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The American Medical Writers Association (AMWA) as a professional organization. Specifically, it functions to:

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

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

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If you read nothing else in this issue of the AMWA Journal, although I certainly trust you’ll make time to go through it cover to cover, then I hope the articles that follow by Tom Gegeny and Tom Lang make it to the top of your list. As AMWA strives to achieve its mission—to promote excellence in medical communication—supporting our members’ educational interests, fostering their professional development, and promoting the profession are key. How do we as medical communicators convey our relevance? How do we demonstrate our proficiency? These are just two of the crucial questions we have been pondering as we explore the development of a certification program.

As Gegeny reviews, AMWA currently offers a certificate program, one that brings value to our members and to our members’ employers and clients alike. A certification program is quite simply the next logical step, and one that will shape our future as the premier organization for medical communicators. Gegeny outlines the history of our efforts regarding certification, describing the accomplishments of a specially appointed task force and outlining next steps in what he refers to as a “historic initiative that will help define AMWA’s next 70 years.” In his piece, Lang highlights the pros and cons of certification and shares his thoughts about models to consider. He writes, “There are good reasons to provide evidence of competency in the profession, just as academic degrees confer some sense of competency in the associated field. The question is how to best assess it.”

In the months ahead, you will be hearing much more about certification. In the meantime, please know that we welcome your questions. We also welcome your input. To do this right, we will need to work together to pool our collective experience and expertise. As opportunities become available to help, we hope you’ll answer the call.

MEDICAL WRITING CERTIFICATION: THE TIME IS NOW

By Thomas Gegeny, MS, ELS
Immediate Past President, AMWA

For more than 70 years, AMWA has promoted excellence in medical writing and communication, offering resources and education in support of that goal. AMWA is a 501(c)3 nonprofit organization with an educational mission. The association’s extensive program of workshops and other opportunities allow members to benefit from and participate in the development and dissemination of information and resources across the spectrum of medical and scientific communication. This endeavor is particularly expansive when considering the various audiences for medical writing, which range from patients to researchers to health care providers to regulatory authorities. AMWA’s educational certificate program has been a cornerstone of its mission and has grown considerably over the past 30+ years, not only in terms of the numbers of workshops offered at national and chapter meetings (this year’s annual conference alone will feature 100 workshops), but most recently in the number of certificates available (moving from a 2-certificate to a 9-certificate program in 2010). The establishment of text-based workshop modules (with mail-in tests to earn workshop credit) has been immensely successful. The opportunity to earn the entire Essential Skills certificate will soon be available via these modules, should a person choose to use them in fulfilling the required credits.

Over time, AMWA’s leadership has been repeatedly approached by members querying whether or not a certification exam will ever become available. Indeed, one of the most frequent misperceptions or casual misstatements about our educational certificate program is that it is a “cer-
tification” program. As useful as the program is for many of us, 8 3-hour workshops (not including homework time) is not adequate to confer a credential or certification of any kind. But AMWA has approached the concept of certification before. In 1996, building on earlier research and work (including an AMWA long-range planning committee), then-President Joel Tau appointed an exploratory task group led by Bob Bonk to investigate the feasibility and potential rationale for AMWA pursuing medical writing certification as an offering to medical communication professionals. A survey of 3 organizations that offered certifications was conducted (Board of Editors in the Life Sciences [BELS], Associates of Clinical Pharmacology, and Public Relations Society of America) to gain basic insights into the procedures and costs involved. Recommendations were made to continue the task group’s work and conduct further research (including reaching out to an expert group such as the National Association for Competency Assurance). Nonetheless, AMWA did not pursue certification at that time given the various legal, financial, and other considerations.

In the 15 years since then, the certification “movement” among professional organizations has continued to expand rapidly. Various trends may account for this growth, including technology developments (eg, the Internet), rapid and substantial increase in information and knowledge, the relatively short “shelf-life” of academic degrees (including the integration of various skills and knowledge into ever-growing areas of specialization), a growing demand by the public for established standards, and the desire overall to avoid regulation where lack of such standards may exist.9 In that time, new groups, such as the International Society of Medical Publication Professionals (ISMPP), have launched their own certification programs, while BELS just celebrated the 25th year of its own program. Most recently, the 2010 AMWA member needs assessment survey asked, “Is professional certification with a competency examination desirable for the medical communication profession?” Of the 1,339 respondents to this question, 878 (65.6%) answered “Yes.”

In recent years, AMWA leadership has noted a number of trends in our own professional “sphere.” For example, formal education opportunities are increasing in medical writing and communication—educational certificates based on accredited courses, and even a few degree-track programs, have emerged. For institutions of higher learning to invest in and offer such classes and programs indicates an initial and perhaps growing recognition by higher education of our profession and the value of medical communication skills in society as a whole. Certainly, initiating such a program will also ensure AMWA’s central role in what could become a widely adapted benchmark to establish a minimum standard for the profession.

Our own educational programs are complementary with more formal programs by offering greater flexibility and additional specialization in relevant content (not to mention speedy incorporation of information relating to new developments). Given the breadth and currency of the AMWA educational program, AMWA will no doubt continue to serve as a resource for further academic program development, and reciprocal exchanges of ideas on integral concepts as well as emerging trends are likely. However, because relatively few medical communicators are entering the profession through these nascent programs, a continuing role for professional education (or continuing education) is essential for medical communicators, as embodied by AMWA’s workshops and other educational programs.

Nonetheless, a further role may exist for AMWA as the largest and oldest organization of its kind. Establishing a certification program allows us to draw on a wealth of history and knowledge to define key competency areas within our profession—and to establish basic standards by which knowledge related to those areas can be assessed in a uniform way. Initiating such a program will also ensure AMWA’s central role in what could become a widely adapted benchmark to establish a minimum standard for the profession.

Of course, no certification exam (especially in our profession) will guarantee actual proficiency, skill, or performance of the individuals who pass it. The exam will not strive to do this, nor should it be used by the organization or any individuals or groups to make claims as such. A certification program will allow AMWA to take greater ownership of established standards that may help further and more formally define our profession. As overall knowledge, ethics, technology, and best practices evolve, such an exam can be further refined and focused on the concepts and elements that help define the medical writing profession.

Given this immense opportunity for the organization, a certification task force was appointed in 2009 by then-AMWA President, Cindy Hamilton. Led by Mary Royer, the group included representatives from several sister organizations, including BELS, ISMPP, the Council of Science Editors, and the Medical Writing Special Interest Area Community of the Drug Information Association. With additional legal consultation and information gathered by AMWA’s Executive Director, Donna Munari, research was conducted on potential certification models (in use by various other organizations), as well as specific requirements that would be necessary because of AMWA’s tax-exempt 501(c)3 status (for example, exam-related activities must be covered...
in a separate budget and be overseen by an independent council or commission that is separate from AMWA’s Board of Directors, with representation from both within and outside of AMWA. Also, AMWA’s education program will remain a separate activity and cannot be required for taking the exam (though it may certainly be considered an available means for helping a candidate prepare or as credit toward eventual recertification). Truly, we owe the certification task force volunteers a debt of gratitude for their work in helping to explore, define, and present viable options and the rationale behind AMWA’s consideration of establishing certification in medical writing.

In spring 2010, AMWA’s Board of Directors was presented with a summary of the task force efforts to date and voted in favor of AMWA pursuing certification. The immediate next steps in the past year have included conducting further research, investigating funding options, and initiating contact with established consultant groups who provide specialized expertise and services in developing certification exams with professional organizations such as AMWA. A key point of recognition has been that any such certification exam in medical writing must be specific to our profession and its content should not overlap substantially with that of other exams, such as those offered by BELS (largely editing and publication standards) or ISMPP (largely ethics and publication planning/best practices). Of course, some areas of mutual content overlap will be unavoidable, but AMWA’s certification model will be uniquely tailored to the core skills and knowledge requisite for professional medical writers in a variety of medical communication environments.

What the exam will look like has yet to be elucidated. That will become clearer once an official certification council or commission is recruited and appointed. Among its various tasks, this group (or specific subgroups) will

1. meet with a contracted vendor to establish timelines and priorities,
2. assist with an in-depth analysis of our profession (key skills and central areas of knowledge),
3. help generate exam “items” that must be validated and incorporated into an item “bank,” and
4. work through the questions and considerations that will define the application/eligibility process and evaluation criteria associated with the examination.

Through preliminary discussions, we recognize that a multiple-choice exam may only be helpful for certain information and that a writing component would likely be required as well. No matter what the format, a certification exam in medical writing must focus on essential skills and knowledge that are central to the work of medical communicators: no matter what specific type of medical writing is being done. For example, the exam must be able to assess a candidate’s ability to extrapolate meaning from data and communicate it clearly and accurately. It might draw on basic knowledge such as what statistical test(s) would be most appropriate for reporting certain types of studies/data, but more complex concepts should also be explored, such as the information that should be presented when reporting tests of a hypothesis. Other key areas might include use of punctuation and sentence structure to ensure clarity, principles of clinical trial design and research reporting, organization of key information in a logical order for a specific topic, knowledge of ethical conduct and relevant guidelines, or more basic information such as the meaning of key medical terms, roots, prefixes, and suffixes. Some suggestions have included the idea of an exam where a writing specialization component can be selected in addition to the standard core area (for example, subsection choices such as patient information, regulatory writing, or research manuscript writing).

However, at this stage, we simply “don’t know what we don’t know” with regard to examination design and validation. We do know that we have a great deal of content expertise within AMWA, which we can draw on when consulting with examination specialists. Once the process is complete, we will have achieved a baseline from which certification in our profession can be evaluated, refined, and modified to reflect our evolving profession over time. Other issues would need to be addressed down the road as well. For example, what will be required to maintain certification? This may involve a choice of either retaking the exam after a set period of time or providing sufficient documentation (possibly a portfolio) of certain qualifying activities (such as teaching, authoring articles, or continuing education, etc).

Please stay tuned for more information as it becomes available. In all likelihood, certification will be at least another 2 years away. But in that time, much work will be required, and many opportunities to contribute will exist. Upcoming articles in the AMWA Journal and various member communications will offer updates and announcements relative to this historic initiative that will help define AMWA’s next 70 years.

References
SEVERAL TIMES IN PAST DECADES, AMWA has considered offering certification in medical writing, for good reasons. Certification can be seen as a measure of competence and one that might justify higher salaries or fees. It can also legitimize the profession by indicating that specialized knowledge, skills, or preparation are at least available, if not required, to be in the profession, meaning that someone could probably not immediately qualify as a certified writer or editor without additional training. Certification can also imply that medical writers deserve a certain respect from other professions, especially those that also offer certification or licensure. Finally, becoming certified indicates a commitment to the field, which can be important for prospective employers.

There are good reasons to provide evidence of competency in the profession, just as academic degrees confer some sense of competency in the associated field. The question is how to best assess it. A typical model consists of a single, general exam covering the basic knowledge common to all areas of a profession or requiring a single pass-fail score to become certified. Another model consists of a series of specialized tests that require candidates to score in the upper percentiles to become certified. A third model is based on portfolio review and oral examinations. I want to stress that AMWA has adopted none of these models but is still considering several ideas, and the process remains open. Here, I simply want to compare these models for whatever insights each might bring to the discussion.

In any case, much of our work is skill-based, and we know that problems in written communication may have several acceptable solutions. These skills are not easily measured, although portfolio review and oral examinations are probably the best way to do so. How else do we assess the ability to organize a text to best communicate specific information to a specific audience for a specific purpose? To see what is missing from a text? To add insights or critical information not considered by authors? Because it is so difficult (if not logistically and professionally impossible) to assess skills in reasoning, creativity, and insight with portfolio review and oral examinations, we are left with testing for knowledge or, at most, basic skills, no matter what testing model we adopt.

In this article, I describe the advantages and disadvantages of a single certification test with a pass-fail outcome and of a series of qualifying exams followed by more specialized certification exams with percentile outcomes. I believe that such a two-stage approach to testing is more comprehensive, more accurate, more useful, and more honest. I also comment on how portfolio review and oral examinations might be used with good effect. I hope that we will not be trapped into thinking that a single test is our only option and that we consider a series of tests or even portfolio review when planning any certificate program.

CERTIFICATION BASED ON A SINGLE, PASS-FAIL TEST

Typical Characteristics of the Test and Testing Process

The typical approach to certification involves developing a test on the most important and common concepts needed to perform at a minimum level of competence. The test might consist of say, 100 questions on core topics and perhaps on one or more specialized topics that are to be completed in, say, 3 hours. Much of the test consists of objective questions (multiple choice; fill-in-the-blank), although some tests may include a more subjective component (if someone is willing to grade it). The tests are often given only a few times a year, at a physical location so it can be proctored, which means that candidates have to be physically present to take the test.

Certification is a serious topic, and because everything depends on a single test, considerable resources are usually invested to create it. In many cases, a consultant is hired to guide the development process, pilot test the questions, and determine whether the test returns the same results when taken by the same people at a later time (test-retest reliability) and whether responses to the questions on the same topic are highly related (construct validity).

The Meaning of Passing the Test

Most tests return a single score. A passing score may be based on several criteria, but the rationale for these criteria is often unspecified or arbitrary (e.g., the traditional grading system where scores above 90% are As, those between 80% and 90% are Bs, and so on). All candidates typically take the same test and must receive at least the same minimum score to pass, irrespective of their professional focus. Thus, a passing grade may mean only that the candidate has recognized the correct answers to perhaps at least, say, 70% of the questions on the most basic facts about the profession.

