuable topics. The final list of sessions according to topic area (track) will be posted on the AMWA website to help make it easier for you to see the benefits of attending and to create your conference schedule. Look for the list of sessions in the next few weeks.

The committee is also working with AMWA headquarters staff on ways to streamline and improve conference sessions and events. For example, we are revising the format of the New to AMWA event and the Conference Coach Connection to provide information of most benefit to new members and attendees and help them best navigate the conference according to their interests. Look for more details on this revamped event in a future Journal article.

CONFERENCE SCHEDULE
The Annual Conference Committee and AMWA headquarters continue efforts to develop an attractive conference schedule that addresses the needs of conference attendees while providing benefit to the association and its members. This task is a challenge because we must balance the needs of attendees with the obligations of the association. For example, many attendees must limit their time away from work and home so they leave the conference on Friday or Saturday. But, meeting prearranged hotel room blocks is essential for keeping conference costs down, allowing AMWA to maintain low conference registration fees and enhance member benefits.

One way to address this challenge is to offer a strong program throughout all days of the conference. Come early or come late, you will have access to an outstanding array of educational and networking events. You can find the preliminary schedule-at-a-glance on the AMWA website.

Award Lectures
Many AMWA members said they miss having a general session that opens the conference. In response, we have scheduled a general session with an award lecture for Thursday morning. In keeping with a tradition at many professional conferences, we have scheduled a general session with an award lecture to close the conference on Saturday afternoon. We are thrilled and honored to announce the recipients of this year’s McGovern and Alvarez awards (see pg 16).
**Sablack Awards Lunch**

Over the years, many AMWA members and other attendees have missed hearing the recipient of AMWA’s highest award to an AMWA member, the Swanberg Award. Traditionally given during the Sablack Awards Dinner on Friday evening, the Swanberg Award lecture is always a delight, but only for those attendees who have paid to attend the special dinner in honor of all AMWA award winners.

The Annual Conference Committee felt strongly that every attendee should have access to the Swanberg Award lecture, so they have rescheduled this important event as a free lunch on Friday. The Sablack Awards Lunch is now another great networking event for all attendees, adding to the value of your conference registration fee. This move has other benefits as well. More conference attendees will be able to share in celebrating the accomplishments of other AMWA award winners, as awards will be presented at various sessions and events throughout the conference. In addition, Friday night becomes a free night for conference attendees to revel in the vibrant nightlife on Beale Street and elsewhere across the city.

**Closing Reception**

This year, we’ve brought back the closing reception as a way to end the conference with a fun networking event. Here’s where you’ll hear the first details about the 2015 AMWA Annual Conference, which will mark AMWA’s 75th anniversary!

**Tours**

Who can go to Memphis without visiting Graceland, St. Jude Children’s Research Hospital, or other Memphis landmarks? AMWA is setting up tours of Memphis highlights throughout the conference. Look for more details soon.

As you can see by these changes and improvements, the Annual Conference Committee and AMWA headquarters do listen to your feedback. The results of the 2013 post-conference survey were important in developing this year’s program. Our goal is to create a conference that offers you professional development programming of the highest quality at a value.

Keep the new conference schedule in mind when making your travel arrangements and hotel accommodations. You can reserve your hotel room now on the AMWA website [(www.amwa.org/2014_hotel_and_travel)](http://www.amwa.org/2014_hotel_and_travel). The conference registration brochure will be available on the AMWA website in early June, and conference registration will open in early July.
Gibson is a leading expert on health care quality, patient safety, and care at the end of life. She led national health care quality and safety initiatives for 16 years at the Robert Wood Johnson Foundation, and she was chief architect of the foundation's decadelong strategy that successfully established palliative care in more than 1,600 hospitals in the United States. She is a member of the American Board of Medical Specialties Public Policy Committee and the Accreditation Council for Graduate Medical Education CLER Evaluation Committee that is assessing quality and patient safety in sponsoring institutions for residency training. She is also a member of Consumers Union Safe Patient Project. Among Gibson's most important books are the critically acclaimed *Wall of Silence*, which tells the human story behind the Institute of Medicine report, *To Err is Human; The Treatment Trap*, which puts a human face on overtreatment; *The Battle Over Health Care: What Obama's Health Care Reform Means for America's Future*, a nonpartisan analysis of the future state of health care and its impact on the economy; and *Medicare Meltdown: How Wall Street and Washington Are Ruining Medicare and How to Fix It*.

➲ Gibson is scheduled to deliver the Alvarez Award lecture on Saturday, October 11.
An unwavering obsession for quality...
Distinguishing people as the principal ingredient in the outsourcing equation.
NEW OPPORTUNITIES FOR MEDICAL WRITERS

Moderator (and speaker)
Lawrence E. Liberti, MS, RPh
CIRS (Centre for Innovation in Regulatory Science), Holland, PA

Speakers
Julie Birt, PharmD
Senior Research Scientist, Global Health Outcomes, Health Technology Assessment Center of Expertise, Eli Lilly and Company, Indianapolis, IN
Sandra Ripley Distelhorst, ELS
Senior Medical Writer and Editor, Northwest Health Communications, Edmonds, WA

By Sarah Zimov, PhD

Here are many opportunities for medical writers to prepare regulatory documents. In fact, many medical writers specialize in preparing clinical study reports (CSRs), standard response letters, regulatory dossiers, and many more. In this open session, the three panelists provided writers with an overview of some of the lesser-known writing opportunities: documents for health technology assessment (HTA) agencies, value dossiers, and consensus statements.

Health Technology Assessment (HTA) Agencies
Lawrence Liberti started the session by introducing the world of HTA. HTA agencies are similar to ‘payers,’ but there are some key differences. Payers are parties other than the patient that cover health costs for a patient; the most common of these are insurance companies and government plans such as Medicare. HTA is performed by public centers, such as the US Food and Drug Administration, the National Institutes of Health (NIH), the Centers for Medicare and Medicaid Services, or the Agency for Healthcare Research and Quality. HTA is also performed by specialized private agencies such as the Cochrane Collaboration, ECRI Institute, Hayes Inc, and the United BioSource Corporation.

“HTAs collect and analyze the information relevant to health decision makers using scientifically sound and transparent methods,” Liberti said. The key here is the connection between clinical data and policy decisions. HTA agencies collect and analyze information during and after the regulatory process. This is very different from the traditional paradigm where payers are considered the “fourth hurdle” to be overcome after animal studies, clinical trials, and new drug application submission and approval. HTA agencies are responsible for evaluating the relative effectiveness of a drug versus safety and cost.

Liberti concluded that medical writers looking for new opportunities could break into this field by developing an understanding of the complexities of drug development, especially as it relates to the “value” of a new medicine. Writers can become familiar with HTA terms and processes, and seek roles in preparing documentation to support the value of new medicines.

Value Dossiers
Dr Julie Birt then presented opportunities for writers in preparing value dossiers—what she calls “the other submission.” Birt explained that pharmaceutical companies submit value dossiers to HTA agencies at regulatory approval and perhaps even earlier. A successful value dossier can lead the way to patient access for a particular drug by influencing decision makers and convincing them of the value to patients and payers for that particular drug. There are four major interrelated components discussed in a value dossier: (1) the burden of disease, (2) cost/cost effectiveness, (3) comparative data, and (4) the drug’s clinical data.

“Medical writers with experience in writing CSRs or other regulatory documents have all the skills necessary to work in the clinical section of value dossiers, although the information is usually formatted differently,” Birt said. She explained that understanding the data required in value dossiers is an opportunity for medical writers to expand their writing skills to a different audience. However, she cautioned that given the broad nature of the information included in HTA documents, and specifically in value dossiers, medical writers should enlist collaborators with the right expertise to help define and support a product’s “value story.”

Consensus Statements
Sandra Ripley Distelhorst finished the session with a discussion of consensus statements. Distelhorst explained that a consensus statement is a comprehensive analysis by a panel of experts of a scientific or medical issue. The consensus statement represents the panel’s collective analysis, evaluation, and opinion based on best available evidence; such statements are developed through the use of one or more of four consensus methodologies. “Consensus statements require a defined process and reporting strategy, but it is important to remember that consensus statements are not guidelines,” she said.

Distelhorst summarized what medical writers should know about consensus statements:
- They are not guidelines, which have more defined standards.
- They provide valuable but limited information.
- There are no clear standards for them, but this could change.
- They are popular as outcomes of conferences or as reports from specialty societies.
- They are popular with local groups trying to make a difference.
- They can benefit from having a medical writer on the team.

“The medical writer’s role is to work with the expert group to determine budget and planning through publication,”
Distelhorst explained. She emphasized that medical writers need to understand how consensus statements differ from guidelines. Writers working on consensus statements should also have project and people management skills.

Consensus statements provide multiple opportunities for writers, as they must be updated periodically. Distelhorst suggested that writers check out conferences for working group “reports” that could be developed into consensus statements or guidelines. She also suggested writers seek opportunities through specialty societies in their area of interest and through health advocacy groups (Table 1).

Sarah Zimov is a freelance medical writer in New Hope, Pennsylvania. 

Author contact: sarah@sarahzimov.com

References


Table 1: Potential Publishers of Consensus Statements

<table>
<thead>
<tr>
<th>Category</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government agencies</td>
<td>National Institutes of Health, National Institute for Health and Care Excellence</td>
</tr>
<tr>
<td>Clinical specialty societies</td>
<td>American College of Chest Physicians</td>
</tr>
<tr>
<td>Disease/health advocacy groups</td>
<td>American Diabetes Association</td>
</tr>
<tr>
<td>Commercial companies and institutions</td>
<td>Payers (eg, Medicare, Aetna, United Healthcare)</td>
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</tbody>
</table>
FDA’S OTHER BOX: MEDICAL DEVICE REGULATION FOR PHARMACEUTICAL WRITERS

Moderator
Jeanne McAdara-Berkowitz, PhD
Principal, Biolexica LLC, Longmont, CO

Speakers
Felicia R. Cochran, PhD
Principal Clinical Research Specialist, Medtronic
Neuromodulation, Minneapolis, MN
Cynthia Carr, PhD
Senior Medical Writer, Ventana Medical Systems Inc, Tucson, AZ
Tim Peoples, MA, ELS, CMPP
Senior Medical Writer, Medtronic Inc, Santa Rosa, CA

By Michelle Eby, PharmD, CCRP

The open session, “FDA’s Other Box: Medical Device Regulation for Pharmaceutical Writers” highlighted the differences between the more commonly known drug regulations and their less familiar device counterparts. The speakers provided an overview of device regulatory pathways as well as a discussion of in vitro diagnostics, a dynamic area of regulation due to the evolving field of personalized medicine.

Dr Felicia Cochran explained how medical devices can range from the simple (eg, tongue depressors) to the complex (eg, cardiac pacemakers) (Figure 1). Medical devices were not formally defined until Congress passed the Medical Device Amendments (Section 201(h)) of the Federal, Food, Drug, and Cosmetic (FDC) Act in 1976. Per Section 201(h), a medical device is “any instrument, machine, contrivance, implant, or in vitro reagent that is intended to treat, cure, prevent, mitigate, or diagnose disease in man.”

Cochran also summarized the structure of the Food and Drug Administration (FDA). Unlike drugs and therapeutic biologics, which are regulated by the Center for Drug Evaluation and Research (CDER), devices are primarily regulated by the Center for Devices and Radiological Health (CDRH). Devices that contain a drug or biologic are reviewed by CDER or the Center for Biologic Evaluation and Research in addition to CDRH. A drug-eluting stent, condom with a spermicide, or an antibiotic-impregnated central venous catheter, for example, must be reviewed by at least two FDA centers.

The regulatory control of a medical device is essentially based on risk. Class I devices are low risk, class II devices are medium risk, and class III devices are high risk. The risk category is determined by the intended use. A device may have multiple risk categories. For example, medical support stockings are deemed class I for general medical purposes and class II for preventing pooling of blood in the legs. The risk category is initially proposed by the manufacturer. The FDA can concur or override the manufacturer’s proposal. There are approximately 780 low-risk devices, 800 medium-risk devices, and 120 high-risk devices on the US market.

From the FDA’s perspective, medical devices are considered to have either significant or nonsignificant risk. Significant-risk devices have the potential for serious risks to the health, safety, and/or welfare of patients. All other devices are considered nonsignificant risk. Significant-risk devices include cardiac pacemakers and orthopedic implants, whereas nonsignificant-risk devices include contact lenses and ultrasonic dental scalers. The degree of risk and amount of historical information determine the level of data needed to move a product to the US marketplace.

