Pathophysiology and Clinical Spectrum of Fibromyalgia. A Brief Overview for Medical Communicators

Research Report: Medical Communication Practice and Trends in Pharmaceutical and Biotechnology Companies

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

- Publish articles on issues, practices, research theories, solutions to problems, ethics, and opportunities related to effective medical communication
- Enhance theoretical knowledge as well as applied skills of medical communicators in the health sciences, government, and industry
- Address the membership’s professional development needs by publishing the research results of educators and trainers of communications skills and by disseminating information about relevant technologies and their applications
- Inform members of important medical topics, ethical issues, emerging professional trends, and career opportunities
- Report news about AMWA activities and the professional accomplishments of its departments, sections, chapters, and members

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ABSTRACT
Fibromyalgia is a common, complex, rheumatic disorder of unknown etiology characterized by chronic widespread pain as well as other clinical features, such as consistent focal areas of tenderness (ie, tender points), stiffness, nonrestorative sleep, fatigue, frequent psychologic comorbidities (such as depression and anxiety), and impaired memory and cognition. Fibromyalgia is a major cause of morbidity, poses a substantial economic burden on the health care system, and has a negative impact on patients’ quality of life. Fibromyalgia is more common in women than in men and may also affect children. Although the pathophysiology underlying this condition is poorly understood, there is a complex interplay of dysfunctional central pain modulatory and neuroendocrine networks. Some studies have found a correlation between the onset and exacerbation of symptoms and periods of physical or emotional stress. Comorbidities that closely mimic the clinical spectrum of fibromyalgia and the overlap in symptomatology with other rheumatic conditions make diagnosis challenging. The overall management strategy for fibromyalgia involves a multidisciplinary pharmacologic, rehabilitative, and cognitive-behavioral approach. The aim of this article is to provide medical communicators with a brief overview of the epidemiology, pathophysiology, and clinical spectrum of this common multidimensional pain syndrome.

OVERVIEW AND EPIDEMIOLOGY
Fibromyalgia is a common, complex, multidimensional, nonarticular rheumatic disorder of unknown etiology characterized by chronic widespread pain.12 Although the condition may be underdiagnosed and highly unpredictable in its course of progression, it is distinguished from other pain disorders by clinical features such as consistent focal areas of tenderness (ie, tender points), nonrestorative sleep, fatigue, and frequent psychologic comorbidities, such as depression and anxiety.1,3 The etiology is multifactorial, with an interplay and interdependence of genetic, hormonal, neuroendocrine, environmental, and behavioral elements.1,4
Fibromyalgia is highly heritable; the risk of fibromyalgia is approximately 8-fold greater for first-degree relatives of people with fibromyalgia compared with the general population.5 Based on epidemiologic studies, the prevalence of fibromyalgia in most nations is 2%-7%. Globally, it is more common in women than in men (approximately 9:1), and may also affect children.6-8 In the United States, the overall prevalence of fibromyalgia is approximately 2%, or 3.7 million people, making it the third most common rheumatic disorder after low back pain and osteoarthritis.9-13 Fibromyalgia has a negative impact on quality of life and imposes a substantial economic burden on patients, their families, employers, and pay- ers.14-17 Aside from substantial direct medical costs, the condition is also associated with indirect costs stemming from lost work productivity.14-16 In a US insurance database analysis of more than 60,000 people with fibromyalgia and age- and sex-matched control subjects, the mean and median total health care costs were approximately 3 and 5 times higher, respectively, for the fibromyalgia group than for the matching control group ($9,573 vs $3,291 and $4,247 vs $822, respectively, P < .001 for each comparison).17 People with fibromyalgia had 4 times as many physician office and emergency department visits, and were almost 4 times as likely to receive pain-related and nonpain-related prescription medications, including antidepressants, compared with the control group (both comparisons, P < .001). Almost half of people with fibromyalgia had health care encounters for symptoms other than chronic widespread pain; namely, headache, abdominal pain, chest pain, fatigue, and gastrointestinal symptoms. Additionally, significantly more people with fibromyalgia had comorbid psychiatric conditions than did the control subjects (P < .001).17
For several decades, researchers have tried to elucidate the pathology in the muscle tissue thought to be the major underlying cause of pain for most people with fibromyalgia. The name fibrositis was initially coined for this disease entity, owing to the speculation that inflammation of muscle tissue was intrinsic to the overall pathophysiology of the condition. Fibrositis was subsequently renamed fibromyalgia syndrome in the mid-1970s following research findings that true inflammation in musculoskeletal or fibrous tissue was not the cause.18 In 1990, the American College of Rheumatology defined fibromyalgia using 2 main criteria:19
• History of widespread pain in the axial distribution (bilateral, upper and lower body, as well as spine) present for ≥3 months
• Excessive tenderness elicited on palpation in at least 11 of 18 specified muscle-tendon points

PATHOPHYSIOLOGY AND CLINICAL SPECTRUM OF FIBROMYALGIA
A BRIEF OVERVIEW FOR MEDICAL COMMUNICATORS
By Madhurima Dhar, MD, MS
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Clinical Features
There are 4 main components in fibromyalgia: pain, fatigue, mood, and function. Along with pain, morning stiffness and fatigue are present in over 73% of people with fibromyalgia. Sleep disturbances are also highly prevalent; it is estimated that up to 99% of people experience some problem with sleep.1,4,8-22 Symptoms of nonrestorative sleep predict increased levels of pain and decreased levels of physical functioning in fibromyalgia. Based on electroencephalographic examinations, the major component of sleep architecture affected is slow-wave sleep or the 4th phase, which is the deepest stage of sleep. Cognitive impairment, often referred to as "fibrofog," and neuropsychiatric disturbances, such as anxiety and depression, also constitute important aspects of the clinical spectrum.1,4,8-22 Auxiliary features of fibromyalgia include skin tenderness, post-exertional pain, exercise intolerance, irritable bowel syndrome, overactive bladder syndrome or interstitial cystitis, tension and migraine headaches, dizziness, fluid retention, paresthesias, restless leg syndrome, and Raynaud’s phenomenon.1,4,8,20-24 Comorbidities, such as chronic fatigue syndrome, myofascial pain syndrome, hypothyroidism, systemic lupus and other inflammatory rheumatic diseases, can complicate the diagnosis of fibromyalgia. However, unlike these comorbidities, fibromyalgia is not associated with abnormal radiographic or laboratory findings.1,4,6,20-22

GENERAL PATHOPHYSIOLOGY
The pathophysiology of fibromyalgia involves a complex, cyclical interplay of dysfunction of the central pain modulatory system, autonomic nervous system, and neuroendocrine network (Figure 1).1,4,8,18,20-24 There are 2 pivotal elements of the central pain modulatory dysfunction in fibromyalgia: central sensitization and temporal summation. Central sensitization implies enhanced excitability of neurons within the dorsal horn of the spinal cord, resulting in augmented spontaneous nerve activity and hyperactivity across multiple spinal segments via large- and small-caliber primary afferent fibers. A key contributor to this neuronal hyperactivity is a phenomenon known as temporal summation, or "wind-up," wherein the intensity of rapidly repeated noxious (ie, painful) stimuli culminates in prolonged stimulation of the unmyelinated nociceptive or pain-sensing group C nerve fibers. N-methyl-D-aspartate (NMDA) receptors, found at the postsynaptic membrane of neurons within the dorsal horn of the spinal cord, may play an integral role in central sensitization and temporal summation of the noxious stimuli. Activation of NMDA receptors by the neurotransmitter glutamate include the peptide neurotransmitter substance P and the release of nitric oxide via neuronal nitric oxide synthase.1,4,8,18,20-24

Once central sensitization has been established, subsequent sensitivity to painful stimuli is increased or exaggerated (hyperalgesia), the threshold for the activation of new noxious inputs is reduced (allodynia), and endogenous nociceptive inhibitory control is reduced, resulting in chronic widespread pain, which is perceived as dull, aching, or burning (Figure 2).1,4,8,20-24 This form of regional neuronal hyperactivity has been demonstrated via neuroimaging techniques, such as functional magnetic resonance imaging and single photon emission computed tomography in studies involving noxious or heat stimuli.25,26 People with fibromyalgia may also have a global disturbance in somatosensory processing rather than an isolated abnormality in pain processing, as indicated by heightened responsiveness or lower threshold for a range of sensory stimuli, including light, auditory, tactile, heat, cold, odor, and pressure.1,4,20-24

Figure 1. The pathophysiology of fibromyalgia involves a complex, cyclical interplay of dysfunction of the central pain modulatory system, autonomic nervous system, and neuroendocrine network, leading to chronic widespread pain, nonrestorative sleep, and cognitive dysfunction. HPA=hypothalamic-pituitary-adrenal
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Because fibromyalgia pain is not associated with peripheral structural damage or inflammation, the underlying cause of interference in pain processing remains unclear. Sensitization of the central nociceptive system may occur as the result of a variety of sensory inputs; namely, a physical insult resulting in traumatized tissue, inflammatory mediators and localized pain, or a psychologic insult, such as chronic stress. Researchers have demonstrated altered pain processing in fibromyalgia via brain imaging studies. Russell et al. found that the level of substance P in the cerebrospinal fluid was 3-fold higher for people with fibromyalgia than in matched controls. In another study, Harris et al. found elevated levels of glutamate in the insula of people with fibromyalgia; these high levels were shown to predict levels of experimental pressure-evoked pain thresholds and clinical pain ratings. Nerve growth factor, which stimulates the production of substance P in small afferent unmyelinated neurons and interneurons, has also been found to be elevated in the cerebrospinal fluid of people with fibromyalgia.

Role of Stress
Fibromyalgia is considered a “stress-associated syndrome” because of its frequent onset after acute or chronic stressors and symptoms are often exacerbated during periods of physical or emotional stress. In addition to central sensitization, the sensory inputs activate circuits of other systems that play a role in stress responses, such as the limbic system, the autonomic nervous system and the neuroendocrine system, including the hypothalamic-pituitary-adrenal (HPA) axis. Although no anatomic or structural pathology has been found within these systems, dysregulation of the HPA axis in people with fibromyalgia is characterized by a low integrated basal cortisol level (measured by 24-hour urinary free cortisol), and blunted cortisol secretion in response to stress-induced pituitary adrenocorticotropic hormone release and exercise. Abnormalities of related neuronal networks, particularly decreased serotonergic activity and an abnormal growth hormone axis, may also contribute to the observed neuroendocrine perturbations in fibromyalgia. The increased sensitivity to stressors and the altered pain processing of fibromyalgia contribute to the typical constellation of symptoms, ie, fatigue (physical and mental), negative mood, nonrestorative sleep, impaired memory and cognitive function, syncope, morning stiffness, Raynaud’s phenomenon, and intestinal irritability.

Dysautonomia, or disturbed autonomic system activity, is another integral element within the clinical spectrum of fibromyalgia. Dysautonomia manifests as hyperactive sympathetic and decreased parasympathetic activity. Chronic stimulation of α-adrenergic receptors of the sympathetic nervous system leads to receptor desensitization, stress hyporesponsiveness, and central hyperalgesia. Selective sympathetic blockade with guanethidine in people with fibromyalgia reduces pain and the number of tender points; norepinephrine injections can restore these symptoms. The enhanced peripheral sympathetic nervous system activity may lead to a generalized peripheral vasoconstriction (in addition to other autonomic responses), which reduces blood flow to skeletal muscles. In this condition, a relatively mild challenge (eg, stretching or light exercise) can evoke ischemia of skeletal muscle, alter muscle metabolism and sensitize ergoreceptors. The decline in energy expenditure of skeletal muscle is indicated by biochemical markers such as low levels of phosphocreatine, resting ATP, phosphorylation potential, nitric oxide, and total oxidative capacity. Discrete histopathologic changes include a reduction in the number and size of skeletal muscle mitochondria, along with muscle degeneration. These changes may underlie the reduced maximal exercise time and exertional fatigue experi-
enced by people with fibromyalgia. Muscle ischemia and altered metabolism activates nociceptors, resulting in a generalized sensitization to pain within the skeletal muscle and multifocal, spatially distributed allodynia and hyperalgesia.\textsuperscript{1,4,8,20-22}

Therefore, changes in peripheral factors, especially intramuscular microcirculation and muscle metabolism, can act as excitatory triggers for multifocal muscle pain and further sensitization of the central pain-processing system. Activation of the central nociceptive system will complete a reverberating feedback loop traversing the intrinsic pathophysiological elements involved in fibromyalgia, wherein a trigger such as tender points, tissue trauma, exercise, or stress, at any point can initiate and express the array of symptoms typical of fibromyalgia.\textsuperscript{1,4,20-22}

**Management Issues**

Management of fibromyalgia is complicated by its unknown pathophysiology and the overlap of its symptoms with other chronic conditions (eg, chronic fatigue syndrome, myofascial pain, systemic lupus). The development of focused and mechanistically based therapeutic modalities targeting the array of symptoms of fibromyalgia has been limited. This is due in part to the debate of whether fibromyalgia is a single entity or a constellation of symptoms. Current management involves integrating physical, psychosocial, and behavioral factors into the overall therapeutic approach. This multidisciplinary approach focuses on the use of a rehabilitation model that integrates exercise, including cardiovascular training, strength training, aerobics (eg, cycle ergometry, walking, jogging, and water-based activities), flexibility training; education (eg, stress management programs, cognitive behavioral therapy, electromyography biofeedback, heart rate variability biofeedback, meditation-based stress reduction, tai-chi, and yoga therapy); and pharmacologic treatments.\textsuperscript{1,2,4,8,12,20,21}

Although the European League Against Rheumatism\textsuperscript{33} and the American Pain Society\textsuperscript{44} recommend the rehabilitative model, it is not a universally accepted treatment algorithm.\textsuperscript{1,4,8,12,20}

The goal of pharmacotherap y in fibromyalgia is primarily the alleviation of pain and improvement of mood-related symptoms. Nonsteroidal antiinflammatory drugs (eg, naproxen and ibuprofen), opioids (eg, tramadol), and corticosteroids (eg, prednisone) are not consistently effective for the treatment of fibromyalgia symptoms because these symptoms are not caused by peripheral structural damage or inflammation. Sedative hypnotics (eg, temazepam, alprazolam, and bromazepam) that modulate the benzodiazepine receptor complex located on the neuronal GABAA receptors have also demonstrated inconsistent relief of symptoms in people with fibromyalgia.\textsuperscript{1,4,8,20,21}

Antidepressants, including selective nonadrenaline reuptake inhibitors (eg, duloxetine and milnacipran), selective serotonin reuptake inhibitors (eg, fluoxetine and paroxetine) and tricyclic antidepressants (eg, amitriptyline, dothiepin), are used for addressing myriad fibromyalgia symptoms. The role of antidepressants in fibromyalgia stems from their potential to dampen pain signals by enhancing the activity of serotonin and norepinephrine within the descending inhibitory system that links the periaqueductal gray and the rostral ventromedial medulla with the spinal cord. Duloxetine has a balanced inhibitory profile of serotonin and norepinephrine reuptake, whereas milnacipran, similar to amitriptyline, preferentially inhibits norepinephrine reuptake but also exhibits weak NMDA receptor inhibition.\textsuperscript{1,4,8,20,21}

Inhibitors of voltage-activated pre-synaptic calcium channels containing the α,δ-1 subunit block the influx of calcium into nociceptive nerve terminals and inhibit the release of neurotransmitters glutamate and substance P, thereby attenuating the abnormal postsynaptic hyperexcitability of these neuronal networks. Functionally, α,δ-subunit ligands (eg, gabapentin and pregabalin) exhibit use-dependent properties enabling them to significantly modulate sustained neuronal depolarization or hyperexcitability, while minimally altering physiological synaptic function.\textsuperscript{1,3,4,8,18,20,21}

The clinical efficacy and tolerability of the therapeutic interventions, as well as their impact on quality of life, vary among people with fibromyalgia. To date, 3 agents have received FDA approval for this indication: milnacipran (Savella), duloxetine (Cymbalta), and pregabalin (Lyrica).\textsuperscript{1,3,4,20,21} A novel compound currently under clinical evaluation for the treatment of fibromyalgia is sodium oxybate, a GABA receptor agonist and sodium salt of the GABA precursor gamma-hydroxybutyrate. Studies indicate that sodium oxybate significantly improves the major symptoms of fibromyalgia (ie, pain, tenderness, sleep quality, and fatigue), possibly by consolidating and improving the quality of deep sleep.\textsuperscript{35}

**SUMMARY**

Fibromyalgia is a chronic and debilitating pain syndrome of unknown etiology and unpredictable course that is characterized by central sensitization and widespread pain in peripheral tissues, psychologic distress, fatigue, and sleep disturbances. The condition has a negative impact on health and quality of life and also imposes a tremendous financial burden. Over the past decade, abnormalities have been identified at multiple levels in the peripheral, central, and sympathetic nervous systems, as well as the HPA axis stress-response system. The overall management of this condition involves a multidisciplinary approach that integrates both pharmacologic and nonpharmacologic therapies that aim to improve the quality of life. An individually tailored, multidisciplinary, pharmacologic, rehabilitative, and cognitive-behavioral approach currently seems to be the most effective.

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RESEARCH REPORT: MEDICAL COMMUNICATION PRACTICE AND TRENDS IN PHARMACEUTICAL AND BIOTECHNOLOGY COMPANIES*

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ABSTRACT

Background: Pharmaceutical companies employ many medical writers, but little is known about their work environments or how work quality and productivity are measured.

Objective: To explore these issues, AMWA and CMR International (a Thomson Reuters company that conducts pharmaceutical/biotechnology industry research) surveyed medical communication managers at pharmaceutical companies.

Methods: The survey was conducted in November and December 2009. Potential participants were identified from AMWA membership and CMR client companies. Payment of a fee to CMR was required to participate and to access resulting data.

Results: Of 13 responding companies (15 individual respondents), 61% were headquartered in the United States, 31% in Europe, and 8% in Japan. All were among the 50 largest in the industry; 62% were among the 20 largest. Medical communication was usually organized into separate departments (80%); regulatory writing and scientific publication functions were always separate from each other. Outsourcing of writing projects had increased during the past 3 years for 47% of respondents; 60% expected it to increase over the next 3 years. More than half (57%) of respondents said the quality of work produced by internal staff members was better than that of outside vendors, and 62% of managers rated the productivity of outside vendors and internal staff as not different. Respondents who hire new managers, writers, or editors said that certificates or certifications from medical communication organizations may differentiate candidates who are considered equally qualified.

Conclusions: Despite the small sample size and other study limitations, this survey provides unprecedented insight into the work of writers, editors, and managers in the medical communication industry. We recommend more research, involving a broad population of communicators, to follow-up on trends and issues identified in this report.

A pproximately one quarter of AMWA members work directly for pharmaceutical companies, biotechnology companies, or clinical research organizations; another one third are freelances, many of whom work indirectly for these firms. Their work involves collaboration with colleagues to develop regulatory submission documents, peer-reviewed manuscripts, presentations for medical congresses, and a wide variety of other types of industry-related communications.

Published research about medical communication in the pharmaceutical and biotechnology industries is limited and tends to focus on financial data and trends. AMWA and its sister organization, the European Medical Writers Association (EMWA), conduct surveys reporting on members’ salaries and the variables that affect them. A 2008 analysis by CenterWatch, a pharmaceutical industry market research firm, reported that the market for regulatory documentation, which was valued at nearly $700 million in 2008, will continue to grow in response to new drug development and increasing demands by regulatory agencies.