A properly designed certification test distinguishes between more- and less-knowledgeable people who take the test. This ability is important.
because those who pass the test are presumed to be more competent or more knowledgeable than those who do not. However, most certification tests are never tested for this ability. To do so, a group of more-knowledgeable writers and a group of less-knowledgeable writers would need to be identified and tested. Only those scoring high on the test should be in the more-knowledgeable group and only those scoring low should be in the less-knowledgeable group. Without this ability to discriminate between groups, a certification test just separates those who passed from those who did not. Therefore, the test does not differentiate between groups of known abilities, it just creates 2 groups.

Given the difficulty of testing for this discriminant ability, most organizations simply assume that those who pass the test are competent and that those who do not pass are not. By definition, passing the test means scoring above a threshold score. Thus, passing can be a matter of a single point. Can we really determine competence at this level of precision? Is a person who scores 1 point above the threshold really that much different from a person who scores 1 point below it?

**Identifying the Content and Sources for the Test**

Another issue in creating any test is identifying the references from which the questions are drawn. For the test to be fair, the information on which it is based must be widely available and identified before the test is taken. However, for a single, broad test, where do we find the content beyond the mechanics of writing as included in a style manual? Much of the formalized, printed knowledge of our profession is scattered or incomplete. We have books on general writing skills and style manuals, but most books on medical writing concern only scientific publications, and published regulatory guidelines are so extensive that their key points may not be easily identified.

**The Problems with a Single One-Size-Fits-All Test**

To indicate overall competence in the profession, the test must also assess several topics, each at an appropriate breadth and depth. In a field as broad as medical writing and editing, determining the topics (and the breadth and depth of their assessment) to be including in a single, limited test will not be easy. For example, how many candidates need to know something about multiple logistic regression analysis, and how much do they need to know? How many need to know how to write a new drug application? How many need to know how to run focus groups to evaluate patient education materials? Each of these topics is directly relevant to some aspect of medical writing, but common sense says it is unfair to test everyone on all of them, even if a test with a limited number of questions could do so.

Still, most professions have a core body of knowledge that all members are assumed to have and for which there are right and wrong answers suitable for assessing with multiple-choice questions. Given the diversity of tasks performed by medical writers and editors however, this core knowledge is probably going to be limited to lower-level topics, such as the rules of copyediting or the fundamental characteristics of tables and graphs. These topics are basic enough to argue that missing a few test questions on them may not be as important as knowing how and when to verify the answers to such questions when they arise. As a result, certification based on a single test does not indicate any particular strengths of individual candidates.

**Certification Based on Qualifying and Specialized Exams**

**Description of the Test and Testing Process**

I propose that we have two stages of testing: a set of general, qualifying tests and a series of specialized certification tests (Table 1). The qualifying tests would consist of the basic writing and editing skills that all members should have. Because these topics are fundamental to the profession, candidates might be expected to pass these tests with, say, 90% accuracy before they can take the certification tests.

These tests need not be extensive or detailed. We should not expect all members to be grammarians. (Do we really need to remember when to use an en-dash and an em-dash? Or the difference between a becquerel, a curie, a sievert, a gray, and a rad?) We just need candidates to have a good command of the basics.

The specialized certification tests should be more detailed. For example, my test on statistical reporting consists of 100 questions. It should be obvious that anyone answering most of these questions correctly in, say, an hour, will almost certainly have a strong command of this topic.

Candidates should be able to choose the specialized certification tests they wish to take. A series of tests on various aspects of regulatory writing would be more valuable to someone working in this field than to someone working in, say, scientific publications. And neither topic can be adequately addressed in a one-size-fits-all test with a limited number of questions. Because a series of tests can assess more topics in more depth, they provide a more flexible, comprehensive, detailed, and honest assessment of a candidate's knowledge.

All tests could be taken online, at any time, at the convenience of the candidates. Scheduling, proctors, and travel and lodging expenses would be unnecessary. Members would pay a testing fee and be directed to a Web site where they would be given a set amount of time to complete each test. Specifying the time needed to complete each test might give candidates the chance to verify some answers but not all; candidates would have to know the material thoroughly.
The Meaning of Passing the Test

I propose that the results of these specialized certification exams not be reported as pass-fail but rather as percentile scores, like those of the Scholastic Aptitude Test and the Graduate Records Examination. To receive credit for the exam, candidates would not have to answer a given proportion of questions correctly; rather they would have to score in the top, say, 30% among all those who had taken the test. Using this approach, certification means something more than passing a test; it means that certified medical writers would rank among the top third of AMWA members who have taken the test because they have demonstrated having more knowledge than the lower 70%.

For clients and employers, percentile outcomes are more useful than pass-fail outcomes because they provide a more realistic assessment of a candidate’s performance, especially if the results were to be presented on a card suitable for distribution in professional settings, such as employment interviews (Figure 1).
The keys to subjectivity

The nature of both fine art and performance arts—and skills in writing and editing—is, in fact, subjective and is best evaluated subjectively.

The problems with portfolio review and oral examinations

The two biggest problems with portfolio review and oral examinations are their subjectivity and the logistic requirements for selecting and training evaluators. In particular, how would evaluators be chosen? Evaluators might have to be trained to improve consistency, or the number could be greatly expanded if enough members volunteer. For example, perhaps the work submitted for review were to be posted to a Web site where any number of members could review it and vote. It may also be that portfolio review and oral examination would be best reserved for higher levels of achievement where fewer candidates would be evaluated.

Conclusions

My thoughts on medical writing certification follow.

- A single test with a limited number of questions can address only a limited number of topics at a limited depth of coverage. A series of tests can ask as many questions as is necessary to assess the nature, breadth, and depth of any number of topics.
- A single test offers only the option of taking it or not. A series of tests offers several different tests that can be taken by different people, with different backgrounds, and with different professional needs.
- A single test would have to based on the lowest common denominator among all branches of the profession, limiting it to lower-level knowledge that, while important, is hardly representative of either the richness of the profession or the strengths of a given candidate. A series of tests could assess higher levels of knowledge in the range of specialties found in medical writing and acknowledges the very real differences among medical writers.
- A single test has a pass-fail outcome, so the difference of a single, arbitrary, score can determine the difference between becoming...
certified or not. Although every test has a pass-fail threshold, a series of tests provides a much broader basis for assessment and reduces the importance of any one test.

• A single test with a single threshold score, unless its sensitivity and specificity have been determined, tells little about the meaning of a passing score, only that the candidate passed the test and thus has a minimum level of knowledge. Such a test does not measure competence, it defines it. A series of professional rankings has meaning not by presuming to measuring competence but by indicating relative standing with one's peers.

• Portfolio review, oral examinations, or both, offer substantial advantages over objective testing, in that they can assess skill as well as knowledge and avoid the problems of test development. Although time-intensive, they also provide the most complete and personal form of evaluation.

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

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1. A record-breaking 100 workshops! (Yes, that’s with 2 zeroes.) So whether you’re working toward a certificate or just want to improve some aspect of your medical writing, there’s going to be at least 1 workshop that’s perfect for you.

2. Career advancement. Those workshops and certificates look pretty good on a résumé.

3. Open sessions. There are 37 of them, and they’re all included with your registration fee. How do you say no to topics like “Be Your Own IT Department” and the Florida-themed “Space-Based Research and the Future of Humans in Space”?

4. Meeting and greeting. You know all those people from your chapter whose names you’ve heard but whom you’ve never met because they live 3 cities away? Stopping by the Chapter Greet-and-Go could fix that.

5. First-class featured speakers. This year, we’ve got senior NASA bioethicist Paul Root Wolpe, popular physician/author Perri Klass, and prolific author and diabetes expert Francine Ratner Kaufman.

6. Jacksonville, complete with sun, the St Johns River, and Cuban food. Not to mention that in October, both the spring-breakers and the Disney World crowd will have their noses deep in their books, so we’ll pretty much have the state of Florida to ourselves.

7. Coffee and dessert klatches. Come for the coffee and dessert, stay for the sheer fun of it.

8. Breakfast roundtables. How often do you get to sit with your colleagues and kick around ideas about better ways to detect plagiarism, work from home, or use your favorite piece of software?

9. The Welcome Reception on Wednesday and the President’s Reception on Saturday. How often do you get to chat over hors d’oeuvres with people who can actually spell “hors d’oeuvres”?

10. One word: Networking.
PHARMACEUTICAL MEDICAL WRITING COMPETENCY MODEL: PRACTICAL APPLICATIONS

By David B. Clemow, PhD
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ABSTRACT
This article describes the practical applications of a medical writing competency model developed by a medical writing task force associated with the Drug Information Association. The model describes work functions, activities, knowledge, skills, and behaviors deemed necessary to perform successfully as a medical writer in the pharmaceutical industry. The focus of this article is on how the model can be a professional tool to help medical writers and medical writing organizations with organizational structure development; recruiting and hiring; onboarding, training, and development; setting expectations and aligning to assignments; performance evaluation and staff retention; and defining the profession.

COMPETENCY MODEL
The Drug Information Association Medical Writing Special Interest Area Community (DIA MW SIAC) Competency Model Working Group developed and endorsed a Medical Writing Competency Model that has recently had its core content published. The model describes the diverse work functions, behavioral benchmarks, and associated critical activities deemed necessary for a pharmaceutical medical writer. For example, the work function document preparation has a behavioral benchmark related to thoroughly gathering, reviewing, and analyzing pertinent resources. A critical activity associated with this benchmark includes reviewing applicable guidelines. The model also describes the technical knowledge, skills and abilities, and behaviors deemed necessary for medical writers. For example, technical knowledge noted within the all medical writers section includes techniques of scientific writing and editing, statistics, and publishing standards. This section of the model is divided into subsections for all medical writers, regulatory writers, and publication writers. The model content was developed by medical writing professionals representing small and big pharmaceutical companies, clinical research organizations, niche vendors, freelances, writers, editors, and managers from the United States, Europe, Japan, India, and Australia.

APPLICATION OF THE COMPETENCY MODEL
A combination of knowledge, skills, and behavior observed to qualify a medical writer as successful in his or her role is needed for a medical writer to be professionally competent, and a competency model outlines the knowledge, skills, activities, and behaviors that competent professionals should demonstrate. Because the Medical Writing Competency Model helps define what competencies a professional medical writer should have to be successful, it can be a tool to aid in activities such as recruiting, training, and evaluating medical writers.

Organizational Structure
Medical writing groups use various descriptors to define their roles; for example, Medical Writer I, II, and III or Writer, Lead Writer, Group Lead, and Manager. Moreover, in regard to levels, a Writer and Group Lead may be considered equivalent to a Medical Writer I and Medical Writer II, respectively, or both may be at the level of a Medical Writer III but have different job expectations and focus on different competencies. For example, a Writer may be responsible for writing tasks for specific documents; a Lead Writer may be expected to lead document-related activities within a cross-functional group; and a Group Lead might be expected to plan and coordinate writing activities across a drug development program. Depending on how the role is defined, different competencies will be applicable. The competency model can help a medical writing organization define its title structure and align the skills needed for each role.

Subsequently, the model can establish expectations of the medical writing role with cross-functional partners. The model can define for business partners the roles and responsibilities of the medical writer in the drug development process. To aid in this alignment, a RACI (responsible, accountable, consulted, informed) tool can be created that outlines cross-functional responsibilities related to each role deemed necessary to complete a particular type of project, task, or deliverable (Figure 1). The RACI can include core, extended, and ad hoc project team members. A RACI can help develop contracts and operational guides with outsourcing vendors.

Recruiting and Hiring
The content of the medical writing competency model can be used to create job descriptions, postings, or advertisements. Instead of just posting a generic description that a medical writer position is available, employers can highlight the work functions to include those beyond document preparation, such as strategic communications and client management. Abilities and activities beyond writing can be added, such as data interpretation, negotiation, and project manage-
ment. Knowledge beyond therapeutic area can be incorporated, such as knowledge of industry guidelines, drug development, and statistics. The model can align the needs of the specific role with the job description. As an example, additional competencies to writing skills should be highlighted if the description or advertisement is for a Group Lead rather than a Writer.

Detailing the job description with specific model content can align the potential recruit and the recruiter or hiring manager on job fit, thereby streamlining the recruiting process. It wastes the applicant’s and the recruiter’s time if the candidate moves through the recruiting and hiring process when he or she is not truly well aligned for the position in the first place. If alliance management and project management are included as core skill sets for the Group Lead role, a medical writer looking to solely work on writing documents will think twice before applying for the position. Accurate job postings help limit applicants to truly appropriate candidates.

An additional way the model can help in the recruiting process is through the development of an abilities checklist. To supplement a résumé and a writing test, an abilities checklist can be an additional applicant screening tool (Figure 2). The checklist needs to be kept generic so that the applicant does not become confused with company-specific jargon. The applicant enters onto the checklist a self score for each competency listed; a scale of 0–5 (or 0–6 if a neutral option is desired) better enables accurate assessment and secondary follow-up than yes-versus-no categorization. This is important because if the applicant has done something one time, he or she might be inclined to answer yes for a competency when in reality the skill or experience is a 1 on a scale of 0 to 5.