Approximately 90% of the devices available in the United States receive premarket notification 510(k) clearance, named after the section of the FDC act amended to include medical devices. To obtain 510(k) clearance from the FDA, the product must be “substantially equivalent” to an existing or predicate device with an equivalent level of safety and efficacy. While laboratory testing is mandatory to obtain 510(k) clearance, clinical trial data are usually not required.

The remaining 10% of the devices in the US market are approved by the FDA using a process called premarket approval or PMA. The PMA is analogous to the new drug application in the drug industry. A PMA is required for class III devices with potential to cause serious illness or injury, and for products not substantially equivalent to class I or class II predicate devices as a result of the 510(k) process.

Cochran compared drug and device development. Both drugs and devices have a premarket and postmarket phase (Figure 2). Unlike the three phases of clinical trials in drug development, the device industry only conducts feasibility and pivotal trials before marketing. To initiate clinical trials for significant-risk devices, the manufacturer or sponsor must submit an Investigational Device Exemption (IDE) and receive FDA approval prior to shipping via interstate commerce. This approval is comparable to the Investigational New Drug Application (IND) in the pharmaceutical industry.
Nonsignificant-risk devices do not require an IDE; however, they do require approval by an ethics panel (eg, institutional review board) before the study can begin.

In contrast to their drug counterparts, device trials tend to enroll fewer participants at fewer clinical sites and entail much smaller budgets. Because premarket data are collected from a lower number of participants, postmarket follow-up studies, patient registries, and product surveillance are very important. For example, after a device is launched, the manufacturer must document and address product complaints and adverse events from all sources.

The second speaker, Dr Cynthia Carr, reviewed in vitro diagnostics (IVD), a subcategory of medical devices. IVDs include products used to collect specimens or to prepare or examine specimens (eg, blood, serum, urine, spinal fluid, tissue samples) after removal from the human body. Examples of IVDs include HIV test kits, home-use pregnancy tests, and blood glucose monitors. Risk classification determines how IVDs are regulated.

As with other devices, the intended use will set the course for determining the product’s risk classification. The FDA considers the harm that may result to the patient and asks:

- Will the misdiagnosis and/or error in treatment caused by inaccurate test result in potential harm to the patient?
- Will false-positive results lead to unnecessary treatment that is invasive, has harmful side effects, or lead to unnecessary psychological trauma?
- Will false-negative results lead to a delay in correct diagnosis, a failure to start or continue needed treatment, false security and the prevention of timely follow-up, or contribute to spread of infectious agents to others?

After assessing these questions, the FDA determines whether an IVD is a device with a significant or nonsignificant risk. As with other devices, significant-risk devices entail tighter controls, including the requirement for an IDE, whereas nonsignificant risk devices enable the sponsor to meet abbreviated requirements.

One type of IVD, a companion diagnostic, is an in vitro diagnostic device or an imaging tool that provides information essential for the safe and effective use of a corresponding therapeutic product. Companion diagnostics usually call for collaboration between a device maker and a pharmaceutical company, and multiple FDA centers are usually involved. Companion diagnostics are commonly used in the field of personalized medicine, defined by Carr as “the customization of health care, with decisions and practices being tailored to the individual patient by the use of genetic or other information.” For example, the COBAS 4800 BRAF V600 Mutation Test is used in melanoma to test for BRAF mutations in the tumor sample. If the skin test is positive, the BRAF inhibitor, Zelboraf, can be prescribed to treat the patient’s cancer.

The final speaker, Tim Peoples, provided a hands-on look at writing in the medical device industry. The field of medical device writing falls in two major focus areas: regulatory/clinical writing and publication writing. Regulatory or clinical writing entails a comprehensive analysis of data with no word limit, and uses objective text. On the other hand, publication writing is detailed but must be concise because of strict word limits and employs persuasive analyses.

Because medical device companies’ writing staffs tend to be smaller than their pharmaceutical company counterparts, these medical writers often multitask and prepare a variety of documents. For example, medical device companies rarely have one department devoted exclusively to writing journal articles. Regulatory documents include the study protocol, case report forms, informed consent, investigator’s brochure, clinical study report, the IDE, premarket notification or 510(k), the PMA, and product labeling. The medical writer may also compose external presentations, including abstracts, posters, slide decks, and Web pages. The intended audience is variable and can include study sites, internal staff and sales force, customers, patients, and health care professionals.

Peoples concluded by saying, “The medical device industry is under greater regulatory scrutiny than in the past. Relatively new research requirements have been implemented, especially in terms of postmarket surveillance. These studies require writers in all domains—clinical for protocols and reports, regulatory for filings and safety monitoring, and publications for evidence.” Beginning medical writers or those from the pharmaceutical industry will find that they have many transferrable skills applicable to the device industry, but need a working knowledge of the device regulations.

Michelle Eby is a consumer safety officer for the Food and Drug Administration in Silver Spring, Maryland.

Author contact: Michelle.Eby@fda.hhs.gov

RESOURCEs

Centers for Disease Control and Prevention: www.cdc.gov/genomics
Food and Drug Administration: www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/default.htm
National Coalition for Health Professional Education in Genetics: www.nchpeg.org
National Pharmaceutical Council: www.npcnow.org
Personalized Medicine Coalition: www.PersonalizedMedicineCoalition.org
CURRENT REGULATORY CHALLENGES FOR SHARING AND PUBLISHING DRUG SAFETY DATA: TRANSPARENCY

Speaker
Mary H. Whitman, PhD
Senior Director, Medical Affairs, Janssen Scientific Affairs, LLC, Spring House, PA

By Michelle Eby, PharmD, CCRP

According to Whitman, “Peer-reviewed publication of safety data must be an ethical obligation to be fulfilled by pharmaceutical companies. Posting safety data on public registers alone is not adequate.” Information in the package insert includes those adverse events occurring only in a limited population during clinical development. These study participants are recruited in accordance with strict eligibility criteria and are often the “healthiest of the sick.” After marketing approval, drugs are given to large numbers of patients with multiple comorbidities and, consequently, there are new and emerging adverse events. Whitman maintains that when updated safety information on a medication becomes available, it is the responsibility of sponsors to communicate any new risks to patients and physicians.

In the course of her discussion, Whitman addressed this critical shortfall in postmarketing safety publications. The paucity of safety data in the public domain led Congress to enact additional safety provisions in the Food and Drug Administration Amendment Act of 2007 (FDAAA). This act gave the Food and Drug Administration (FDA) unprecedented authority to require postmarketing studies and safety registries that are observational but constitute real-world experience. Before 2007, it had been optional to post study methodology on ClinicalTrials.gov. Posting of the protocol elements for a trial is now required before a study can begin. Study results, including adverse events and a brief abstract, are now required to be posted within 12 months of study completion, irrespective of whether or not a publication exists (for Phase 2 though Phase 4 studies) for drugs that are approved. FDAAA imposes significant monetary, civil, and criminal penalties for noncompliance.

Since FDAAA, there has been a large increase (more than 85%) in the number of clinical trials registered on ClinicalTrials.gov, but results, and therefore, safety data, remain underreported. The reason for this is multifactorial. Before 2007, the International Committee of Medical Journal Editors (ICMJE) was the first to require posting of clinical trial methodology on ClinicalTrials.gov as a condition for peer review of manuscript submissions. However, the ICMJE has not required study results to be posted. Why? According to Whitman, “the journals want to be the first to break the embargo.”

Whitman noted that FDAAA’s requirements for reporting are minimal and include a 500-word abstract, and summary data tables of baseline characteristics, participant flow, outcomes, and adverse events; there is no narrative, discussion, or conclusion. The study information, existing in tabular format, is not always interpretable to clinicians and patients. Publication in a peer-reviewed journal is still recommended. Nevertheless, ICMJE has not strengthened its position on FDAAA compliance. ICMJE’s position is: “It is important to note that the ICMJE requires registration of trial methodology but does not require registration of trial results; it recognizes the potential problems that could arise from the posting of research results that have not been subjected to an independent peer-review process.”

In August 2012, in an attempt to increase transparency and address what he calls “an underreporting of clinical trial results,” Ed Markey (then a US representative and now a senator) proposed The Trial and Experimental Studies Transparency Act (TEST Act) to expand the registration and reporting requirements under FDAAA. The proposed TEST Act:

- Requires registration of all interventional studies of drugs, biologics, and devices regardless of phase (including Phase 1), design (ie, including single group trials), or approval status (approved or unapproved) before the first participant is enrolled.
- Strengthens the requirement to have results posted on ClinicalTrials.gov within 1 year of the completion of the trial, irrespective of approval status.
- Requires all foreign trials that are used to support marketing in the United States to be registered and comply with the reporting requirements – 80% of drugs entering the US market were clinically tested overseas but were not heretofore required to be registered.
- Mandates but provides for delayed submission of results (up to 2 years after trial completion) for medical interventions that have never been approved for any indication.
- Requires results reporting whether or not an application is submitted to the FDA for approval (eg, novel therapeutic agents) so that adverse outcomes would be posted even if abandoned by the manufacturer to alert others of potential dangers and putative toxic effects that would necessitate monitoring of that class of agents.
- Improves transparency of clinical trial results so that companies will be less able to hide negative study results, safety signals, and adverse events.

The TEST Act, reintroduced in May 2013, would mandate that the basic results for all trials be posted within 1 year after
trial completion irrespective of approval status of a biologic, drug, or device. Neither FDAAA nor the TEST Act mention the need to post observational safety data even though drug safety registries are often mandated as a postmarketing commitment.

In addition, there is concern that the TEST Act would actually increase rather than decrease publication bias. Sponsors may feel less compelled to publish study results because the basic results will already be in the public domain via a “data dump” posting without any interpretative value for patients. Time pressure and a desire for low visibility may result in more positive trials being submitted quickly to journals and the negative trials being posted on ClinicalTrials.gov. Another concern is the effect on journals: If they accept manuscripts after public posting, it may affect how publications are scored in Journal Citation Reports.

According to Whitman, “Safety data from all sources should be both posted and published for complete transparency and the benefit of patients.” Both FDAAA and the TEST Act do not address the compelling need to publish mandated observational safety data in peer-reviewed journals. Safety data, safety signals, and pharmacovigilance findings may not be perceived as interesting to publishers and journal editors but are vital to understanding the risk-benefit of drugs and devices throughout the life-cycle of a product. By monitoring the safety of a product or device in real-world clinical practice with minimal exclusion criteria, postmarketing safety registries are increasingly being mandated by health authorities globally. There are many avenues to publish these safety data and, with the help of new legislation, public awareness of safety issues can be improved.

Michelle Eby is a consumer safety officer for the Food and Drug Administration in Silver Spring, Maryland.

Author contact: Michelle.Eby@fda.hhs.gov

MARKETING BINGO!

Speaker
Elizabeth (Bette) Frick, PhD, ELS
President, The Text Doctor, LLC, Boulder, CO

By Karamarie Fecho, PhD

Effective marketing is essential for the freelance medical writer or editor, but for many, it is often given a low priority, is avoided altogether, or is considered complete after the business cards are printed. Elizabeth (Bette) Frick asserts that this “if you build it, they will come” attitude to running a business is completely ineffective. She encourages freelances to view marketing as a continuous, evolving process that requires an overall strategy for success. She compares it to swimming—if you stop, you sink—or gardening, in which planting seeds is simply the first step in the long nurturing process.

Frick emphasizes that marketing must be factored into the freelance’s current or desired annual income (eg, 5% of target income). This is a critical consideration because to maintain a given income level over the long term, the freelance must continuously market products and services (again, the concept of swim or sink). Apart from business cards, marketing expenses may include costs related to professional society dues and travel expenses, printing (eg, brochures and postcards), postage, meals and entertainment, gifts to clients, website and e-mail maintenance, and a subscription to a service such as Constant Contact, an online marketing company that offers a variety of marketing products and tools for small businesses.

Inspired by the teaching strategies of her late stepdaughter, who incorporated plenty of games into her Anchorage, Alaska, classroom, Frick has developed a technique—Marketing Bingo—that can be used to gauge one’s current marketing prowess and develop an evolving tactical strategy to ensure a successful freelance career. Marketing Bingo is essentially a 5 × 5 matrix of 25 marketing tactics, organized in Bingo format, from the most passive (column 1) to the most active (column 5). Marketing Bingo can be used in a variety of ways. For instance, a freelance can use the organized list of tactics to view a snapshot of the business’s marketing plan. The tech-

“Operating without a marketing plan is akin to driving a car with the windows painted over. Don’t try it!”
—Jay Conrad Levinson
Guerrilla Marketing Weapons: 100 Affordable Marketing Methods for Maximizing Profits from Your Small Business.1

nique also can be used to determine how many tactics one is currently engaged in and which ones are working best. The freelance can then decide whether the current tactics are sufficient (ie, one’s income goals are being met) or whether a change in strategy is indicated; if the latter proves true, then
Marketing Bingo can be used to identify a new set of tactics. Ideally, the freelance's marketing strategy would include enough tactics to achieve Marketing Bingo (ie, five across, down, or diagonal). At the very least, Frick recommends that freelances engage in a minimum of five marketing tactics at any given time.