Much remains to be learned, however, about the evolving roles of medical writers and the environments in which they work. In 2009, AMWA began an exploration of options for conducting research into the work of medical communicators, with the objective of furthering its mission to promote excellence in medical communication and to provide educational resources in support of that goal. The 2008 AMWA Member Needs Assessment noted the desire of AMWA members for industry research. AMWA representatives (authors SH, TG, LL, and CH) approached CMR Consulting, a Thomson Reuters Company that provides research and consulting services to global pharmaceutical and biotechnology companies, to discuss collaboration on such research. CMR’s clients include large pharmaceutical and biotechnology companies in the United States, Europe, and Asia; its work focuses on research and development productivity and strategy. Although medical communicators do not work exclusively for the pharmaceutical and biotechnology industries, these industries appeared to offer an opportunity for pilot research using existing survey and reporting technology developed by CMR. For CMR, the research would provide its clients with new insights into the roles and operations of medical communicators in the research and development process. This report describes the results of that research.

METHODS

Survey Instrument

We developed a survey instrument to conduct research among managers of
departments producing scientific publications and regulatory documentation in pharmaceutical and biotechnology companies and clinical research organizations (CROs). The instrument was a self-administered Web-based survey consisting of 59 questions in 8 categories: organizational structures, products and services, outsourcing, resources, education and qualifications, productivity metrics, quality metrics, and cycle time/review cycle metrics. Survey categories were proposed by research team members and were reviewed by 7 key opinion leaders (KOLs), identified from AMWA membership lists, who were representative of the target survey population. We drafted the survey questions and revised them based on feedback from KOLs. Questions were multiple choice, with free-text fields provided when the response “other” was chosen. While we finalized the survey questions, CMR programmers developed the user interface based on an existing shell. Research team members tested the survey, and programmers made final corrections.

Survey Funding
Because no AMWA funding was available for this project, participating companies were required to pay a fee to CMR, for which they would receive customized reports comparing their own responses with blinded data from other participants. AMWA team members and KOLs performed their work on an uncompensated volunteer basis.

Survey Marketing
The AMWA Executive Committee formally approved the survey project in July 2009. Communication with AMWA members about the survey began in August 2009, with a 1-paragraph announcement in the AMWA Update e-mail newsletter (sent monthly to all members) that included a response link. We also posted information on the AMWA Web site. AMWA members received a second AMWA Update announcement in September 2009, and CMR offered information at its booth at the AMWA annual conference in October 2009. From August through October 2009, CMR staff members marketed the project to CMR’s existing clients and contacts in the United States, Europe, and Japan. CMR also sent a prospectus describing the project to anyone who expressed interest. Finally, AMWA and CMR team members conducted telephone and personal follow-up from August through October 2009.

Data Collection, Analysis, and Access
Participants were provided secure access to the survey instrument online, and data entered through this interface were collected and stored in secure servers managed by CMR. At the close of the survey, the database was locked and analysis was conducted with the use of SQL Server. The results were presented via an online analysis tool through which participants could compare their responses with the overall survey dataset. Although CMR analysts were able to identify participants during data processing and analysis, data were blinded so that respondents’ identities were not disclosed to other participants. CMR provided AMWA with a final report of the aggregated data from all participating companies; AMWA did not have access to the identities of respondents or individual company data.

RESULTS
Participating Companies
A total of 15 individuals in 13 companies participated in the survey. Respondents were directors and managers of medical communication departments in large pharmaceutical and biotechnology companies in the United States, Europe, and Japan (Figure 1). Although we also marketed the survey to CROs and medical device companies, none participated. Of the 15 individual respondents, 7 had responsibility for regulatory submission documents, 5 for scientific communication, and 3 were responsible for both types of medical communication.

Organizational Structures, Resources, Products, and Services
The medical communication functions were separate and distinct organizational structures in all the participating companies; however, responsibility for specific document types was sometimes shared between communication departments and other functions. Document types for which respondents had either sole or shared responsibility included educational materials, health technology assessment dossiers, peer-reviewed publications, presentations, posters, book chapters, and regulatory documentation. None of the respondents were responsible for competitive intelligence, market research, marketing materials, or public relations. For half of respondents, preparation of regulatory documents occupied 90% to 100% of their departments’ time.

The median size of the medical communication groups represented in the sample was 19 full-time employees (10th and 90th percentiles: 9, 45). Although 73% of respondents said their departments had grown over the last 3 years, only 47% expected department growth in the next 3 years; most others expected no change. Most departments were staffed primarily by full-time employees, supplemented by a small proportion of contractors and part-time employees. Most employees worked on-site.

Medical communicators reported collaborating extensively with other

Figure 1. Profile of participating companies.
departments, including clinical development (93%), pharmacovigilance and regulatory operations (both 87%), clinical operations and preclinical research (both 73%), marketing (60%), legal (53%), pricing or health outcomes (40%), manufacturing (33%), and public relations (20%). Extensive collaboration was reported for all the document types produced.

**Outsourcing**

Most investigator brochures and clinical study reports (phases 1–3) were developed in-house (Table 1). Respondents’ companies outsourced preparation of all educational materials, annual reports, protocols, health technology assessment dossiers, and marketing materials; most slide presentations, abstracts, and posters; and half of manuscripts for scientific publication.

Outsourcing of writing and editing increased in fewer than half of companies over the past 3 years (Figure 2), but outsourcing of writing will likely increase over the next 3 years in the majority of companies. Outsourcing of editing, project management, quality control (QC), and fact checking was not expected to change in the majority of companies. Most respondents (93%) cited resourcing constraints as the most important reason for outsourcing; other common reasons were good experience with particular vendors, specialized vendor knowledge, and cost. Respondents reported that a median of 3 full-time employees (10th and 90th percentiles: 0.2, 12) were required to support their outsourcing efforts. Medical communication departments outsourced work to individual freelances and to agencies in approximately equal proportions, although some respondents used only agencies and others used only individual freelance writers and editors.

**Out-of-country Vendors**

The use of out-of-country vendors was rare: out-of-country vendors wrote only 2.5% of peer-reviewed manuscripts, and no other document types. Respondents reported no other use of out-of-country vendors and no use of emerging-economy vendors. However, half of respondents expected to increase their use of out-of-country vendors over the next 3 years. Three quarters of respondents (75%) cited document quality problems and lack of face-to-face communication as the first or second most important obstacle to using out-of-country vendors.

**Quality and Productivity**

The most commonly used measure of quality was the number of errors or misinterpretations requiring correction (67%), followed by the number of errata arising after publication (50%) (Figure 3). Forty percent of organizations measured quality by the success of the document in meeting its objective, either as a successful regulatory application or an accepted manuscript.

**Table 1. Responses to Survey Questions Regarding Which Types of Documents Are Most Commonly Produced In-house or Are Outsourced**

<table>
<thead>
<tr>
<th>Document Type</th>
<th>Median Proportion (%) Produced In-house</th>
<th>Median Proportion (%) Outsourced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other regulatory documents (eg, briefing books)</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>Investigator brochures</td>
<td>90</td>
<td>10</td>
</tr>
<tr>
<td>Product license applications</td>
<td>90</td>
<td>10</td>
</tr>
<tr>
<td>Phase 3 clinical study reports</td>
<td>82</td>
<td>18</td>
</tr>
<tr>
<td>Phase 2 clinical study reports</td>
<td>82</td>
<td>18</td>
</tr>
<tr>
<td>Phase 1 clinical study reports</td>
<td>70</td>
<td>30</td>
</tr>
<tr>
<td>Manuscripts for scientific publication</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Slide presentations</td>
<td>30</td>
<td>70</td>
</tr>
<tr>
<td>Abstracts</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>Posters</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>Annual reports</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Book chapters</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Investigational New Drug (IND)/Investigational Device Exemption (IDE) applications</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Clinical trial applications (non-IND/IDE)</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Clinical trial protocols</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Drug master files</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Educational material for healthcare professionals</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Educational material for patients or caregivers</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Health technology assessment dossiers</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>IND/IDE annual reports</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Marketing materials</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>News articles, press releases and other content for the public or investors</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Patient informed consent forms</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Product license annual reports</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Product license renewals</td>
<td>0</td>
<td>100</td>
</tr>
</tbody>
</table>
Productivity was measured most frequently by the number of documents completed in a given timeframe or the actual time required to produce a specific draft (Figure 3). Comparison of results with previous years and the proportion of documents produced on schedule were also reported as productivity measures.

More than half of respondents (57%) said that the quality of work of internal staff members was of higher quality than that of outside vendors, whereas 43% reported no difference (Figure 4). The productivity of internal staff members and outside vendors was seen as not different by 62% of respondents (Figure 4).

**Education, Qualifications, and Certificates**

Approximately half (53%) of staff members in respondents’ medical communication departments earned their initial degree in the life sciences. One third held a doctoral degree in the life sciences, and 30% held a master’s or professional allied health degree. For entry-level writers, approximately half of respondent companies required candidates to have a bachelor’s degree, 23% required a life-sciences degree, and 15% required a doctoral degree. For entry-level editors, 75% of companies required a bachelor’s degree and 17% required a doctoral degree. Nearly 90% of staff members had at least 3 years’ experience, and 60% had at least 6 years’ experience. Within participating companies, all writers, editors, and managers were members of professional associations. AMWA membership was most common (80%), followed by the Drug Information Association (DIA) medical writing special interest area community (SIAC) (60%) (Figure 5).

Most companies value certificates or certifications from medical communication organizations when hiring new managers, writers, and editors (Figure 6). Many respondents said these factors could help to tip the balance in favor of one candidate over another equally qualified candidate.

**Review Cycles and Cycle Time**

For most document types, the median number of review cycles was 3, with a range of 2 to 4 for most document types and a median of 20.5 cycles for product license annual reports. The median total work time from the physical assignment of resources to final document completion ranged from 2 or 3 days for an abstract to 60 days for the clinical summary of a product license application. Respondents provided detailed data about the elapsed time and number of working days required to produce 25 different document types, including median time required for each step of the process.

**DISCUSSION**

This research into the medical communication operations of 13 companies in the United States, Europe, and Japan found that medical communicators worked in distinct organizational structures producing a wide variety of document types. Managers reported growth in the past 3 years, but expected no change in their department’s growth over the next 3 years. This finding is similar to those of the 2008 and 2010 AMWA member needs assessments in response to questions about hiring trends.1,6 Development is outsourced for many document types. This finding is consistent with outsourcing data reported by CenterWatch, which found that 41% of respondents used outsourced medical writing services.2 Many managers perceived no difference in the quality or productivity of the work of outside vendors compared with that of
one half to measure productivity. This finding suggests an area in which additional research might help to identify innovative metrics.

Nearly two thirds of medical communicators have master’s or doctoral degrees, and 60% of staff members have at least 6 years’ experience. Professional association membership was universal in this population; most staff members in these companies were members of AMWA, which is not surprising because AMWA databases were used to identify potential participants.

We were encouraged to see that advanced degrees, extensive experience, and professional association membership were common; we consider these characteristics to be signs that medical communication is maturing and increasing in stature as a profession. Another encouraging sign is that certificates and certifications conferred by medical communication organizations were considered valuable by 92% of respondents hiring editors and 79% of those hiring writers (Figure 6). Such certificates and certifications provide evidence of a communicator’s commitment to achieving professional excellence.

A striking finding was that medical communication is not solitary work; writers, editors, and managers collaborate extensively with colleagues in other departments in their organizations. Extensive collaboration and review were reported for all the document types produced. These data suggest that scientists and communicators are forming effective partnerships in which each contributes his or her specialized knowledge and skill.

Although the small size of this sample limits the ability to generalize from these results, our findings contradict widely held beliefs but are consistent with the limited data available regarding medical communication staffing trends and outsourcing.2 The survey had a potential for bias on the basis of its participant-recruiting focus on AMWA and existing clients of CMR, which tend to be large companies, and the survey did not directly ask what overall proportion of work was outsourced. It would be useful to obtain information from a broader population of medical communicators in different organization types, such as universities, health centers, and communication agencies, as well as those in countries outside the United States and Europe.

Despite these limitations, this survey provides unprecedented insight into the work of writers, editors, and managers in a large

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**Figure 3. Quality and productivity measures.**
segment of the medical communication industry. For organizations like AMWA, the extent of collaborative work suggests the need for new research and education regarding mechanisms and best practices for collaboration in medical communication. Future research should also include smaller employers to characterize the ways in which they might differ from larger employers. A broader population of participating communicators would also be desirable, potentially through collaboration with other medical communication organizations, as was recommended by Karen Woolley in her 2009 Keynote Address to AMWA members.7 We recommend that AMWA continue its commitment to industry research, conducting follow-on studies to identify emerging trends and issues. This research complements AMWA’s regular membership and salary surveys to provide members with a greater understanding of the medical communication industry.

CONCLUSIONS
Medical communication departments in pharmaceutical companies are efficient organizations with well-educated, experienced, professional staff members. They measure success by both quality and quantity and find productive, high-quality communicators both in their own organizations and among their vendors. Medical communicators who wish to thrive in this environment should continue to pursue education, skills training, and research so they will be prepared for the opportunities ahead.

Acknowledgments
The authors thank members of the AMWA Executive Committee for their assistance in identifying potential participants and developing the study questionnaire. We also thank Donna Munari and the AMWA headquarters staff for providing AMWA membership data and administrative support.

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References

AMWA and CMR will soon begin a 2011 research program, based on the methodology of the research reported here. More information is available online (link) or by e-mailing Research_2011@amwa.org.
PHARMACEUTICAL MEDICAL WRITING COMPETENCY MODEL*

By David B. Clemow, PhD,* and the Drug Information Association Medical Writing Special Interest Area Community Competency Model Working Group*

*Scientific Communications Consultant, Eli Lilly and Company, Indianapolis, IN

In 2009, members of the Drug Information Association (DIA) Medical Writing (MW) Special Interest Area Community (SIAC) Competency Model Working Group developed a competency model to describe the work functions, activities, knowledge, skills, and behaviors deemed necessary to perform successfully as a medical writer in the pharmaceutical industry.

To understand the basis behind the content of the medical writing competency model, it is important to define competency. Competency is the ability of an individual to perform a specific role successfully; a competent professional is one who has a combination of knowledge, skills, and behavior qualifying him or her to perform a particular role or job successfully.1,2

A competency model defines what competence looks like for a given profession and contains a professionally agreed-upon written list of the skills, knowledge, and behavior (competencies) that defines successful job performance. The model typically includes an outline of activities that a person in the role must perform to be successful.

The content of this competency model encompasses the diverse skills of a pharmaceutical medical writer, including the essential, but not sufficient, core skill set (writing) that differentiates a medical writer from other pharmaceutical professionals. The model has 2 main structural components, the first focusing on 9 work functions deemed to be activity areas where competency is needed. For each of these work functions, there are associated behavioral benchmarks; and for each benchmark, there are several related critical activities. The second structural component of the model describes technical knowledge, skills and abilities, and behaviors deemed necessary for competent medical writers. This section is divided into subsections for all medical writers, regulatory writers, and publication writers.

Presented here is the core content of Version 1.4 of the Competency Model that was made available to DIA membership in June 2009. Only some introductory text and text related to supervisors of medical writers and additional general abilities was excluded to adjust for space limitations.

The content expressed in this model is based solely on the opinion of the individual contributors and should not be attributed in any way to the Drug Information Association (DIA) or any of the companies/organizations (or employees or departments within the companies/organizations) with which the contributors are employed or affiliated. The DIA Medical Writing Special Interest Area Community was used as a conduit for members to gather medical writing professionals to develop the model. The Working Group Members are listed in an expanded online article. Editor’s note: The model is presented here as submitted, without editing.

WORK FUNCTIONS, CRITICAL BEHAVIORS, & ACTIVITIES

› Work Function: DOCUMENT PREPARATION

Behavioral Benchmark 1: Thoroughly gather, review, and analyze pertinent resources or data to produce a high-quality document that meets internal and external customer needs.

Critical Activities:
1. Review applicable guidelines (eg, regulatory, publication, company, and industry), templates, and/or research literature.
2. Obtain, compile, and organize the appropriate data, background information, and other materials needed to compose the document.
3. Analyze and interpret data and other information in order to determine the best approach to composing the document.

Behavioral Benchmark 2: Plan document architecture and content with cross-functional areas by bringing the team to consensus, thus ensuring that the document contains the information necessary to meet internal and external customer needs.

Critical Activities:
1. Meet with cross-functional team (eg, statistics, clinical development, medical, and regulatory) members to review gathered information and guidance to plan for a high quality document that meets industry and company requirements, standards, regulations, and development (eg, clinical, nonclinical, biopharmaceutic, clinical pharmacology, and CMC) needs.
2. When applicable (eg, clinical study reports or manuscripts), participate in planning sessions for statistical output; ensure output content meets regulatory or publishing requirements and clinical development needs.
3. Work with cross-functional team and external consultants (eg, regulatory affairs or publication planning) to determine the purpose of the document (eg, support an indication or other label claim).
Behavioral Benchmark 3: Author document, integrating cross-functional input, to ensure that the document communicates the information necessary to satisfy internal and external audience needs.

Critical Activities:
1. Compose the initial draft of a document by referring to all information compiled in preparation for composition.
2. Integrate into the initial draft the input, expertise, and opinions from members of the authoring team and internal/external experts and business partners.
3. Build persuasive and scientific-based arguments when drafting documents that will support the regulatory, publication, or other purpose of the document.
4. Provide advice, support, and composition for designing content that can be reused in other deliverables (content reuse; eg, summary document to label).

Behavioral Benchmark 4: Revise document while facilitating issue resolution among team members to deliver a document with quality, speed, and value.

Critical Activities:
1. Revise document drafts based on the review comments from authoring team or extended team members to ensure inclusion of all relevant input from the team.
2. Compose the final document by referring to reviewers’ input and other information compiled.
3. Ensure data consistency and document integrity across the document by critically evaluating comments and incorporating them appropriately.
4. When authoring team or reviewers are in disagreement, facilitate and negotiate issue resolution and decision-making and incorporate outcomes into the draft/final document.
5. Document resolution and the rationale of significant decision.

Behavioral Benchmark 5: Edit documents within the expectations of the level of edit (format, proofread, microedit [copy edit or line edit], macroedit [substantive or content edit], rewrite, or translation edit) needed for the deliverable based upon document type, stage of development, and request from authoring team.
[Editing may fall to a medical or scientific editor role rather than the medical writer depending upon the organizational situation.]
5. As document preparation progresses, assess and prioritize needs (eg, information, input, and resources) in order to stay on track with work plan.

Behavioral Benchmark 4: Demonstrate leadership during conflict, disagreement, or timeline delays, thereby facilitating document completion in a professional and timely manner.

Critical Activities:
1. Maintain awareness of potential delays, problems, or gaps of information that exist in the team effort of document preparation in order to effectively manage the process.
2. Mediate conflict among team members and others by negotiating, compromising, persuading, and facilitating the open exchange of ideas and opinions in order to come to consensus.
3. When necessary, influence or negotiate change of the timeline with other team members in order to have a viable back-up plan when the document preparation process has delays.
4. When necessary, enlist the aid of project management and/or functional management to ensure progress on document preparation and completion.

Behavioral Benchmark 5: Facilitate document approval, finalization, electronic publishing and submission, as applicable to the job function.
[Submission and publishing may fall to a separate submission or publishing group.]

Critical Activities:
1. Facilitate document management activities to ensure that the document is approved and ready for publishing/submission in a timely manner according to agreed-upon timelines.
2. Ensure appropriate formatting and hyperlinking for e-publishing and submission.
3. Facilitate publishing and submission activities to meet final document delivery timelines by acting as a liaison between publishers, submission experts, and the authoring team.
4. Ensure quality document submission to regulatory bodies, congresses, or journals (acceptance by target audience), following applicable guidelines (eg, instructions to authors for a manuscript), formatting, and hyperlinking for e-publishing.
5. Ensure appropriate document life-cycle management (eg, short- and long-term storage, archiving, and retrieval).
6. Contribute to the development, implementation, and maintenance of document management system.