Secondarily to the applicant filling out the activities or competency checklist, the interviewer can use the checklist to target interview questions to specific areas of interest as well as examine the integrity of the applicant who filled out the assessment. For example, if an applicant noted 5 out of 5 regarding protocol development competency, the interviewer may want to ask about how many protocols she has actually written and what specific role she played in the development of those protocols.

Competency-linked interview questions are another screening tool to help the hiring supervisor try to make a hiring decision based on true demonstration of the competencies. The questions can be focused on trying to discern the true skill level related to the competencies specifically deemed necessary to be successful in the posted position. The questions should be tailored to determine where the applicant sits on the competency scale (novice, beginner, practitioner, knowledgeable practitioner, or expert) as well as define what role the applicant specifically took in the project or task of interest.

**Onboarding, Training, and Development**

Successful onboarding is important and is focused on integrating new employees into their new situation to position them for success. New employee assessment from the résumé, interview, and abilities checklist can help target onboarding, training, and early project assignments.

Training is ongoing throughout an employee’s tenure and is needed to maintain and build knowledge, skills, and competency. The competency model can be a guide to help assess what knowledge and skills are missing or underdeveloped in an employee. Assigned training can be based on the needed competencies, and a development plan can be created to fill noted

<table>
<thead>
<tr>
<th>Task</th>
<th>Writer</th>
<th>Lead Writer</th>
<th>Group Lead</th>
<th>Role 3</th>
<th>Role 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deliverable 1</td>
<td>R</td>
<td>A</td>
<td>C</td>
<td>I</td>
<td>I</td>
</tr>
<tr>
<td>Activity 1</td>
<td>R</td>
<td>A</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Activity 2</td>
<td>I</td>
<td>C</td>
<td>A</td>
<td>R</td>
<td>I</td>
</tr>
<tr>
<td>Deliverable 2</td>
<td>I</td>
<td>R</td>
<td>A</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>Activity 1</td>
<td>I</td>
<td>R</td>
<td>A</td>
<td>C</td>
<td>I</td>
</tr>
<tr>
<td>Activity 2</td>
<td>I</td>
<td>R</td>
<td>A</td>
<td>C</td>
<td>I</td>
</tr>
</tbody>
</table>

**Figure 1.** Example of a generic RACI (responsible, accountable, consulted, informed) tool that can be created using the competency model. The RACI tool outlines cross-functional responsibilities related to each role deemed necessary to complete a particular type of project, task, or deliverable.

<table>
<thead>
<tr>
<th>Competency</th>
<th>Score 0-5</th>
<th>Skill</th>
<th>Score 0-5</th>
<th>Behavior</th>
<th>Score 0-5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competency 1</td>
<td>X</td>
<td>Competency 1</td>
<td>x</td>
<td>Competency 1</td>
<td>x</td>
</tr>
<tr>
<td>Competency 2</td>
<td>X</td>
<td>Competency 2</td>
<td>x</td>
<td>Competency 2</td>
<td>x</td>
</tr>
<tr>
<td>Competency 3</td>
<td>X</td>
<td>Competency 3</td>
<td>x</td>
<td>Competency 3</td>
<td>x</td>
</tr>
</tbody>
</table>

**Figure 2.** Example of a generic abilities checklist that can be set up using the competency model. The checklist can be used as an additional screening tool for job candidates and can help a hiring manager target interview questions.
The competency model also helps supervisors align with their staff during career development discussions and help employees know where they fall within the organizational job structure and associated promotion process.

<table>
<thead>
<tr>
<th>Work Function: Medical Writer I</th>
<th>Knowledge, Abilities, Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Job Level</td>
<td></td>
</tr>
<tr>
<td>Medical Writer I</td>
<td>Expectation 1</td>
</tr>
<tr>
<td></td>
<td>Expectation 2</td>
</tr>
<tr>
<td></td>
<td>Expectation 3</td>
</tr>
<tr>
<td>Medical Writer II</td>
<td>Expectation 1</td>
</tr>
<tr>
<td></td>
<td>Expectation 2</td>
</tr>
<tr>
<td></td>
<td>Expectation 3</td>
</tr>
<tr>
<td>Medical Writer III</td>
<td>Expectation 1</td>
</tr>
<tr>
<td></td>
<td>Expectation 2</td>
</tr>
<tr>
<td></td>
<td>Expectation 3</td>
</tr>
</tbody>
</table>

**Setting Expectations and Aligning to Assignments**

The technical ladder, in concert with the competency model, can be a tool for supervisors to set and align on expectations with their writing staff, which is a key endeavor to maintain high-quality supervisor-employee relationships. A key is to not use the model as a simple checklist. It is important to evaluate the success of a project with regard to how it was completed and not just whether it was completed, which is why behavioral concepts are integrated into the model. If the writer accomplished the task but it was associated with poor performance, it is likely that he or she is not fully meeting expectations related to competencies or the role.

Supervisors aligning employees to project assignments based on the demonstrated proficiency of their competencies can be critical for success. Not all medical writers are good at everything. A writer may be considered an expert in technical and analytical skills but a novice in project management or negotiation skills. An individual without interpersonal skills may not be best suited for developing a new sponsor-vendor partnership. Staff competency strengths should help dictate which assignments go to which staff members. However, assignments outside of one's comfort zone or area of strength can be important for development. In these cases, it is important to evaluate an employee's potential for growth in the competency area being considered, as some may have the potential while others may already be at their peak proficiency. Additionally, it is important to avoid situations where an employee is given tasks that he or she is very good at completing but hates doing. An ongoing dialogue between supervisor and writer is important to maintain a balance of what is needed for the organization, what is needed for the employee, and agreement on the employee's proficiency level across competencies.

**Performance Evaluation and Staff Retention**

Competency is shown through action in variable situations and context, with demonstrated outcomes of the job being completed with quality, speed, and value. It is important to measure performance against set expectations. Scoring competency proficiency on a scale of 1 to 5 can be an integral tool for discussing feedback during merit evaluation conversations. Along with quantifiable metrics such as cycle time and number of documented quality-review issues, structured feedback can also be valuable and quantifiable. A feedback survey can be a tool to collect data from peers and team members regarding an employee's performance related to competencies deemed important for job evaluation (Figure 4). Results can be integrated into a performance evaluation form filled out by the supervisor that can be helpful in aligning supervisor-employee ranking on competency proficiency (Figure 5). Having an employee also fill out the form alone or in concert with the supervisor can be helpful in gaining alignment.

For feedback, it is important to discern isolated incidents versus consistent patterns. For performance evaluation, it is important to weight competencies appropriately when creating an overall performance score or comparing scores across role levels (for example, a Medical Writer versus a Senior Medical Writer). Different competencies or levels of proficiency (breadth and depth) might be expected at different levels of a job role.

Along with other criteria, the performance evaluation form can help a
supervisor make decisions regarding rewards and promotions. An interesting exercise is to compare the proficiency levels separately assessed by an employee, one of the employee’s coworkers, and a supervisor of the employee. This exercise is good for setting expectations, having performance discussions, giving assignments, and discussing development plans, as it leads to transparency, clarity, alignment or understanding of misalignment, and more content employees.

Happy employees are much more likely to be retained. Writers can use the competency model to discern areas of interest, enjoyment, challenge, and growth. Supervisor-employee alignment on expectations and project assignments linked to an employee’s interests, strengths, and need for challenge can help keep the employee satisfied in his or her role, which in turn helps the supervisor with retention.

Defining the Profession
A particular competency may be important for one medical writer but not another. For example, detailed therapeutic area knowledge may be less applicable when a writer works in an environment where clinical scientists are driving therapeutic area information. Project management is important for all medical writers, but more so for those who may be overseeing a large number of outsourced projects. Many medical writing niches exist, adding variability about which competencies are deemed most important: work environment (pharmaceutical versus freelance), document type (publication versus regulatory), phase of development (phase I versus phase IV), area of business (clinical versus health outcomes), and functional structure (therapeutic versus cross-therapeutic). Thus, the importance of various competencies discussed in the model depends on the situation, and one should focus on the model elements that are most applicable to his or her particular circumstance; that is, adjust the model to the situation.

The model does not cover the entire nuance that exists within the full spectrum of the medical writing profession. For example, the model covers core competency for a pharmaceutical medical writer regardless of work environment, but it does not cover the competency needed to run a freelance business, an environment in which a large number of pharmaceutical medical writers work. The model was designed with pharmaceutical medical writers in mind, and therefore some medical writing niches are not well represented, such as publishing, continuing medical education, patient education, and academics. The model is not company-specific, and there are significant nuances in role expectations from job to job and company to company. So, overall competency should be examined with additional tools and the model should be adjusted to the situation.

It is important not to be overly dependent on the model, as no one can be fully competent across all of the areas covered in the model. It is also important to be flexible, as role expectations often change over time due to changes in technology, regulation, globalization, work environment, industry dynamics, and partnership interactions.

<table>
<thead>
<tr>
<th>Work Function 1:</th>
<th>5 Excellent</th>
<th>4 Good</th>
<th>3 Average</th>
<th>2 Poor</th>
<th>1 Unacceptable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral Benchmark 1</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
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<tr>
<td>Critical Activity 1</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Critical Activity 2</td>
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<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Critical Activity 3</td>
<td>○</td>
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<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Critical Activity 4</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

Figure 4. Example of a generic technical ladder that can be structured with use of the competency model. A technical ladder can help supervisors align with their staff during development discussions and help employees know where they fall within the organizational job structure and associated promotion process.

<table>
<thead>
<tr>
<th>5 Exemplary</th>
<th>4 High Successful</th>
<th>3 Successful</th>
<th>2 Low Successful</th>
<th>1 Unsuccessful</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work Function 1</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Behavioral Benchmark 1</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Critical Activity 1</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Knowledge or Ability 1</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

Figure 5. Example of a generic performance evaluation form that can be developed with use of the competency model.
Despite professional variability and the fact that medical writers in different environments may require different tools, have different educational backgrounds, and have variable responsibilities, all medical writers need a similar core competency. Medical writers are scientific storytellers who provide logically organized, succinct scientific content to tell a medical or scientific story from beginning to end, cutting through clutter and highlighting essentials.

While the competency model can be a key tool for employee development and supervisor oversight, it can also be the basis for the development of company, professional organization, university, and certification-based educational programs. The model can be one tool that helps define the medical writing profession.

There are limitations of the competency model, starting with how one defines medical communication and whether medical writing is a distinct discipline. In addition to medical writing, medical communication is often associated with multiple professional roles, including but not limited to medical liaisons, medical information associates, medical educators, medical editors, and potentially technical writers, electronic document managers, and even marketing associates. Most of these roles have a medical writing component, but none of them should be categorized as medical writers. Medical communication is an overarching term; despite some overlap, roles are distinct, and the competency model focuses on the medical writer role.

Deciding which competencies are core and setting priorities for competencies are challenges. Perhaps medical writing is still too broad of a professional concept for a competency model to define the profession. Perhaps an individual model is needed for each medical writing niche. Most important is whether medical writers actually demonstrate the competencies described in the model. Medical writing professionals need to use the model, believe in it, contribute to its development, agree on its content, and demonstrate the competencies in order for it to be deemed as a professional standard. If there is no uptake of the model, then it defines nothing. If the competencies are defined by practitioners and not others who lack understanding, then the competency model can be a building block for defining the medical writing discipline. Medical writing professionals need to ensure that people using the medical writer label actually meet disciplinary standards. Supervisors need to hire qualified individuals, hold their staff accountable to competency expectations, and ensure medical writers are in roles, situations, and organizational structures that enable them to demonstrate competency.

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

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References

REMINDER:
PLAN YOUR CHAPTER EVENT AT THE ANNUAL CONFERENCE

The Chapter Greet & Go at the 2011 Annual Conference is designed to give attendees an opportunity to meet with members of their chapter. The Chapter Greet & Go is scheduled for Thursday, October 20, 5:30–6:15 PM, and is intended to be a launching point for your unique chapter event at the conference. The event is scheduled early enough to allow chapter members ample time to meet with each other before the start of the Coffee and Dessert Klatches. Talk to your chapter members and make plans early to get together for dinner at a nearby restaurant or another venue to socialize and network.
SCIENCE SERIES

THE RISKS AND HAZARDS OF INTERPRETING AND REPORTING HEALTH STUDY MEASURES: A SIMPLE, PRACTICAL OVERVIEW

Jan S. Redfern, PhD, and Desmond Thompson, PhD

*President, Redfern Strategic Medical Communications, Inc, Goshen, NY; †Consultant to Regeneron Pharmaceuticals, Inc, Tarrytown, NY

ABSTRACT

To ensure accurate interpretation and reporting of study findings, medical communicators should understand several key measures that are used to determine the efficacy of interventions in health studies. This article 1) provides a practical overview of important measures of effect typically used in health studies, including absolute risk, absolute risk reduction, relative risk, relative risk reduction, odds ratio, hazard ratio, and number needed to treat; 2) covers the use and misuse of these methods; and 3) gives examples of how these measures should be correctly interpreted and reported.

Health studies, such as randomized clinical trials, are critical in assessing the effect of particular exposures and interventions. The results of these studies represent the cornerstone of evidence upon which decisions are made relating to medical practice and public health.1 In health studies, outcomes of interest are often compared between 2 or more study groups with various measures to determine the effect of a particular exposure or intervention (Table 1). For many medical communicators without a strong statistical background, critically appraising, accurately interpreting, and appropriately reporting the results of health studies can be a challenge.