In her discussion of tactics, Frick included at least one from each column that is less common among freelances. From column one (most passive), Frick noted the importance of promotional giveaways such as pens, Post-it pads, letter openers, or her own bendable rulers and "doctor kits," which contain handy first-aid supplies. All of these giveaways should be branded with the freelance's company logo and tagline. (For the record, Frick's brand and tagline are "The Text Doctor, More than a bandage for your ailing text."

From column two, Frick includes signage, and accordingly, her license plate reads "TEXT DR." Other options include press releases and advertisements in local newspapers, business reviews, and medical journals. The third column includes cold calls. Frick provided examples of hefty profits from cold calls she has made, some made years before signing a contract. Perhaps most entertaining was an anecdote about her grandson. She recalls his terror of a tarantula named Rosie, who was part of a "petting zoo" of sorts at a local museum. Frick's grandson was clearly intrigued by Rosie but too terrified to touch her until multiple attempts brought him closer and closer. When Frick gave him a huge plastic tarantula, he crowed, " Gamma—I hold Rosie!" The same desensitization strategy might very well work for the introverted freelance. Column four includes the tactic of underwriting or sponsoring industry events. This tactic clearly involves an expense, but it is also a relatively benign way of "getting one's name out"—as long as you make sure you are acknowledged in meeting notes, advertisements, banners, or publications. Finally, the last entry in column five (most active) provides the tactic of getting awards and other recognition for one's work. Frick recommends that freelances submit their work for awards and then publicize the award everywhere, including on the business's website, press releases, newsletters, and other business or professional society websites. This last tactic definitely takes active marketing, but it could prove to be highly successful; it also is a great way to bolster confidence.

Overall, Frick views marketing as an experiment in which you keep trying new tactics (or hypotheses), keep the ones that work (at least for the time), ditch the ones that don't work, and add new ones for future evaluation. To quote Samuel Beckett: "Try again. Fail again. Fail better." 

Katamarie Fecho is a freelance medical and scientific writer at Copperline Professional Solutions, LLC, in Chapel Hill, North Carolina.

Author contact: kfecho@copperlineprofessionalsolutions.com

References
The best way to present your unique value proposition is the marketing headline, Hadley said. But “titles and duties are totally ineffective” when creating that headline, he added. When some attendees questioned that concept, he mentioned that whatever stereotypes the listener has about your job category immediately get attached to you when you present your title. For example, accountants tend to be thought of as boring, so starting out by saying you are an accountant makes it difficult for others to move past that stereotype. He believes the point is to first get people wanting to know more, so if you leave them wondering, that is a good thing. Your marketing headline must speak to the other person and what you can do for him or her on a basic level.

Creating your unique value proposition involves recognizing your current and desired skillset, articulating problems you have solved, and discussing results you have created, Hadley said. You must think hard about what you have contributed in the past: What compelling accomplishment can you describe about why you are now looking or why your job search is taking so long?

Hadley also suggested creating a grid of stories that highlight diverse skills, such as leadership, negotiating, editing, writing, and project management. Developing and internalizing stories from this grid can help professionals to articulate their value more naturally in conversations.

It’s good to have these one-liners and a marketing headline for ordinary conversations with coworkers or people you meet at conferences, Hadley said. But it is especially important to know what you want to say during influential conversations, such as job interviews or meetings with potential clients. Hadley suggests entering these influential conversations with the goal to “help the other person succeed by producing a solution that best meets their needs.”

Kelly Schrunk works from her home near Syracuse, New York, as a bookwormeditingservices@gmail.com medical editor for Med Communications Inc.

**Author contact:** bookwormeditingservices@gmail.com

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**Box 1. Assessment of Current Visibility**

**Self-assessment**

Score yourself from 1 to 10 for each item.

A. I’m fully engaged in my current job.
B. I have a clear picture for the next step I want in my career.
C. I have a unique value proposition that I can communicate clearly and concisely.
D. I have a large network of contacts inside and outside my current employment setting.
E. My entire network understands my unique value proposition and my desired next step.

**Evaluate Your Self-assessment**

- Low rating: 1-4
  > Ask: How is this item holding me back?
- Medium rating: 5-7
  > Ask: Should this be more of a priority?
- High rating: 8-10
  > Ask: How can I take advantage of my success in this area? Am I as good as I think, and who can I ask for honest feedback on my self-assessment?
- For job seekers: What does this assessment show about why you are now looking or why your job search is taking so long?

**Box 2. Tool for Creating Marketing Headline**

**Strategy 1**

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**Strategy 2**

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<th>work with</th>
<th>guide</th>
<th>assist</th>
<th>your target company/employer</th>
<th>who struggles with (or is frustrated by)</th>
<th>a challenge / problem you can solve</th>
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Bad things happen to good freelances. No matter how good you are, things will not always work out with clients. I have been working with some of my clients for as long as I have been in business, and with most of my other clients for years. But I have also had my share of bad experiences, usually because the client hired someone who hadn’t been involved in the project’s design and wasn’t happy when I did what I had been asked to do. These things happen and shouldn’t be taken personally.

Never ignore your instincts. When your instincts tell you to walk away from a project or a client, run. During my early years in business, a client’s new medical director wanted me to leave out key information (I didn’t, because that would have been unethical). I knew that I needed to fire the client, but when they asked me to work on a project I had submitted a proposal for, I felt obligated to do so. This client ended up not paying me for part of the work because I refused to make an always-deadly disease seem like something patients could easily manage. I later learned that a colleague had the same experience with the client on the same project. Later in my freelance career, when I faced similar situations that couldn’t be resolved, I fired the client and felt great about it, even in one case where the client represented about 40% of my business.

IT challenges decrease dramatically when you use a Mac. When I launched my business in 1997, the only thing I worried about was managing my own IT. As it turned out, I was absolutely right to worry about this. When I had a problem, the PC maker would tell me it was a software problem and the software maker would tell me it was a PC problem. No one would help me and I was wasting a lot of time. Then I bought a Mac and my technical problems almost disappeared. From my perspective, Macs just work better than PCs. And when I have a problem, there’s great support available. I can go to a Mac store and meet with a Mac genius (they actually like to help), or I can pay for phone support as needed. Apple also offers a reasonably priced service plan for phone support and online support.

—Lori De Milto

As a freelance, I have learned that what I miss most about working full time at a company is the in-house IT support. I have found that it is useful to buy my PC from a local computer shop that services the computer and not online or at a big store like Staples or BestBuy. I may have paid a little bit more for my PC than I would have had I bought it at a big store, but if I have any IT questions, I can tap the local computer guy’s brains for help. I have also had them come out and hook up the computer to my printer at my house, so I didn’t have to worry about where all the wires went, or how to get all the components to sync properly with the Wi-Fi network.

Another thing I have learned is that keeping meticulous records of receipts helps at tax time. I use www.shoeboxed.com because otherwise the receipts just sit here gathering dust and distracting me from my work. I send Shooboxed all my receipts in a blue envelope they provide; they scan them and make the data captured available in various output forms that can be used with Quicken, QuickBooks, or other programs. I export my data to MS Excel spreadsheets by category for itemizing purposes. From the receipt, they’ll give me vendor, date, amount, and type of expense. If there are any errors, I can correct them and give them information so they know in the future, for example, that all receipts from “Panera Bread” should always be in the meals/entertainment category.

—Melissa L. Bogen
The one major aspect of a freelance business I wished we had known when we started our business was the vital importance of having a diverse client base. It was only after a dramatic loss of income that we realized that working on six different prescription products for eight different clients/departments within one pharmaceutical company is not a diversified business.

We were heavily involved with McNeil Pharmaceuticals in our early years, mostly to the exclusion of all other clients. We worked with six different product managers plus the medical affairs department, international division, medical meetings, corporate communications, public relations, and sales training departments. We had photo ID badges that enabled us to access all areas of the building except the clinical research laboratories. At one point, I was “inside” 2 days a week at my freelance rate. Unfortunately, the 1982 Tylenol poisonings occurred, totally affecting a sister company within the J&J family, of which McNeil Pharmaceuticals was one. Instantly, all budgets for all departments and products companywide, including the prescription products we were involved with at McNeil Pharmaceuticals, were cut dramatically. We were able to finish some already-contracted work, but most planned future projects were canceled. We scrambled long and hard to replace the lost revenue and sadly, lost one of our best clients who eventually merged with another sister company within the J&J family.

Our solution was to develop a mixed client base among pharmaceutical, medical education, advertising, and communication companies; medical associations; and medical publishers. Today, although a month or two may go by when we are only working for a few clients, we are constantly aware of the dangers of our client base not being fully diversified and work hard to rectify the imbalance when it does occur.

—Elizabeth L. Smith

I have freelanced throughout my career as a professional writer. Still, when I started my full-time freelance business in 1989, I was naïve to the business aspects of the business. On one hand, this is probably a good thing because I never imagined I couldn’t be successful. But on the other hand, at the time I didn’t know as much about the business aspects of running a freelance business as I wish I had.

Things like setting project fees, knowing what other writers charged for their services, knowing what the “traffic would bear,” and the dynamics of negotiating were new to me. I learned most of my lessons the hard way. That’s good for me because I learn much better from my failures than from my successes.

My AMWA friends and colleagues, plus the many workshops and open sessions I attended, all fueled my education. Today I continue to attend every educational and networking opportunity I can because there is always something new to know, a different way to do something that I’ve never considered. I value greatly what everyone—from the most experienced freelance to the most inexperienced—has to offer.

Another important aspect of what I want to share here, and that some readers may not expect, is that I am very glad for my naïveté during my early years as a freelance—the things I didn’t know then that I know now. How can that be? Just as we are responsible for our successes, I believe we are equally responsible for holding ourselves back from succeeding. The funny thing is, I believe a big part of what holds us back are the things we know, or think we know, that keep us from attempting. One of my favorite business quotes comes from William Shakespeare’s Measure for Measure, and I kept it pinned to the wall in my office for many years where I could always see it and always be reminded of it. It says, “Our doubts are traitors, and make us lose the good we oft might win, by fearing to attempt.” In 2002, when I began evolving my business model to include subcontracting, I was my own worst enemy. On the basis of what I “knew,” there seemed no way possible for subcontracting to be financially successful. This is a perfect example of me getting in the way of my own success. I got past it by erasing what I “knew” from my mind and moving ahead, learning and adapting as I went, and believing I could be successful.

So as thankful as I am for the business knowledge I have today that I wish I knew earlier, I am most thankful for the inexperience that makes anything possible. There is an opportunity for us to use our naïveté to our advantage, at any stage in our careers.

—Brian Bass

The most honest answer I can give is “everything.” Looking back over the 25 years that have passed since I made the decision to become a freelance medical writer, it is difficult to pinpoint just one thing that I know now but didn’t know then, because it really is just about “everything.” I would have to say, however, that collecting payment in a timely manner was the most important thing I had to learn—and I learned it the hard way. When I first started out, I never sent a bill until I was sure the job was completed to the client’s satisfaction. That seemed to work until one of my clients declared Chapter 11 protection from bankruptcy while still owing me for several jobs. From then on, I began billing a third of the project price as a project initiation fee, another third upon delivery of a first draft, and the final third when the project is fully completed.

—Donna L. Miceli
**Q** Do you have a strategy for approaching a potential new client when you don’t know anyone in the organization, even when no ad or opening has been posted?

**A** I research the company to identify the most appropriate person to contact. (Sending anything to human resources is tantamount to sending it into a black hole.) This could be the marketing director, brand manager, or account manager. LinkedIn is a great resource for such sleuthing. Sometimes, however, you have to pick up the phone.

Never send an e-mail or introductory letter without a name of someone to receive it. For instance, don’t send anything to info@thecompany. It’s a waste of time, and, as busy freelances, we don’t have time to waste.

I approach potential clients with a short, introductory e-mail highlighting my relevant experience. I include a link to my website and résumé, and promise to follow up within a few days if I don’t hear from them. They also receive my marketing postcard and are entered into my database so they receive my newsletters and other announcements. That way, even if I don’t hear back from them on my initial approach, they might contact me later as they get to “know” me better through these other marketing tools.