Work Function: STRATEGIC COMMUNICATIONS AS INTEGRAL PROGRAM (PROJECT) TEAM MEMBER

Behavioral Benchmark 1: Analyze proposed programs, individual studies, and related documents for their ability to deliver the information required by the target audience (eg, regulatory authority) with accuracy and consistency.

Critical Activities:
1. Understand issues affecting design of product strategy, and understand how study design, data capture, and statistical analysis plan design will affect downstream documents.
2. Critique ability of product strategy (eg, submission or publication plans) to deliver to business objectives or meet regulatory needs, and identify where new, additional, or alternative arguments are needed.
3. Understand where all intended messages will be located across individual documents within a program, and ensure alignment of messages across documents.
4. Ensure that study designs and document designs will contribute the necessary information to meet audience needs.

Behavioral Benchmark 2: Align, coordinate, and build consistent information and messages across all individual documents (eg, multiple document components of a New Drug Application; eg, documents for same compound developed separately over time [eg, protocol 1, protocol 2, study report 1, and study report 2!]), starting with initial strategic plans, continuing through study-level documents to final program-level deliverables (eg, prescribing information for a regulatory submission or publication of key journal articles for a publication plan).

Critical Activities:
1. Lead cross-functional teams to develop a messaging strategy across a program of work (eg, building a clinical submission or data disclosure plan).
2. Develop prototypes or key message language for key documents to aid in consistent and integrated messages. Help ensure alignment of these development documents with downstream documents (eg, study report, submission document, manuscript, and intended product label).
3. Manage issues that impact messaging strategy (eg, high-light impact of unexpected results or data quality issues).
4. Set program-level standards (eg, style conventions).
5. Build convincing clinical or regulatory arguments in the absence of direct data, using logic, analogy, and therapeutic area science.
6. Ensure that data and the way data are described are consistent across documents.

Behavioral Benchmark 3: Act as a document and cross-document specialist, providing intellectual leadership and contributing document knowledge and expertise.

Critical activities:
1. Ensure historical records are kept electronically (eg, regulatory rationale or rationale for agreed upon variation).
2. Ensure that the project team plans are consistent with
targeted audience (eg, regulatory authority) document requirements; provide alternatives and suggestions based upon experience.

3. Ensure that the project team’s arguments and strategy are sound, consistent, and in alignment with strategy (eg, do not present an argument to a regulatory body inconsistent with a previously sent argument) and audience requirements.

4. Act as a document content historian for program/project team and proactively provide insight, ensuring that team decisions, key messages, issue resolution, and positioning are reflected within and across all program documents.

Work Function: MULTIPLE DOCUMENT COORDINATION (eg, SUBMISSION OR PUBLICATION PLANNING AND OVERSIGHT)

Behavioral Benchmark 1: Develop an agreed upon and complete work plan, with all needed tasks, subtasks, timelines, and assigned roles and responsibilities that enables the team to work efficiently and effectively to meet all tasks.

1. Discuss tasks (eg, plan, data production, write, review, edit, quality check, and publish) and subtasks (eg, deliverables, table-figure-listing delivery, and literature compilation) and how the tasks relate across documents, subtasks, and roles and responsibilities of authoring team members and reviewers.


3. Identify resource constraints that may affect timely delivery.

Behavioral Benchmark 2: Lead other writers (as project lead writer, submission coordinator, or publication coordinator) to deliver on work plan with quality and timeliness.

Critical Activities:
1. Manage contribution of other writers working on individual documents.
2. Ensure that appropriate (right person at right time) input and decision making occurs within program team.
3. Ensure that key information received in project or program meetings gets appropriately disseminated such that that project strategy is maintained and that data or key wording changes are incorporated appropriately across documents (eg, changes to safety text mirror label text updates).

Behavioral Benchmark 1: Thoroughly gather, review, and analyze pertinent resources needed to produce high quality document templates and standards.

Critical Activities:
1. Obtain and review current/new regulatory, publication, and industry organization document guidelines, as well as industry initiatives (eg, publications on regulatory websites or information gathered at professional conferences).

Behavioral Benchmark 2: Create and implement agreed upon presentation and document templates and associated guidance tools to allow authoring teams to quickly author quality documents that meet regulatory, corporate, and industry needs and requirements.

Critical Activities:
1. Create document style, format, and writing guides and presentation and document templates to meet regulatory, corporate, and industry needs and requirements.
2. Lead review and obtain approval of new or updated guides and templates, gaining input from local and global stakeholders (eg, regulatory affairs).

Behavioral Benchmark 3: Maintain document style, format, and writing guides, and presentation and document templates.

Critical Activities:
1. Facilitate adherence to and maintenance of guidelines, standards, and templates through interactions with department, corporate, global, CRO, and alliance partners.
2. Proactively determine the needed creation of new or changes to existing guidelines, standards, and templates.

Work Function: OUTSOURCING, ALLIANCE PARTNER, & CLIENT MANAGEMENT

Behavioral Benchmark 1: Ensure that a governance structure is in place with the partner, including guiding and operational principles and associated tools.

Critical Activities:
1. Develop a governance structure that includes operational oversight, whether for one document or an entire development program to ensure a successful relationship.
2. Develop communication plans to ensure continued partner alignment and satisfaction.

Behavioral Benchmark 2: Build and maintain collaborative relationships with partner (CRO, vendor, alliance partner, client, etc) for an effective, efficient, productive, and professional working relationship.
Critical Activities:
1. Use relevant tools and resources to determine whether to use own or partner tools, standard operating procedures, and templates.
2. Participate in bid defense, contract development, work alignment, and/or operation meetings.
3. Build a relationship with the partner in order to enhance communications and effectiveness.
4. Be responsive and available to answer questions from the partner as needed.

Behavioral Benchmark 3: Together with the partner (CRO, vendor, alliance partner, client, etc), develop and implement a complete timeline and work plan that enable the team to work efficiently and effectively.

Critical Activities:
1. Negotiate with partner to determine the author, plan, data production, write, review, edit, quality check, and publishing processes, roles, and mutual expectations.
2. Consult with partner to determine the specifications of document flow and archiving.
3. Negotiate with partner to determine the timeline that will be used for documents.
4. Provide input into work plan.

Behavioral Benchmark 4: Review document, consult with relevant functions, facilitate issue resolution with partner, and maintain general project oversight to deliver a document with quality, speed, and value.

Critical Activities:
1. Review work products from partner as needed.
2. Mediate disagreement and conflict among team and partner by negotiating, compromising, persuading, and facilitating the open exchange of ideas and opinions in order to come to consensus.

Behavioral Benchmark 5: Develop partner assessment program and associated tools to ensure quality deliverables and a maintained positive partner relationship.

Critical Activities:
1. Develop feedback system for checking and maintaining quality document delivery and client/vendor satisfaction.
2. Conduct training and regular lessons learned sharing.

Work Function: CONTINUOUS DEVELOPMENT OF KNOWLEDGE & SKILLS

Behavioral Benchmark 1: Complete training and development activities while eliciting and responding to competency-related feedback to maximize the development of skill sets that benefit the company, client/partner, and career objectives.

Critical Activities:
1. Maintain familiarity and compliance with company and industry competency maps, curriculum maps, technical ladder guidelines, and/or performance management processes in order to establish, pursue, and achieve behavior, outcome, and individual development needs and goals.
2. Perform self-assessment of one’s knowledge and skill set regarding technical and soft-skill areas in order to note gaps and needs for personal development planning.
3. Elicit formal and informal feedback regarding one’s knowledge, skills, and abilities (technical and soft-skill) in order to note gaps and needs for personal development planning.

Behavioral Benchmark 2: Identify and pursue developmental opportunities from a variety of sources (training classes, readings, subject matter experts [SMEs], coaches, professional organizations [meetings, conferences, or seminars], or colleagues), both internally and externally, enhancing critical competencies in a manner that benefits company, client/partner, and career objectives in order to continuously improve skills and knowledge.

Critical Activities:
1. Maintain and enhance technical knowledge, skills, and abilities.
2. Continually improve non-technical knowledge, skills, and abilities.

Work Function: SHARING KNOWLEDGE & EXPERIENCE

Behavioral Benchmark 1: Share knowledge and experience internally and externally to increase competencies, thereby enhancing effectiveness in meeting function, company, client/partner, and career objectives while being resource-focused, service-oriented, and promoting knowledge sharing.

[Coaching (shared learning) activities are particularly important when medical writing "teams" are constructed with "lead writers" assigned to deliver on more complex deliverables (eg, regulatory submission packages); in such situations the lead writer may review multiple documents and coach other writers to ensure quality and timely deliverables that are accurate and consistent across documents.]

Critical Activities:
1. Anticipate and proactively assist individuals (particularly those new to medical writing) by assessing their needs and then providing formal or informal coaching to aid in their development: share technical information, give guidance (eg, best practices), answer questions, and direct them to appropriate resources and contact persons.
2. Review documents and provide meaningful feedback to medical writers on both form and content of documents.
3. Provide assistance (mentor) and help to others in the
areas of soft skills, people interactions, and how things get done with customers/business partners.

4. Provide informal and/or formal feedback on performance, skill, and knowledge-related issues in order to help individuals improve in these areas.

5. Participate in professional association activities (eg, Drug Information Association, American or European Medical Writers Association).

› Work Function: PROCESS IMPROVEMENT

**Behavioral Benchmark 1: Identify best practices and anticipate the need for change in current or future processes, driving efforts to ensure that medical writing processes remain aligned with changing requirements.**

**Critical Activities:**
1. Evaluate critically the current processes, practices, and technologies used by medical writers to find more effective and efficient approaches.
2. Proactively identify and evaluate changes occurring in the internal and external environment to determine ways that processes, technologies, or guidelines can be adjusted to meet changing environment, and then implement and adapt to those changes to improve quality, efficiency, and effectiveness.

**Behavioral Benchmark 2: Develop, implement, and communicate best practices that increase quality, consistency, efficiency, and effectiveness of processes and deliverables.**

**Critical Activities:**
1. Participate on process improvement teams, committees, or similar initiatives in order to partner with others in the effort to improve processes.
2. Through appropriate channels, develop and introduce new processes, methods, or technologies in order to enhance medical writing operations.
3. Communicate process improvements through multiple internal (eg, across departments) and external (eg, professional groups) channels to promote consistency and facilitate their widespread use.

**KNOWLEDGE, SKILLS, ABILITIES & OTHER CHARACTERISTICS**

**ALL MEDICAL WRITERS**

**Technical Knowledge**
1. Techniques of scientific writing and editing
2. Software and systems, including but not limited to:
   • Document management (including associated version control principles, Electronic Records and Electronic Signatures [ERES], records retention, and best practices and approaches)
   • Word processing or authoring (eg, Word)
   • Spreadsheets (eg, Excel)
   • Presentations (eg, PowerPoint and Visio)
   • Databases (eg, Access)
   • E-mail/calendaring (eg, Outlook)
   • Table/figure creation (eg, SigmaPlot)
   • Adobe Acrobat
   • Reference or bibliography management (eg, Reference Manager or EndNote)
   • Publishing
   • Literature searching (including best practices and approaches) and other internet and intranet portals (eg, SharePoint), resources, and search tools
   • Other (eg, file conversion - one format to another)
3. Company policies, procedures, and tools (eg, style guides, templates, and project management worksheets)
4. Functional roles of other members of the authoring team (eg, role played by statistics, clinical research /medical, regulatory, and legal)
5. Industry guidelines:
   • Pharmaceutical regulatory
   • Applicable professional, pharmaceutical, health, and journal organization/society guidelines
   • Clinical trial registry and results posting (eg, FDAAA and State of Maine)
   • Copyright laws and application of those laws, publisher guidelines, or contracts
   • Standards Developing Organizations and their developing standards
6. Science:
   • Therapeutic area, including the safety and efficacy profile of the compound being studied and the associated disease state of interest. [Medical writers should be able to write across therapeutic areas when they have access to drug and therapy area experts on their authoring/project teams.]
   • Biological sciences (from tertiary studies, academics, or other experience)
   • Chemistry, Manufacturing, and Controls
   • Biopharmaceutics
   • Pharmacology (including pharmacokinetics and pharmacodynamics)
   • Absorption, Distribution, Metabolism, & Excretion (ADME)
   • Drug (eg, phases of drug development) and clinical (eg, clinical trial design) development (eg, compound-specific information), including drug development
• Scientific method, including hypothesis testing and clinical research methodologies

7. Statistics: accepted methods of data analysis (descriptive and inferential statistics) and techniques for communication of statistical results

8. Publishing standards, including e-publishing

9. Training (eg, lead writer trains junior writer): adult learning concepts; instructional design (planning the content or delivery of instruction) and communication design (planning the content and delivery of messages for a given purpose)

Technical Skills and Abilities

1. Interpret and communicate clinical and numerical data, verify consistency in data, calculate with data (eg, basic math formulas/concepts), and collect data (eg, chart reviews)

2. Comprehend and communicate scientific concepts; interpret and communicate clinical, nonclinical, bio-pharmaceutic, pharmacology, ADME, and CMC data and information

3. Learn, understand, and communicate statistical concepts, terminology, and analyses within text and tables/figures; interpret results from statistical tests and understand level of significance results; utilize appropriate statistical terminology in tables, figures, and text; present scientific concepts and statistical analyses in a clear and concise manner, making the concepts as simple as possible to fit the targeted audience; express statistical issues as text

4. Author quality documents:
   • Prepare a well written and well thought out structural outline
   • Write with the intended audience in mind; determine document organization and content (within and across documents) that meets project purpose and audience needs
   • Prepare text that is credible and compelling
   • Prepare text that is simple, plain, clear, concise, and correct, with the correct use of spelling, grammar, and punctuation
   • Prepare a correct and complete reference list
   • Prepare table of contents, indexes, hyperlinking, and other document organizational components
   • Design and prepare appropriate figures and tables

5. Conduct an effective literature search

6. Create and layout slides and posters

7. Project manage deliverables; ensure appropriate sponsorship/accountability assigned, work, contingency, timeline, roles/responsibilities, and communication planning and implementation, issue resolution, change control, and meeting organization and facilitation

8. Manage information; manage scientific information flow and accuracy and consistency of that information

9. Edit documents (revise, correct, or rearrange content, language, style, or structure) based upon 'level of edit', with each level of edit containing the tasks associated with the previous level of edit:
   • Format: align with template, company, journal, congress, or regulatory guidelines
   • Proofread (read and mark corrections):
     – Noncomparison proofread (mark absolute errors): internal consistency (text, numbers, and language), reference validation, and style and mechanics (spelling, grammar, punctuation, capitalization, word use, use of units, and abbreviations)
     – Comparison proofread (compare 2 versions of the same document or similar content from 2 related documents [eg, protocol and study report])
   • Microedit (language, copy, line, or mechanical edit): review of text at or below level of paragraph to improve grammar, word choice, flow, voice, syntax, style, logical inconsistencies, clarity, and reduce duplication (eg, text vs table)
   • Macroedit (substantive edit): evaluate content and organization of document at level of document section ensuring congruency, tone, structure, consistency, logic, and completeness, and that needs of audience are met (manage a document's concept and intended use)

10. Quality check documents (check document against source); fact or data check (verify one set of data against another; verifying the accuracy of claims)

11. Rewrite existing documents

12. Interview for information (obtaining needed information from spoken conversations); Focus-group test (obtaining verbal feedback from readers on the qualities of a text)

13. Report information (render an accurate account of a verbal presentation) and summarize (condense someone else's text)

14. Review document content (analytically edit and critically appraise); evaluate statistical presentations and general research methods; peer review (assess the quality and completeness of scientific content and specific research methods based upon personal knowledge); regulatory review (verify adherence to requirements and standards)

15. Translate (transcription) documents from one language to another, appropriately and accurately expressing the content of a text written in one language in another

(This is a specific skill that may (likely will) fall to a professional scientific translator rather than a medical writer; however, translation also refers to the need to conform to American, British, and Indian English, which is needed by medical writers; additionally, bilingual communication skills (English plus local language) is an important skill needed for medical writers in non-English speaking regions)
16. Publish documents; visually design a publication; render (page design), web design, illustrate (drawing or painting biomedical images), photograph (taking photos of scientific images such as surgical procedures); technical draw (eg, rendering charts, graphs, and maps) [This is a specific skill that may (likely will) fall to a professional publisher rather than a medical writer; however, visual design also refers to slide design (layout) and poster design (layout), which is a skill needed for medical writers; additionally, medical writers often have to ensure documents are publish ready (eg, formatted appropriately)]

Behavioral Skills for Technical Contributions
1. Organized
2. Manages time well
3. Pays attention to details
4. Manages multiple tasks
5. Builds positive and productive relationships
6. Makes effective decisions
7. Demonstrates learning agility (ie, is able to come up to speed on new projects quickly
8. Negotiates
9. Resolves conflicts
10. Copes with and adapts to change
11. Creates solutions and influences adoption
12. Strong leadership skills and teaming skills
13. Results and performance driven with bias for proactive action
14. Actions are commercially astute
15. Actions are ethical (eg, ensures appropriate copyright, authorship requirements, and acknowledgements are met; ensures that there is no plagiarism or falsifying and that the subject’s and patient’s best interest are met)
16. Ability to globally work share when working with global project teams
17. Cultural sensitivity and ability to efficiently and productively work in a multicultural teams

REGULATORY MEDICAL WRITERS

Technical Knowledge
1. Regulatory guidelines, such as:
   - International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines and regional regulatory authority interpretation of guidance (every ICH guidance that is relevant to the required task or role, eg, Common Technical Document (CTD) guidance (ICH M4) or electronic CTD guidance (ICH M2)
   - Labeling guidance, including Structured Product Labeling (SPL) and Physician Labeling Rule (PLR)
   - Guidelines for interactions with prescribing physicians
   - e-Submission guidance (eg, ICH, Regulated Product Submissions [RPS], and Study Tagging Files [STF])
   - Regional guidelines (multiple and topic specific):
     - United States (eg, Food and Drug Administration [FDA] Code of Federal Regulations [CFR])
     - Japan (Ministry of Health, Labour, and Welfare [MHLW]/ Pharmaceutical and Medical Devices Agency [PDMA] guidance)
     - Other regions, including important differences in document-related and e-submission guidance.

2. Regulatory authority and global initiatives
3. Understanding of clinical, nonclinical, and CMC requirements to support major regulatory filings
4. Standardization initiatives, such as:
   - Clinical Data Interchange Standards Consortium (CDISC)
   - Clinical Data Acquisition Standards Harmonization (CDASH)
• New Drug Application (NDA; Marketing Authorization Application [MAA]), New Drug Submission [NDS], Supplemental NDA [sNDA], and Supplemental NDS [sNDS]
• non-eCTD Electronic Submissions (NEES) or other modified e-CTDs, and regulatory submission documents for countries that do not accept ICH CTD format
• Nonclinical Study Report
• Pediatric Investigational Plan (PIP)
• Periodic Safety Update Report (PSUR)
• Premarket Approval Application (PAA)
• Premarket notification (510k)
• Protocol (Phase 1-4)
  – Clinical Pharmacology Trial Protocol
  – Clinical Trial Protocol
  – Observational Study Protocol
  – Protocol Amendment
  – Protocol Addenda
• Regulatory Response documents (responses to regulatory agencies; eg, submission inquiries, Japan and EU LOQ, and Canada Clarifix)
• Regulatory submission for countries that do not accept ICH CTD format
• Risk Management Plan (RMP; Risk Evaluation and Mitigation Strategy [REMS])
• Risk Profile
• Safety Narratives
• Safety Updates
• White Paper
3. Prepare documents suitable for e-publishing and that are publishing ready

**PUBLICATION MEDICAL WRITERS**

**Technical Knowledge**

1. Publication guidelines, such as:
   • Good Publication Practice for Pharmaceutical Companies
   • Uniform Requirements for Manuscripts Submitted to Biomedical Journals
   • Position Statements from medical writing organizations (eg, AMWA, EMWA, and ISMPP)
   • Interactions with prescribing physicians, investigator-authors
2. Publication Planning and Coordination
3. Publication planning systems/software
4. Reporting guidelines, such as:
   • Consolidated Standards of Reporting Trials (CONSORT) – for randomized trials
   • CONSORT for Abstracts

**Technical Skills and Abilities**

1. Prepare a publication plan (publication strategy: what publications to where, when, and why, with subsequent implementation and tracking of plan) [Publication planning is a specific skill that may fall to a professional publication planner; however, this is also a general skill needed for publication medical writers]
2. Prepare (write/author) publication documents, such as:
   • Manuscript for a peer-reviewed journal
   • Review article (narrative or systematic review)
   • Abstract for a conference
   • Poster for a conference
   • Slide presentation
   • Response to reviewer document
   • Conference report
   • Journal article summary
   • Tables and figures suitable for publication
3. Prepare documents that are journal publication ready (meet journal guidelines)

**Application of the Model**

Because the model defines what competencies a professional should have, it can be a tool for organizational structure; recruiting and hiring; onboarding, training, and development; setting expectations and aligning to assignments; performance evaluation and staff retention; and defining the profession. An article on how to apply the model is scheduled for the September issue of the *AMWA Journal*.