A lack of familiarity with measures of effect can result in a misinterpretation of a study's results. An excellent example of this comes from the media's interpretation

<table>
<thead>
<tr>
<th>Definition</th>
<th>Range of Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absolute Risk (AR)</td>
<td>• Expressed as a percentage, fraction, number (1, event will always occur; 0, event will never occur), or rate (events per person-years at risk)</td>
</tr>
<tr>
<td>Absolute Risk Reduction (ARR) or Absolute Risk Difference</td>
<td>• Typically expressed as a percentage (0%, no difference between control and treated groups)</td>
</tr>
<tr>
<td>Relative Risk (RR)</td>
<td>• RR = 1, risk of outcome identical in both groups • RR &lt; 1.0, risk of outcome lower among treated/exposed vs control/unexposed • RR &gt; 1.0, risk of outcome greater among treated/exposed vs control/unexposed</td>
</tr>
<tr>
<td>Relative Risk Reduction (RRR)</td>
<td>• Typically expressed as a percentage (0%, treatment produces no reduction in risk; 100%, treatment reduces all risk)</td>
</tr>
<tr>
<td>Odds Ratio (OR)</td>
<td>• OR = 1, odds of outcome identical in both groups • OR &lt; 1.0, odds of outcome lower among treated/exposed vs control/unexposed • OR &gt; 1.0, odds of outcome greater among treated/exposed vs control/unexposed</td>
</tr>
<tr>
<td>Hazard Ratio (HR)</td>
<td>• The larger the HR, the greater the chance that the end point will occur sooner in a treated patient than in a person in the control group • HR = 1, treatment produces no effect • HR = 2, twice as many treated patients (vs control patients) experience an event • HR = 0.5, half as many treated patients (vs control patients) experience an event</td>
</tr>
<tr>
<td>Number Needed to Treat (NNT)</td>
<td>• Ranges from 1 (favorable outcome expected to occur in every patient receiving therapy) to infinity • The greater the NNT, the closer the treatment approaches no effect beyond control</td>
</tr>
</tbody>
</table>

* A binary event has only 2 possible outcomes (eg, dead or alive, fracture or no fracture).
† The odds of an outcome is determined by dividing the probability that an outcome occurs by the probability that it does not. The probability of an outcome is determined by dividing the number of times it occurs by the total number of observations.14,17
‡ A hazard represents the rate at which events happen.14,17
of a study by Schulman et al published in The New England Journal of Medicine. The purpose of the study was to investigate whether a patient’s race and sex influence a physician’s decision to request diagnostic cardiovascular procedures to manage chest pain. The study found that both women and black individuals were less likely than men and white individuals to be referred for cardiac catheterization; referral rates were 84.7% for women and black individuals, and 90.6% for men and white people (odds ratio = 0.6).

As reviewed by Schwartz et al, major news media picked up on this article and, focusing on the odds ratio, ran headlines such as “Heart Care Reflects Race and Sex, not Symptoms” and “A Recent Study Shows That Doctors Diagnose Black and White Patients Differently.” The basic message reported by the media was that, compared with white individuals and men, black individuals and women were 40% less likely to be referred for cardiac testing. This interpretation, however, misrepresented the study’s results. While many factors contributed to this misunderstanding, an important aspect was how the media inappropriately equated odds ratio with relative risk. When the same results were analyzed more appropriately in terms of relative risk, it was apparent that black individuals and women were 0.93 (ie, 84.7% + 90.6%) times less likely to be referred than white individuals and men—in other words, physicians were actually 7% (not 40%) less likely to order cardiac catheterization tests for black or female patients than for their white or male counterparts.

To help medical communicators more capably interpret different measures of effect, we review how key outcome measures can be calculated from health research data, the advantages and disadvantages of each measure, and potential pitfalls in the interpretation of each measure. Particular emphasis is placed on distinguishing between relative risk and odds ratio, since these terms often lead to confusion and misinterpretation of the results of health studies. Throughout, we present the topics without the use of technical jargon or complex equations, making it easier to gain insight into these measures. Readers who want a more in-depth understanding of these topics are encouraged to attend an AMWA epidemiology workshop.

**ABSOLUTE RISK**

Absolute risk is the chance of a particular dichotomous outcome (such as dead/alive or fracture/no fracture) occurring over a defined period in a given population (eg, patients of a given age with stated risk factors). Absolute risk is calculated by dividing the number of patients experiencing an outcome by the total number of patients in that particular group.

An example of how to calculate absolute risk is given in the Box at right with data from a randomized controlled trial comparing the effect of vitamin D3 supplementation with placebo on seasonal influenza A in children. The absolute risk of seasonal influenza A in children in the placebo group was 18.6% over 17 weeks. Absolute risk can be expressed as a percentage (as in this example), as a fraction, as a number between 1 (ie, the event always occurs) and 0 (ie, the event never occurs), or as a rate, such as events per person-years at risk (ie, the actual time in years that all patients contributed to the observation period).

**ABSOLUTE RISK DIFFERENCE**

The arithmetic difference (not the ratio) in absolute risk between the control and treatment groups represents the absolute risk difference. With use of the same data in the Box, the decrease in risk (ie, the absolute risk reduction) of seasonal influenza A developing as a result of vitamin D3 supplements is calculated as follows: 18.6% − 10.8% = 7.8%. Stated another way, vitamin D3 supplements reduced the absolute risk of seasonal influenza A by 7.8% (ie, 0.078) over 17 weeks.

Absolute risk difference is often used to facilitate risk management in clinical practice and in related situations (eg, health policy decisions) and is a helpful tool for developing health care treatment strategies. Absolute risk difference provides information on whether a particular intervention will be clinically meaningful in general terms, but it is not an easily comprehensible measure of the effects of an intervention. Nevertheless, an important aspect of determining the absolute risk difference in a clinical trial is that it permits calculation of a more user-friendly and more easily conceptualized outcome measure—the number needed to treat (discussed below).

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Example of How to Calculate Absolute Risk, Absolute Risk Reduction, Relative Risk, and Relative Risk Reduction

- A total of 430 children were randomly assigned to receive either placebo or vitamin D3 for up to 17 weeks (334 children [167 per group] completed the study)
- Number of cases of influenza A: 18 occurred in 167 children receiving vitamin D3, and 31 occurred in 167 children receiving placebo
- Absolute risk of influenza A over 17 weeks
  - Placebo group: 31 ÷ 167 = 18.6%
  - Vitamin D3 group: 18 ÷ 167 = 10.8%
- Absolute risk reduction over 17 weeks: 18.6% − 10.8% = 7.8%
- Relative risk: 10.8% ÷ 18.6% = 0.58
- Relative risk reduction: 100 x (1− 0.58) = 42%

---

Relative Risk and Relative Risk Reduction

The most frequently used method of summarizing treatment effects of event outcomes in health studies is to cal-
ulate the relative risk. Relative risk is the probability (ie, the incidence) of an outcome in an active-treatment group divided by the probability (ie, the incidence) of the same outcome in a control or placebo group. A relative risk of 1 indicates that the risk of an outcome is identical in both groups; a relative risk less than 1.0 indicates that the risk is lower among treated/exposed persons than among control/unexposed persons; and a relative risk greater than 1.0 indicates that the risk is higher among treated/exposed persons than among control/unexposed persons.

With use of the data in the Box, the relative risk of seasonal influenza A is calculated by dividing the risk of influenza in the vitamin D3 group by the risk of influenza in the placebo group: 10.8% ÷ 18.6% = 0.58.

A related term, relative risk reduction, expresses the absolute risk reduction as a percentage of the risk or incidence in the untreated group. When simplified, relative risk reduction is calculated as 100 times the difference of 1 minus the relative risk. With use of the data in the Box, the relative risk reduction is calculated as follows: (1 − 0.58) × 100 = 42%. In other words, vitamin D3 supplements resulted in a 42% relative risk reduction in seasonal influenza A infection compared with placebo.

It is important to recognize that, for both relative risk and relative risk reduction, the same proportional reduction occurs regardless of the magnitude of the absolute values. For example, a 75% relative risk reduction would apply equally to a change in the absolute risk from 24 to 6, from 16 to 4, from 4 to 1, or from 1 to 0.25, but the absolute risk difference would vary (18, 12, 3, or 0.75, respectively). Thus, without knowledge of the baseline absolute risk (ie, the incidence rate) in the control group, it is not possible to fully appreciate the impact of a particular intervention on the basis of relative risk or relative risk reduction alone. A physician may be swayed to initiate a new therapy on the basis of clinical trial results that showed a 50% reduction in outcome compared with standard therapy but may be less impressed if an absolute risk of 2 in 1,000 decreased to 1 in 1,000, even though this also represents a 50% reduction in risk. In general terms, the efficacy of a treatment (in relation to control or another treatment) can be adequately assessed by relative risk reduction, but the absolute risk and the absolute risk difference are needed to provide the context in order to more completely appreciate the effect of a treatment on the population of interest.

**ODDS RATIO**

The odds of an event (a within-group measure) is determined by dividing the probability that an outcome occurs by the probability that it does not. The probability of an outcome is calculated by dividing the number of times it occurs by the total number of observations. The odds ratio (a between-group measure) is defined as the odds of an event in the experimental or exposed group divided by the odds of the same event in the control or unexposed group as follows:

\[
\text{Odds Ratio} = \frac{\text{Exp Group Positive}}{\text{Exp Group Total} - \text{Exp Group Positive}} \div \frac{\text{Control Group Positive}}{\text{Control Group Total} - \text{Control Group Positive}}
\]

where Exp indicates experimental or exposed.

The following 2 examples illustrate how to calculate the odds ratio. In a hypothetical randomized trial conducted over 5 years, 70 of 100 adult women gained bone (determined by bone densitometry) while receiving antiresorptive therapy and 10 of 100 adult women gained bone while taking placebo. The simple odds (within group) of gaining bone is 7 to 3 for women receiving antiresorptive therapy compared with the odds of 1 to 9 for women taking placebo; the odds ratio (between groups) is therefore \((7/3) \div (1/9) = 21\). These results indicate that the odds of gaining bone with antiresorptive therapy is 21 times the odds of gaining bone with placebo. In contrast, the relative risk (a between-group measure) calculated with the same data would be \(70 \div 10% = 7\). Thus, patients receiving antiresorptive therapy are 7 times more likely to gain bone than patients taking placebo.

In the above example, the odds ratio is greater than 1 because the odds of the outcome (gained bone) is greater among treated patients than control patients. For some trials, however, the odds of an outcome (eg, fracture, hospitalization, death) is lower among treated patients than control patients, and, thus, the odds ratio indicating treatment benefit is less than 1. This is illustrated by a second example, which involves a published randomized trial that compared the effect of either intensive therapy or standard therapy (control) for glycemia on the progression of diabetic retinopathy in patients with type 2 diabetes. At 4 years, 104 of 1,429 patients (7.3%) had progression of diabetic retinopathy in the intensive therapy group and 149 of 1,427 patients (10.4%) had progression in the standard therapy (control) group. The simple odds of progression were \(104 \div (1,429 – 104) = 1/12.74\) or 0.0785 for patients receiving intensive therapy and \(149 \div (1,427 – 149) = 1/8.58\) or 0.1166 for patients receiving standard therapy; the odds ratio is therefore \(0.0785 \div 0.1166 = 0.67\). These results indicate that the odds of progression with intensive therapy is 0.67 times the odds of progression with standard therapy, corresponding to a relative odds reduction (analogous to relative risk reduction) of \(33\% (1 – 0.67 = 0.33 \text{ or } 33\%\). The relative risk calculated with the same data would be \(7.3\% \div 10.4\% = 0.7\) (ie, a 30% relative risk reduction).

In the second example, the odds ratio is numerically comparable to the relative risk because the outcome occurs infrequently (<11%). However, when the specific outcome occurs frequently (such as in the hypothetical example above), the odds ratio poorly approximates to relative risk (21 vs 7,
respectively) and may seemingly overestimate the treatment effect—the greater the frequency of the outcome, the greater the exaggeration of effect.\textsuperscript{10,12} The study by Schulman and colleagues\textsuperscript{3} illustrates an extreme case of this phenomenon. In that study, the event rate (referral for catheterization) was extremely common (>85% of patients).\textsuperscript{3} In those circumstances, the odds ratio poorly approximated to the relative risk, actually magnifying the observed effect by almost 600%. When the incidence rate is greater than 10%, it is unwise to interpret the odds ratio with the simplified language afforded by the relative risk.