—Debra Gordon

I don’t approach a new client without knowing someone in the company. At the very least, I will have met them or gotten their card at an AMWA annual conference. People usually find me from word of mouth among my AMWA colleagues or my detailed LinkedIn profile. New clients who find me from LinkedIn say they find me from the key words I have used.

—Melissa L. Bogen

Direct mail has always worked well for me. When I am actively looking for clients, I develop a catchy 8.5 × 11 tri-fold mailer and send it out to a targeted list of potential clients that I would like to work with. I send the mailer to an appropriate contact person within the organization, which I determine based on various lists I have compiled. About 4 months later, I send another direct mail piece to remind potential clients I am out there. This is a fair bit of work and expense, but I have nearly always gotten one or two new clients from each campaign. Direct mail needs to be done right, though—a well-written and designed mailer printed on nice paper sent to the right list. Fortunately, the Web has lots of great information about direct mail.

—Lori De Milto

### Freelance Forum Bookshelf

**Q.** What books do you recommend for medical writers and editors?

**A.** Beyond the obvious books that all freelances should have, such as the *AMA Manual of Style*, the *Merck Manual*, *Dorland’s Illustrated Medical Dictionary*, and the *Physician’s Desk Reference* (PDR), I have found several other, lesser-known books, to be particularly useful for the type of generalist medical writing I do. Here are just four of them:

- *The Writer’s Lawyer: Essential Legal Advice for Writers and Editors in all Media*, by Ronald L. Goldfarb and Gail E. Ross, which is especially helpful when working on projects that involve coauthoring books.
- *The Corporate Scriptwriting Book: a Step-by-Step Guide to Writing Business Films, Videotapes and Slide Shows*, by Donna Matrazzo, which is particularly helpful for pharmaceutical sales training projects that often involve video or slide show scripts.
- *Nursing Drug Handbook*, published by Lippincott Williams, which is simpler to use and understand than the PDR, and is more than adequate for most nonregulatory projects.

—Donna L. Miceli

*The Accidental Medical Writer*, by AMWA’s Brian Bass and Cynthia Kryder, is a wonderful resource for new freelance medical writers. It offers insights and information that took me years to learn on my own, and will inspire you to succeed.

—Lori De Milto
In our last issue, my column titled “Quote...and Misquote” tried to emphasize the importance of checking and double-checking all quotations. Mistakes are out there waiting to happen. In that column, I included the following:

*If men could get pregnant, abortion would be a sacrament.* In 1971, Gloria Steinem said this was a John Kennedy salty observation. Decades later, Steinem confessed that the real author was an Irish cab driver, an elderly woman who was driving Kennedy around Boston in the early 70s.

I was proud of all my quotations and especially liked the Kennedy one—very funny. All of them came from different (and reliable?) sources.

Still in my pride, a few days after the publication went public, I received a nice note from an interested and sharp reader (maybe my only reader—or the only one with sufficient courage to challenge me), politely questioning the dates. For example, we all know Kennedy was assassinated in November 1963, so how could he have been riding in a cab in the early 70s?

Stymied, I looked for my original source but could not find it. However, all the draft copies, rough notes and everything else I had pertaining to that column showed exactly what I had written in that column. So I did what I should have done before (*ex post facto*). I went on an intensive search (or at least sort of intensive). My correspondent was right about the conflict of dates BUT...BUT...BUT...I found no reference to President Kennedy; what I did find was the name of Florynce Kennedy attached to this same story. Florynce was an attorney and civil rights activist of that time apparently noted for her sharp comments. I got the idea—or somebody did—that Kennedy obviously meant President John F. Kennedy. I do not know if that was my judgment or someone else’s. But I apparently messed things up.

Going back to one of the sources I had used in part for the column (*The Quote Verifier* by Ralph Keyes, an excellent reference book), I found that Gloria Steinem in 1973 published a compendium of Florynce’s salty observations, including the one under discussion. To quote Keyes:

Since then, this feminist truism has generally been attributed to Kennedy (Florynce). However, a decade after making this attribution, Steinem admitted that the quip’s real author was an Irish cab diver, an elderly woman, who—while ferrying her and Kennedy (Florynce) around Boston in the early 70s—said ‘Honey, if men could get pregnant, abortion would be a sacrament.’

Well, somehow I goofed—or perpetuated someone else’s goof. And I apologize. *Mea culpa.*

But somehow my mistakes help emphasize the point I was making: Be careful—VERY CAREFUL—with all your quotations. I learned.

**References**

Like so many of our colleagues, we met and established a productive professional friendship by networking at a local AMWA event. As careers in medical writing tend toward a nonlinear path that requires extensive yet distinct expertise, we both have found it helpful to reach beyond AMWA to increase our knowledge and expand our professional networks. While some medical communicators focus on a specific subdiscipline their entire career, many of us find we must take on new topics as we assume new roles or manage our freelance routine. Many of us, as sole communications specialists on a project often working remotely from home, find we need a strong collaborative support system that may be found in professional societies.

Michelle Sauer is a freelance editor/writer and a research administrator. Hilary Graham has focused on research promotion and public relations. While both of us started at the bench, we have since transitioned through multiple positions with various responsibilities as our careers have progressed. Professional societies are often the easiest route to expand your knowledge and network with individuals that have similar expertise. While the majority of AMWA members consider AMWA to be their primary information resource,1 we have personally found several other societies to be of value and describe them below. We have also included a table of organizations that may be of interest to you (Table 1).

**Freelance**

**Sauer:** Personally, I have found that AMWA and the Board of Editors in the Life Sciences (BELS) have led to the most freelance work. Their directories are often searched by companies and individuals looking for writers with credentials. BELS has a rigorous, 3-hour credentialing test that will provide an added level of comfort to possible employers. The exam is offered at least 3 times during the year and requires the applicant to have a bachelor’s degree and 2 years of experience. Exceptions can be made for experience and education, and they are detailed in the application to take the test. The requirements of the application include a résumé, documentation of education, three letters of reference, and a $50 deposit. After your application is approved, you reserve your test date with a $200 fee. Obtaining the ELS after your name can be a rationale for employers to provide a merit increase, so please do not be dissuaded by the upfront cost. Although BELS does not have a stand-alone meeting, it does have gatherings at the annual conferences of AMWA and the Council of Science Editors (CSE). BELS also has a very low renewal cost ($25 per year) compared to other societies.

There was a new booth at the national AMWA conference this year: the Editorial Freelancers Association. Although neither of us is a member of this group, it is certainly high on our list to pursue. Their website is highly informative, with resources, a member directory, and active job listings. They provide a portal for prospective employers to find you as well. While their general and annual meeting is always hosted in New York, they have highly active chapter activities throughout the nation. An up-to-date calendar of educational and social events is provided online. Events are open to nonmembers at a higher fee so you can check the organization out before committing to the larger membership fee.

**Grant Development**

**Sauer:** Editing grant proposals is a natural extension for many medical writers. This is how many of us may become involved in research administration. The National Council of University Research Administrators (NCURA) is probably one of the most recognized and popular organizations for people doing this work. Its focus is more on research grant rules and regulations, but membership here is a great way for writers to learn about the wants and needs of grant
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sponsors. I have found NCURA’s workshops and open discussions with program sponsors and program officers to be very valuable. You can get a heads-up on the tone and focus of upcoming grant announcements. Membership in NCURA gives you access to listserves and weekly webinars, providing you a wealth of information in a heartbeat.

Many NCURA members also go on to attain research administration credentialing. This designation is from the Research Administrators Certification Council. This stamp of approval is meant to show a familiarity with federal rules and regulations. As federal funding has become more difficult to obtain, many colleges and universities are hiring professionals who know how to write a grant proposal. Adding expertise in regulatory requirements will make your résumé stand out. Certifications are available for knowledge of the pre-award process alone (CPRA) or for both pre- and post-award processes (CRA). Like the test for BELS, these tests require an application and upfront fee, but the credentials can definitely provide a concrete measurement of your knowledge. This adds value to your position at work, as you will be seen as an expert and information source. Study groups are also available to help prepare for the exam.

National Organization of Research Development Professionals is another organization that is an excellent place for a grant writer. A rather new organization (6 years old) that I recently joined, its membership is filled with grant development and research office workers who are either trying to improve grant proposals underway or to find writers for initial drafts of proposals. Their listserves are very active with job opportunities and information. In addition, they are quick to hold a conference call if there is a particular area of interest.

**Publications**

**Sauer:** The International Society for Medical Publication Professionals (ISMPP) is probably the next most beneficial organization to a medical writer. Their membership is focused on industry, pharmaceutical and medical device publications, and they provide a wealth of educational workshops, much like AMWA. They also have a credentialing system (CMPP, for Certified Medical Publication Professional) that could prove of great value if you are trying to show that you have writing experience/knowledge. The CMPP requires active participation in medical writing and education and must be renewed every 5 years. ISMPP was founded in 2005 and has been incredibly active. Their membership is over 1,000. They host a national meeting every year and produce a multitude of web-based seminars. ISMPP also has initiated committees that have resulted in important guidance documents regarding ethics (a good publication practice document known as GPP2), legislation interpretation (Sunshine Act), and publishing (the Medical Publishing Insights and Practices initiative).

The International Publication Planning Association offers both a Midwest regional meeting and an annual national meeting. This society is purely focused on industry publications, but I found it helpful even as a professional in academia. Many clinical trials involve counterparts from industry, and understanding their perspectives changed the way I interacted with them. There are not a lot of resources attached to membership in this organization, as their sole purpose is to gather people together for meetings. Their meeting locations are usually very nice, but their registration fees can be upwards of $1,500. One major benefit is free membership.

The Council of Science Editors (CSE) is tailored to journal editors and managers. I have not found it to be as helpful or valuable for me, because the organization focuses on the challenges related to journal management and publication, while my focus has usually been on journal manuscript preparation. However, there are areas of common ground. Ethics and authorship are important issues that are discussed at all meetings, and their importance has been made clear through various publications, such as the CSE’s White Paper on Promoting Integrity in Scientific Journals, updated in 2012. Besides, it is never a bad thing to know major journal editors by their first name. CSE also recently initiated a Publication Certificate Program that may be of interest to many.

**Communications**

**Graham:** While the Society for Technical Communication (STC) traditionally focuses on serving engineering, computer science, and environmental disciplines, their programing is beneficial to medical communicators too. Face-to-face meetings at the national and local levels as well as webinars focus on best practices in document design, usability, accessibility, web development, information architecture, and technology. While this group’s focus may seem far afield at first glance, I have always walked away from meetings with new knowledge that is easily relatable to my work.

If you are interested in learning more about best practices in business and mass communications, the International Association of Business Communicators (IABC) and the Public Relations Society of America (PRSA) may be the associations for you. Both associations are active at the national and local levels and provide networking and educational opportunities as well as professional recognition via awards. Many freelance medical communicators would be well served by learning the basics of PR in order to expand their business opportunities. With topics that include conducting a SWOT (strengths, weaknesses, opportunities, and threats) analysis, branding a small business, communicating change, and collaborating globally,
relevance will not be difficult to find. Health Academy is a special interest group in PRSA that has rich digital discussions and a face-to-face conference each year. While PRSA is focused on strategic communications, IABC takes a word-level approach to print documents and digital media, such as tips for writing headlines that grab attention. Both associations also provide guidance on soft skills like working across generations and building interpersonal leadership qualities.

**Regulatory**

*Graham:* If you are involved in drug discovery and/or development, DIA and the Regulatory Affairs Professionals Society (RAPS) should be on your radar. DIA is a large global organization that has membership and education programming for each discipline required in the drug development pipeline. The general conference can be quite overwhelming, with an attendance of approximately 7,000 people, but it provides the opportunity to network with people looking to hire medical writers. The DIA’s Medical and Scientific Communications Annual Forum is much smaller and only provides sessions on communications, regulatory writing, and publications. Depending on your preference and motivation, one of the DIA conferences may work for you. DIA does not have chapter-level activities but does have a large selection of online offerings that can keep members up-to-date between conferences.

RAPS provides both a certificate program (based on completing a series of courses) and a certification program (based on meeting eligibility requirements and passing an exam). The certification tests four regulatory-related competencies (strategic planning, pre-approval, approval, and post-approval) and is offered at third-party testing sites. The certificate program focuses on pharmaceuticals and/or devices and can be completed through online courses. RAPS offers webcasts, workshops, conferences, and chapter events, making participation exceedingly convenient.