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

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**References**

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ISMPP—Founded by Medical Publication Professionals for Medical Publication Professionals
AMWA’s 71st Annual Conference
October 20–22, 2011, Jacksonville, FL

The American Medical Writers Association (AMWA) is heading to the Sunshine State and the historical, fun-filled city of Jacksonville, Florida, for the 71st AMWA Annual Conference.

Jacksonville is located in the First Coast region of northeast Florida and is centered on the banks of the serene St Johns River. Jacksonville is the largest city in the state of Florida and captures the essence of a lifestyle and landscape that is unsurpassed. It is where unpretentious metropolitan style meets stunning natural beauty.

The Hyatt Regency Jacksonville-Riverfront Hotel is the site of AMWA’s 2011 Annual Conference. A premiere downtown hotel, the Hyatt offers the best in customer service, with incredible city and river views. Don’t miss the breathtaking sight from the hotel of the lighted bridges that bring the river to life every evening.

Located about 1 block from the hotel is Jacksonville Landing, a waterfront dining and shopping complex complete with outdoor dining opportunities and calming breezes. After an exciting day of sessions and conference activities, a stroll to Jacksonville Landing for some sunset viewing and a little dinner is the perfect way to end the day.

Also along the St Johns riverfront is a burgeoning arts district that rises from the diverse urban landscape. Take some time to visit the Riverside Arts Market under the soaring canopy of the Fuller Warren Bridge. Jacksonville operates the largest urban park system in the United States, providing facilities and services at more than 337 locations throughout the city. Exploring the great outdoors and relaxing in the beauty of unspoiled nature is one of the easiest things to do in Jacksonville.

AMWA is lining up several exciting tours that showcase the best of Jacksonville and the surrounding area, including a behind-the-scenes tour at the Jacksonville Zoo, which will highlight the native animals of the state, such as red wolves, bald eagles, and the Florida panther.

In the mood to discover a bit beyond Jacksonville? Then make sure to sign up for AMWA’s Sunday tour of St Augustine. The nation’s oldest city, St Augustine charms visitors with its quaint setting, historical buildings, and intriguing shops and eateries. As part of this tour, you will visit the famous “Fountain of Youth” and delight in the story of the city as told by a life-long native of “The Ancient City.” The characters and history of this city by the sea will literally be brought to life during this tour. It is an experience you don’t want to miss!

Jacksonville offers everything AMWA attendees could want in a conference city: moderate year-round temperatures, beautiful sunsets along the waterfront, numerous shopping and dining options, incredible art and music, and the all-important warm Southern hospitality!

Mark your calendars for AMWA’s 71st Annual Conference, October 20–22, 2011, and allow yourself some time to explore and delight in this fascinating city and all it has to offer. Get to know Jacksonville…where Florida Begins!
Invest in yourself and in your career!

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- Take the steps to advancing your career and education!

Budget-friendly, great location, and full of opportunities—this is a conference you can’t afford to miss.

Visit www.amwa.org for the latest information and updates.

We look forward to seeing you in Jacksonville, Florida!
An Overview of the Drug Research and Development Process

By Peggy Boe, RN, a Barbara Snyder, MA, b and Marijke H. Adams, PharmD, PhD c

a Freelance Regulatory Writer, Wilmington, NC; b Director, Medical Writing, Warner Chilcott, LLC, Mason, OH; and c President, MH Adams & Associates, Inc, Davie, FL

Those of us who have been writing regulatory documents for several years are often asked, “How can I break into regulatory writing from my background in (fill in the blank) basic science academics, nursing, medicine, technical writing, medical communications, etc?” Getting started is not easy, but it’s not impossible either.

Medical writing as a profession did not exist when AMWA began about 70 years ago. The writing then was done by physicians or other members of the research teams. Most people became medical writers by being in the right place at the right time and climbing the career ladder with a lot of hard work and on-the-job training. Today, medical writing has evolved into a recognized career choice with a growing number of opportunities for formal training at the university level. If you’re not ready to enroll in an academic program, you can gain a basic understanding of the concepts involved in regulatory writing in other ways. A good place to begin any training is to learn about the drug development process and the regulations and guidelines that direct the research and provide the basis for the associated documents. This article is a starting point from which medical writers can (and should) continue to research and learn on their own in order to transition into the realm of regulatory writing.

Research and development (R&D) for drug products includes many highly regulated steps that are required to develop a drug substance into a marketed product, with each of the following components:

1. Chemistry, Manufacturing, and Controls (CMC)
2. Nonclinical (also called Preclinical) Testing
   - In vitro (laboratory) tests
   - In vivo (animal) tests
3. Clinical Testing
   - Phase 1 trials to evaluate the safety of the drug
   - Phase 2 trials to determine the appropriate drug dosage regimen to be used in Phase 3 trials
   - Phase 3 trials to evaluate the efficacy and safety of the drug

CMC and Nonclinical Testing

Drug development starts with choosing a drug candidate for development. Such candidates may be referred to as the new chemical entity (NCE), the drug substance, or the active pharmaceutical ingredient (API). The substance is evaluated in vitro (in a test tube, culture dish, etc) in a laboratory to determine how the substance functions. Thorough evaluation of the substance’s chemistry defines its properties and helps to ensure its quality and stability. These CMC processes and analyses guide development of a drug formulation for in vivo (live animal) testing to determine its effects (i.e., its pharmacology). Nonclinical studies are performed, often simultaneously with CMC processes, following specific protocols, and employing rigorous control processes that must be documented for the results to be accepted.

Nonclinical testing could be the subject of its own article, but some examples include testing to determine which enzymes interact with the drug, the drug’s ability to bind with protein in the cells, and metabolites that are formed from the drug as it is broken down in the body. Basic routes of absorption into the body, distribution throughout the body, metabolism by the body, and excretion from the body (also known as “ADME”) are also tested. Such tests are part of the initial pharmacology studies (the effects of chemical compounds on living organisms), including both pharmacokinetics (PK; the effect of the body on the drug) and pharmacodynamics (PD; the effect of the drug on the body).

Various animal species are used in the nonclinical testing, depending on the chosen route of administration as well as anticipated ADME results. The goal is to choose the animal species with a specific characteristic that will closely approximate similar outcomes in a particular human organ. The toxicologic profile of the substance must also be evaluated. Examples of toxicity studies include testing for adverse
effects on specific organs or organ systems, cancer (carcinogenicity), and effects on reproduction. Various dose levels are tested to determine the no-observed-adverse-effect level (NOAEL) and the minimum lethal dose (MLD), which are later used to calculate an acceptable dose for humans. Animal testing is closely monitored by animal care boards, and the minimum number of animals required to achieve the study goals is used.

Because an active ingredient is rarely given alone, before moving on to clinical development (research in humans), ingredients are added to the drug substance to support acceptable routes of administration. This new formulation (the drug product) may contain excipients, such as substances to control release of the API or a buffer to improve the stability of the product. As with the drug substance, the drug product also undergoes extensive CMC evaluation to determine, in part, appropriate manufacturing processes and container and closure systems (eg, bottles vs blister packages for oral tablets). Additional nonclinical studies may be conducted using the drug product to ensure that the excipients do not adversely change the PK, PD, or toxicology profile of the API. In the regulatory world, all of the processes that lead to drug product development are governed by Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP).

Once the pharmaceutical company (the sponsor) has successfully formulated the drug product and can support its manufacturing process and once the nonclinical studies show an acceptable risk profile, it is time to move on to clinical research, which is governed by Good Clinical Practice (GCP).

Initial Regulatory Submission
In the United States, submission of an Investigational New Drug (IND) application to the Food and Drug Administration (FDA) is required before a sponsor can begin any trial in humans and can legally ship the drug product across state lines. The IND will include everything the sponsor knows to date about the product, including CMC documentation; nonclinical study reports and a summary describing the results; a general investigational plan describing how the clinical research will progress over time; a clearly defined protocol defining the who, what, how, when, and where of the first proposed clinical trial; an investigator’s brochure (IB) summarizing information relevant to the clinicians who will conduct the clinical trials (investigators); and other administrative documents. The primary objective of the IND is to demonstrate that the product will not put the initial human subjects at undue risk. The FDA regulations describe all of the required information and documents that must be included in the IND before the sponsor will be allowed to start human trials.

The regulatory writer needs to know enough about the regulations and drug development process to ensure that the IND documents are written concisely and clearly, with enough information to demonstrate that the sponsor has exercised due diligence to protect the health of subjects exposed to the new product. This responsibility must not be taken lightly.

Clinical Testing
Clinical trials are described by phases that can overlap, although they are usually conducted in sequential order. Phase 1 begins with testing to determine the maximum safe dosage and continues the pharmacology testing in healthy human subjects. Phase 1 trials assess how well the product is tolerated, the drug’s PK profile in humans (eg, when the maximum concentration occurs and how fast the drug is eliminated), and other objectives. Depending on the drug's pharmacology, additional trials may be needed in subjects with specific characteristics. Such subset populations may include a specific age range, race/ethnicity, or sex, or concomitant disease such as diabetes or kidney disease. Other Phase 1 trials might include evaluation of the effect of food or alcohol on PK and PD results or the potential for the tested drug to interact with other prescription drugs. Phase 2 trials continue the effort to determine the optimum safe dosage and begin to assess efficacy for the targeted indication. Because Phase 2 trials usually provide the first evidence of efficacy, they are sometimes called “proof-of-concept” trials. Data from Phase 3 trials, which include a much larger population with the targeted indication, provide the most conclusive evidence of safety and efficacy.

Regulatory Submission for Marketing Approval
All results (CMC, nonclinical, and clinical through Phase 3) are included and summarized in the New Drug Application (NDA), the means by which the sponsor seeks approval from the FDA to market the product as a new prescription drug in the United States. It takes about 1 year for the FDA to review the NDA and to decide whether the product can be marketed. During that time, the FDA may ask the sponsor questions and request additional analyses of the data; in some cases, these requests may literally stop the review clock until the sponsor responds appropriately. In addition to its own review, the FDA may also convene a panel of experts (an Advisory Committee) who will review the documents submitted by the sponsor and give an opinion as to whether the FDA should approve the drug. If the product is approved, research will continue via additional clinical trials (to assess longer-term effects) and collection of post-marketing reports of adverse effects in patients for whom the drug is prescribed.

Role of the Regulatory Writer
Regulatory writers, with their varied backgrounds and interests, play a key role in documenting the research results throughout all of the phases and are expected to understand
the role an assigned document plays in the cycle of drug development. Conditions under which subjects are studied are very different in Phase 1 compared with Phases 2 and 3. Terminology, trial methods, and standardized text are not necessarily interchangeable, although they do overlap. The documents most regulatory writers begin with may include clinical trial protocols, subject safety narratives (a description of an adverse event in a specific subject), and informed consent forms. Many writers learn the trade by performing quality control (QC) reviews of documents written by others, which helps a new writer learn variations in document types as well as styles and presentation concepts inherent to scientific writing. Next, the writer might then advance to helping write a clinical trial report or an IB.

Attention to detail is crucial in regulatory documents, beginning with the documents that the newest writers are assigned. Mistakes in the clinical trial protocol can vary from minor administrative annoyances to major problems that can render the trial results useless. The financial impact of having to create protocol amendments to fix such mistakes can be tremendous, especially in a large Phase 2 or 3 trial, and the additional paperwork required with each amendment can be an administrative nightmare. In a worst-case scenario, faulty trial methods could compromise the overall quality of the data or perhaps even render them unusable, which could require rerunning the entire trial—an extremely expensive endeavor. Amendments and trial conduct issues can sometimes be avoided if the protocol is written by a regulatory writer who is familiar with GCPs, has a working knowledge of the regulations guiding trial conduct, and pays attention to details.

The good news is that all regulatory documents are created by a team effort, usually including clinicians, statisticians, regulatory affairs personnel, and other subject matter experts; no one person has to know everything that goes into these documents. But the regulatory writer needs to know enough about the drug development process, the regulations and guidelines, and what the other team members do (and why), to be able to write comprehensive documents with goals, objectives, methods, results, and conclusions that are within context for varying targeted audiences. Regulatory writers should depend on the team members for their individual subject matter expertise but should also know the regulations and guidelines that drive team members’ input and recognize that these individuals are generally not professional writers. Sponsors depend on the regulatory writer’s primary expertise—professional writing skills—to get the job done. At the end of the drug development process when the marketing application goes to the FDA, every document counts. Flaws in logic, inconsistencies in data or methods, etc, will at the very least result in the application being put on hold while the sponsor responds to questions. In a worst-case scenario, if the submission content does not reflect industry standards or contain appropriate information, the FDA may issue a refusal-to-file (RTF), and all of the hard work will have been for naught. A good regulatory writer can help the sponsor avoid such painful lessons.

Although the tendency in the industry is to think of regulatory writers as those who write the clinical documents, some regulatory writers prefer to focus on other IND and NDA sections. Regulatory writers who focus on the CMC documents, for example, often have a strong background in chemistry and analytical methods. Others may choose to focus on writing nonclinical summary documents. Often the experienced clinical writer will do some nonclinical writing as well, as key nonclinical findings form the basis of some of the clinical summaries and are certainly a large part of the IB updates provided to investigators over the course of drug product development. The most advanced regulatory writers will find themselves assigned to IND and NDA summaries, in which data from multiple studies are often integrated, and to other documents such as overviews, introductory documents, and sometimes briefing packages to prepare for meetings with the FDA. To get a feel for the volumes of documentation that is submitted with an NDA, picture a tractor trailer filled with boxes of paper. Today, of course, most submissions are prepared and delivered electronically, but the volume of required documentation has not changed. Being a contributor on a submission writing and compilation team is perhaps one of the most rewarding experiences for a regulatory writer.

**Initial Resources for Regulatory Writing**

All regulatory writers should self-train using available resources, many of which are online. (See resource lists as online exclusive). Start by reading parts of Title 21 of the Code of Federal Regulations (CFR) and become familiar with searching the Federal Register, where proposed changes to federal rules are posted. Compliance with the CFR is mandated by US law. The FDA also produces its own guidance documents; compliance with these documents is not required by law but is strongly recommended. Also study any International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use guidelines applicable to whatever document you are assigned. Protocols, informed consents, and IBs are discussed in the ICH E6 Guideline and clinical trial reports are covered in the ICH E3 Guideline.

It can be difficult to keep up with the changes in regulation and guidance; fortunately, the major components of regulatory documents do not often change drastically. And just imagine how impressed your team will be if you are the first person to point out a new regulation or guideline governing a document you are writing!

To maintain and grow your skill sets, no matter where you live and plan to work, try to attend any workshops and other educational opportunities that may be available to
enhance your knowledge, to keep up with the latest updates, and to learn helpful tips from your peers. For starters, both AMWA and the Drug Information Association (DIA) offer medical writing training.

This all sounds like a lot—and it is! But it is also challenging and exciting. And when you do get your first break, you will find that the opportunities to continue learning and growing with the field can reach as far as your imagination, skills, and energy will take you.

**Acknowledgment**
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**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:** Peggy.boe@gmail.com.

Now that you have read this overview, test your knowledge of the following regulatory terms and acronyms. (Each term is defined in the article.)

<table>
<thead>
<tr>
<th>ADME</th>
<th>CMC</th>
<th>CFR</th>
<th>FDA</th>
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<td>NCE</td>
<td>Nonclinical</td>
<td>NOAEL</td>
<td>PD</td>
<td>Phase 1</td>
<td>Phase 2</td>
<td>Phase 3</td>
<td>PK</td>
<td>R&amp;D</td>
<td>RTF</td>
<td>Sponsor</td>
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</tbody>
</table>

Now that you have read this overview, test your knowledge of the following regulatory terms and acronyms. (Each term is defined in the article.)

According to the World Health Organization, the following are the 10 most common reasons for rejecting a manuscript.

1. Content of the paper not suitable for an international journal of public health
2. Design of the study not appropriate for the question asked
3. Lack of novelty and/or timeliness
4. Lack of ethical committee approval and/or informed consent
5. Lack of an appropriate search strategy
6. Conclusions not justified by the results
7. Lack of a feedback step in descriptions of audit
8. Insufficient sample size
9. Lack of a clear message to the public health community
10. Secondary analyses of demographic surveys or simple prevalence studies that are difficult to generalize

**Reasons for Manuscript Rejection**

*Source: World Health Organization Bulletin*  

The 2011 Annual Conference will offer the open session “Your Paper Has Been Rejected. Now What?” to offer guidance on dealing with a rejected manuscript.
Images (www.ncbi.nlm.nih.gov/images), a new database linked to PubMed Central, allows users to search for figures and illustrations, some of which may be freely reproduced. Type in keywords such as topic or author, and you'll get a list of citations to medical and life science journal articles, along with thumbnails of the relevant figures they contain. Simple topical searches can return thousands of hits, so you may need to be quite specific or use the Advanced Search feature. Images and data can be saved to your collection and shared with others through My NCBI. Figures identified may be reproduced without charge as long as the article is labeled as being distributed under the terms of the Creative Commons Attribution License, or a similar license, and the original author and source are credited.

The Alliance for CME (www.acme-assn.org) has launched a series of online learning tracks for CME professionals. Termed CALLS (Competency Assessment & Lifelong Learning Series), the program includes 6 components, priced separately: “Proficiency in CME” (15-21 hours); preparation for the CCMEP certification exam (16-18 hours); a set of 51 sample CCMEP exam questions; and three 12-week certificates: Best Practices in Assessment and Evaluation, Directing Physician Self-assessment for Learning and Change, and Facilitating Improvements in Healthcare by Addressing Barriers. Each certificate requires a final project, so the Alliance has prepared a guide for managers that explains how companies will benefit. Group discounts are available, and individuals are welcome to form a “Community of Practice” with colleagues of their choice.

Authors of meta-analyses rarely report the funding sources of the randomized controlled trials (RCTs) they include, according to research published in The Journal of the American Medical Association (2011;305[10]:1008-1017). Michelle Roseman and colleagues reviewed 29 meta-analyses from high-impact journals and the Cochrane Database, which synthesized data from 509 RCTs. Of those, 318 RCT reports disclosed a funding source, 219 disclosed that the trial was funded wholly or in part by the pharmaceutical industry, and 126 had at least one industry-employee author. Nevertheless, only two of the 29 meta-analyses reported the funding sources of included RCTs. Of the 6 meta-analyses that assessed risk of bias, none considered funding as a possible source of bias. Roseman et al suggest that reports of meta-analyses should disclose the funding sources and any author-industry financial ties of the RCTs analyzed, and that this information should be included when evaluating potential sources of bias.