The main disadvantages of using odds ratio rather than relative risk are that 1) it provides only an approximated estimate of the effect of interest and 2) the concept of odds tends to be more difficult for most people to grasp. In contrast, the interpretation of relative risk is more intuitive and is generally easier to comprehend since the ratio of actual event rates is closer to what most people think of when they consider the likelihood of an event occurring. However, for some study designs, notably case-control studies, incidence rates are not available, and, thus, relative risk is impossible to compute. A case-control study is designed to quantify the relationship between exposure variables (eg, smoking) and disease by comparing individuals with the disease of interest (cases) with a random sample of individuals without the disease (controls).\textsuperscript{13} In this setting, only odds ratios can be calculated, and this is done with use of the odds of exposure rather than outcome.\textsuperscript{10}

HAZARD RATIO
The hazard ratio is commonly calculated to analyze statistical differences in survival or time-to-event data between treatment groups.\textsuperscript{14,15} Time to event represents the period in a clinical trial (or other health study) from recruitment to the occurrence (usually the first occurrence) of a disease end point, the resolution of a sign or symptom, or the censoring of a given participant’s follow-up (eg, as a result of being lost to follow-up, dying of another cause, or withdrawing from the study). The hazard ratio is a ratio of event rates over time and is not strictly equivalent to relative risk, which is a ratio of event numbers, although sometimes the 2 concepts have been used interchangeably.\textsuperscript{14}

The interpretation of the hazard ratio depends on the nature of the event. When the absence of an event is beneficial (eg, absence of cancer), a hazard ratio less than 1 indicates a beneficial outcome of therapy compared with the control. However, when the presence of an event is beneficial (eg, the disease is cured), a hazard ratio greater than 1 indicates a desirable outcome.

An example of how the hazard ratio can show differences undetectable by analysis of the relative risk or odds ratio is illustrated by a simple hypothetical clinical trial designed to compare the occurrence of a particular clinical event (eg, a fracture) over 10 years in 2 groups of patients (10 in a treatment group and 10 in a placebo group). In this hypothetical trial, the same number of fractures (3) occurred in each group; however, in the placebo group, all 3 fractures occurred at year 1, and in the treatment group, all 3 fractures occurred at year 9.

To calculate the hazard ratio, the event rate for each group is calculated from the total number of person-years at risk. For the placebo group, the total number of person-years at risk is calculated as follows: \((7 \times 10) + (3 \times 1) = 73\) person-years. The fracture rate is therefore \(3 / 73 = 0.04\) (ie, 4 patients per 100 person-years at risk). In the treatment group, the total number of person-years at risk is greater because more patients lived a longer period before a fracture occurred: \((7 \times 10) + (3 \times 9) = 97\) person-years. The fracture rate for the treatment group is therefore \(3 / 97 = 0.03\) (ie, 3 patients per 100 person-years at risk). The corresponding hazard ratio, \(0.03 / 0.04 = 0.75\), indicates that, compared with placebo, the treatment produced a 25% risk reduction in fractures over 10 years, calculated as \(100 \times (1 – 0.75)\).

Interestingly, the corresponding 10-year fracture odds ratio is \((3 / 7) \div (3 / 7) = 1\), and the 10-year fracture relative risk is \(30\% \div 30\% = 1\). Both indicate the absence of a difference in the incidence of fracture over the entire study period.

Kaplan-Meier curves provide a simple means of visualizing the cumulative proportion (or percentage) of patients surviving or experiencing an event at multiple time points and can provide useful information about temporal trends. The Figure shows Kaplan-Meier curves for the time to treatment failure in a placebo-controlled trial of antimicrobial therapy for acute otitis media in children.\textsuperscript{16} A total of 161 children received amoxicillin-clavulanate or placebo over 7 days, and the time to treatment failure was determined. As shown in the Figure, the curves separated early and remained separate. The hazard ratio (0.38) showed that amoxicillin-clavulanate resulted in a 62% attenuation in the progression to treatment failure, calculated as \(100 \times (1 – 0.38)\).

It is clear from these analyses that clinically relevant outcomes between groups can be easily missed when only 1 time point is used (eg, the end of a trial). Important temporal patterns, such as early worsening of diabetic complications, latency periods for cancers, and acute effects of hormone-replacement therapy on cardiovascular disease, can therefore be missed by focusing only on single point-in-time comparisons, such as relative risk or odds ratio analyses.

The overall hazard ratio, though, does not give any information about the relative speed or how much faster a particular end point might occur in 1 group compared with another.\textsuperscript{17} Instead, the hazard ratio indicates the chance that a treated person who has not had an event at 1 time point will have that event at a subsequent time point compared with people in
Figure 1. Kaplan-Meier curves for time to treatment failure in a randomized clinical trial comparing amoxicillin-clavulanate with placebo for acute otitis media in children. Kaplan-Meier curves essentially show a “picture” of the event rate over time. Treatment failure was based on the child’s overall condition (including adverse events) and otoscopic signs of acute otitis media. From Tähtinen et al; used with permission from the Massachusetts Medical Society.

A control group (or in another treatment group). The larger the hazard ratio, the greater the chance that the end point will occur sooner in a person in a treatment group than in a person in a control group. A hazard ratio of 2.0, however, does not indicate that an event will occur twice as quickly in 1 group as in another. It is true, though, that the person has twice the risk of experiencing the outcome compared with a person in the other group.

**NUMBER NEEDED TO TREAT**

The number needed to treat indirectly gives an estimate of the risk-benefit profile of a particular therapy. In other words, it provides an estimate of the number of people who would need to be exposed to potential drug risks and side effects to prevent 1 person from experiencing a particular outcome. The number needed to treat can also be used to provide an estimate of the cost of therapy for a particular outcome (ie, how many people need to receive the treatment to avert 1 unwanted outcome), thereby better enabling a rough assessment of the cost-effectiveness of different agents. This concept can also be applied to similar measures (number needed to harm, number needed to screen, etc).

The scale for the number needed to treat theoretically ranges from 1 to infinity. A number needed to treat of 1, which is rarely found in practice, indicates that a favorable outcome would be expected to occur in every person receiving the therapy (but not in any person receiving the control). The greater the number needed to treat, the closer the treatment approaches a neutral outcome (ie, no effect beyond placebo). A number needed to treat of negative 1 indicates the worst-case scenario, in which everyone who receives the control (but not the therapy) experiences a favorable outcome.

The number needed to treat can be calculated as the reciprocal of the absolute risk reduction. For example, in the Heart Protection Study, a randomized controlled trial with patients at high cardiovascular risk, the absolute risk of all-cause mortality over 5 years was 12.93% (1,328 deaths among 10,269 patients) in the simvastatin group and 14.68% (1,507 deaths among 10,267 patients) in the placebo group over 5 years. The absolute risk reduction resulting from exposure to simvastatin is 1.75% (ie, 14.68% – 12.93%). Stated another way, simvastatin reduced the absolute risk of dying by 1.75% (0.0175) over 5 years. The number needed to treat is therefore 57 (ie, 1 ÷ 0.0175). This means that 57 people would need to be treated with simvastatin over a 5-year period to prevent the death of 1 person.

The number needed to treat can also be calculated by determining how many clinical events have been averted (or caused) by a specific exposure or intervention. In the Heart Protection Study example, 1,468 persons in every 10,000 would be expected to die within 5 years (ie, the rate in the placebo group). However, the study’s results suggest that the use of simvastatin would decrease this death rate to 1,293 per 10,000 every 5 years. Therefore, simvastatin appears to have averted 175 deaths per 10,000 people over a 5-year period. This means that 1 death would be expected to be averted for every 57 people treated (ie, 10,000 ÷ 175).

Finally, the number needed to treat may be computed from the baseline risk in the untreated (reference) population and the relative risk reduction attributed to therapy. For example, assuming a relative risk reduction of 30% (0.3) and a spontaneous risk of events of 10% (0.1), the number needed to treat is 33, calculated as 1 ÷ (0.3 × 0.1). A simple nomogram has been proposed to allow rapid calculation of number needed to treat from these 2 variables. It is tempting to use the placebo group in a clinical trial as a reference population, but care should be exercised in this scenario because clinical trial populations are usually subject to inclusion and exclusion criteria and, thus, do not generally reflect the broader population. The incidence in the placebo group is not a surrogate for the incidence in the general population. In addition, it is preferable to use a relative risk reduction derived from a combined analysis of multiple randomized clinical trials rather than from a single study.

Although it is a clinically useful tool, the number needed to treat has limitations and should not be used to compare different outcomes across disease conditions. Its numerical values should ideally be considered inextricably linked to a specific disease, intervention, and duration of study. Thus, it is inappropriate to directly compare number needed to treat values among different trials when the therapeutic intervention, outcome, disease (and severity), and specified observation period are not the same.

**SUMMARY**

Relative risk, its companion relative risk reduction, and hazard ratio are the preferred measures for summarizing data comparing treatment interventions, with the proviso that they are also considered in relation to absolute differences, since ratios may appear to exaggerate clinical effects. The odds
ratio is more complicated to calculate and understand, and it should be considered only cautiously (and in certain circumstances) as a reasonable approximation of an applicable relative risk. However, when the event rate is low (usually <15%), the odds ratio may be considered a reasonable approximation of the relative risk. Although the absolute risk difference does not provide a measure of the proportional effects of an intervention, it does provide useful information about whether a particular intervention will be clinically meaningful in general terms. The absolute risk difference and the number needed to treat should not be used to compare the efficacy of interventions among different clinical trials and are useful only if the true risk (ie, the underlying baseline incidence rate) of the population of interest is known (ie, the risk obtained from epidemiologic data).

Author disclosure: The authors note that JSR owns stock in and has an unrelated service agreement with Merck & Co, Inc, and that DT was an employee of Merck & Co, Inc, prior to agreement with Merck & Co, Inc, and that DT owns stock in and has an unrelated service.

The authors note that JSR was an employee of Merck & Co, Inc, prior to agreement with Merck & Co, Inc, and that DT owns stock in and has an unrelated service.

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References

Help AMWA Address the “Ghostwriting” Controversy

AMWA members are encouraged to participate in a brief survey designed to provide answers that are essential for the continued well-being of medical writing and editing. This survey, a follow-up to surveys conducted in 2005 and 2008, will help to determine the following:

• Proportion of substantial contributions by medical communicators that are undisclosed in submitted manuscripts
• Proportion of medical communicators who request acknowledgment
• Effect of familiarity with publication guidelines on disclosure

Your participation in this survey will be anonymous and will take less than 5 minutes to complete.

The survey will be conducted November 8-21, 2011.

Watch for more information in the AMWA Update.
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**DEVELOPING CONSENSUS MANUSCRIPTS: FROM PLANNING TO PUBLISHING**

**Sandra Ripley Distelhorst, ELS**, Publications Editor, Breast Health Global Initiative, Freelance Medical Writer, Seattle, WA  
**Leslie Sullivan**, Managing Director, Breast Health Global Initiative, Fred Hutchinson Cancer Research Center, Seattle, WA  
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**Introduction:** The Breast Health Global Initiative (BHGIG) has successfully published consensus manuscripts based on global summit presentations and expert panel workgroups since 2002. The most recent BHGI global summit, held June 9-11, 2010 in Chicago IL, resulted in four consensus publications: an executive summary published in *The Lancet Oncology* and three consensus statements published in a Supplement to *The Breast.*

**Methodology:** The BHGI developed a consensus methodology for guideline development modeled after the National Comprehensive Cancer Network. This guideline consensus process was formally endorsed by the Institute of Medicine in 2004. The methodology for guidelines was modified to accommodate the development of consensus statements. Four phases were identified as critical to the consensus statement publication process: pre-summit planning, summit deliverables, post-summit manuscript development, and manuscript publication and dissemination.

Pre-summit planning includes convening a scientific committee to set the agenda and select moderators, presenters, expert panel members, and manuscript working group co-chairs. Summit deliverables include the expert presentations, panel discussions, and working group afternoon sessions where manuscript outlines are approved and writing sections are assigned. Post-summit manuscript development includes compiling individual section drafts into the outline, distributing drafts to working group members for comments and edits, facilitating online discussions for topic areas with diverse expert opinions, and incorporating comments and edits into a final draft for review and approval. A press release and an e-news bulletin are part of the publication and dissemination phase.

**Discussion:** The BHGI summits provide an important opportunity to develop international consensus statements but require extensive pre-summit planning, active summit participation by diverse and respected experts, and timely group collaboration in post-summit manuscript development. Fast-track consensus statement development (within 6 months) is possible with a well-developed project plan and dedicated participants, but can be challenging when working with busy multitasking subject matter experts from around the world.
PUBLIC DISCLOSURE OF CLINICAL TRIAL RESULTS: WHERE DOES THE MEDICAL WRITER FIT IN?
Melody Enscoe, MS, MA, RAC, General Manager, Principal Scientific Writer, Sage Scientific Writing, LLC, Durham, NC
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With the increasingly stringent requirements in the US and abroad for publicly disclosing results of applicable clinical trials using central data banks and/or summaries in a prescribed format, medical writers in the biopharmaceutical industry are finding themselves being called upon to participate in or lead this effort. As a result, we are building processes with our regulatory, biometrics, compliance, and clinical colleagues for effective, timely, clear, and efficient communication of key study results.

We propose to explore the ways in which medical writers can fit into these processes, from understanding the evolving regulations governing results disclosure to playing a large role in generating the information to be disclosed. As many companies are grappling with these requirements, the medical writer now has a new way to apply their medical/regulatory writing skills, and must become comfortable working with technically challenging data entry tools, conveying dense information in restrictive formats, and understanding the needs of the lay audience.

This poster will summarize what the medical writer can offer to this process as they become involved with public disclosure of clinical trial results for the companies in which they work or for the clients that they serve as independent contractors.