**Personal Development**

*Graham:* The Association for Women in Communications (AWC) and the Healthcare Businesswomen’s Association (HBA) provide chapter and national level networking opportunities and programming that focuses on personal skill building and broad industry trends. Because these associations do not cater to any one professional discipline, they provide excellent opportunities to step outside your immediate professional network. AWC members, in my experience, are on the creative side of the spectrum, with careers in public relations, graphic design, and digital media, whereas HBA members tend to be physicians or lawyers, or in pharmaceutical sales or hospital administration.

**One Size Does Not Fit All**

When considering the value of a professional association membership, determine which society will best meet your needs, which may include:

- Access to high-quality educational content and enjoyable programs
- Opportunities to earn credentials or win awards
- Opportunities to network with colleagues nationally and regionally
- Mechanisms to increase your professional reach and connect with future employers

Remember that any one association may not offer all that you need and that multiple memberships may provide you the platform upon which to expand your network, knowledge, and career to their fullest potential.

**Author disclosure:** The authors report that they have no commercial associations that may pose a conflict of interest in relation to this article.

**Author contact:** hngraham@me.com

**References**

Thomas M. Schindler, PhD, directs a group of 24 regulatory medical writers at Boehringer Ingelheim Pharma in Germany. A member of both AMWA and the European Medical Writers Association (EMWA), he has a varied background in medical writing and editing, having worked in contract research organizations, medical publishing, and small and large pharmaceutical companies. He has long been interested in studying the medical writer job market and defining the skills involved in being a medical writer. We spoke recently about a study he had conducted with Sabrina Heisel-Stoehr to examine the types of skills mentioned in European job advertisements for medical writers and how they compared with the skills and abilities listed in the Pharmaceutical Medical Writing Competency Model, which was published in the AMWA Journal. Heisel-Stoehr and Schindler reported their findings in the journal of the European Medical Writers Association, Medical Writing. He also discussed the research at the DIA meeting in Boston last year.

—Victoria J. White, editor, AMWA Journal

Q. For our readers who are unfamiliar with the competency model, can you tell us a little bit about what that is and why you were interested in studying it in comparison with job advertisements?

A. The competency model was created by a number of outstanding medical writers from around the world. They developed a model in which they tried to delineate what it takes to be a medical writer, what makes it different from other jobs in the pharmaceutical production chain. The model describes work functions of medical writers in the pharmaceutical industry and the knowledge, skills, and behaviors needed to carry them out.

I was particularly interested in this model, as I am often in the situation of having to recruit people. In hiring people, I wanted to have a firmer grounding than just choosing based on the ability to pass an interview and a writing test. What are the sort of abilities one should be looking for in applicants? I found it a very good initiative. The medical writing profession has always had a difficult time of standing up to the more traditional ones in clinical research, like the medical people, the statisticians, the pharmacokineticists, and the project managers. The model can help medical writers develop their own career structure, their own model of working.

Q. What was your research question?

A. My coauthor Sabrina and I wanted to look at how people who are doing the job of medical writing define their skill-set and see if this was in agreement with what employers say they want from medical writers. Employers might have a very different point of view. As a substitute for getting employers’ opinions directly, we looked at 3 years’ worth of advertisements, from 2009 to 2011, on the EMWA website. There were 146 adverts to go through. That is not a very large number, but we have good reasons to believe that it captured most of the international postings for medical writing jobs in Europe during that time.

Q. How did you systematically study the advertisements?

A. We read the PDFs of each posting to determine whether it was for a regulatory writer or a publications position. Then we looked at the wording in the adverts. We looked for where each skill or task would fit into one of the categories for the competency model.

Q. Was the categorization fairly straightforward? Would other people doing the categorization come to the same sorts of conclusions about where to place them in the competency model?

A. One would hope so. Due to the space limitation in a posting, people tend to use slightly more general language rather than the detailed and sophisticated categorization that is used in the model. We therefore had to devise what we called mapping rules, which are detailed in the paper, to determine which entry that we commonly found in the job
posting would go into which category of the model. I think you can debate if the mapping rules are appropriate, but we believe they are and hopefully someone applying the same set of criteria would come to the same conclusions.

Q. So having done all that, what did you learn?

A. Half of the listings were for regulatory, and half were for publications writers. Things related to science tended to be more frequently asked for in regulatory postings. Regulatory postings also more frequently mentioned knowledge about international rules such as the ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use), or knowledge of statistical concepts. In a nutshell, the regulatory listings were more science-based than those for publication writers. In many instances, the adverts for regulatory writers asked for more skills and a more varied background than did those for publication writers.

The writing guidelines and guidances of GPP2, CONSORT, PRISMA, etc., were not mentioned once in the postings, which is surprising, because for medical writers working on publications, they have quite an impact.

Q. Why do you think those guidelines wouldn’t be mentioned? Those are things that you and I would think of as important.

A. This is speculation, but it may reflect the perception of the profession in the different arenas. In the regulatory environment, I think that medical writers have achieved a certain standing, and their skillset may be more understood and spelled out. For publications writers, 93% of the postings mentioned as their first and most important requirement the mastering the techniques of scientific writing and editing. They were much less about working interculturally, being able to deal with statistical concepts and guidelines and so on. For publications writers, recognition of their skills and contributions may be less developed. The representation of their work in the field is one that doesn’t seem to do justice to what they are doing in their everyday life.

Q. Have you done anything with your research findings in your professional life?

A. I think that for us it has clarified internally the requirements we are looking for. It has helped us to design a wish list for what we would like to see in an applicant for a position. Our advertisements are much more detailed now.

Q. It seems like this sort of research could also help individuals, as they work to develop their own skills.

A. Yes, and another goal of the research was to help organizations such as AMWA, on the American side, and EMWA, on the European side, to give them an idea of where to focus their educational efforts.

The overall aim is to really support the differentiation of our job versus other jobs in clinical research, to make it clear to people outside of the profession that medical writing is a profession with a fairly defined skillset that is different from other jobs; not everybody can be a medical writer or can become a medical writer. You need certain skills and abilities. We are different and special and our skills need to be recognized. We contribute substantially to drug development both on the regulatory side of things and on the side of publication and the dispersal of information about medicine and research.

References

How do I use Twitter for work? It amazes me that people are now asking that question. Not long ago, when I told someone that I was on Twitter, he or she would respond, “Great, so you know what everyone had for breakfast,” or “How many pictures of cats can you look at before you lose your mind?” Or if someone had actually spent a little time with Twitter or any other form of social media, I would hear, “But how do you find the time for it?”

Yes, there is something for everyone on Twitter, so that of course means there also are many things there that you will have no interest in. A first glance at Twitter posts may leave you baffled about what is going on there; the magic happens when you finally figure out how to make Twitter work for you. I have to thank my blog-writing friend Mina Burrows for introducing me to Twitter. I had just left my corporate position and wasn’t interested in reentering the corporate world elsewhere. Mina had been a leader in our corporate communications team at our former biopharmaceutical employer, and she had been encouraging me to “use my voice” and break into the blogging world. I had no idea meeting her for a quick coffee and an exchange of industry gossip would rock my world so profoundly. When I told her of my plans for starting my own training facilitation and medical writing business, she immediately started to sell me on the importance of a blog. Always generous with her experience and time, Mina took all the information she needed from me to set up my Blogger account and get me started. She even created my news feeds for blogging ideas. She was determined to see me up and running and would not be dissuaded. Once that was done, she wasted no time introducing me to Twitter. Full disclosure, I was so skeptical she had to practically drag me screaming into social media. She insisted I open a Twitter account right there, so @scopedbylarry was born at that very moment on the Starbucks patio.

The Giant Reception Room
It took me 6 months of playing around with Twitter to get comfortable and decide whether this was just a fun diversion or whether it was a serious tool. As it turns out, it’s both. To me, that has been the fascinating part about Twitter, that I really can’t box it nicely with a label. I found myself having a lot of fun with it and realized at the same time I was finding it useful in my business—“establishing my brand,” as it were, in business-world jargon. (Please, after 33 years in the corporate biopharmaceutical world, jargon is practically my second language, or maybe my third, after sarcasm.) Another tip: Sarcasm can sometimes get lost in 140 characters on Twitter. More on this in a bit.

The successful formula for me was building relationships by following people and attracting followers to my Twitter feed. I started by posting a few links to stories that were of interest to me, and I chose a few people to follow. I realized that what I was doing was treating Twitter as if it were a giant reception at a conference, except it was online and featured an astonishing diversity of personalities. My behavior was much the same as I worked the “cyber room,” interacting with a few fellow attendees. Instead of walking up to the fellow party guest in the corner, in Twitter I started by searching for tweets that concerned topics of interest to me and seeing who had posted them, then I would post a reply to that person. Conversations were struck up in some cases, and in some cases I moved along. Often a person would strike up a conversation that I enjoyed pursuing and just as in real life, occasionally I would find myself in a conversation that I would try to extract myself from. Those situations often put into my mind an expression that my grandmother would use when squabbling erupted among us grandchildren: “Y’all play pretty now.” I quickly realized this could aptly be applied to Twitter conduct. Just like everything else in life, you get out of it what you put into it.
At some point, I realized I was (and here comes that corporate jargon again) “networking.” As I enjoyed conversations, I would follow certain people and when people found value in what I posted, they would follow me. I found that by organizing my Twitter pals into Twitter lists, this was an advantage for all parties. Too many people treat networking like a one-way activity. It should be about sharing. So when you post ideas and thoughts in tweets, people are much more likely and willing to share ideas and thoughts with you. My followers began to fall into five distinct groups of people with whom I was interacting regularly. I developed my Twitter lists to arrange these groups of people around my diverse interests and projects. They became a fun and valuable source of material for me.

The Cyber Cocktail Party
The next phase was not so much like attending that big giant open reception with all sorts of people. I instead concentrated on the people in my Twitter feed, the people I chose to follow. I liken this to hosting a rather large cyber cocktail party. As I interact with people in one group, all my followers (not just that group) see these interactions in their feed when they follow me. So I may be talking vaccines and sterile products with a few folks at the same time I am having a discussion of my trip to the Netherlands with another group, all the while commiserating with a few other people about the MERS (Middle East Respiratory Syndrome) outbreak or Chikungunya in the Caribbean. Lots of conversations take place simultaneously. Just as in a gathering of friends who are not acquainted, you have to pay attention as you bounce among those conversations. You begin to connect those conversations to each other when appropriate, and suddenly you have connected your friends to each other. It’s much the same on Twitter, but you are doing so without the advantage of body language or intonation, so at times it’s a bit tricky. Still, more than a few of my followers have worked their way into conversations with other groups of my followers, just as I have discovered people to follow and interact with when I view my followers’ tweets.

One of the best ways to enhance your networking on Twitter is by retweeting other people. This goes back to my cocktail party analogy. When you are hosting a cocktail party, you have to keep those hors d’oeuvre platters circulating to keep your guests happy. On Twitter, retweeting provides your followers with tasty treats. Part of your reputation on Twitter is built on what you discover to tweet and what you retweet from others. This helps your followers also discover other Twitter accounts they will want to follow. As you perfect this formula, you become a preferred Twitter host.

Ideas for Articles or Projects
In the 4 years since joining Twitter, I have attracted a really smart group of followers whom I enjoy interacting with and many who have been great to bounce ideas off for stories and posts. Whenever I need to research a topic, I will throw out a tweet, and often my followers will have great ideas or their followers will have suggestions that work for me. Frequently my followers will post tweets with links that I archive because I just know they will be useful for me on a course I am writing or a workshop I am building.

One of my favorite uses of Twitter is to live-tweet events. These past few years, I have really enjoyed tweeting at various medical and scientific conferences, including at AMWA’s. I was fascinated to discover that during the American Society for Microbiology (ASM) meeting in Denver last year, my tweets from the conference had been retweeted to followers in all 50 US states and 25 countries around the world (yes, there are all sorts of apps to measure your Twitter use, presence, and reach). I got a great laugh when the analytics revealed that my Twitter handle @scopedbylarry was one of the 25 most frequently tweeted words at the ASM conference.

Effective Twitter Use
Various apps are available to help folks manage their Twitter traffic. TweetDeck, for example, can help you organize your Twitter stream so that you can easily see the content you want, including tweets from a select group of users, direct messages to you, mentions of your Twitter name, saved searches, and so on. If you want to evaluate your presence and performance, tools such as TweetLevel can lead you to people who post the most on a specific topic, TweetReach can tell you how far your tweets travel, and TweetGrader has a formula to help you measure your effectiveness of Twitter. New tools and apps arrive almost weekly. Many are free and some have paid upgrades as well. A little online research will open the door to a whole new world of Twitter tools (See Resource Sidebar).