Ghostwriting of federally funded research may be punishable by the US Department of Health and Human Services (HHS), according to Dr Frances Collins, head of the National Institutes of Health. In a letter (http://digbig.com/5bdqfr) to Paul Thacker, formerly an investigator for US Senator Chuck Grassley, Dr Collins said that in some cases ghostwriting could be considered plagiarism. The HHS Office of Research Integrity (http://digbig.com/5bdqfs) considers plagiarism a form of research misconduct, and, if it is proven, the possible consequences for researchers range from a letter of reprimand to debarment (temporary suspension from seeking research grants).

Ever had a beef with a reporting guideline? For example, do you chafe when trying to write a 250-word abstract that includes all the elements prescribed by the CONSORT Extension for Abstracts? Officials at the EQUATOR Network are looking for examples of how useful—or not useful—various reporting guidelines are for medical writers and editors. “You don’t need to write a lot; a few sentences about your experiences, both good and bad, would be fantastic,” they say. Send your comments to shona.kirtley@csm.ox.ac.uk. Comments will be posted on the EQUATOR Network Web site (www.equator-network.org), which is a good place to look if you want to learn more about the many guidelines for reporting research findings.
RPS has created the industry’s first Pharmaceutical Resource Organization (PRO) to provide business process outsourcing solutions for clinical drug development. Pharmaceutical, Biotechnology and Medical Device companies that partner with RPS have experienced:

- Increased integrated control of clinical trials;
- Improved and substantially better on-time delivery of programs; and
- Marked reduction in the overall lifecycle costs compared with traditional outsourcing strategies.

By combining the largest recruitment team with true clinical oversight, RPS has achieved a service level that is well above the capabilities of any CRO or staffing company in this industry.

As a member of our team, you will enjoy the flexibility of contract work with the security and benefits of a permanent industry position. You’ll have the opportunity to work in an area of interest and expertise at the top Sponsors. At RPS you’ll appreciate:

- A team of RPS professionals fully dedicated to the enhancement of your career
- Exciting positions, designated to a project for the life of the project
- Highly competitive salary
- Comprehensive benefits package:
  - Medical and dental insurance
  - Vision care
  - Company sponsored disability and life insurance plans
  - 401(k) plan
  - Generous paid vacation
  - Paid corporate holidays
  - Corporate credit cards and calling cards

Join An Industry Leader!
**Freelance Forum**

**Q** – Is there any benefit to referring to yourself as an “independent medical writer/editor” or “medical writing (or editing or communications) company” rather than “freelance”?

**A** – Interesting question, since I refer to myself and my business all 3 ways, depending on the circumstances. For example, when talking informally with other freelance folks or communicating on the AMWA freelance listserv, I refer to myself as a “freelance medical writer.” When talking with clients, other than some AMWA members with whom I have worked for many years, I refer to myself as “President of Smith Simon Company, a medical communications (and education if applicable) company, incorporated in Virginia.” This distinction lets them know that we are incorporated and that our business is an established, bona fide entity. Finally, in those instances when I am working under contract for an agency or another communications firm and meeting the ultimate client (pharmaceutical company internal staff), I refer to myself (if asked) as an “independent medical writer under contract for this project with XYZ Company.” To further confuse the issue, some of us use the term “professional medical writer,” which I have also used with clients. While slight variations of meaning occur with each phrase, any one of them can communicate a person’s status, depending on the situation. “Independent medical writer/editor” or “medical writing (or editing or communications) company” seems to imply a more professional status than “freelance.” (Note: We are no longer referring to ourselves as “freelancers,” as many of us did in the 1980s and 1990s.)

— Elizabeth Smith

**A** – From my perspective as someone who has identified herself as a “freelance medical writer” for more than 25 years, I don’t see any benefit to referring to myself any other way. That said, I don’t use the word “freelance” (or “independent medical writer”) on my business card. I use the “company” name DLM Writing Services, and identify myself as a “specialist in healthcare communication.” However, that was not a calculated decision to avoid the use of the word “freelance.” It just seemed more appropriate for a business card. Although I’ve heard some AMWA members comment that they think the word “freelance” has a negative connotation, I’ve never seen any evidence of that, and I don’t think it discourages companies from accessing the AMWA Freelance Directory or posting ads on our Freelance Opportunities listserv to find prospective employees.

— Donna Miceli

**A** – Since the organizations to which I’ve belonged (AMWA, Council of Science Editors, Society for Technical Communication, Teachers of Technical Communication, and San Diego Professional Editors Network) placed me in the professional category that they selected, the choice was not up to me or other members. “Freelance,” as defined in Webster’s Dictionary, has been the universal choice of category by those organizations, and that term has been preferred, for the most part, to “freelancer,” which does not appear in Webster’s. I don’t use a profession category on my business card; it simply states: “Phyllis Minick, Writing and Editing.”

— Phyllis Minick

**A** – I don’t know if there’s any benefit at all to calling yourself one thing or another. I don’t refer to myself as a “freelance” medical writer anymore (in that exact vernacular), but there’s no particular reason why. When people ask me what I do, I say I do regulatory writing for the pharmaceutical industry, and then I might add that I work on a freelance or independent basis. But this isn’t 100% true, because I do have contractual arrangements with a few companies to do work for their clients, so technically I don’t “freelance” for those clients, although I do work with some other clients directly. One of my freelance colleagues has recently put “Contract Medical Writer” in the signature line of her e-mail. When I asked her why she chose that term, she replied that it seemed like a “quick, concise way to describe my relationship with clients.” She added, “Often I’m hired by the medical writing team but work with others who assume/think that I’m an employee, and that simple phrase (if they read it!) lets them know my relationship with the company.” I rarely use signature lines, but when I do, I just put my name followed by “Medical Writer” on the next line, with only phone and fax numbers included. To me, it doesn’t matter whether I make the “contract,” “freelance,” or “independent” distinction—as long as people keep hiring me!

— Sherri Bowen
A – Clearly communicating what we do is important. That means using the right words for the audience: potential clients, clients, and contacts. The term “freelance writer/editor” is clear, simple, and effective. Just about everyone knows what this means. “Independent medical writer/editor,” on the other hand, is still a. And independent is implied in the term freelance. In fact, Merriam-Webster defines freelance as: “a person who acts independently without being affiliated with or authorized by an organization.” A person who acts independently cannot be a “medical writing (or editing or communication) company,” as a company is “a group of persons or things” (Merriam-Webster). There is one exception to this: the legal classification of a freelance business. Many freelance writers use the business structure of an LLC (limited liability company) or a corporation. My freelance business is an LLC, and this is noted in my marketing materials. But I introduce myself as a freelance writer because that clearly communicates what I do.

— Lori De Milto

A – Absolutely! As communications professionals we know that words have power. They inform as well as influence. There is nothing wrong with the word “freelance.” However, I prefer to use this word to refer to how I work rather than to define myself. I’ve mentioned many times in presentations and conversations with colleagues that it is important for us to treat ourselves as businesses. Doing so communicates to our clients that we are serious about what we do and that we’re here to stay. One way we communicate professionalism to our clients is through our business structure—for example, choosing to be an LLC or S-Corp rather than a sole proprietor. Another way to communicate our professionalism is by referring to ourselves in more business-like terms, such as “independent medical writer/editor” or “medical writing/editing/communications company.” A rose by any other name may smell as sweet, but communicating to our clients and potential clients that we mean business is sweeter still!

— Brian Bass

A – For most of my career I have referred to myself as a medical writer or a medical communications consultant. When asked where I worked, I replied that I established my own business, Chandos Communications, and that my clients included pharmaceutical/biotech, managed care, and other health care companies. Generally this has been sufficiently descriptive, though sometimes the person would say, “Oh. You mean you’re a freelance?” Over the last few years, I have used the term freelance medical writer frequently. I’ve never called myself an independent writer. Now after polling several individuals, both in and outside this profession, I’ve decided to go back to calling myself a medical writer/editor.

— Cathryn Evans

medical communications consultant, which is in fact more descriptive of my business and services. I think individuals should call themselves whatever they choose and it is probably best to use the term that most closely describes what you do. If you are a freelance medical journalist, then why not use that term (“I am a freelance medical journalist”)? If an editor, then freelance medical editor. If you are truly a medical communications consultant and/or have truly established a business, then use those descriptors.

A “contract writer” might be a better term for the person who is not in business, is not self-employed but, rather, works as a “temporary employee” for a temporary employment agency. That is, s/he is hired by the agency and not the company to perform medical writing duties on-site for some specified duration; is paid by the agency; has payroll taxes deducted; receives some employee benefits; and is given a W-2 at the end of the year (as opposed to a 1099, which is reserved for the self-employed). This “contract writer” is not truly a freelance or an independent writer—s/he is a transient or temporary employee. This temporary agency scenario has increased greatly over the last 10 years. It gives the company the best of all worlds: the pay includes no benefits, sick leave, vacation time, administrative costs for the employee because s/he works for the agency. The company pays the agency a fixed amount for the hours worked; the agency pays the writer quite a bit less than it receives from the company; and the writer who does not want to be a permanent employee has regular work without having to establish a business and market himself/herself. However, if employed by a single employer for 50% or more of his/her time, a writer is not legally able to take the same kind of tax deductions allowed for a truly self-employed medical writer. This distinction is rather important because the tax structure is an important aspect of being in business.

Perhaps AMWA should conduct some market research surveys on the question—not to determine what people are presently calling themselves but to learn something about the perception of the terms by the medical profession, the pharma/biotech industry, health care organizations, and other businesses that hire medical writers. Then we might have information that is a bit more objective about the question of what is the ideal description we should be using.
Parallel Structure: The Right Way to List, Compare, and Contrast

By Laurie Thomas, MA, ELS
Madison, NJ

- Parallel structure is easier to illustrate than to explain.
- In matters of principle, stand like a rock; in matters of taste, swim with the current.
  —Thomas Jefferson
- Outside of a dog, a book is man’s best friend. Inside of a dog, it’s too dark to read.
  —Groucho Marx

The sentences above are examples of good parallel structure because the sentence elements (i.e., words, phrases, and clauses) that are of equal rank (i.e., that are coordinate) are expressed in the same grammatical form. Consider the following example:

J He likes bicycling, canoeing, and to go on hikes.
A He likes bicycling, canoeing, and hiking.

Why use 2 gerunds and an infinitive phrase when you could use 3 gerunds? In this article, I’ll give you some simple tricks for spotting which items in a sentence should be parallel and direct you to some resources for further study.

Proper use of parallel structure makes it easier to say exactly what you mean and easier for the reader to figure out what you meant. It also makes your writing more pleasant to read. Thus, it should come as no surprise that the AMA Manual of Style instructs medical communicators to pay attention to parallel structure.1

Spotting parallelisms

You need to think about parallel structure whenever you see any of the following:

- Sentence elements that are joined with a coordinating conjunction
- Items that are being listed, either within a sentence or in bulleted lists or tables
- Items linked by correlative conjunctions
- Comparisons
- Verbs of being

Coordinating conjunctions

The main coordinating conjunctions used in English are and, but, or, nor, and for. They are called coordinating conjunctions because the elements they join are of equal grammatical rank. Thus, these elements ought to be in the same grammatical form. Here’s an example from the AMA Manual of Style:

J Surgery, radiation therapy, and to give chemotherapy are possible therapeutic approaches.
A Surgery, radiation therapy, and chemotherapy are possible therapeutic approaches.

Lists

Sometimes, the coordinating conjunction is implied, such as in a bulleted list or among the elements in a table. In a list, the elements should all be in the same grammatical form: all phrases or all sentences; all statements or all commands. The order of the items should also be logical. The items could be organized alphabetically, by importance, by time sequence, or in some other order.

If you can’t make the items in a bulleted list or table parallel, ask yourself whether they really constitute a list. It might make sense to separate them into 2 or more lists or to rewrite the section as a paragraph.

Correlative conjunctions

Correlative conjunctions are pairs of conjunctions that work together. Either… or and neither… nor are common examples. Be especially alert for the placement of prepositions in constructions involving these correlative conjunctions, as in this example from the AMA Manual of Style:

J Poor drug efficacy may be caused by either lack of absorption or increased clearance.
A Poor drug efficacy may be caused by either lack of absorption or increased clearance.

Note that either always goes with or and neither always goes with nor. You can use these correlative conjunctions to link more than 2 elements:

J Neither snow nor rain nor heat nor gloom of night stays these couriers from the swift completion of their appointed rounds.
A
Comparisons

Comparisons often involve the conjunction than, the construction as... as, or a verb of being. These sentences can be marred by faulty parallel structure and/or faulty comparison. Faulty parallel structure means that the items that are being compared are not in the same grammatical form. Faulty comparison means that the items being compared are not what the writer really meant to compare.

Here's a good example of a faulty comparison that involves a verb of being. Notice how the use of a demonstrative pronoun improves the sentence:

🔗 The results of this study are similar to the Nurses’ Health Study.
🔗 The results of this study are similar to the results of the Nurses’ Health Study.
🔗 The results of this study are similar to those of the Nurses’ Health Study.

Faulty comparisons often result from an elliptical construction, which means that words have been left out of the sentence. If you find an ambiguous sentence like this while editing, query the author. Don’t guess.

Ambiguous: He is closer to his father than his mother.
Clear: He is closer to his father than to his mother.
Clear: He is closer to his father than his mother is.

Be particularly alert for the word than. You might want to search your document electronically for all instances of than. Look at the elements that are being compared by than. Watch out for faulty parallel structure and faulty comparisons. Also consider moving the items that are being compared as close as possible to the word than:

🔗 Treatment with A was associated with more pronounced antidepressant effects during the first weeks of treatment than B, which suggests a more rapid onset of action.
🔗 During the first weeks of treatment, antidepressant effects were more pronounced in the group treated with A than in the group treated with B; this finding suggests that A has an earlier onset of action than B has.

To find other comparisons, search for the character string compar, which will turn up all instances of the words compare, compared, and comparison. Note that compared with phrases are adjectival; thus, they will try to modify whatever noun they directly follow. Sometimes it is better to say than in as opposed to compared with.

🔗 Heartworm infection is more common in dogs compared with cats.
🔗 Heartworm infection is more common in dogs than in cats.

Verbs of being

A verb of being is like an equal sign. Think about what the sentence is equating, and whether you can put the elements on either side of the verb of being in the same grammatical form.

🔗 What you see is what you get.

How to build your skills

Once you review the parts of speech and some basic rules of English syntax, it gets easier to recognize and correct faulty parallelisms and faulty comparisons. Besides learning the underlying principles, editors must learn the grammar terminology, which will enable them to explain to authors why any given editorial change needs to be made. One invaluable yet free resource is Capital Community College’s Guide to Grammar and Writing, especially the page on parallel form: http://grammar.ccc.commnet.edu/grammar/parallelism.htm.

Author contact: Lthomas521@verizon.net.

References

For many professionals, a valuable benefit of membership in a professional organization is the opportunity to obtain current and relevant knowledge in their field. Also important is the ability to distinguish oneself as having attained a level of expertise and experience in his or her field. This is particularly important in the rapidly changing pharmaceutical and clinical research industries.

What Is RAPS?
The Regulatory Affairs Professionals Society (RAPS) is an organization for regulatory professionals in the pharmaceutical, biotechnology, and medical device industries. Regulatory professionals work in all areas of research and development and throughout a product’s lifecycle. Their role is to understand current regulations and guidelines in order to make strategic decisions during product development, approval, and marketing. RAPS provides education, training, and networking opportunities, as well as other professional development resources for regulatory professionals.

Why Might Medical Writers Be Interested in RAPS?
Because there has been relatively little formal education available, medical writers come to the profession from varied backgrounds and much of the knowledge is learned in the form of on-the-job training. Regulatory medical writers are quite often involved in writing clinical study protocols, which are produced before the clinical study is initiated, and clinical study reports, which are produced at the conclusion of each study. Also, in some companies, regulatory medical writers work closely with regulatory professionals to develop meeting requests and briefing packages for the investigational new drug (IND) application submission as well as write clinical summaries and clinical overviews for new drug application (NDA) or common technical document (CTD) submissions.

For medical writers who are new to regulatory writing or those who are hoping to branch out into writing different types of regulatory documents, AMWA offers a specialty certificate in Regulatory and Research for specialized regulatory/drug development writing and science research skills. Currently, a dozen workshops are available that focus on different topics ranging from an overview of the regulatory aspects of the drug development process to the specifics of writing a clinical study report or an investigator’s brochure.

Regulatory medical writers who have gained some experience in the field, may benefit from the RAPS Regulatory Affairs Certification (RAC) program, which focuses on the federal regulations governing the product development and approval process for drugs, biologics, and medical devices. Obtaining the RAC credential provides a broader depth of knowledge about the entire process from a regulatory affairs perspective. This knowledge can enhance regulatory medical writers’ understanding of how the documents they write fit into the regulatory submission package.

What Is Regulatory Affairs Certification?
The RAC program is administered by the Regulatory Affairs Certification Board (RACB), which is responsible for the content, policies, standards, and administration of the program. Four certifications are available:

- RAC (US): knowledge of US regulations
- RAC (EU): knowledge of European Union regulations
- RAC (CAN): knowledge of Canadian regulations
- RAC (General Scope): knowledge of the general scope of practice of regulatory professionals

The RAC examinations are geared toward professionals already working in the regulatory affairs field and cover a wide range of regulatory topics and health care products. To assess whether individuals meet the established criteria within each testing domain, 3 types of questions are included on each examination: recall, application, and analysis. The RAC examinations take approximately 2 hours to complete and consist of 100 questions that are presented in multiple-choice format.

“Regulatory Affairs Certification distinguishes professionals committed to the regulatory profession and the regulatory process, as well as to continued learning about the changes in this dynamic area,” says RAPS Executive Director Sherry Keramidas, PhD, CAE. “For medical writers, it demonstrates an understanding of regulatory issues and practices that others writing on health care and medical topics may not grasp to the same extent.”

What Is the Process for RAC?
Candidates for the RAC apply to take an examination for one
of the 4 certifications (US, EU, CAN, and General Scope). To be eligible, candidates must meet 1 of 2 basic requirements: have a bachelor’s degree (or equivalent) or at least 3 years of regulatory experience.

The computer-based examination is offered twice per year (April 1 through May 31 and October 1 through November 30) at testing facilities worldwide. Currently, the fee for the 2011 examination is $325 for RAPS members and $510 for nonmembers, and the registration deadlines are February 15 for the spring exam period and August 15 for the fall exam period. The nonmember fee includes 1 year of RAPS membership.

After obtaining the RAC credential, individuals must apply for recertification every 3 years. Recertification is based on participation in continuing education opportunities such as attending conferences; speaking or writing on regulatory topics; or serving as an officer, director, or committee member of a professional society relevant to the regulatory affairs profession. Currently, 36 credits are required to obtain recertification; these credits can be obtained through a wide range of professional activities related to the regulatory profession, the biomedical sector and health care product life cycle, as well as related areas of professional development. The recertification process involves completing the recertification application form and submitting the recertification fee ($100 for RAPS members; $285 for nonmembers).

For More Information
For additional information on RAPS, visit the RAPS Web site at www.raps.org.