QUALITY AND EFFICIENCY IN CLINICAL DOCUMENTS THROUGH STRUCTURED AUTHORING AND CONTENT REUSE
Suzanne Klein-Streigsuth, Electronic Document Specialist, Sanofi-Aventis, Bridgewater, NJ
Michael Robbins, Domain Manager, Clinical Technology and Information Management-Solutions Delivery and Integration, Sanofi-Aventis, Bridgewater, NJ

Introduction: Existing processes for authoring, reviewing, and approving clinical documents create unnecessary workload and delays, and perpetuate errors, inconsistency, and submission-readiness compliance issues. We will share our methodology for developing a program that pairs structured authoring (organization of content into a standard hierarchy) with content reuse (breaking content into “chunks” to facilitate reuse in different locations across documents) to reduce the effort involved and shorten timelines in producing documents.

Objectives: We will improve processes and reuse content to increase quality, save time, and reduce cost in producing clinical documents (time/cost savings up to 30%) by implementing a system of technology solutions and processes that enables all of the following:
• Concurrent authoring of clinical documents
• Reuse of content across documents
• High level of consistency and accuracy of information presented
• Progressive review of content on the component or document level

Methods: Using a flexible approach, we are doing the following:
• Identifying bottlenecks and redundancies in current workflows
• Establishing a library of searchable components for reuse or repurposing
• Creating document maps that list components in the order appropriate to each document type and identifying dependencies/locations across documents
• Providing a user-friendly authoring environment that allows authors to focus on scientific content rather than format
• Designing end-use-specific outputs of final documents

Criteria for Success:
• Full management support of the “big picture” and required budget; IT support for technology requirements
• Comprehensive training/support, coupled with an intuitive authoring environment to foster enthusiastic user acceptance and confidence in this new way of writing documents
• Incremental rollouts of technology and process, providing “quick wins” for targeted user populations
• Logical content/document architecture
• Establishment of processes for governance over creating/modify reusable content components, to optimize the structured authoring and content-reuse methodology and to ensure adherence to company/health authority standards

IMPROVING EFFICIENCY IN COMPIlATION OF CLINICAL STUDY REPORT APPENDICES
Henry Li, PhD, Senior Medical Writer, Talecris Biotherapeutics, Research Triangle Park, NC
Kim Hanna, MS, Vice President, Clinical Development, Talecris Biotherapeutics, Research Triangle Park, NC

A clinical study report (CSR) is an extremely complex document that details the conduct, results, and conclusions of a clinical study. In addition to the text body that summarizes the study conduct and presents the study results, a CSR contains multiple appendices of study-related information, a few of which include the study components.
HOW TO ACHIEVE A CONCISE AND FOCUSED FDA MEETING REQUEST AND INFORMATION PACKAGE

Dolores Massari, Director, Regulatory Affairs, Hurley Consulting Associates Ltd., Chatham, NJ
Fiorenza Falcioni, PhD, Director, Pharmacology, Hurley Consulting Associates Ltd., Chatham, NJ

Interacting with the FDA may sound intimidating, but formal meetings with the FDA provide sponsors and applicants guidance on the development of new drugs or the review of marketing applications. The goal is an efficient, well-managed, and productive meeting that provides the information that sponsors and applicants seek. A well-written meeting request and briefing book are the first steps in achieving a successful FDA formal meeting.

In accordance with FDA guidelines, the written meeting request must include the general nature of the critical questions that will be asked, where the meeting fits in the overall product development plans, a list of specific objectives or outcomes expected from the meeting, and a proposed agenda. If the FDA grants a formal meeting, the sponsor or applicant provides an information package, called a briefing book, to the FDA within the predetermined time frame.

The contents of the briefing book should support the objectives of the meeting and will vary depending on the product, indication, phase of drug development, and issues to be discussed. The briefing book should provide current and accurate summary information relevant to the product and any additional information needed to elicit responses to issues raised by the sponsor, applicant, or the FDA. Carefully worded, focused questions are needed to obtain answers from the FDA that will advance the drug development program. The briefing book should be well organized by topic and should not be voluminous. Consideration should be given to summarizing data in bulleted lists or tables.

GLOBALIZING MEDICAL WRITING: EMBRACING A BRIGHT FUTURE

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Amy Myers, Senior Medical Writer, PPD, Seattle, WA

The biopharmaceutical industry increasingly relies on outsourcing, particularly in areas where there is high demand for global experience and therapeutic expertise. To meet these needs, Medical Writing Departments are executing globalization strategies by positioning people, systems, and infrastructure in locations that meet the needs of their clients. This global model creates opportunities for colleagues from many different geographical regions and cultures to work collaboratively to complete client deliverables.

Medical writing is an ideal discipline for globalization, and an integrated global team offers many advantages. Global working allows growth into new markets and the possibility of new or expanded service offerings. A project can be built around the clock with colleagues in different time zones contributing during their respective days creating a true 24-hour working day. In addition, employees learn about different cultures through interactions with other team members.

There can be difficulties working as a global team, such as language barriers, appreciating the subtleties of different cultures, and even activities as seemingly simple as scheduling a meeting for the whole team. Despite the challenges, globalized medical writing teams can deliver exceptional service,
consistent quality, and innovative ideas that help clients and partners achieve their research and development goals. We will describe the benefits and challenges of the globalization efforts for a medical writing team.

### BIOMEDICAL AND HEALTH INFORMATICS: A ROLE FOR MEDICAL COMMUNICATORS

*Victoria Sadler, PhD, Associate Professor of Technical Communication, Metropolitan State University, Saint Paul, MN*

*Julie Jacobs, MS, RN, Officesm@rts Inc., Minneapolis, MN*

Medical communicators possess knowledge and skills in many different areas, adapting to changes in how healthcare information is created, disseminated, and applied. This poster will discuss the growing field of biomedical and health informatics (BMHI) in the US, summarize the types of expertise and knowledge in the fields of informatics and of medical communication, and highlight the areas where knowledge and expertise overlap between the two fields. Its purpose is to argue for the role of medical communicators in BMHI, particularly in the domains of clinical informatics and consumer health informatics, both of which involve implementing electronic health records (EHR) and patient-specific personal health records (PHR).

Clinical informatics is of particular interest now due to the federal mandate for implementation of EHRs by 2015 and consumer health informatics is working to meet a major goal of healthcare policymakers and providers: personalized healthcare via information technology. Examples of EHR implementations in various sites (a hospital cancer clinic, physician offices, and critical access hospitals) will be provided to show how medical communicators have headed implementation teams. Examples of contributions by medical communicators to the design and delivery of personalized healthcare, and suggestions for potential contributions to the improvement of PHR, will be provided.

Medical communicators are needed now to help in the implementation of EHRs and in shaping the future of electronic communication with healthcare consumers. Expertise in user-centered design and delivery of complex information (which encompasses analyzing audiences and their communicative contexts; conducting usability tests; and advocating for users/consumers of information) aligns with many competencies for a career in BMHI.

### THE NEED FOR JOURNAL COPYEDITORS TO PERFORM A SYSTEMATIC CONSISTENCY CHECK BETWEEN THE ABSTRACT AND THE FULL-TEXT ARTICLE

*J. Elizabeth Troy, Freelancer, Lansdale, PA*

**Background:** Adding a systematic consistency check to my journal copyediting procedure generated additional author queries, but it was unclear whether this effort led to corrections in the published articles.

**Objective:** To examine how often queries noting inconsistencies in abstracts led to revisions in the articles of a peer-reviewed medical journal.

**Methods:** This pilot investigation included 3 issues of the journal. I reviewed all queries involving inconsistency between the abstract and other parts of each manuscript. I classified the queries as proactive (revising text and asking whether the revision was OK) or passive (adding a query without revision). I also flagged particularly important inconsistencies (eg, omitting “not” from a statement). I used the published issues of the journal to determine whether authors had ultimately revised the articles to resolve the inconsistencies, and I tallied the queries in each category.

**Results:** The 3 journal issues contained 49 articles with full abstracts; 41 (83.7%) had carried ≥1 consistency query involving the abstract. The 129 queries were evenly split between information found in the abstract but nowhere else in the manuscript (63; 48.8%) and information that differed between the abstract and other parts of the manuscript (66; 51.2%). Overall, 71.3% (92 of 129) of the queries led to revisions in the published articles. Seven inconsistencies were particularly important; 100% of them were corrected. Twenty-seven (20.9%) of the 129 queries were proactive, and authors accepted 100% of the associated revisions. Of the 102 (79.1%) passive queries, 65 (63.8%) led to revisions in the published articles.

**Conclusions:** Copyeditors should perform a systematic consistency check between the abstract and the rest of a manuscript, because the majority of resulting queries lead to revisions in the final document. When possible, copyeditors should proactively revise text to make it consistent and query whether the change is acceptable, rather than simply querying the author.
Introduction to Regulatory Documents in New Drug Applications

By Peggy Boe, RN, a Barbara Snyder, MA, b and Mark Weiss, MA, MS c

a Medical Writer, Research Pharmaceutical Services, Inc., Wilmington, NC; b Director, Medical Writing, Warner Chilcott (US), LLC, Rockaway, NJ; c Apothecaries International, Inc., Congers, NY

In the June issue, “Regulatory Insights” provided an overview of the drug research and development process. The current article builds on that overview with a description of the major regulatory submission documents that comprise a New Drug Application (NDA) to the United States Food and Drug Administration (FDA).

During the writing and review process, the medical writer is likely to lead production of many of these documents, working with subject matter experts (SMEs) and reviewers from several departments. When the documents reach the FDA, agency reviewers are assigned to the components associated with their specific areas of expertise. They will review the documents and use them to write their own reports in support of their recommendations for the application’s approval or denial. However, all functional area members of the FDA review team are likely to read and refer to the summary and overview documents to gain an overall understanding of the product. The quality, safety, and efficacy information is documented in the chemistry, manufacturing, and controls (CMC) nonclinical, and clinical sections of an NDA, respectively.

Chemistry, Manufacturing and Controls (CMC)
CMC information is categorized into sections on the drug substance (DS) (or API [active pharmaceutical ingredient]) and drug product (DP). Essentially, the DS is the active ingredient, and the DP is the finished dosage form (eg, tablet, capsule, solution) that contains the DS and other ingredients. The CMC section documents that the manufacturing processes for the DS and DP are well understood and that the materials can be manufactured consistently to stated quality standards and can maintain their shelf life under stated storage conditions (Table 1). Refer to the International Conference on Harmonisation (ICH) M4Q (R1) Guideline for more information.

Nonclinical Documents
Nonclinical Study Reports are written for both in vitro (test tube) and in vivo (live animal) studies conducted by scientists in specialized laboratories. These reports usually include an introduction, discussion of methods and results, conclusions, and appended data and figures. Studies typically comprise the fields of pharmacology, pharmacokinetics (PK), and toxicology and provide the foundation for planning the clinical study program.

Nonclinical Written Summaries contain brief lists of the key results of each pharmacokinetic, pharmacology, and toxicology study, as well as short descriptions of methods and discussion of issues with the data or study conduct. One written summary document is created for each of the 3 nonclinical fields (PK, pharmacology, and toxicology).

Nonclinical Tabulated Summaries are also compiled by field, with each study presented in its own table that includes such parameters as species, sex, route of administration, dose, and key findings. The nonclinical study reports are the primary source documents for writing the tabulated summaries.

The Nonclinical Overview is a concise (no more than 30 pages) discussion of the entire nonclinical program, pointing out key findings and their implications relative to the product’s mechanism of action and the safe use of the product in humans. The nonclinical written and tabulated summaries are the primary source documents for writing the overview, with individual study report data referenced as needed. Refer to the ICH M4S (R2) Guideline for the nonclinical content in an NDA.

Clinical Documents
A Protocol is the “instruction manual” for a clinical study, providing the what, when, how, and why. It describes the objectives and design of the study, treatments to be administered, eligibility criteria for subject participation, procedures to be performed, parameters to be measured and data to be collected, data management processes, and plans for statistical analysis of the data. Refer to ICH E6 Guideline for additional information.

An Investigator’s Brochure (IB) summarizes all known data on an investigational product that are relevant to the study of that product in human subjects. It provides the physical, chemical, and pharmaceutical properties and formulation of the drug, results from nonclinical and clinical studies, any previous marketing experience, and specific

1, 2, 3, 4
guidance for the investigator to mitigate risks. The information in the IB eventually becomes the basis of the product’s label. Refer to ICH E6 Guideline for additional information.4

The Clinical Study Report (CSR) describes the study methods as planned in the protocol and the results of actual study conduct. Discussions and conclusions of final data include subject disposition (how many subjects were initially screened, enrolled, included in the analyses, and completed the study); demographic information (ie, characteristics of the subjects at baseline – before any study drug was given); and results of primary and secondary endpoints (eg, PK, efficacy, and safety results). CSRs usually include tables and/or figures that summarize the data in addition to listings of data for individual subjects (generally in appendices). They typically also include narrative summaries for subjects who experienced a serious adverse event during the study or withdrew from the study due to an adverse event. Refer to ICH E3 Guideline for additional information.2

Reports of Integrated Analyses include the Integrated Summary of Efficacy (ISE) and Integrated Summary of Safety (ISS). These documents are stand-alone reports of pooled data (data combined from multiple studies that have similar methods and endpoints), with all of the data appended. Pooling is typically done on the primary data that support the sponsor’s claims of the product’s safety and efficacy. This integration provides reviewers a consolidated analysis of the data in a broader population and examination of a greater number of subset populations. According to the FDA, the titles “ISE” and “ISS” are actually misnomers, as these documents are expected to include detailed interpretation of data rather than basic summaries of the data. Refer to the 1988 FDA Guidance on the contents of a marketing application, as well as the 2008 FDA Guidance on the ISE.6,7

True clinical summaries are also required, as 4 separate documents: Summary of Biopharmaceutic Studies, Summary of Clinical Pharmacology, Summary of Efficacy.