Twitter has allowed me to meet and interact with many colleagues who have been such great resources for my writing projects. I have enjoyed collaborating with several of my Twitter buddies, and have met some very fascinating fellow tweeters when we have had tweet-ups—in-person gatherings of people who tweet—at various meetings. I have developed several “real life” friendships and professional relationships that I truly enjoy and find beneficial to my freelance business. These days the questions I get about my Twitter experience have evolved compared with those early days. Now people usually want to know who my followers are. My Twitter followers are just like the people in the rest of my life—a very diverse
group whom I enjoy very much. If you follow me on Twitter, you get to see them all.

At last year’s AMWA conference, I attended the open session Effective Social Media Strategies for Health Communicators. Felicia Hudson and Brande Martin led a concise but very useful overview of the main social media platforms; the discussion they facilitated resulted in some very useful tips for professional use of social media. I was adopting them to suit my freelance needs before the session even ended. The takeaways I have implemented include setting a weekly time limit for using Twitter. I admit I am very flexible with that one, but as a freelance, flexibility is important, as I have to change gears quickly and dramatically at times. Twitter actually lends itself to that flexibility. I can back away a bit when I am busy and I can quickly drop in and check it out at a moment’s notice wherever I can establish an Internet connection on my phone, tablet, or laptop.

In the open session, we also did a little sharing about conflicts on Twitter. It is no different from other human interactions, so on occasion disagreements occur. We have the additional challenge that when we are online, we are communicating without benefit of inflection, body language, or other nonverbal cues to help us process messages. I mentioned earlier that we would get back to topic of sarcasm. Be sure to use it only with care. The laws of communications apply on Twitter, so what we intend to say and what people think we are saying can be two different things. With Twitter, we soon learn that it can be challenging to say what we want in 140 characters. Nuances can get lost, and emotions can sometimes run high. As in the real world, it is helpful to graciously apologize when you offend someone (even unintentionally) and equally as important to accept an apology graciously when one is offered.

My favorite takeaway from the open session was the suggestion to keep an idea file. This one has been invaluable for me. In my typical fashion, I have expanded that idea into multiple files. I keep files on tips on using Twitter and files on various topics for future articles and blog posts. My Twitter colleagues have been fabulous sources of ideas for blog posts* as well as materials that I know I will use in future projects. To return the favor, I keep idea files of things I can post and share for them to use as well.

Another open session at the annual conference in Columbus, Hands on Demonstration: Beyond Index Cards: Using Scrivener and Zotero, by @DrJudyStone, turned out to nicely dovetail with the social media session. I learned how I could easily use those two writing tools to work with the electronic idea files being filled in part by Twitter. These apps are saving me time and freeing office space from paper clutter in the process. This was a huge win for me.

Roundtables and open sessions that will further explore Twitter use are being planned for this year’s annual conference in Memphis. Those of us who use it all have stories and experiences, and we will have opportunities to exchange them. Maybe we can even have a beginner’s session to help get a few hesitant folks started. Or perhaps we can be a bit more daring and go rogue by organizing a tweet-up off-campus, so to speak. Meanwhile, happy tweeting, and, as my grandmother used to say, let’s “play pretty” as we do so.

Acknowledgment: The author thanks Mina Burrows, @minaborrows, author and blogger, for introducing him to Twitter. He also thanks and credits Brande Martin, @brandemartin, content manager at The College of American Pathologists, Felicia Hudson, @feliciahudson, writer and communications consultant at Hudson Creative, and Dr Judy Stone, @DrJudyStone, infectious disease physician, medical and science writer, and author of the Scientific American blog Molecules to Medicine (at http://blogs.scientificamerican.com/molecules-to-medicine/) for their outstanding workshops at AMWA’s 2013 Annual Conference. Their ideas contributed to this piece. The author also endorses these four contributors as great people to follow on Twitter.

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

Author contact: l.lynam@thelynamgroup.com and on Twitter at @scopedbylarry

RESOURCES

Twitter Speak From @ to Z – Terms & Definitions
http://searchenginewatch.com/article/2065933/Twitter-Speak-From-to-Z-Terms-Definitions

Free Twitter Tools to Measure Reach and Engagement

*On my blog at http://thelynamgroup.blogspot.com, I recently wrote about the Chikungunya outbreak spreading in the Eastern Caribbean. The post illustrates how Twitter helps me with my blog. The post begins “In early December of 2013 while scanning my Twitter feed I spotted a very curious retweet…”
According to a recent analysis by the Internet security firm Kapersky Lab, unwanted and potentially malicious spam messages now make up more than 70% of all e-mail traffic. The amount of spam that reaches an individual’s in-box will vary depending on the filtering resources provided by e-mail hosting services and Internet service providers, but personal Internet habits can also have a huge influence on this burdensome problem.

One approach to avoid becoming a target for spam is to keep e-mail addresses private, and especially to avoid posting them publicly on websites or blogs, where spammers and cybercriminals can easily capture them. Of course, if you have a website for business purposes, failure to post your contact information presents a significant barrier to connecting with potential customers. Using a contact form is an easy solution but opens yet another avenue for automated spamming programs, which can fill out and send forms repeatedly.

Enter the CAPTCHA, or Completely Automated Public Turing Test to Tell Computers and Humans Apart. CAPTCHAs ask users to read and retype a small string of random, visually distorted text. Because this task is easily accomplished by humans but very difficult for computer programs, it acts as an electronic gatekeeper to validate the legitimacy of submitted forms.

According to Andrew Berkowitz, a longtime Web developer and the chief product officer at TeamSnap, adding CAPTCHAs to a web-based form is relatively easy these days. For websites based on the WordPress blog and web publishing platform, plug-ins are available that can be installed from the WordPress administrative panel, without the need to use complicated web coding (http://wordpress.org/plugins/captcha/). For people who prefer to work directly within the code, they can use reCaptcha, which provides instructions for developers (www.google.com/recaptcha). Although useful for limiting form-generated spam, CAPTCHAs can create their own headaches if the text they produce is so difficult to read that they frustrate actual users. There are alternatives, including setting minimum time limits for filling out forms, or adding checkboxes or math questions for humans to fill out, or hidden form fields that only automated spam programs complete. Another fun alternative is PlayThru, from the Are You a Human website. PlayThru requires users to complete an interactive game (such as assembling a face from parts) before being able to submit a form (http://areyouahuman.com/site-owners/playthru/).

No method is ever foolproof, and Berkowitz, who manages websites in his spare time, provides an amusing anecdote as evidence. “On one of our comedy-related sites, we just have users answer the very simple math problem, ‘what’s 3 + 3.’ Amusingly, we occasionally get complaints from people who can’t submit the form, and inevitably it’s because they are writing a joke in the answer box.”

Author disclosures: The author has no financial conflicts to disclose. Andrew Berkowitz is the author’s brother-in-law and designed the website for the author’s company, Biolexica LLC.

Author contact: jeanne.berkowitz@biolexica.com

References
Editors going over a manuscript almost always have three choices: Reject the article, arrange for a rewrite of it, or simply edit it. Sometimes it is an easy decision, but other times a challenging one.

But then again, the growth of the publication market has created a number of new editorial positions, for example, acquisitions editor, copy editor, rewrite editor, and many others. As a result, the “editor” reading the manuscript at any one time may have all or none of the complete editorial function, confusing the issue. Here, I will limit the discussion to those editors who deal directly with the manuscript; in many cases, it is the copy editor or one who serves that function.

Some years ago, I submitted a medical article to a state journal. There was a single editor, the executive director of the association. I received back his completely rewritten manuscript, plus he had written a totally different conclusion than I had reached. I decided at once not to debate the subject, challenge the editor, or try to work out an arrangement, which seemed highly improbable. I simply responded with a simple note that said I withdraw my article from submission.

Of course, I was mad. I did not, or do not, challenge his right to make this decision; it’s his publication. However, if the article was really that bad, he should have rejected it. But to be nice about the rejection, he could have explained what faults he found, and whether he wanted me to rewrite it and resubmit it—meaning he liked the theme but had objections to the way it came out. He could have rejected it outright— it’s his decision. However, even glossing over his egregious mistake in changing my conclusions (especially since he was not a physician), his total rewriting was intolerable to me. I believe it was not within his province to do that without first consulting me.

Since then, I have found other overreactions from editors—fortunately very few—in a lifetime of writing.

I once wrote a letter to the editor. These are the most highly personal items submitted to or appearing in any publication. They are expressions of personal opinion and must accurately depict the feelings and beliefs and verbalizations of the letter writer. Someone in the editorial department decided that it needed a lot of changes, and when I received the edited copy I realized that it was no longer my letter; it was the letter of that editor even though it carried my name. I appealed to the editor-in-chief because it was no longer my article. He reversed the changes and restored my letter to its original form.

Strictly personal communications such as this should never be changed. Most newspapers have a policy somewhat like this: Reject letters that contain obvious discrimination or libel; correct references to previous letters; correct spelling; correct dates or other facts, and (without changing a single meaning) shorten the letter for reasons of brevity. I personally believe that errors of grammar, punctuation, and spelling should be left intact, as it gives additional information about the writer—although most publications do not do that. However, since it carries the writer’s name and is his or her personal opinion, it never should have anything more than tweaking, no ideational changes.

I have written regular, signed columns for three periodicals. These are known as opinion columns—you know, like Leonard Pitts, George Will, or Kathleen Parker, but I am not comparing myself to any of them in any way. But if I am a bylined author and the material is my opinion (even though I may not be a national authority), there should never be a reason to change any of it. Correct unintentional misspellings if they occur but never ideas or expressions. Imagine getting a column submission from an author like J. D. Salinger and trying to “edit” it to be clearer and less confusing (in the editor’s mind).

I submitted a column to one of my periodical publications, and it was completely rewritten. Apparently it was handed to a copy editor for editing. That meant editing, not rewriting—just correct obvious mistakes. This was an opinion column, an expression of some ideas that were primarily mine or conjecture (which is also a privilege of

By Arnold Melnick, DO / Aventura, FL
a bylined column). Also remember that a writer is allowed to become a regular columnist because someone believed that he or she has clear ideas, has certain positions on specific subjects, and is capable, at least, of writing a readable and correct composition.

These three episodes bring forth several principles that I believe guide (or should guide) copy editors or those who do that similar task. It is not the editor's province to act like, "I can do it better" than he.

There seems to be a hierarchy among material submitted for publication.

- To me, the highest position is the letter to the editor. Except for the usual management of such material—such as editing for "grammar, brevity, and clarity" (the policy of the Miami Herald)—no changes should ever be made if the letter is going to be used. It is a signed document, submitted in anticipation that the writer's opinion and words would stand as written. It is a reader-writer's forum and really not subject to editing. (In fact, I believe that even grammar should not be corrected because it is the writer; it tells the reader something about him or her.)
- The second hierarchical editing position is the signed opinion column. It is not offered as an intrinsic part of a periodical but presents an outside opinion written by a skilled writer; it should be subjected to no changes. Who am I, as an editor, to challenge a "name" or opinion columnist? If necessary to comb out an opinion, a publication can always pair it with a counterpoint article, and I have seen that done. It is my impression that syndicated columns are submitted (sold) to publications with no changes allowed—either grammar or opinion or writing. If a newspaper, for example, finds fault with a particular column, they may refuse to run that column (but will pay for it anyway).

I have been connected with many editors who were great—and I learned much from them. Over the past few years, in writing for those three professional publications, I encountered editors who operated a system I believe is the correct way to edit. For one of the publications, I was also the editor, so there were no disputes. The other two editors (one was Lori Alexander of the AMWA Journal), were both much better editors than I. When I submitted a manuscript, they would post on it their recommendations or suggestions, without any undue fuss. Probably, on average, there were three to five comments for each manuscript. (I would say that is a reasonable average for differences of opinion). Over time, in about 50% of the cases, I agreed with the editor and let her proceed, and about 50% I disagreed, explained my reasoning, and my opinion was accepted. In a scattered few, interestingly, my response was that the editor's changes did not alter the meaning and was not better than my original, but if they preferred theirs, I was willing to go along.

- Other articles (news or scientific articles) are submitted with the understanding that publication decisions, form of the material, and needed changes are apt to be made. Still, I believe that a complete rewrite should never be made without consulting the original writer, as there may be differences that can be accounted for. In insoluble differences, either the publication has the right to reject, or the author has the right to withdraw the article.
- Reporter's articles (or telephone calls) to a rewrite desk. This is the lowest rank. The rewrite editor would then compose the final copy, without additional input from the reporter. No need for further discussion of that here.