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<tr>
<th>TIPS ON STUDYING FOR THE RAC EXAM</th>
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<tr>
<td>• From the RAPS Web site [<a href="http://www.raps.org">www.raps.org</a>], download the RAC Candidate Guide and content outline for the relevant RAC examination</td>
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<tr>
<td>• Read the relevant RAPS-developed RAC examination preparation book thoroughly (eg, Fundamentals of US Regulatory Affairs)</td>
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<tr>
<td>• Review the relevant laws, regulations, and guidelines mentioned in the RAC examination preparation book</td>
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<tr>
<td>• Join the local chapter of RAPS in your area, if available, and attend meetings and educational opportunities</td>
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<tr>
<td>• Attend any relevant workshops, online courses, or Webcasts sponsored by RAPS</td>
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<tr>
<td>• Take any available online self-study exams offered by RAPS</td>
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<tr>
<td>• Form a study group and meet regularly to prepare for the exam, including reviewing practice exam questions</td>
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CALENDAR OF MEETINGS

AMWA Annual Conference
October 20-22, 2011
Jacksonville, FL

AUGUST
International Society of Managing and Technical Editors
August 9-10, 2011
Washington, DC
Web site: www.ismte.org

OCTOBER
American Association of Dental Editors
October 8-9, 2011
Las Vegas, NV
E-mail: aade@dentaleditors.org
Web site: www.dentaleditors.org

Association for Women in Communications
October 13-15, 2011
Tulsa, OK
Web site: www.womcom.org

National Association of Science Writers Workshops/Council for the Advancement of Science Writing
New Horizons in Science Conference
October 14-18, 2011
Flagstaff, AZ
E-mail: diane@nasw.org (Diane McGurgan)
Web site: www.casw.org

Public Relations Society of America
October 15-18, 2011
Orlando, FL
Web site: www.prsa.org

American College of Clinical Pharmacy
October 16-19, 2011
Pittsburgh, PA
E-mail: accp@accp.com
Web site: www.accp.com

Regulatory Affairs Professionals Society
October 23-26, 2011
Indianapolis, IN
E-mail: raps@raps.org
Web site: www.raps.org

American Public Health Association
October 29-November 2, 2011
Washington, DC
Web site: www.apha.org/meetings

NOVEMBER
Association for Business Communication
November 17-20, 2011
New Orleans, LA
E-mail: abcjohnson@sfasu.edu (Dr. Betty S. Johnson)
Web site: www.businesscommunication.org
Let’s say you discover that you are out of eggs, and need some badly. You rush out to the market specifically to pick up some eggs. As you run to the egg counter, you pass the butter display. “Whoa! Right, I’m running low on butter, so I’ll pick up some while I’m here.” Then you get your eggs and hurry to reach the cashier, and your aisle is blocked with a huge display of tuna fish at a price that’s wow! “Hey, I can’t pass this up. Always can use more tuna—especially at that price.”

That’s how so much is sold at supermarkets, as well as department stores. Without impulse buying, most stores and other merchants might be out of business or be much smaller. Rarely does a shopper buy only what’s on his or her list, or mind.

Readership by impulse

Picture doctors who take a copy of NEJM home, and when they settle into their easy chairs after dinner (you know this is a fictitious story), they carefully thumb through the journal, but they don’t know what they want to read, so they skim through until they spot something of interest. Then, they notice an ad, for something they forgot to order for the office, or a special illustration, or chart, or picture. They stop, look at it, and decide to investigate further. Now we have readership by impulse.

Rare indeed is the person who starts at page 1 of a journal and reads straight through to the last page. We are all part of readership by impulse. Things catch our eyes and strike a chord in our brains, and we read something we had not anticipated reading. (We didn’t know it was there!)

Why is this important to writers and editors? Because we have to prepare our material with a thought about what will attract a reader; what will prompt readership by impulse?

Take this column. I do not fantasize that hundreds of members pick up their Journal and turn with bated breath to Melnick on Writing. No, indeed (even though I hope that a few friends do!) You pick up this Journal, turn the pages, look at this issue’s contents and decide what to read and what to skip. Then, as you turn the pages, you spot my column. “I wonder what he’s writing about this time?” The answer that pops into your head is usually either “That’s a dull topic,” or “That title sounds interesting.” I, too, get readership by impulse.

What readership by impulse means to us is that everything we write, everything we lay out, everything we develop graphics for is made to attract that reader. If the publication has a special announcement or ad that it wants most readers to see, it usually is placed where a glancing eye might spot it and pay attention. Build your graphics around it, attach it in some way to a highly read area (that’s why cover advertising is so much more expensive than mid-book).

So, we writers must not think everyone is going to read what we write. We must aim to attract that impulsive reader.

One of the primary attractions is the topic. If the subject you are writing about strikes a chord with the browser, you’ll get a reader. Unfortunately, most of us have little to no control over what topics we write on.

An attractive title is a shoo-in for the impulse reader, and you may be able to influence this. I expounded on clever titles many years ago in this publication in “Titillating Titles and Humorous Heads” (and explored it again later in another publication as “Title is Vital”). Here are just a few stellar examples, the first 2 by great AMWA members:

“The King’s English…and so is the Queen” (Edie Schwager’s wonderful presentations on grammar)

“After Fifty and Still Nifty” (Ada Kahn, a chapter on sex in her book Midlife Health)

“A Cure for the Whom-Sick” (Patricia O’Connor, in her book Woe is I)

“Nobody Likes to Write–But Everybody Likes to Have Written” (Joel Saltzman in his book If You Can Talk You Can Write)

And one of my own: “Each To Their Own Taste (Gr...)

(article in Science Editor)

Now that you understand all this about readership by impulse, you may go back to the rest of the Journal and see what captures your impulse.
Build Your Future With Us

Medicine is ever-changing and always fascinating—and in healthcare information, education, digital services, and consulting, KnowledgePoint360 is a global leader and innovator.

We add value by providing authoritative information and actionable insights for busy practitioners and for our pharma and biotech clients. That added value stems from the exceptional expertise of more than 640 professionals—medical writers with advanced degrees, digital experts, account executives, high-level pharma veterans, graphic artists, and many others. Recruiting, training, and retaining the best team in the industry is a high priority for us.

This is the place to grow your career—and with two new divisions, expansion across our business, and 6 offices in the U.S. (plus 5 in Europe), we have many opportunities open. To join a professional, fun, and highly innovative team, look at our current vacancies at www.knowledgepoint360.com

To learn about the many ways we can help you communicate, see www.knowledgepoint360.com

ACUMED | BlueMomentum | Clinical Bridges | CodonMedical | eMedFusion | FireKite | Gardiner-Caldwell Communications | GeoMed | Interphase | Medex-Media | Physicians World | Physicians World Europe | Physicians World Speakers Bureau | Scientific Connexions | StemScientific | TGaS Advisors
Edie has long been our resource for answers to our questions about grammar, word usage, and style. Since her move to a nursing home, Edie is uncomfortable answering such questions without citing her sources—to which she no longer has access. Beginning with this issue, we will be asking Edie different kinds of questions—about her life, her career, her philosophies, her perspective. Edie would be delighted to hear from AMWA members who have questions about her life and her passion for medical communication. Send your questions to Kelly Flaherty, who has been helping Edie with her column over the past year. Contact Kelly at k.flaher@usp.edu. Here is a verbatim (edited) transcript of Kelly’s recent interview with Edie.

**Q:** What is the most important attribute a medical writer should have?

**A:** Integrity. Integrity is the most important thing a medical writer or editor must have. Above all, do your homework. If you have to, bone up. Get every source you can. Even Google. You can trust Google more than you can trust Wikipedia. Do not rely on Wikipedia. They are not always correct. They may try very hard, but I’d be very careful accepting anything on Wikipedia at face value.

**Q:** Are you thinking of intellectual honesty?

**A:** Yes, and of course, intellectual honesty means not faking. There are times when you will refuse a job because it is over your head. I can tell you that I have refused more than one job because I didn’t know enough about it to do a good editing job. Don’t be shy about consulting with the writer, a physician, perhaps. If there is something that really bugs you, and you’re not sure that you should include it or change it, talk to the writer. I have discovered that the higher in the food chain, the more gracious they are about talking to you and discussing whatever is on your mind.

One of my greatest regrets having had this stroke is that I don’t have my computer. That’s why I’m not too comfortable about answering questions unless I understand them perfectly. I always like to cite resources to back up my answers; I think it’s important, and I have made that suggestion almost every time I’ve answered a question.

**Q:** You have worked mainly as a freelance, right?

**A:** About freelancing: you will note that “freelance” is every part of speech: noun, verb, adverb, adjective… and so it comes in handy. You will note also that it is 1 word. No hyphen is necessary any longer, although at one time it was used. I have made my living for 40 years freelancing, and have loved every minute of it. It has only sharpened my love for the language and for its power, and for its authority, and for its beauty. That helped a great deal, to get me through some bad spots, like working until 2 am to meet a deadline. Most of my assignments were by request. But as you know, I love writing as well, as attested to by my 2 books. My second book, *Better Vocabulary in 30 Minutes a Day*, has sold, last I heard, 33,000 copies.

One important thing is to be adaptable. Go with the flow—unless you don’t like the flow or you think it’s wrong. If you are a freelance editor and you have a reputation, be prepared to give workshops. And hone your speaking skills.

Writing is a great profession. Editing also is a noble profession. I have discovered that people who know how to write do not necessarily know how to edit. But those who edit must know how to write.

**Q:** What’s your favorite book?

**A:** My favorite book is the World Almanac.

**Q:** Why?

**A:** It will answer all of your non-Dear Edie questions. (Laughs)

**Q:** Even with the Internet now?

**A:** You want to know the currency of Bulgaria, you can go to the World Almanac.

**Q:** That’s true, but you can find that information online too.

**A:** Not everyone has a computer.

**Q:** Not everyone has the World Almanac, either.

**A:** Just kidding. But anyway, favorite book—that’s a good question. One of my favorite books is by John Allen Paulos, who teaches mathematics at Temple. It’s called *A Mathematician Reads the Newspaper*. It’s about coincidence. Fascinating.

**Q:** A Harris interactive poll recently asked a sampling of Americans if there were any books to which children should be limited in the library. A number of topics were included, such as the Bible, evolution, vampires, drinking, smoking, sex, violence, coarse language, and others. The subject to which most respondents—62%—objected was explicit language.

**Q:** What are your thoughts on this?

**A:** I agree with that. It goes back to intellectual honesty and integrity. I do not think that children should be exposed to ugliness in any form, and I believe that obscenity is ugly. Nobody ever accused me of being a prude. I can take or make a joke as well as anyone, but I do not like treading on people’s toes—even mine.
AMWA's annual conference is billed as the most budget-friendly conference targeted to medical communicators. In my experience, it’s also much more people-friendly than the typical professional meeting. It’s powered by volunteers who give hundreds of hours of time to share their knowledge, and the approximately 900 attendees always try to ensure that newer AMWA members feel welcomed and connected. As you’ve seen elsewhere in these pages, this year’s conference will be held on Wednesday, October 19, to Saturday, October 22, at a lovely riverside hotel in Jacksonville, FL.

The AMWA Web site can help you decide whether to attend the conference and/or send your staff. At the right side of the home page, look for these resources:

- What’s at the Annual Conference For Me?
- Getting the Most from AMWA’s Annual Conference (slides)
- Maximize Your Conference Experience
- Frequently Asked Questions
- Top 10 Reasons to Send Your Employee
- Top 10 Reasons to Attend the Conference

The Web site can also help you choose from among the hundreds of events: workshops (available whether or not you’re enrolled in a certificate program), free open sessions, breakfast roundtables, and much more. Already, the 2011 Program in Brief is posted on the home page. By the first week of July, additional materials will appear there to help you plan your schedule. These will include a list of breakfast roundtables (with links to a description and agenda for each), a list of Thursday night coffee klatches, the full conference program, and the registration form (see sidebar). Headquarters will also send information via the AMWA Update (the monthly e-mail newsletter) and e-blasts.

Many conference attendees take workshops for credit toward certificates. As of 2010, AMWA has completely revamped its certificate curriculum, and the Web site can help you understand the changes. Carefully reading the information posted there is particularly important if you enrolled in a certificate program prior to 2010. At the left of the home page, click on Education/Certificates and choose from the submenus. If you log into the site, you will be able to see a list of the workshops you have completed for credit (“My Curriculum Record”). If you experience any difficulty with logging into the site, contact Mark Rosol, Member Services Coordinator, at mark@amwa.org.

Conference Registration Opens
July 25 at 11:00 AM Eastern time

The full conference program will be posted at www.amwa.org the first week of July. Because of all the choices available, you will want to set aside time to read the program carefully before July 25, especially if this will be your first conference.

Online registration will be available, with a credit card number required. Alternatively, you will be able to register by downloading a form from the Web site and returning it to headquarters by fax, e-mail (after scanning it), or mail, along with a credit card number, check, or money order. Forms unaccompanied by payment will not be processed.

No matter what method you use to register, your form will be processed manually at AMWA headquarters in the order in which it was received. Watch for announcements about which workshops are expected to fill quickly. If you plan to enroll in one of them, you will want to register early—preferably first thing on July 25.

An “early bird” rate will be available through September 9. The last day to pre-register for the conference will be October 5. After that, you will be able to register on-site in Jacksonville.
Social Media Sites to Keep on Your Radar

By Cynthia L. Kryder, MS, CCC-Sp
Phoenixville, PA

Just when you thought you had a handle on social media, some fresh networking opportunities are making a splash in 2011. Here are some sites to keep on your radar.

Google Buzz (www.google.com/buzz). This site represents Google's latest attempt to enter the social networking community. Connected to Google's popular Gmail and Google Maps applications, Google Buzz has the potential to become widely used. Similar to Facebook and Twitter, Google Buzz allows users to create a profile, post status updates, and post pictures and videos. When you make your status updates public, the information gets added to what's known as the “Buzz” layer on Google mobile maps.

Focus (www.focus.com). Focus is a network of business and technology professionals who answer questions, publish research, and speak at Focus-sponsored events, including Roundtables, Webcasts and Summits. One feature of Focus is the open, high-quality business information that is free, accessible, and powered by the community. Once you ask a question, you'll receive multiple answers almost immediately from experienced professionals. As a member you can personalize the information you want to receive on Focus by following specific topics and experts.

Xing (www.xing.com). Xing labels itself as “The professional business network with more than 10 million members worldwide.” Similar to LinkedIn, Xing enables members to market themselves professionally, connect with other professionals, search for jobs, and network at live events. Xing has more than 45,000 specialist groups you can join. Xing also is the only social network in the world with full SSL encryption to maintain security of your personal information.

SpeakerMatch (www.speckermatch.com). SpeakerMatch is a unique site that matches speakers with speaking opportunities. Meeting organizers can post open calls for speakers at no cost and can search the online speaker showcase for speakers who might meet their needs. SpeakerMatch is targeting a diverse group of emerging professional speakers, business leaders, technical gurus, and other subject matter experts who purchase subscriptions or pay fees to become part of the speaker showcase. If you're looking for speaking opportunities, this site might be for you.

Library Thing (www.librarything.com). LibraryThing, an online community where book lovers connect with like-minded people, is simply addicting. I've included it on this list just for fun. Think of it as the world's largest book club where you can browse members' libraries, read their book reviews, and swap reading suggestions. Once you create an account you can catalog up to 200 of your book titles for free. Catalog more books for an annual fee. LibraryThing also offers members the opportunity to participate in its Early Reviewer program, which provides free prerelease books to members who are willing to review them.

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Did You Hear? …there’s an AMWA Journal Blog

Log on to http://amwajournal.blogspot.com and join the growing list of followers of the AMWA Journal Blog, the newest interactive component of the AMWA Journal. The AMWA Journal Blog gives you the opportunity to
- Access online resources related to Journal articles
- Review current Journal articles in the context of other online resources, especially articles in previous issues of the Journal
- Take part in one-question surveys on timely topics
- Comment on Journal contents

Visit the blog today!
Our AMWA LinkedIn discussion page has been full of helpful and informative advice. When new member Jane Sherwin, of Belmont, MA, commented that she would like to explore AMWA’s options for people whose background is more in the humanities than science, Karen Becker provided contact information for Helen Osborne, a leader in health literacy, who lives in nearby Natick, MA. Candice Hughes, of Darien, CT, asked AMWA members to share the top characteristics that editors/managers look for when hiring medical writers as freelancers. Brian Bass, president of a NJ-based marketing and advertising firm gave this succinct answer: “On time, on target, on budget. First time, and every time.” This is sage advice for medical writers and for freelancers who want to get hired and rehired by clients in any industry. Others listed the ability to work with teams, as well as flexibility, and good referencing and annotating ethics. The discussion branched out with a request for tips on how to expand into new therapeutic areas. Responses included developing a diverse resume and being confident in the ability to learn and adapt to new concepts quickly.

When Stacey Chapman Tobin, of Chicago, asked for advice on finding commercial general liability insurance for her freelance medical writing/editing business, she learned about many options from AMWA peers. From defining the 2 types of insurance (general business and errors and omissions), to becoming an LLC or an S Corporation to alleviate personal responsibility, medical writers shared how they handled similar requirements from clients, as well as solutions.

Another colleague inquired about how to access medical journals online without paying for multiple subscriptions. Our members shared tips for stretching their budgets in these tough economic times. This question resulted in 19 comments, with suggestions of how to access free articles from libraries, databases, Web sites, document delivery services, as well as some paid, but cost-effective journals. Melissa Bogen, of NY, posted links to 4 free, open-access journal sites and 15 other (paid) sites.

Networking is alive, well, and integral to growing our businesses. It is comforting to know that AMWA members and their wealth of resources are just a cyber-discussion away. In a growing marketplace, where colleagues can be located across the United States or even across the world, it is beneficial to be able to reach the voices of experience without leaving the office. To access less recent discussions, scroll down to the bottom of the page and click on “Show more.” Recently, I received an e-mail from Atlanta-based AMWA member Sarah Cutler, who after reading my LinkedIn column in the AMWA Journal noticed that she grew up in the same Florida neighborhood in which I live now. It is, in fact, a small world. As anthropologist Margaret Mead once wrote, “Never doubt that a small group of thoughtful, committed citizens can change the world.”

Check in on AMWA’s LinkedIn Group—ask a question, or offer some good advice that will change someone’s professional world for the better. Until next time, looking forward to connecting with you on LinkedIn!

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Blog Log

By Debra Gordon, MS, Independent Medical Writer, Williamsburg, VA

This issue’s Blog Log takes you on a whirlwind tour of blogs related to continuing medical education (CME). Many are from CME companies, but they still contain interesting information, particularly if you spend a lot of time in the CME space. A caveat: I have to say that I was disappointed in the quality and quantity of CME-based blogs; I see an unmet need in the market!


CEProFles digitally tracks, organizes, and stores an individual’s continuing education (CE) data (continuing education is education for nonphysician health professionals). Its blog, however, covers both CE and CME. Recent postings including information on CE for massage therapists, as well as links to articles about noncompliant CE/CME providers.

Cleveland Clinic’s Center for Continuing Education: www.clevelandclinicmeded.com/

This site is best if you need CME or CE credits or just want a good sense of what’s happening in certain therapeutic areas. For instance, a recent blog discusses an article in a rheumatology journal that highlights differences between erosions and joint space narrowing, then links to a related CME Webcast. The site nicely organizes its content by therapeutic area.

CME Buzz: http://www.cmebuzz.com/

This is the site to start with if you’re looking for a variety of information related to CME, including programs and publications. If you sign up, you can post your own CME information/programs, even create your own page. Unfortunately, it doesn’t appear to have a very active membership. Or rather, it’s a good idea, just not very well executed.

CME Linkages: http://debragist.blogspot.com/

This blog is written by CME provider Debra L. Gist. She posts links to industry trade magazines and lay articles that might be of interest to those in the CME community (ie, an article in The New York Times about overradiated brain scan patients that would be ideal for inclusion in a needs assessment about radiology education). She also linked to an article on the misuse of implantable cardiac defibrillators that I plan to use in an upcoming gap analysis. I recommend this site to any medical writers responsible for needs assessments/gap analyses.