Table 1. Chemistry, Manufacturing and Controls (CMC) Information Typically Found in a New Drug Application (NDA)

<table>
<thead>
<tr>
<th>Section</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Overall Summary [GOS]</td>
<td>Provides an overview of all of the CMC content; emphasizes critical product parameters, and discusses key issues that integrate information from other sections of the NDA.</td>
</tr>
<tr>
<td>Drug Substance (DS)</td>
<td></td>
</tr>
<tr>
<td>General Information</td>
<td>Chemical names, structure, physicochemical, and other relevant properties of the DS, and biologic activity of the biomolecule.</td>
</tr>
<tr>
<td>Drug Product (DP)</td>
<td></td>
</tr>
<tr>
<td>Description and Composition of DP</td>
<td>Description of dosage form, quantitative composition, packaging, and diluents.</td>
</tr>
<tr>
<td>Pharmaceutical Development</td>
<td>Information that established the appropriateness of the dosage form, and the formulation, manufacturing process, container closure system, microbiologic attributes, and usage instructions specified in the application.</td>
</tr>
<tr>
<td>Excipients</td>
<td>Specifications, test methods, validation of test methods, and information on excipients of human or animal origin.</td>
</tr>
<tr>
<td>Both DS and DP</td>
<td></td>
</tr>
<tr>
<td>Manufacturing</td>
<td>Names and addresses of all manufacturers, description of the manufacturing processes and process controls, and flow diagrams. Information on the quality control of raw materials, control of critical processes, validation of aseptic and sterile processes. For biotech-derived substances, description of the processes that involve cell banks, gene splicing, and monoclonal antibody production. Quantitative batch formulas for DP.</td>
</tr>
<tr>
<td>Quality Control of DS/DP</td>
<td>Quality control specifications, test methods, validation of the test methods, justification of the specifications.</td>
</tr>
<tr>
<td>Reference Standard</td>
<td>Chemical and other information about the reference standard[s] used for testing the DS and DP.</td>
</tr>
<tr>
<td>Container Closure System (Packaging)</td>
<td>Description of packaging materials in contact with the DS or DP specifications and test methods.</td>
</tr>
<tr>
<td>Stability</td>
<td>Protocols, test methods, data, summary of results. Information used to support stated retest dates and storage conditions for DS and shelf life and storage conditions for DP.</td>
</tr>
</tbody>
</table>
and Summary of Safety. These documents should summarize all of the clinical data available using all of the clinical study reports, the reports of integrated analyses, and any other information available as source documents (literature, postmarketing results from other regions, etc). The 4 documents should be approximately 400 pages combined, with references to full study reports and other source documents as needed.

The Clinical Overview, similar to the Nonclinical Overview, should be no more than 30 pages and should include a critical discussion of the entire clinical study program (negative results as well as positive), to clearly justify the benefits and risks of the product. The clinical summaries are the primary source documents for the overview, as well as references to individual study data as needed to support the justification for approval. The Clinical Overview may also include nonclinical data if they are relevant. Refer to the ICH M4E (R1) Guideline for guidance on all of the clinical documents.6

Summary
Within the pharmaceutical industry, medical writers often specialize in and have primary responsibility for documents in 1 of 3 specific areas: CMC, nonclinical, or clinical. However, a medical writer who is working on a full marketing application is likely to read, refer to, and incorporate information from a spectrum of regulatory documents. Regardless of his or her particular area of expertise, it is important for the medical writer to have an understanding of each of the documents that together tell the research and development “story” that leads to marketing approval.

References
Tools and Trends in Medical Communication

By Faith Reidenbach, ELS, CMPP
Caley-Reidenbach Consulting, LLP, Corvallis, OR
www.caleyreidenbach.com

❖ 28 Web tools for searching the biomedical literature are detailed in a free online article in Database (http://digbig.com/becfd).

❖ 21 standards for systematic reviews appear in a new report from the Institute of Medicine, Finding What Works in Health Care (http://digbig.com/5becek). Requested by Congress, the standards apply to systematic reviews of the comparative effectiveness of medical or surgical interventions. In addition to addressing how to select studies, synthesize the findings, and assess the quality of the evidence, the standards specify the elements of the final manuscript. They also stipulate that the manuscript should be published “in a manner that ensures free public access.”

❖ 6 free apps of general interest to medical communicators have been released. For the iOS platform: MedPage Today, Medscape Mobile, the Micromedex drug reference, NEJM This Week, and PubMed Mobile. For the Android Market: WebMD.

❖ 4 noteworthy reporting guidelines (guidance on writing specific types of journal articles) are out. Here are the identifiers you can type into PubMed to find them: the GRIPS statement for reporting genetic risk prediction studies (21423587); a pair of articles about economic evaluation as part of randomized controlled trials (21474510 and 21423587); and an article about reporting uncontrolled case series (21163373).

❖ 3D—sort of—models of human anatomy are online at www.healthline.com/human-body-maps. You can rotate a male or female model and, with the click of a mouse, choose to see one of the major organ systems. Or, mouse over a body area to get a closer view and access descriptive text. Designed for an educated lay audience; should also be useful to many medical communicators.

❖ 2 innovative approaches to medical research: (a) In an observational study of lithium for amyotrophic lateral sclerosis, researchers collected information that patients had shared on the social networking site PatientsLikeMe.com, then matched each patient to multiple controls (http://digbig.com/5becja). PatientsLikeMe openly acknowledges that it sells patient-reported data to industry, and all 4 authors of the study report are employees of the site. (b) Researchers from the RAND Corp. demonstrated that data mining—the use of a computer algorithm to search PubMed—identifies “numerous associations” between drugs and side effects (http://digbig.com/5becjb). Notable example: Data mining detected adverse cardiac effects of rofecoxib (Vioxx) as early as 3 years before the US Food and Drug Administration withdrew that drug. (Tip of the nib to Ed Silverman.)

❖ 1 new clinical trials registry: EudraPharm.eu now features the EU Clinical Trials Registry, a publicly accessible version of the EudraCT database. (Eudra is the acronym for European Union Drug Regulatory Authorities.) The registry is gradually being populated with data about all pediatric trials and all phase II to IV trials in adults conducted in the European Union since May 1, 2004.

❖ Quintiles, a global pharmaceutical services company, has published the guidelines it developed for its employees and contractors about using social media (http://digbig.com/5becak). It’s a great starting place for companies that are considering such a move, especially those that, like Quintiles, already have an extensive social media program. Nice touch: The guidelines were first released via Twitter.

❖ Zero: That’s the amount of evidence for the claim that open-access journal articles are cited more often than subscription-access articles, according to a 3-year study published in The FASEB Journal (http://digbig.com/5becfe). However, in the analysis of more than 3,000 articles, the number of downloads of open-access articles was about double the number of subscription downloads. In addition, open-access articles reached about a third more unique online visitors within the first year after publication. These findings suggest to me that when helping clients choose a target journal, publication planners should ask about desired outcomes.
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!
Q — Many certifications are available, and AMWA is now in the initial stages of developing a certification examination in medical communication. Is certification useful for freelance medical communicators?

A — I had the Board of Editors in the Life Sciences (BELS) certification for many years before any potential client asked me if I had it (when inquiring about my editing experience). In fact, I can't tell you how many times I've had to tell people that "ELS" does not stand for English as a Second Language! I don't even really do editing anymore, but I still keep the certification acronym after my name and degree on my business cards because I am proud of this accomplishment. I don't think it really helps me attract clients, though, especially since I do more writing than editing. Experience, reputation, and doing good work are what attracts clients and keeps them.

— Sherri Bowen

A — Although I do not personally have any certifications as of yet, I do believe they are valuable for helping to attract and keep good clients. The reason is simple—differentiation. There are a lot of great medical writers and editors out there. Many make simple mistakes to sabotage their success, such as blowing a deadline or a budget, or treating a client badly. That leaves a smaller pool of really great medical writers and editors. Many of those are uncomfortable promoting themselves, taking on multiple assignments at once, or stepping out of their comfort zones. That leaves an even smaller pool of fantastic medical writers and editors. When you're among them, anything you can do to differentiate yourself will help you attract and maintain clients. Board of Editors in the Life Sciences (BELS), Certified Medical Publishing Professional (CMPP), and Certified Medical Professional (CCMEP) certifications, and hopefully someday soon, AMWA certification, tell current and prospective clients that you take yourself and your profession seriously and that you are committed to upholding the highest degree of quality and keeping yourself current with changes in our industry. When clients are deciding between several fantastic freelances, certification can easily translate into opportunity for the smart and savvy freelance.

— Brian Bass

A — I am in favor of AMWA developing a certification examination in medical communication, and believe it can have a positive effect on our profession; but I think the answer to this question really depends on where you happen to be in your career. For those who have well-established careers as freelance medical writers/editors, I doubt that certification will have any effect on attracting and maintaining clients. On the other hand, for those early in their careers as freelance medical communication, certification may very well be helpful in attracting clients. As for maintaining clients, certification won't mean a thing unless you can actually do the job and do it well.

— Donna Miceli

A — Education, whether formal (eg, AMWA's certificate program or the certification exam under development), or informal (what we learn every day in the course of our work), is always beneficial. The more we know, the better we can serve our clients. But in my experience, "extra" education hasn't helped me attract or maintain clients. When I started my freelance medical writing business in 1997, I had a BA and a master's in journalism and 15 years of writing experience, including a few years of writing about health and medicine part time. I enrolled in AMWA's certificate program and earned a core certificate in editing/writing in 2002. I enjoyed the courses, just as I enjoyed graduate school. But I don't think any of my clients has cared that I have a graduate degree in journalism or a certificate from AMWA. I specialize in medical marketing communications, which is different than the scientific medical writing that many freelance writers do. I write Web content, newsletters and newsletter articles, profiles, reports, brochures and more, mostly for hospitals/health systems, foundations, associations and medical communications companies. Being certified may be more important for scientific freelance writers.

What I have seen though, is that sometimes people don't understand the difference between a certificate and certification. One of my clients likes to introduce me to the doctors I'll be interviewing for him as a certified medical writer, even though I've explained many times that I have an AMWA certificate but am not a certified medical writer.

When the AMWA certification examination in medical communication is ready, will I take it? Yes. Although I don't expect it to directly help me attract or maintain clients, going through the certification process will make me a better freelance medical writer, which will help me better serve my current and future clients.

— Lori De Milto
Defining the Value of AMWA Certificates

By Kristina Wasson-Blader, PhD, ELS, CMPP

KWB Health Communications Inc, Edmond, OK

Among the variety of associations that offer certificates and certifications that medical communicators can obtain, AMWA offers certificates in 5 tracks of specialization. These include Essential Skills, Composition & Publication, Regulatory & Research, Business, and Concepts in Science and Medicine. Medical communicators can earn a certificate in any or all of these areas from AMWA by successfully participating in a defined number of educational workshops and/or self-study modules. Advanced workshops in these specialty areas are also becoming available for those who want additional training.

However, how one defines the value of an AMWA certificate may not be as tangible as the cost to obtain it. Several AMWA members have learned that a certificate is valuable when seeking a career change, confirming knowledge and skills, enhancing credibility among peers or clients, and remaining up-to-date with industry practices and trends. In addition, a certificate can improve a job candidate’s chances of securing a new job, according to some AMWA members who are hiring managers.

Medical Communicators’ Perspectives

At the beginning of 2010, Susan Aiello, DVM, ELS, Chair of the AMWA Committee on Expanded Certificate Program, announced the changes and expansion of the AMWA Certificate Program. Through the assistance of a few self-study modules, the first recipients of the new Essential Skills certificate have been awarded. One recipient, Bette Frick, PhD, ELS, joined AMWA in 2008 after 20 years as a corporate trainer. Although her corporate training business survived several recessions, she felt it was time to expand her business services and found medical editing was a suitable match to her skills and her corporate client base.

With her PhD in English (albeit 22 years old) and many years of professional experience, she thought the 3 Essential Skills workshops and 5 self-study modules would be a “breeze” but found that she still had a lot to learn. To Dr Frick, the value of her certificate lies in the educated confidence she now brings to her medical editing work: “These courses were good for humility purposes. I learned so much...about grammar, terminology, and best practices in the field. The workshops helped bring science and English closer together.” She now plans to earn the Concepts in Science and Medicine certificate.

Another recipient of the Essential Skills certificate, Darren Carter, MD, relied on the self-study modules to complete his certificate in only 8 months. The President and CEO of Provistas, Inc., Dr Carter began looking for a career change about a year ago and thought medical writing would be a good fit.

“Earning the certificate has given me the confidence to seek out medical writing and editing projects and also has gotten me involved in AMWA,” says Dr Carter. He is already enrolled in the Regulatory & Research certificate track and is also considering the Composition & Publication certificate.