That brings us to editing and what I think it means. It implies to me carefully reading the manuscript to be certain that it makes sense and is relatively clear in its exposition. Step two would be correcting any obvious errors—wrong dates, incorrect spelling of names, places or other, or unintended grammatical errors. The third step may be to suggest better wording in some small area or even improved logic (so the writer can consider it). Finally, an editor notes an egregious omission of a pertinent factor or two that should have been included. Let the writer see it and then work out any differences between them. And, of course, suggestions to make the manuscript conform to the style of the publication are always in order.

Merriam-Webster's long definition of edit does not contain the word rewrite but does use the terms "alter, adopt, or refine."

Both writing and editing are honorable professions and should always be working together—a long as both continue to operate within their own spheres.

Dr Melnick, retired executive vice chancellor of the Health Professions Division of Nova Southeastern University, has been writing a column for the AMWA Journal for 12 years. He has published 12 books on pediatrics or medical communication and has produced a monthly column for The DO magazine of the American Osteopathic Association for 10 years. He has written more than 230 professional columns or articles, including for such journals as the American Journal of Public Health, Medical Economics, and Academic Medicine.

Readers, What Do You Think?

What is your philosophy of editing? How has it been shaped by your experiences as a reader, writer, or editor? Has it been affected by research on the effective communication of medical or scientific information? Are these questions applicable to the medical communication sphere in which you work?

Submit your responses to JournalEditor@amwa.org for possible publishing in an upcoming issue. Dr Melnick also welcomes your comments at melnick5050@comcast.net.
The Peasants Are Revolting!

By Laurie Endicott Thomas, MA, ELS

If the king exclaims, “The peasants are revolting!” is he expressing his contempt for the peasantry, or is he alarmed that they are rising up against him? The king’s exclamation could convey either meaning. Thus, it is ambiguous. The English word ambiguous comes from a Latin word that originally meant to drive in both directions and is often used to describe a word or sentence that can be interpreted in two or more ways. The word ambiguous can also be used to convey that something is doubtful or uncertain, especially because it is obscure or indistinct.

Poets often use ambiguity deliberately, for poetic effect. Comedians often use it for comedic effect. In contrast, medical communicators must avoid ambiguity. Medical communicators do not want to confuse or mislead their readers.

Ambiguity in a sentence can result from two different kinds of problem. Semantic ambiguity results from a word having more than one possible meaning. In contrast, syntactical ambiguity results from a problem in the structure of the sentence. The ambiguity in the king’s exclamation results from a combination of the two. The verb revolt means to renounce allegiance or subjection. If are revolting represents the present progressive form of to revolt, it would mean that the peasants are currently rising up against their oppressors. However, the word revolting can also be used as an adjective that means extremely offensive or distasteful. The meaning that you derive from the king’s exclamation would thus result from how you parse the exclamation—how you break the sentence down into its parts of speech. Should you interpret are revolting as the present progressive form of to revolt or as a linking verb (are) and an adjective that serves as a predicate complement?

By itself, the statement does not give you enough information to decide which meaning of revolting was meant. To clear up the confusion, you have to rely on information from outside the sentence. In other words, you have to rely on the statement’s context. The word context came from the Latin word contextus, which in turn came from a word meaning weaving together. Thus, context can refer to the parts of a discourse that surround a word or statement. It can also refer to the environment or setting in which something happens.

If you are present when the king says, “The peasants are revolting!” his facial expression and tone of voice would probably clear up the ambiguity. Is his nose wrinkling in disgust, or are his eyes wide with fear? Facial expressions, tone of voice, and prosody (rhythm and intonation) are lost when a sentence is written down. The loss of this contextual information means that writers must be particularly careful to avoid writing sentences that could be misconstrued.

In good technical writing, the meaning of each sentence is clear and unambiguous. Ideally, the meaning of each sentence should be immediately obvious. The reader should not have to waste time and energy in puzzling out the meaning of ambiguous sentences from their context.

Semantic ambiguity is a common problem in medical writing. For example, the word nursing could refer to the duties of a nurse but it could also mean breastfeeding. The AMA Manual of Style specifies that the word nursing should be used only to refer to the duties of a nurse. Words such as breastfeeding or lactation should be used to refer to breastfeeding.

An even more common word that can be ambiguous is since. Since originally meant after, but it could also be used to imply a cause-and-effect relationship. One way to avoid confusion is to use the word since only to indicate timing. If you mean to express a causal relationship, you should write because instead. Of course, if you slavishly replace all instances of since with because, your writing could sound as if you are off to see the wizard: because, because, because,
Semantic ambiguity is a common problem in medical writing. For example, the word nursing could refer to the duties of a nurse but it could also mean breastfeeding. Because I occasionally use since to mean because, but only if the tense and aspect of the verbs in the sentence make it clear that since means because:

- Since I am the only person who has not been drinking, I’ll be the designated driver.

English is particularly prone to syntactical ambiguity because it is relatively uninflected. For example, we don’t change the endings on a noun to indicate whether the noun is the subject of a verb, or the direct or indirect object of a verb, or the object of a preposition. To avoid syntactical ambiguity, we have to pay careful attention to word order and the use of prepositions. The following sentence would not be ambiguous if it were in Latin, which declines nouns for case.

- John is closer to his mother than his father.

Because of the lack of inflection, we cannot tell which relationships the writer intends to compare. To clear up the ambiguity, you have to add either a verb or a preposition, depending on which meaning is meant. If you are editing someone else’s work, you will have to ask the author which meaning is correct:

- John is closer to his mother than his father is.
- John is closer to his mother than to his father.

There are three things that you can do to reduce the ambiguity in your writing: (1) study your dictionary; (2) study the *AMA Manual of Style*, particularly the section on correct and preferred usage; and (3) learn how to diagram sentences. Studying your dictionary will alert you to words that have more than one meaning. The AMA style manual will alert you to many ambiguous words and syntactical problems, especially those that occur frequently in medical writing. Learning how to diagram sentences will help you identify many syntactical problems that affect the meaning of your sentences.

**Author contact:** LthomasS21@verizon.net

**References**

In his book *The Nazi and the Psychiatrist*, Jack El-Hai tells the story of a young psychiatrist, Dr Douglas M. Kelley, whose assignment was to evaluate the leaders of the German Third Reich. Kelley, a US Army officer, was assigned the duty of making sure that these men who were accused of war crimes against humanity were psychologically fit to stand trial in Nuremberg. As Kelley talked with the elite of the Nazi regime, he became especially fascinated by the dominant figure, the former Reichsmarshall Hermann Göring. Although Kelley’s official mission was to ensure their sanity, his personal goal evolved to answer his own questions: Was there a common mental flaw in these prisoners? Did they share a psychiatric disorder that caused them to participate in the evil deeds? His quest to explore the psychological recesses of the minds of the Nazis led eventually to his own demise.

Born in 1912, Douglas Kelley grew up in a family whose history in California ran deep. His mother was a member of the eccentric McGlashan family, whose passion was to find memorabilia of the horrid happenings at Donner Pass. She was one of the first women admitted to the California bar. Kelley’s father was a dentist who was active in civic life.

Douglas Kelley graduated from medical school at UC Berkeley at 24. He abandoned his first inclination to become a brain surgeon to pursue work in psychiatry at the New York Psychiatric Hospital. In addition to his interest in magic, he dabbled in arcane and strange studies such as the effect of the full moon on mental patients. The Rorschach inkblot test for analyzing personality had just come out, and he was also influenced by the thinking of Alfred Korzybski and the emerging field of general semantics. His first major interest was studying the plight of traumatized war veterans of World War I, which later led to the assignment at Nuremberg to evaluate the mental fitness of the Nazis.

Kelley developed a rapport with Göring, who would talk only with him. Kelley worked hard to relate to the men in the Nuremberg cells; however, the interaction with the Nazis was slowly affecting him personally. Kelley found that Göring was a strong, ambitious person dedicated to his country who was also convinced he had done nothing wrong. He was very worried and very concerned about his family. After months of evaluating Göring and the other men, the young psychiatrist could not find a common thread that reflected the depraved Nazi mind; instead, he became convinced that they were just ambitious, energetic, and hard-working individuals.

In December 1945, Kelley left Nuremberg to return to the United States. The trial of Göring went on for many grueling months; his execution was then scheduled for October 16, 1946. Before he could be executed by hanging, Göring swallowed a vial of potassium cyanide that he had had hidden for months.

Although Kelley acquired fame in civilian life back in the United States, all was not well with his personal life. He spoke and wrote often about the qualities that allowed of group of men to cruelly dominate a country. He wanted people to see that anyone could become like these men and that America could become Germany. His personal agony, which included family conflicts in addition to his memories of the Nazis, was too much to bear. On New Year’s Day, 1958, after a bitter family fight with his wife, he emerged from his room with a vial in his hand, then put something in his mouth and swallowed. Ironically, it was potassium cyanide, which Göring had used years before.

Author Jack El-Hai is a master storyteller, weaving numerous facts and resources into a story more alluring than a novel. He has created snapshots of the mind of a psychiatrist as he is probing the minds of Nazi killers. The book leaves the reader pondering questions about the nature of man. Kelley struggled with the question of whether any ambitious, driven person, when given similar circumstances as the Nazis, have acted in the same way. He was convinced that such a person would. The book is certainly food for thought for anyone who is interested in psychiatry and the psychology of personality.

I have always been interested in psychiatry and mental health; at one time, I had even considered them as possible professions. I am not sure I would have come to the same conclusion as Douglas Kelley about the nature of man. But for anyone who is interested in history, psychiatry, and the psychology of personality, this book is very readable and will keep you turning the pages.

— Evelyn B. Kelly, PhD

_Evelyn Kelly is a freelance writer in Ocala, Florida._
Priorities and Promises

By Brian Bass / 2013–2014 AMWA President

I have had about a month’s gentle nudging from our editor, Vicki, to write my article for the spring issue of the *AMWA Journal*. I could have taken time from any of dozens of business days during that time to write in the comfort of my office. I could have taken my laptop to the couch and written in even greater comfort any weekend. But here I am at the last minute, crammed into an impossibly small seat in coach as I fly back from the winter Executive Committee (EC) meeting in San Antonio, Texas, finally writing my article. Yet somehow, this is the perfect time and place.

It’s not that writing this article hasn’t been a priority. Rather, other priorities have commanded my attention first. My top priorities have been helping to manage the business of AMWA, which is a promise I made to you when you elected me to this position, and running my business so my family can eat, which is a promise I made to my wife.

Prioritizing helps us tackle the important things in our lives in an effective and efficient manner, and nowhere has this been more apparent to me than in San Antonio over the past few days. At the business meeting at the annual conference last November, I shared with you AMWA’s plans for the coming year. The plan comprises 21 items in five categories—all focused on furthering AMWA’s mission. A primary goal for our EC meeting was to prioritize the items within the plan that had been developed, so we can transform our ideas into accomplishments.

We prioritized the five categories, then we prioritized each item within each category. This way, all department administrators within AMWA are empowered to guide their committees strategically, all committee chairs are empowered to guide their committees tactically, and all committee members are empowered to implement our plan confidently.

Perhaps the most interesting, although not surprising, result of our activities was the recognition that expanding our educational offerings is pivotal to our commitment to continuously enrich the member experience. Expanding our educational offerings, of course, goes hand in hand with other priorities, including expanding how those educational offerings are delivered, which goes hand in hand with expanding our technological infrastructure to accommodate those offerings now and in the future. Furthermore, it is vital that what AMWA is doing, and what is available to members and potential members, must be clearly and frequently communicated.

With our priorities in place, we are moving forward. Preparing to launch the certification exam in 2015, moving AMWA into online learning, and strengthening our online community and our chapters, are all in the works. And that is just the beginning. I am excited about where AMWA is headed and how we are getting there, and I want you to be excited, too. There are so many ways the priorities we have set forth will benefit members at both the chapter and individual level. In the months ahead, you will be hearing much more about this from me, from your department administrators, and likely also from other AMWA friends and colleagues, through various channels ranging from print and direct mail to e-mail and social media.

If you haven’t already checked out my blog (available via the AMWA.org home page), I urge you to do so. It’s a great way for me to stay in touch with you regularly, and for you to stay in touch with me.

The bottom line is that YOU, our members, are our top priority. That’s not a new idea, but I want you to know it and always remember it. Sometimes it may seem that the decisions of your EC and/or your Board of Directors (both consisting of energetic and committed volunteers who are first and foremost AMWA members just like you), are not in your personal best interest. But they are always in the best interest of AMWA.