Author contact: Debra@debragordon.com.
My 2 daughters dance in our local performing ballet company, a commitment that has become somewhat of a family affair. My husband and son help move costumes and sets to the theatre before performances. I have begun wielding a needle and thread for the first time since sixth-grade home economics.

Although I have little formal training, I have found myself nervous stitching away, thanks to the gentle needling (and encouragement) of the more seasoned “sewing moms.” This spring, the girls spent weeks rehearsing for a performance of Swan Lake, and I—now with a couple years under my belt—spent hours sewing feathers onto skirts, altering leotards, and even burning the midnight oil creating a headpiece for the star of the show.

Sitting in the greenroom, taking care of a few last-minute alterations and crossing my fingers that the costume malfunctions would be few and far between, I took a look around and got to thinking about all the volunteers in action.

It reminded me a lot of AMWA, and the feeling I get whenever I’m around our members. I was struck by the similarities; how many of us get involved in our organization to learn, and how many of you so willingly give back to help each other grow. I never dreamed I’d be trimming tulle or shortening straps for the ballet. And when you first joined AMWA, I’m sure many of you never envisioned all you would learn or accomplish, or the ways in which you might get involved. And while I am not likely to ever take center stage at the ballet (the paying public can breathe a sigh of relief at that), my volunteer work with AMWA has served me well in another performance arena—the workplace. I have grown professionally in so many ways, an experience I know many of you also have had as you have set out on your own careers.

Last quarter, I wrote to express my appreciation for all you do. This time around, I thought you might like to hear from another AMWA leader—AMWA President-Elect Barbara Snyder, currently the Director of Medical Writing at Warner Chilcott (US), LLC. Like our other officers, Barbara has served in numerous leadership roles within AMWA over the years. I thought I’d ask her a few questions and share her comments with you:

Why is AMWA important to you?

AMWA is my professional family—the organization I choose to devote time and energy to and the people who inspire me. The annual conference is where I go to recharge my batteries.

In what ways has your AMWA membership been meaningful to you? What has been your favorite experience or fondest memory?

Through AMWA, I’ve gained skills that have allowed me to grow throughout my 30-year career and I’ve met people I consider some of my closest friends. I have many fond memories, but the one that epitomizes the spirit of AMWA to me relates to one of the first annual conferences I attended—it was 1983 in San Antonio and Bob Iles was there with his wife Phyllis. I was there alone and knew no one and Bob and Phyllis took me out to dinner along the River Walk. They were so warm and welcoming that I knew I had found the right organization for me. I also remember the first year I went to the Asilomar conference in Monterey. Edie Schwager was teaching a workshop and that’s where I really got to know her. We’ve been lifelong friends ever since.

What do you want current (new and longtime) and/or prospective members to know most about AMWA?

To the longtime members I say thank you—thank you for sharing your knowledge, your expertise, your experience, and yourselves.

To new members I say get involved, speak up, volunteer—I guarantee you’ll get as much out of it as you put in.

To prospective members I say come grow with us!

What do you want members to know about being or aspiring to be an AMWA volunteer or leader?

It’s sort of like the Army—“the hardest job you’ll ever love.”

Our members are what’s best about AMWA. So while I’m at it, I promise not to cajole you into picking up a needle and thread. But I’d love it if you took some time to reflect as well. Let me know how you would answer these questions. It would be great to hear from you!
SLATE OF CANDIDATES
FOR 2011-2012 ELECTION

Each year, the slate of AMWA officers is chosen by the Nominating Committee, which consists of the president-elect (who serves as chair) and 6 voting members who are not members of the Executive Committee (EC). The Nominating Committee receives from AMWA headquarters the names and biographies of all members meeting the criteria for the 3 elective offices: president-elect, secretary, and treasurer. Members of the committee discuss the potential candidates and select 1 candidate for each position. The names of these candidates are then presented to the Board of Directors for approval at its spring meeting.

The following candidates were approved by the Board of Directors at its spring 2011 meeting:

President-elect: Doug Haneline, PhD
Secretary: Karen Klein, MA, ELS
Treasurer: Judi Pepin, PhD

President: The president-elect automatically assumes the office of president at the annual business meeting held during the annual conference of the following year. The 2011-2012 AMWA president will be Barbara Snyder, MA. Barbara has 30 years of experience in medical writing for the pharmaceutical industry, starting as the first medical writer hired by Bristol-Myers in 1981. She has set up and led medical writing departments at Lorex Pharmaceuticals, Procter & Gamble Pharmaceuticals, and Warner Chilcott Pharmaceuticals and is currently the head of Medical Writing at Warner Chilcott (US), LLC. She has been active in AMWA activities at both the chapter and national level for many years, serving as president of the Ohio Valley Chapter; Annual Conference Administrator; Administrator of Publications, Development, and Education (2 years); and member of the following committees and task forces: Budget & Finance Committee (5 years), Education Committee (2 years), Constitution & Bylaws Committee (2 years), Science Curriculum Task Force (2 years), Workshop Leader Benefit Task Force (2 years), Nominating Committee, Elections Task Force, Eric Martin Award Committee (chair), and Swanberg Award Committee.

She has also served as chair of this year’s Search Committee for the new Executive Committee. Her activities with AMWA annual conferences include chairing networking roundtables and coffee klatches, serving as moderator and presenter for open sessions, and coordinating roundtable sessions. She received the President’s Award for outstanding service to AMWA in 2003 and was awarded AMWA Fellowship in 2006.

President-elect: The president-elect (1) must be a fellow of AMWA, (2) must have held at least 2 different positions on the Executive Committee (EC) in the past, (3) must have served on the EC for a minimum of 2 full years, and (4) must be a current member of the EC when his or her name is being considered by the Nominating Committee.

Doug Haneline, PhD, a teacher of literature and writing for more than 30 years, has been at Ferris State University in Michigan since 1984. He teaches research writing, advanced composition, medical writing, science fiction, American and British literature courses, and introductory Latin. Doug is a doctoral graduate of Ohio State University, with prior degrees from Middlebury College and the University of Delaware. Doug has been an AMWA member since 1986 and Fellow since 1992, and is currently AMWA secretary. His previous AMWA service includes the following: Administrator of Awards; Administrator of Education; Annual Conference Administrator; chair of the Medical Book Awards Committee; president of the Michigan Chapter; and member of the following national-level task forces: Certification, Academic Freedom and Conflicts of Interest, AMWA-Higher Education Partnerships, and Alternative Learning Technologies. In addition, he has been the coordinator of Annual Conference Special Interest (Educator) Sessions, a member of the AMWA Journal Editorial Board, and a member of several committees, including the Development, Nominating, Swanberg Award, Fellowship, Publications, Education, and Constitution & Bylaws. Outside of AMWA, Doug served on the Michigan Humanities Council, the state affiliate of the National Endowment for the Humanities. He is an AQIP and PEAQ Peer Reviewer for the Higher Learning Commission.
Secretary: The secretary must have served in at least 2 different positions on the EC within the 5 years immediately preceding his or her consideration by the Nominating Committee and must be a fellow of AMWA.

Karen Klein, MA, ELS, an AMWA member since 1989 and Fellow since 2006, is the Associate Director, Grant & Manuscript Development at Wake Forest University Health Sciences in Winston-Salem, NC. Karen is currently the Special Project/Communications Administrator and has served as the Administrator of Awards, the Annual Conference Workshop Coordinator (2 years), Administrator of Publications, and Administrator of Public Relations. She led roundtables at numerous annual conferences, and has been a workshop leader, a coffee and dessert klatch leader, and an open session moderator. She was a reviewer of the 1997 AMWA Biomedical Essays collection; is a peer reviewer/manuscript editor for the AMWA Journal; and has contributed several articles to the AMWA Journal. She has been a member of several national committees and task forces, including the Eric Martin Award Committee (2 terms, with 1 term as chair), the Budget & Finance Committee, the Special Projects/Communications Committee, the Student Scholarship Committee, the Task Force on Nonmember Publications, the Task Force on Science Workshop Framework, and the Task Force on Partnering with Higher Education. Karen earned the Editor in Life Sciences designation from BELS in 1991 and designation of Certified Grant Professional in 2008.

Treasurer: The treasurer must have served at least 1 full year on the Budget and Finance Committee within the 5 years immediately preceding his or her consideration by the Nominating Committee.

Judi M. Pepin, PhD, has been a member since 1997 and is currently serving a fourth term as AMWA's treasurer. She served on the 2006-2007 EC as Administrator of Development and held 3 terms as a member of the Budget & Finance Committee, and 1 term as a member of the Web and Internet Technology Committee. Judi also served 6 years as treasurer for the Ohio Valley Chapter (2000-2006) and was the Ohio Valley Chapter delegate for 3 years (2003-2006). Judi is currently a medical writer at Procter & Gamble Pharmaceuticals in Mason, OH, where she has been employed since 1990. She holds a doctorate and a master's degree in pharmacology and toxicology from the University of Connecticut School of Pharmacy, Storrs, CT, and a bachelor of arts degree in biochemistry from Smith College in Northampton, MA. She completed her postdoctoral training in the department of vascular cell biology and atherosclerosis at Cleveland Clinic.

Procedure for Additional Nominations
According to AMWA's Bylaws (Article III.2b), additional nominations for president-elect, secretary, or treasurer may be made by any member whose dues and special assessments are current, provided that any such nomination is submitted in writing to the secretary of AMWA at least 30 days before the annual business meeting (at the annual conference in Jacksonville, FL, October 21, 2011). Any individuals so nominated must meet the criteria outlined in the Bylaws (Article III.1.a through 1.d) for their names to be placed on the ballot. Such a nomination must state clearly the qualifications of the candidate, must be signed by 50 members in good standing as of the date of receipt of the nomination, and must be accompanied by a letter from the candidate stating that he or she is willing to serve if elected.

References

Questions about the structure and governing bodies of AMWA? Review 2 articles previously published in the AMWA Journal.1,2

Questions about how the AMWA election works? Visit www.amwa.org and review new Election Process FAQs posted in the members only section.
By Bettijane Eisenpreis

One day in 1979, Grace Darling was riding in an elevator at Baylor University Medical Center in Dallas, TX, chatting with a group of physicians, some of whom she knew. When she exited the car, one of the strangers in the group got out too. To her amazement, he offered her a job. And so began her 29-year career in the Department of Plastic Surgery of the University of Texas (UT) Southwestern Medical Center.

“His name was Fritz E. Barton, Jr, MD, and he had just become interim head of his division at the medical school,” Grace says. “He asked me to become a research/publication assistant. I was intrigued and within a couple of weeks had changed jobs.”

Born Graciela Carreño in Havana, Cuba, Darling was in the 10th grade when both of her parents were rounded up as enemies of the Castro government. Her mother, released after several weeks, sent Grace and her brother to live with an aunt in Miami while she tried to find and free her husband. Unable to get him released, she left Cuba for Miami in December 1961. Grace and her brother never again saw their father; he died in captivity in 1967.

The family moved to Puerto Rico, where Grace graduated from high school with honors. After her graduation, her mother suddenly decided to relocate to Miami. Grace was able to register late at the University of Miami and graduated in December 1967 with a BS in biology. She went on to graduate school at the University of New Mexico, where she met fellow biology student John Darling. They married in November 1968, and the following spring Grace received her MA in vertebrate biology.

Through 4 years of college, Grace had worked as a medical transcriber at a local hospital. Because her first language, Spanish, is Latin-based, she learned medical terminology easily. She began to work as a medical transcriber, eventually starting a medical transcription service with 3 employees. In 1975, she dissolved the company and went to work for Baylor University Medical Center in Dallas as a quality assurance coordinator, a position she held until joining the Department of Plastic Surgery.

Initially, Grace was put in charge of a version of grand rounds, in which one of the faculty members or residents in training would research a specific topic and produce a review paper. As the papers became longer and more extensively researched, Dr Barton decided to incorporate and issue them as a national publication.

Darling says, “I was already acting as the grammar hawk and knew the plastic surgery literature better than most, so how hard would it be to keep the books? And that is how I came to be managing editor of Selected Readings in Plastic Surgery, which at its peak was read by more than 1,200 subscribers in 64 countries and 6 continents. In 1980, the journal was incorporated as a nonprofit publication, although I continued to be an employee of the university until I retired in 2008.”

Darling first learned about AMWA in 1984 when the then-editor of the journal Plastic and Reconstructive Surgery spoke of it during a national conference in Dallas. Immediately after joining, she set out to attend as many workshops as possible, earning her core curriculum certificate and several advanced curricula in short order. She is a regular at annual conferences, having missed no more than 4 in more than 25 years.

“Along the way I also joined the Council of Biology Editors (now CSE) and the Society for Technical Communication and sat for the first exam by the Board of Editors in the Life Sciences,” she says. “Subsequently I became the first editor of the BELS Notes and was the second or third person to earn diplomat status in BELS. My greatest professional pleasure was to serve as publication manager for first the CBE Bulletin and then Science Editor and to work under 2 superb editors, Martha Tacker and Barbara Gastel.”

Darling has served several terms as membership liaison for AMWA’s Southwest Chapter (Dallas/Fort Worth), and in 2006-2007 was the chapter’s student scholarship chair. At the 2001 Annual Meeting she collaborated with Barbara Gastel in leading a workshop on medical terminology.

“Grace and I worked closely together for several years on Science Editor and its predecessor,” says Barbara Gastel. “Throughout, I was thoroughly impressed. Grace had great ideas for improving the publication; showed exceptional copyediting, proofreading and problem-solving skills; and could always be counted on. She was also lots of fun to work with! I’m glad AMWA annual conferences have served as a chance to keep getting together with Grace.”

“AMWA has given me fond memories, lots of friendly acquaintances, and a few dear friends,” says Darling. “What kept me going to all those annual conferences (after the credits became superfluous) was the lifelong friendships I developed with some AMWA members. I am very lucky and grateful for the challenges and opportunities I’ve had in my professional life.”
No business owner likes publicly declaring weakness, so what I am about to say feels like a dirty secret: my company (of one) has no Internet presence. No Web page, no blog, no tweets, no Facebook. I do have an outdated LinkedIn page, which I will revise as soon as I find time. In spite of my absence from cyberspace, business is good. Well, mostly.

The main reason I haven’t devoted time to online marketing is because I’ve been too busy with paid work. I get new clients mainly by word of mouth, which tends to self-select for those who are a good match. Easy, right?

Last year, a potential client saw my name in the acknowledgments of journal articles I had worked on and wanted to talk with me about a project. He eventually found my name in an issue of the AMWA Carolinas Chapter online newsletter and contacted a former chapter executive committee member to get my e-mail address. It shouldn’t be this hard for new business to find me. So I started thinking.

Maybe it’s time to ramp up my online presence. Back in the old days of say, 2008, this meant a Web site. Now it means a Web site, Facebook page, Twitter account, and maybe a blog. If you have Twitter, you need to be actively tweeting and following other people’s tweets. You have to say interesting things, and you have to notice and promote other people’s interesting things.

My mind is already present in enough places: running a household, raising my son, spending time with my husband, doing paid work, and writing my novel. Every morning I get up early to spend an hour and a half on creative writing. This is my mind’s playtime, a chance for me to express my own thoughts in peace.

At about 7:30 am, my attention turns to getting everyone in the house up, clean, fed, and where they need to be. Decisions must be made: blueberry or cherry jelly on the sandwich, thick or thin outdoor coat? And questions to answer from my 6-year-old: Is the Earth going to get sucked into a black hole? Why isn’t Christmas more than once a year?

Some days at work I can focus on 1 or 2 projects without much interruption. I treasure those times. Other days, work turns into frantic multitasking. Emergency e-mails and phone calls from clients. Changes in project scope or direction. And so I juggle. Don’t get me wrong: I am very grateful for all of my clients and their projects. But I am constantly aware that I am packaging other people’s thoughts, not mine.

At 3:30 pm, I pick up my son. By the time we get home, there is dinner to start, a reading assignment to do, and a sword fight to act out. Mom shift goes on until 8:30 pm, when we close the book on a bedtime story. Then, amidst the final chores of the day, I’m lucky to get in 15 minutes of yoga and 20 minutes of reading or talking with my husband.

Now, some of you have a similar schedule and still make time for tweets and blogs. I commend you. But I’d argue that the tweeting and blogging gets done because it is satisfying in some way. Personally, I can’t bear the thought of “following” everyone on Twitter. It’s enough to follow my son’s 6-year-old logic and my clients’ needs.

This brings me to the conclusion that a static Web page is probably the best way for me to have an Internet presence. But how does one go about this? If you have recommendations a Luddite can embrace, e-mail me at jking@augusteditorial.com.

Internet Presence
By Jennifer King, PhD, ELS
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Answers to word search puzzle (n=50)

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Resources for Regulatory Writers

_online Resources_

Compiled by Peggy Boe, RN, Barbara Snyder, MA, and Marijke H. Adams, PharmD, PhD

US Regulations and Regulatory Guidance
Code of Federal Regulations (CFR)
www.gpoaccess.gov/cfr
(Start with Title 21, Parts 50, 54, 56, and 58, 312, and 314)
Federal Register (FR)
www.gpoaccess.gov/fr
Food and Drug Administration (FDA)
www.fda.gov
Center for Biologics Evaluation and Research (CBER)
www.fda.gov/BiologicsBloodVaccines/default.htm
Development and approval process for biologics
Center for Devices and Radiological Health (CDRH)
www.fda.gov/MedicalDevices/default.htm
Center for Drug Evaluation and Research (CDER)
www.fda.gov/Drugs/default.htm
Development and approval process for drugs
www.fda.gov/Drugs/DevelopmentApprovalProcess/UCM200705.htm
FDA Basics
www.fda.gov/AboutFDA/Transparency/Basics/ucm2021108.htm
FDA Basics for Industry
www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm204416.htm

International Standards
International Conference on Harmonisation
www.ich.org/home.html
ICH Quality guidelines (ICH “Q” series; these address CMC issues)
ICH Safety guidelines (ICH “S” series; these address nonclinical issues)
ICH Efficacy guidelines (ICH “E” series; these address clinical issues)
ICH Multidisciplinary guidelines (ICH “M” series; these address 2 or more of the other categories)

Professional Organizations
AMWA
www.amwa.org
AMWA Guidelines/Ethics: Publication and Ethical Guidelines and Statements from other organizations
www.amwa.org/default.asp?id=461
Other Resources
www.amwa.org/default.asp?id=269
Clinical Data Interchange Standards Consortium (CDISC)
www.cdisc.org
CDISC glossary and abbreviations
www.cdisc.org/glossary
Drug Information Association (DIA)
www.diahomeln/DIAHome/Membership/SIAC.aspx
Regulatory Affairs Professional Society (RAPS)
www.raps.org

Books
Compiled by Deana G. Betterton-Lewis, MS, RAC, and Suzanne M. Lawton, RAC, CCRP
Describes for the novice medical writer the standard practices used in writing regulated clinical documents for the drug and biologics industry.

Covers the material that is the basis of the RAC (US) examination and is a good foundation for preparing to take the exam, although the material should be supplemented by reviewing the Code of Federal Regulations and FDA guidance documents. Relevant books are also available for the other examinations.

Provides a good background and overview of the drug development process and the history of federal regulations regarding clinical research in the United States.

Although targeted toward clinical research associates, this book provides a good overview of clinical research.
If you are a medical writer whose primary function is writing manuscripts and collaborating with authors to submit article to journals, the Mulford Health Science Library is a Web site worthy of bookmarking. Hosted by the University of Toledo, Health Science Campus, the Mulford Health Science Library, Instructions for Authors in the Health Sciences Web site offers a database that includes over 6,000 journal titles in the health and life sciences, with links to each journal’s instructions to authors. All links bring up a journal’s home page, its instructions to authors page, or a PDF version of the latter. There is an A to Z index provided, as well as a means of searching by keyword, in which users can enter any word within the journal title or the first few letters of the journal title.