Sometimes the decisions we make require change, and change is never easy. But as I said during my remarks at the business meeting, change happens whether we attempt to outrun it, attempt to get in its way, or get on board. By getting in its way we’re likely to get run over by change, but by getting on board we have the opportunity to steer change in the right direction.

Our charge is to protect AMWA and help it grow in line with its mission. As we approach our 75th anniversary, I am reminded that our existence as an organization isn’t about longevity—it’s about relevance. My promise to you is that we, the volunteers and staff of AMWA, will continue to work tirelessly to ensure AMWA remains relevant to our members, to our profession, and to our industry.

When the time is right for you, I hope you will join us as a volunteer at the chapter or national level in this worthy endeavor. Member engagement is another of our top priorities, and I personally promise you will be glad you did.
In Memoriam

Elizabeth Seton Stone

Elizabeth Seton Stone, a leading light of the Pacific Southwest Chapter for nearly 30 years, died on December 24, 2013, in Whittier, California. Born in 1920 in Pennsylvania, Elizabeth lived her life in blazing color, signaled by her red hair and dazzling wardrobe. New chapter members remember her warm welcome at meetings, and many Asilomar nights were brightened by her stories of a rich professional career, spiced with radicalism and romance.

Elizabeth served AMWA’s Pacific Southwest Chapter as secretary from 1981 to 1983, president from 1985 to 1987, and chair or co-chair of four Asilomar conferences from 1987 through 1995. She also led several AMWA workshops and served on numerous national AMWA committees; she was awarded AMWA fellowship in 1989. Elizabeth’s legacy includes work as a medical editor for the Journal of Clinical Neuroscience and speechwriter for Dr Frank Jobe of the Kerlan-Jobe Sports Medicine Clinic in Los Angeles. Speakers at her memorial service on January 8 also recalled her volunteer work for classical music and lifelong learning organizations. She is survived by her four children, four grandchildren, and two great-grandchildren.

—Sue Hudson

I walked into my very first AMWA meeting and looked for a seat in the back, preferably near a door so I could escape in midmeeting if things got boring. I was interested in medical writing, but I had major doubts about my ability to break into the field. Someone touched my arm, and I turned to see a charming woman with flaming red hair who introduced herself as Elizabeth Stone and invited me to sit next to her.

Our meeting was at the Los Angeles Press Club in 1986. Elizabeth explained that she was a freelancer with several projects. She worked at Los Angeles County Harbor General Hospital in the Department of Medicine, editing manuscripts for the chair. She was the managing editor of a medical journal in neuroscience. She was a speechwriter for a sports medicine orthopedic surgeon. She was active in the local chapter of AMWA.

Elizabeth's welcome was as profound as it was simple. No one had to stand around looking lost in a sea (or pond) of strangers. And years later, when we were codirectors of the Asilomar conference, she took great pleasure in entertaining the conference attendees at the skit on the last night of the meeting and she made sure to include newcomers and speaker guests in the merriment.

—Lanie Adamson

I met Elizabeth at Asilomar in the early 1980s. She was a kick and somehow reached Elizabeth. I actually don't know how this happened if things got boring. I was interested in medical writing, but I had major doubts about my ability to break into the field. Someone looked for a seat in the back, preferably near a door so I could escape in midmeeting if things got boring. I was interested in medical writing, but I had major doubts about my ability to break into the field. Someone touched my arm, and I turned to see a charming woman with flaming red hair who introduced herself as Elizabeth Stone and invited me to sit next to her.

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—Lanie Adamson

“...I knew you were going to be a wonderful teacher.” High praise, indeed. I will miss her.

—Tom Lang

Elizabeth was my friend for more than 30 years, and I miss her terribly. Early in our friendship, Elizabeth, a fellow opera lover, invited me to go with her to the L.A. Music Center to see Wagner’s Tristan und Isolde. I met her at her house in Long Beach, and then she drove the two of us into Los Angeles. Until then I didn’t know that, for a simple 20-mile trip to downtown, the well-dressed woman wears driving gloves (to protect her hands) and driving shoes (to prevent scuffs on her elegant high heels). Cheers, Elizabeth! I hope the heavenly choirs are meeting your standards for great music.

—Michele Vivirito

The main reason I attended a second meeting of the AMWA Pacific Southwest chapter is the warm welcome I received from Elizabeth Stone and Michele Vivirito at my first meeting in 1986. Such genuine hospitality and friendliness to a stranger has been rarely seen, in my experience.

I also remember Elizabeth for the first time I drove up to the Asilomar conference. She had told me the organizing committee would be there early, and I should arrive any time on the day before the official start of the conference. I drove up Highway 101, and when I reached Salinas, I feared that with the distance I still had to cover, from Salinas to Pacific Grove, I would arrive too late to join Elizabeth and the others in time for the work party and then dinner. I found a pay phone, telephoned the Conference Center, and somehow reached Elizabeth. I actually don’t know how this was possible, because it was long before the days of cell phones, and Asilomar was famous for not having telephones or TVs in the rooms.

Miraculously, Elizabeth came on the phone, and told me to just come on ahead, that the committee was working away putting the conference program booklets together, and I could help when I arrived. It all came true, just as she said. Her sweet inclusiveness made me feel part of the group, and when I arrived at Asilomar, she made sure I truly was part of the group.

She was always nice to everyone, and generous with her time and advice. Elizabeth was a big reason I enjoyed participating in our AMWA chapter. She is, and will be, missed.

—Lorraine Schacher
In Memoriam

Alamada B. Barrett

Alamada B. Barrett, a member of AMWA for 30 years, died in November 2013 at the age of 92. She was for many years a medical editor at the UCLA Jules Stein Eye Institute. She served AMWA as an annual conference workshop leader (the Microediting workshop) and networking breakfast leader. She also wrote the chapter on microediting for the 1994 publication Biomedical Communication: Selected AMWA Workshops. "Mada," as she was known to her friends, will be remembered for her love of good writing, her community engagement, and her lively and courageous spirit. She will be missed by her many friends in AMWA.

—Michele Vivirito

The tributes to Elizabeth Seton Stone (prepared by Lanie Adamson) and Alamada Barrett appeared first in Postscripts, the newsmagazine of the Pacific Southwest Chapter.

Update from the Certification Commission

By Thomas Gegeny, MS, ELS, and Marianne Mallia, ELS

2014 Certification Commission Co-Chairs

The Certification Commission is continuing its work toward implementing a certification examination for medical communicators. The Commission has two new members: Bart Harvey, MD, PhD, who will chair the Exam Development Committee, and Jim Cozzarin, ELS. They join David Clemow, PhD, Barbara Gastel, MD, MPH, Sue Hudson, and Karen Potvin Klein, MA, ELS, GPC, who is serving as liaison from AMWA’s Executive Committee, and the two co-chairs. Much more information will become available about the exam as the launch date approaches, currently slated for the 2015 AMWA Annual Conference in San Antonio, Texas. In upcoming months, the commission will be

- Finalizing additional policies and procedures and developing a formal Policies and Procedures Manual;
- Developing a candidate handbook, which will include information about the exam and a list of study resources;
- Finalizing application procedures; and
- Ensuring the writing, review, and approval of items for the exam bank continues.

These tasks were summarized in the last “Quarterly Update from the Medical Writing Certification Commission” [AMWA J 2013;28(4)192].

In November 2013, the eligibility requirements for taking the examination were presented to AMWA’s Board of Directors. The two major qualification criteria include education and experience requirements. First, candidates must have a baccalaureate degree from an accredited college or university; the degree can be in any field of study. Candidates must provide a transcript as part of the application submission process. Second, candidates must have completed a minimum of 2 full-time work years (or equivalent) of medical writing experience in a paid capacity. As part of the application process, candidates must provide two letters of support from individuals who can document the candidate’s previous or current relevant work experience. Also, candidates must provide a current résumé with a short description of duties carried out in each position.

AMWA has made great progress toward this initiative but only through the dedication and hard work of volunteer members in partnership with AMWA’s staff, led by Susan Krug, CAE, and Lauren Ero, MS, MEd. More information about the certification exam and related processes will be shared in upcoming AMWA Updates and in the AMWA Journal. Stay tuned!

New Year, New Look

Enjoying the AMWA Journal’s new look? All compliments go to the designer, Amy Boches, for creating a cover-to-cover update. I am thrilled with how it has turned out and hope you will be too.

In addition to Amy, I am also indebted to AMWA staff and leaders, and a long list of volunteers for supporting the investment in color on every page and for providing great ideas about the layout.

Some of you may be surprised to have received this issue in the mail, as quite a few of you have selected the option (in your membership profile at amwa.org) of viewing the Journal only online. AMWA headquarters and leadership wanted to make sure that members were aware of the Journal’s redesign, so this issue was mailed to AMWA professional members with a US postal address.

Please take some time to read this issue from beginning to end. If you have any comments on the design or text, or have ideas for future issues, please be sure to contact me at JournalEditor@amwa.org.

—Victoria J. White
I was disappointed in the recent article on readability and text cohesion. The research errs in critical assumptions, uses long-discredited concepts, and provides little useful information to medical writers.

The authors “examined whether reading grade level is correlated with text cohesion.” They analyzed 55 online patient education texts with a computer program that measured textual cohesion, then correlated the results to those of a readability formula applied to the same texts. They concluded that “relying solely on reading grade level to indicate readability of medical information may overlook the importance of text cohesion.”

The authors incorrectly describe reading grade level as “the number of years of education required for a reader to understand the written information.” Actually, say, a 9th-grade reading level means that half the 9th graders tested for comprehension of a normed text answered half the questions correctly. The concept of reading grade level has several other serious problems.

The authors acknowledge many limitations of readability formulas. However, these limitations are prohibitive. The authors nevertheless tested one, and with a program designed specifically to “overcome the shortcomings of readability formulas.” The formula and the program count qualitatively different parts of a text—one counts words, the other, repeated words. The importance of any association between these functionally unrelated parts is unclear.

The Coh-Metrix program measures cohesion, a topic worth studying. One measure it uses is based on the “given-new contract,” a composition technique in which information in the previous sentence (the “given” information) is generally repeated in the first part of the next sentence, before “new” information is introduced. The technique does improve cohesion and should be known—and used—by medical writers.

Cohesion is part of a larger concept called “coherence.” A text is cohesive if its parts are linked, but it is coherent only if it makes sense; a text can be cohesive but not coherent. That is, cohesiveness is measured by examining the text, but coherence is measured by examining the reader. A good medical-technical writer can use cohesion to create coherence, but our value comes from improving coherence, not cohesion.

There is another problem, however. The authors conducted research outside their area of professional expertise, presumably because they believed they knew enough about writing to do so. Unfortunately, they fell victim to some common myths about writing. In fact, the conventional notion of writing does not reflect the advances in technical writing of the past 40 years, and therein lies the problem. We need the medical community to know that there is much more to writing than is generally believed and that we, as professionals, apply this additional knowledge and expertise to make the documents we prepare more effective.

—Tom Lang

References

The first step in developing a readability formula is to test comprehension of a set of passages using a sample of readers with known reading skill. Reading a grade level score is then given to each passage based on the reading grade level of the readers who comprehend the passage. Tom Lang has described this step in his letter. His description that “a 9th-grade reading level means that half the 9th graders tested for comprehension of a normed text answered half the questions correctly” is correct in this context.

The next step of developing a readability formula is to identify which text features (eg, letters per word) are strongly correlated to the variance of comprehension scores in the sample readers. As a result, most readability formulas include a word factor (eg, word length) and a sentence factor (eg, sentence length) to yield the best prediction of the comprehension scores.

We agree with Mr Lang that there are numerous ways to improve text readability beyond the use of readability formulas. For example, we have tested the effect of text cohesion on improving reading and comprehension of colorectal cancer screening information in adults. We chose to look at a readability formula in the study reported in the AMWA Journal because these formulas are still in use and often become a standard to indicate text readability. A text that is written in such a way as to be scored as easy to read by such metrics may not actually have the text cohesion that potentially could aid in comprehension. This study offers some support for not relying solely on these formulas.

Finally, in our effort to study strategies that can assist in producing easy-to-read and easy-to-understand health information for the common goal of improving health, we do not presume to know more about writing than our colleagues in the profession of medical writing.

—Chiung-ju Liu, Kristen E. Yates, and Susan M. Rawl

The authors are from the Indiana University School of Nursing, Indianapolis, IN.

References
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