The Mulford Library Web site is also a useful portal for medical writers, providing a convenient way to access such important industry documents as author guidelines, reporting standards, copyright, and author rights.

The Center for Teaching and Learning English Writing Lab http://hanyangowl.org
Although this site is designed to teach non-English-speaking Koreans how to write scientific manuscripts, I thought the site would also be of use to AMWA members because it contains a wealth of information on grammar, sentence structure, and usage, as well as step-by-step instructions for writing papers and submitting them to journals. The site is sponsored by the Hanyang University English Writing Center in Seoul, Korea. The Writing Lab is the work of Adam Turner, who is Director at the Center and teaches both graduate and undergraduate writing classes at the University.

There are two main areas of interest to medical communicators. The Biomedical & Life Sciences page contains the Sections of the Research Article, which covers the structural components and what to include where, and does so very comprehensively. Examples of “poor writing” along with their better counterparts are given throughout the section. Under the same heading, viewers can find Tips on Medical Writing, which includes advice on writing abstracts, case reports, and grants, as well as topics not often covered, such as writing effective titles and keywords, responding to reviewer comments, and composing the submission letter.

Whether you consider yourself a well-polished wordsmith or a not-so-savvy grammarian, there is much to be gained by visiting the Core Writing Skills page. In addition to tips on grammar, there is information on vocabulary building, sentence flow, transition words, and links to other grammar and writing Web sites. There is also a section on using references correctly, avoiding plagiarism, and suggestions on rewriting passages in your own words. There is also a separate Presentation Skills page. All in all, I found the site quite useful.

The Cell an image library™ http://www.cellimagelibrary.org/pages/about
The Cell an image library™ is hosted by the American Society for Cell Biology and is supported by the National Institute of General Medical Sciences (NIGMS) and the National Institutes of Health. The project is intended as a public resource and is a repository of images, videos, and animations of cells, all of which capture a wide diversity of organisms, cell types, and cellular processes. The purpose of the database is to advance research on cellular activity, with the ultimate goal of improving human health, and is designed as a public resource primarily for research, and secondarily, as a tool for education.

The image library includes images acquired from historical and modern collections, from publications, and by recruitment. Through high resolution, videos, and animations, the image library enables viewers to observe cellular architecture and functions. One can explore the image library by cell process, cell component, cell type, and organism, or by most recent. Clicking on an image brings up an enlarged version, plus a detailed description. Close to 2,600 images are in the public domain; others are copyright protected or licensed under a Creative Commons Attribution License. Go explore and view the fantastic intricacies of cellular life!
The Immortal Life of Henrietta Lacks
Rebecca Skloot

To medical researchers, she was simply “HeLa,” a tissue cell culture vital to the development of a wide array of new drugs and diagnostic tests. To her five children, she was Henrietta Lacks, the mother they scarcely knew, who died of cervical cancer in 1951 at age 31.

In The Immortal Life of Henrietta Lacks, Rebecca Skloot tells the history of the HeLa cells and their many extraordinary contributions to science, including the development of the flu vaccine, advances in gene mapping, and secrets of cancer and aging. But beyond that, she reveals the real life story of Henrietta Lacks, an impoverished, black Southern woman whose virulent cancer gave rise to the first “immortal,” or endlessly dividing, human cells ever grown in a laboratory.

Skloot describes the Lacks family’s shock and lack of understanding when they found out more than 20 years after Henrietta’s death that cells, taken without her knowledge, were still living. “They said they got my wife and she part alive,” recounted David Lacks about the phone call from a researcher. “They said they been doin’ experiments on her....”

Skloot lets family members speak for themselves and avoids making judgments. Henrietta’s daughter Deborah becomes a main character of the story, when after initial resistance, she joins the author in her quest to discover who her mother was. Deborah soon recognizes the paradox: “Truth be told, I can’t get mad at science, because it help people live, and I’d be a mess without it. I’m a walking drugstore! I can’t say nuthin bad about science, but I won’t lie, I would like some health insurance so I don’t got to pay all that money every month for drugs my mother cells probably help make.”

In her decade-long investigation of the story, Skloot interviewed hundreds of doctors, researchers, bioethicists, health policy experts, lawyers, and journalists as well as members of the Lacks family and their friends and neighbors. The resulting account achieves a remarkable balance between scientific and humanistic issues. The book covers patient privacy, informed consent, cell ownership, and financial gain from cell-line patents. At the same time, it discusses race, civil rights, religion, and journalistic ethics.

Skloot does a remarkable job weaving together many threads into a cohesive, clearly written tale. The book’s broad scope makes it suitable for both medical and lay audiences. But perhaps medical writers will most appreciate the efforts of the author to write accurately and understandably about a complex subject.

—Nancy Knoblock Hunton, MS

Nancy is a freelance health and science writer in Acton, MA.

Inside the Outbreaks: The Elite Medical Detectives of the Epidemic Intelligence Service
Mark Pendergrast
Boston: Houghton Mifflin Harcourt

Although you may never have heard of the Epidemic Intelligence Service (EIS), the shoe-leather epidemiologists working for this organization have been investigating medical mysteries and improving public health worldwide since 1951. Until this book was released earlier this year, this subsection of the Centers for Disease Control and Prevention was unfamiliar to all but those involved in public health.

As an infectious disease epidemiologist, I worked with an EIS officer during my stint with the Los Angeles Department of Health Services. I wanted to know more about the EIS epidemiologists who were directly involved in the most important public health accomplishments of our time: the dissemination of the polio vaccine and eliminating smallpox from the earth.
The last case of naturally occurring smallpox occurred in 1977. What I hadn’t known before reading this book was that eradication efforts were often stymied by cultural issues, not medical ones. In parts of India, for example, people worshipped the smallpox goddess and refused to be vaccinated. One innovative EIS officer would imagine a pop song in his head and start dancing with local children, and a team member would vaccinate them while they were dancing. This would not pass muster as informed consent in today’s world, but it got the job done then.

The recent declaration of a pandemic of H1N1 influenza mirrors earlier flu pandemics. Prendergast describes the worldwide outbreak of Hong Kong flu in 1968, when the newly developed vaccine could not be disseminated quickly enough. Sound familiar? One in every five US residents caught Hong Kong flu, and thousands of people died.

As I write this, millions of eggs are being recalled nationwide because of Salmonella contamination. Salmonella outbreaks were routine tasks for EIS officers starting in the 1960s, including one involving cracked eggs that were covered with chicken droppings. Ironically, these disgusting and dangerous eggs still qualified as kosher, because the eggs were not fertilized.

One EIS officer calculated the economic impact of an outbreak of Salmonella at a restaurant in 1973. The restaurant stored raw chicken in plastic pans, which were later used for making potato salad. Total costs, based on the 125 people who became ill, were $30,000, which dwarfed the $10.70 it would have cost the health department to inspect the restaurant, recognize the improper storage methods, and prevent such an outbreak from occurring in the first place.

This book describes investigations of conditions that were emerging infectious diseases then, but are household words now: human immunodeficiency virus, Lyme disease, Legionnaire’s disease, and Ebola fever.

Hospital infections were a major problem historically, as they are now. One outbreak of Enterobacter bacteria was traced to intravenous fluids. The manufacturer had replaced the bottle cap liners, which had been made of a bactericidal rubber, with plastic that did not kill contaminants. This single change led to infections in 378 patients, and more than 10% of them died.

Although early EIS officers were involved primarily with infectious disease, non-infectious conditions are also investigated. An EIS officer started the first poison control program in the country after determining that a summertime cluster of child deaths in the inner city were due to lead poisoning from eating paint chipped from tenement walls. I had not been aware that sunlight mobilizes heavy metals like lead from the bones into the bloodstream.

Decisions made early in the history of the EIS continue to have implications on public health today. For example, as a result of an outbreak of psittacosis (parrot fever) in turkeys in 1954, turkey growers started injecting their flocks with antibiotics, not anticipating the potential implications on public health in the future, i.e., the increasing rates of antibiotic-resistant infections in humans.

Prendergrast was given complete access to the EIS archives, which included documentation of investigations for which causes could not be identified. He also makes clear that the EIS officers sometimes made mistakes, as when an officer predicted in 1970 that malaria would be eliminated in Nepal by 1973. The author does not sugarcoat the negative aspects of the EIS, including megalomaniacal personalities, a desire to prevent transparency in publicizing outbreaks [particularly those in hospitals] and their investigation, and rampant sexism.

Prendergrast is a long-time journalist and author of four previous nonfiction books for the general reader. There were times, however, when I was plowing through an overdose of material, even though this subject is mother’s milk to me. I would have preferred fewer stories written with greater depth.

My decision to become an epidemiologist was sparked by reading The Medical Detectives, two volumes by the late Berton Rouéché. For any medical writer interested in delving into epidemiology, I’d recommend Rouéché’s books over Inside the Outbreaks as an introduction to the field.

—Jane Neff Rollins, MSPH

Jane Neff Rollins is a freelance scientific writer in Montrose, CA.
Dear Editor:

In their article, “Writing for Readers with a Range of Reading Skills,” the authors, Leonard and Cecilia Doak, have done an excellent job of showing the value of evidence-based writing techniques. Although I update some of this evidence below, I don’t mean to detract from an otherwise worthwhile article.

The recommendation to consider readability formulas is ill advised, although they are still used, as the authors note. However, much research shows that applying these formulas doesn’t improve comprehension, and they were never intended to be prescriptions for writing anyway. In addition, the formulas do not incorporate other factors affecting comprehension, such as legibility, word spacing, figures, tables, lists, white space, content complexity, relevance, and readers’ backgrounds and motivations. Also, unfortunately, a well-written paragraph and the same paragraph written backwards (making it meaningless) have the same readability scores.

Another problem related to the formulas is the definition of “reading grade level.” A 6th-grade reading level does not mean that a reader with at least a 6th-grade education can understand it. Rather, it means that half the 6th graders tested for their comprehension of the text can answer correctly half of the questions about it. So, if we test 10 children on 10 questions and all children answer all 10 questions correctly, the comprehension “success rate” is 100%. But if 5 children answer only 5 of the questions correctly—the circumstance that defines reading grade level—the “success rate” is only 25%. So a text written to a grade level has a comprehension “failure rate” of about 75%. Variation in selecting readers for testing, choosing the texts to be tested, and constructing the tests themselves also make these formulas unreliable.

The article states that, “…in general, text is easier to read and understand for people at all literacy skills when text has shorter average sentence lengths and words with fewer syllables.” The statement is basically true, although length is not necessarily the critical factor. Less complex and less ambiguous sentences and more familiar and more concrete words probably have a greater effect on comprehension. Shorter sentences are simply less likely to be complex, and common words tend to have fewer syllables. The article also states that “…it is well known that active voice… make[s] for easier reading.” In fact, the passive voice is generally understood as easily as the active voice and sometimes better. What reduces comprehension is the combination of passives and nominalizations (verbs turned into nouns), and passives in subordinate clauses, not the passive voice itself.

With the exception of considering readability scores when preparing written communication, the advice from the authors, even if not technically accurate, is quite sound. Their article includes much evidence-based advice that all medical writers should apply in their work. I am pleased that the Journal is attracting and publishing such articles and compliment the authors for an interesting and useful presentation.

—Tom Lang

Tom Lang Communications and Training, Kirkland, WA

References


In Cairo, Egypt, whose population approximates 20 million with growth of nearly 1 million every 9 months, sanitation is sadly lacking. In this environment of ancient monuments, blowing sand, dust, and smoke, the Theodor Bilharz Research Institute (TBRI) responds to disease. Reasoning that adding a story about medical writing would add another dimension to the tour of Egypt that my husband, Stan, and I had planned, I did a computer search of hospitals. I chose TBRI because it was the largest and had the most diverse services; the institute’s Web site (www.tbri.sci.eg) pictured a handsome site in Giza facing the Nile and listed full hospital and outpatient clinical services, 8 clinical research departments, 12 research divisions, complete medical laboratory services, and a nursing school. I had no luck, however, when I attempted to contact staff at the institute by e-mail. My e-mails were blocked, and phone calls simply disconnected. Finally, though, our tour company forwarded my request directly. Bingo! Just 4 days before our departure, I received a warm, welcoming response from Professor Dr Inas El Defrawy, Head of the Microbiology Department at TBRI and Editorial Secretary of The Egyptian Journal of Schistosomiasis, Infectious and Endemic Diseases.

Travel from San Diego, CA, to Cairo, Egypt, is a 26-hour venture with 3 transfers. Despite a delayed flight in London and missing my original appointment, Prof Dr El Defrawy accommodated my new schedule and provided a car, driver, and escort. Promptly at 11 AM, our escort, Amira Talal El Far, stepped out of a compact car at my hotel’s curb and welcomed me with a hug. As we negotiated the completely chaotic traffic during the 40-minute drive, she described studies for her predoctoral master’s degree at Cairo University and her work as a research assistant to Prof Dr El Defrawy. Amira plans to continue her studies at medical school soon to become a doctor, following in her father’s footsteps.

Our first sight of TBRI was the contemporary building shown on the Web site, and immediately across the street was the Nile River, carrying the load of trash and plastic bottles that we often saw along its course. Inside the entrance of TBRI was a scaffolding placed to perform the repairs in progress that were notable throughout the building. Modern Egyptians seem to be a sturdy population who have continuously rebuilt their culture. Those we met apparently accepted as a fact of life the unending decay and, when possible, rehabilitation of buildings. The warmth of my welcome and interest in the reason for my visit overtook the start of my meeting with Prof Dr El Defrawy. As I entered her office, 2 other women rose: Prof Dr Soheir Saiid Mansy, Head of the Scientific Technical Office, Deputy of the Clinical Laboratories Division and former Head of the Electron Microscopy Department, and Prof Dr Hoda Yehia, Professor of Pathology and Electron Microscopy and Supervisor, Bureau of the TBRI President. My first thought was surprise that women are clearly well-accepted medical professionals here. I thought that these dignified professors must wonder why I’m here, so I assured them, “I am not here to sell my services as a medical communicator. I hope to tell members of my professional society about publications in this institution” (as I had written by e-mail).

TBRI is a private hospital and research center founded in 1962 by Dr Ahmed Moussa, a world-renowned pioneer in the field of tropical medicine. At that time, schistosomiasis was among Egypt’s most common endemic diseases. Schistosomiasis, also known as bilharzia, has infected more than 200 million people worldwide, making the scope of this disease second only to malaria. Generally, the blood, liver, and bladder are affected and sometimes (but rarely), the brain or spinal cord as well.

Upon an agreement between Germany and Egypt, TBRI was established and named for Theodor Bilharz, who discovered the schistosome parasite in its victims. Funding and staff of TBRI came from both countries to
fill the laboratories and outpatient clinics, which opened in 1978, and later the hospital, which was inaugurated in 1983. The institute’s 25-year anniversary publication cites the institution’s total size as over 25,000 square meters in 4 buildings, including the hospital with both inpatient and outpatient sectors, laboratories, animal quarters, and supply center.

In answer to my first query, “Please tell me about your publication process,” I was shown the TBRI organization chart, which lists “Information and Documentation Centre.” With a smile, Dr Mansy handed me slick-paper copies of her 3 latest publications, one of which was titled “HCV has Transforming Potential to Retrovirus: an Ultrastructure Hypothesis.” Hepatitis C virus infection has become an overwhelmingly common affliction in this hot, overcrowded, poverty-stricken city and a major area of research at TBRI. After more than an hour’s conversation about the range of their publications—similar to those of most large medical institutions: journal articles, book chapters, grant proposals, lectures, slide and video presentations, etc, my hosts suggested that we tour the institution.

After winding through the convoluted hallways, our first stop was at an impressive meeting: Surgical Grand Rounds for an international meeting of the European Society of Gastrointestinal Endoscopy. As we viewed a videotaped surgery underway in a surgical center on our left, Prof Dr Ibrahim Mostafa, Chairman of Gastroenterology and Hepatology, welcomed us. He took the time to explain that this yearly meeting was a teaching seminar directed particularly to young physicians from Africa. He hosted this seminar to spread his department’s expertise to others from countries where such training is not available locally. As part of Prof Dr Mostafa’s continuing education objective, and exemplifying the work of TBRI’s publication department, his videotaped presentation is scheduled to accompany his lecture at the Arab Health Congress in Dubai and is available on the TBRI Web site.

Next on our personalized tour of TBRI was the Information and Documentation Centre, the focus of my inquiry. The Centre’s 5 units include decision support, library, documentation and publication, computer and information technology, and information systems and statistics. Here the *Egyptian Journal of Schistosomiasis, Infectious and Endemic Diseases* is published. The library, headed by Prof Dr Botros and Prof Dr ElBassiouni, boasts a collection of texts, mostly in English, that are focused on liver and endemic diseases, particularly schistosomiasis. With particular pride, my hosts drew our attention to the dissertations and theses of their MD, PhD, and MSc students. Because the environment of books, study tables, and rows of computers was so familiar, I realized that the environment of medical science truly brings together caring humans worldwide.

By now, I was growing concerned that I had taken too much time from these hard-working professionals, but their smiles hinted at a special climax to what had become a highlight of my travel experience. They led the way through a dignified anteroom, where a receptionist announced our arrival by intercom. She then ushered us into the adjoining office and introduced us to Prof Dr Gihan ElFandy, Chair and President of TBRI. Considering the group of dark-suited gentlemen present, we had clearly interrupted a meeting; nevertheless, Prof Dr ElFandy greeted us with a brilliant smile and firm handshake and
immediately made us feel that our visit was her highest priority. We had not the slightest sense of being hurried; rather, she completely fulfilled the scope of her words expressing the Institute’s desire for world-class achievement printed in TBRI’s Silver Jubilee Report: “The institute plans to maximize the benefit from its human and financial resources in research and training, building a technological database and developing hepatic surgeries to introduce liver transplant, which can open for us new a horizon in this field.”

A little breathless from the quickly passing hours of this information-filled visit, we returned to Prof Dr El Defrawy’s office. She and Prof Dr Mansy and Prof Dr Yehia now felt so much like colleagues that I was comfortable in asking about the near universal use of head scarves. I explained that the reason for my question was the situation in Turkey, where numerous college women had committed suicide because of the prohibition on this custom, and France, where an uprising had occurred over the same issue. Here in Cairo, the dusty air certainly warrants the use of scarves. Without annoyance at my impertinent question, the women simply invoked tradition. The closing conversation was an invitation to return and to consider presenting a medical writing workshop.

I cannot close without describing the return to our hotel. Anyone who reads about Cairo knows that traffic is a problem. The incoming trip from hotel to TBRI that took 40 minutes elongated to 3 hours going in the opposite direction—mostly at a dead stop. The compensation was time to converse with our lovely young escort, Amira. Her engagement party would take place in the coming weekend, she said with a smile, and her fiancé was her father’s choice, which she thought was good. Still, though, the couple could not go out together without permission. The wedding would not take place for at least a year or so, after housing had been found. As we chatted, an open truck filled with oranges slowly pulled up alongside. All traffic had stopped. Finally, the driver of a truck 2 lanes over must have gotten bored, because he reached out, selected an orange, and ate it. We too found Egypt hospitable.

Since then a remarkable change has overtaken Egypt. The country’s young people, fired to action by Internet activist Wael Ghonim—the Google executive—now demand democracy and openness. Should this stance prevail, communication could play a heightened role, and medical science would certainly benefit. AMWA’s self-study and workshop programs may offer benefits that enhance medical communication. For those of us in the business and art of communication, arranging a session to teach, learn, or simply meet our global colleagues during travel is a grand opportunity for new friendships and creative ventures.