Sergio Lozano, MD, began his certificate work with the original core curriculum, but he switched to the Essential Skills certificate program when it became available. Dr Lozano, who is the Scientific Publications Support Coordinator at the University Hospital UANL in Monterrey, Nuevo Leon, Mexico, told his employer about AMWA’s certificate program and suggested that he complete the certificate. With the support of his department head, he made “a strong effort to finish as soon as possible,” and it took 2 years of workshop participation to complete the course work for his certificate. His motivation for getting the certificate, he says, was “to provide credibility of my skills in editing to researchers in our organization and to provide proof of training in biomedical publication for my department.” The value he sees from his certificate is having “more confidence in my work and more support from my department and the University Hospital.” He is now working toward a Composition and Publication certificate.

Long-time AMWA member Mary Ann Wojcik, MS, ELS, a former analytical chemist, earned her first 3 certificates, Pharmaceutical, Editing/ Writing, and Freelance, within the previous AMWA educational program. Her most recent certificate, which took 2 years to complete, is in Composition & Publication. She says that when she interviewed for her current position at Novartis Pharmaceuticals Corp., 2 of the 5 interviewers noted she had earned AMWA certificates. “Now, my colleagues ask me questions about syntax and
correct word usage.” As a consultant for the last 7 years, she paid for her professional development. “It can get costly... however, the benefits outweigh the expense,” she says. Marjorie Winters, another long-time AMWA member with a degree in English, recently completed her Science Fundamentals certificate. She says, “The courses consolidated the bits and pieces of information in several different therapeutic areas that I acquired through my years of medical writing.” She has also earned the Pharmaceutical and Editing/Writing certificates, and is now enrolled in the Regulatory & Research track because “a great deal has changed since I took regulatory courses several years ago... because more clinical trials are performed worldwide, it is now necessary to be well versed in both FDA and EU documents, which I would expect to be covered in the courses offered for this certificate. Electronic submissions are becoming the norm, and employers expect medical writers to be able to produce them.”

Hiring Managers’ Perspectives
For Lisa Rinehart, MS, ELS, who hires both freelance and full-time writers at Med-IQ, having an AMWA certificate will not guarantee that a candidate or first-time freelance writer will get the job but she notes, “It does add to the professional persona of the potential candidate and gives me the impression that the writer or editor cares about excelling in the profession, likes to learn, and knows the value of connecting with and learning from AMWA colleagues. AMWA certificates help me trust that a potential candidate is credible and professional and has the skill set to do the job.”

However, not all managers see the value of attending AMWA workshops as professional development. One writer, who works in patient education and wished to remain anonymous, claims, “Obtaining an AMWA certificate was not encouraged or supported financially.” She adds, “I wish our section’s management felt differently.”

When Barbara Snyder, MA, was a hiring manager, she did not require her writers to have AMWA certificates before they joined her department but she did consider it a definite plus. She explains that she would give preference to those who had AMWA certificates over those who did not when all other things were equal. Once a writer joined her department, she included professional development as an annual goal and used pursuit of an AMWA certificate as an example of something that would fulfill that goal.

Some managers do require their medical communicators to obtain AMWA certificates. Like Snyder, Marianne Mallia, ELS, the Scientific Publications Manager at the Texas Heart Institute, does not require that job candidates have AMWA certificates. However, she does expect all of the writers and editors on staff to work toward AMWA certificates if they do not have them when they are hired. As Mallia states, “I want everyone who works with me to continue their professional development.”

Defining the Value of Your AMWA Certificate
The perspectives of these AMWA members suggest just a few of the reasons for obtaining AMWA certificates. Including a completed or in-progress certificate on a résumé provides an opportunity to demonstrate to potential employer or client that a medical communicator is actively engaged in professional development by keeping up-to-date in the field. It can also provide an opportunity for writers and editors to educate the managers on how to stay current with trends and best practices in the field. Thus, one question remains: how do you define the value of an AMWA certificate?

References
What Is the Drug Information Association?

By Melissa L. Bogen, ELS

Bogen Editorial Services, Chester, NY

Among the various professional associations a medical writer might consider joining in addition to AMWA, the Drug Information Association (DIA) stands out as an organization that can provide opportunities for education and building professional relationships with industry experts worldwide in a multitude of fields related to drug and medical device development.

Founded in 1964 and incorporated in Maryland, the DIA grew from a founding group of 30 professionals employed in academia and the pharmaceutical industry into a multidisciplinary scientific organization of more than 23,000 members from 80+ countries who work in every facet of the discovery, development, and life-cycle management of pharmaceuticals, medical devices, and related products, in such settings as the pharmaceutical industry, government and regulatory agencies, academia, contract service organizations, biotechnology firms, and other related organizations.

**DIA Mission**
The DIA is committed to the broad dissemination of information related to the biopharmaceutical industry among its members. The DIA’s mission is to improve health and well-being worldwide by

- providing invaluable forums to exchange vital information and discuss current issues related to health products, technologies, and services;
- delivering customized learning experiences;
- building, maintaining, and facilitating trusted relationships with and among individuals and organizations that drive and share DIA values and mandates; and
- offering a multidisciplinary neutral environment, respected globally for integrity and relevancy.

**How Does DIA Differ From AMWA?**
While AMWA supports communication on a multitude of topics for medical writers in a variety of settings, the DIA is a global forum for knowledge exchange in various areas of interest related to the pharmaceutical and biotechnology industries: human resources, new medical devices, pharmacueticals (from drug discovery through postmarketing safety and surveillance), biostatistics, project/data management, ethics—just about anything associated with bringing new products to market.

**Why Might an AMWA Member Consider DIA Membership?**
Medical writers with an interest in how drugs and devices are developed would do well to consider joining the DIA, because DIA’s professional development opportunities, meetings, and worldwide access to industry leaders allow such writers to expand their repertoire and network and enrich their career.

AMWA member Art Gertel, Vice President of Strategic Regulatory Consulting, Medical Writing, & Quality Assurance at Beardsworth Consulting Group, Inc., in Flemington, NJ, is a member of DIA and provided some perspective on the advantages of DIA membership. “Although medical writers are often focused on one particular aspect of a project (eg, writing up the results of a study), the entire scope of medical writing is interconnected like a spider web, with lots of points of contact to many aspects of the drug/biologic/medical device development process,” said Gertel. “The DIA helps expose medical writers to many disciplines associated with bringing new therapeutics to market. These include such diverse topics as biostatistics, Good Clinical Practices (GCP), project/data management, ethics, liability, and intellectual property, among others.”

Gertel added that one unique advantage of DIA is that US Food and Drug Administration (FDA) and European Medicines Agency (EMA) regulators attend and present at DIA meetings, allowing for invaluable interaction and networking opportunities. Also, hundreds of vendors have booths at the meetings, enabling attendees to talk to service providers and pharma industry leaders and learn about new technologies and opportunities in the field.

**DIA Meetings**
The DIA holds 2 major meetings: in Europe in March and in the United States at the end of June. While the
European meeting is smaller and Eurocentric (with about 3,000 attendees), the US meeting tends to be larger and global in focus (with about 8,000 attendees attending the 2011 meeting in Chicago). In addition, each year, DIA conducts more than 50 conferences/meetings around the world designed to provide updates on the latest innovations and information that affect all disciplines of drug and medical device development. For example, discipline-specific meetings are being held in 2011 on electronic regulatory submissions; overview of drug development; orphan drug designation; the future of structured product labeling; cardiovascular safety in diabetes, obesity, and oncology clinical development; labeling harmonization; project management; pediatric drug safety; and strategies to accelerate vaccine development, among other topics.

To describe just 1 meeting, the 9th Annual Electronic Submissions Conference, held in October 2010 in San Diego, CA, focused on solutions to global submission challenges, and discussed the development and implementation of an electronic submission strategy to accommodate submission to multiple countries.

DIA also offers an extensive online learning program, which includes live and archived Webinars (didactic sessions), online training (live, multiday Web-based sessions), and e-learning (Web-based courseware accessible 24 hours a day, 7 days a week). Current online training courses include the following topics:

- Basics of the IND
- Basics of the NDA
- Good Clinical Practices for the Clinical Research Professional
- Clinical Statistics for Nonstatisticians
- High Performance Biopharm Teams
- Fundamentals of Project Management for the Nonproject Manager
- Development of a Clinical Study Report
- Art of Writing a Clinical Overview

DIA members receive member discounts to all conferences and annual meetings, training courses, and Webinars.

Special Interest Area Communities

Special Interest Area Communities (SIACs) are subgroups within the DIA that provide a discipline-specific, global community where members can share common experiences and knowledge and connect with others in their particular field. SIACs also assist DIA in identifying professional development needs in particular interest areas and in providing information to members in career and professional development, to meet those needs.

Among the 25 SIACs is one for medical writing (MW). The MW SIAC noted that international demand for high-performing medical writers has increased as companies have come to rely on professional medical writers to develop regulatory- and publication-based documents in support of therapeutic products. This increase in demand heightened interest in identifying the specific attributes associated with superior medical writing.

A little more than 2 years ago, David Clemow, PhD, Scientific Communications Operations Consultant at Lilly USA (and currently Chair of the DIA MW SIAC), established an international MW Competency Model Project Team within the MW SIAC comprising thought leaders and other professionals and industry experts. The team began to identify the work functions and specific competencies (ie, knowledge, skills, and behaviors) they believed were necessary to succeed as a medical writer. The completed model was published in the June 2011 issue of the AMWA Journal, and a description of how it can be applied begins in the current issue on page 106.1

Other Member Benefits

Membership includes subscriptions to several DIA publications:

- Drug Information Journal, DIA's peer-reviewed, scholarly journal
- Global Forum, which presents important news from DIA conferences and workshops, as well as practical tips, regulatory and global updates, upcoming DIA events, program notes, and more
- ePublications, including timely FDA and regulatory updates delivered via e-mail
- Contract Service Organization Directory

Additional membership benefits include the following:

- Access to comprehensive online career center
- Members-only searchable index of DIA articles
- Opportunities to join committees and to volunteer as a speaker, session chair, or author
- Discounts to industry products and services
- Networking opportunities through the Online Membership Directory

For more information on DIA and membership, visit www.diahome.org.

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

Author contact: Melbogen@optonline.net.

References

By Thomas Gegeny, MS, ELS, and Scott Thompson, ELS
Web and Internet Technology (WIT) Committee
Pocket Training Subcommittee

We were pleased to announce the launch of the Pocket Training series of mini tutorials during the AMWA 2010 Annual Conference. Designed to address a variety of topics of special interest to medical communication professionals, Pocket Trainings are similar to the Short (How-To) Sessions offered at our annual conferences in that they present practical ways of how to accomplish specific tasks and solve certain problems. Seven Pocket Trainings are currently available through the AMWA Web site (www.amwa.org), with more to follow soon (Table 1).

Table 1. Pocket Trainings Currently Available and in Progress

Currently Available
- Editing and Organizing References in EndNote
- Editing Text and Reviewing Comments in Adobe Acrobat
- Making the Most of Your Ad in the AMWA Freelance Directory
- Telling It Like It Is: Informed Consent in Plain Language
- Auto-Updating and Cross-Referencing Table and Figure
- Numbers in Microsoft Word 2007
- Creating Hyperlinks in Microsoft Word 2007

Currently in Progress
- Making Bibliographic Style Easy with PubMed
- Creating Your Own Podcasts

Pocket Trainings are an excellent way to share helpful knowledge with peers and to gain experience and recognition for developing an instructional or informational resource. Any AMWA member can propose and develop a Pocket Training based on his or her own expertise and experience, and there is an abundance of potential topics (Table 2). The topics of these mini tutorials can be quite focused (eg, editing text and reviewing comments in Adobe Acrobat) or more generally applicable (eg, creating your own podcasts), but all are oriented toward medical communication professionals and use specific medical communication-related examples. Pocket Trainings in print are no longer than 4 PDF pages. They may also take the form of a short slide presentation, podcast, or other multimedia format.

Table 2. Some Potential Topics for Pocket Trainings

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<th>Potential Topics</th>
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<tr>
<td>- How (and Why) to Diagram Sentences</td>
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<td>- How to Animate Microsoft PowerPoint Presentations</td>
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<td>- How to Become More Involved in AMWA</td>
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<td>- How to Choose a Document Comparison Software Tool</td>
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<td>- How to Choose an Internet Browser (Internet Explorer vs Firefox vs Google Chrome)</td>
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<td>- How to Create and Edit PDF Bookmarks and Hyperlinks in Adobe Acrobat</td>
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<tr>
<td>- How to Create Effective Slide Presentations</td>
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<td>- How to Create Hand-Generated Table Quality Control (QC) Forms (for Simple QC and Re-Creation of Tables)</td>
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<td>- How to Generate a Table of Contents (TOC) with Microsoft Word</td>
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<tr>
<td>- How to Incorporate Comments Made Electronically</td>
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<td>- How to Negotiate a Contract (Perhaps Related to Project Assumptions and Expectations)</td>
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<tr>
<td>- How to Optimize Web Content for Search Engines</td>
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<td>- How to Organize a Chapter Meeting</td>
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<td>- How to Prepare for an Employment Interview</td>
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<td>- How to Publish a Book</td>
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<td>- How to Respond To Reviewers’ Comments</td>
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<td>- How to Use LinkedIn and Other Social Networking Applications</td>
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<tr>
<td>- How to Use the PDF Document Security Features in Adobe Acrobat</td>
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<tr>
<td>- How to Write a Press Release</td>
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<td>- How to Write Easy-to-Read Brochures</td>
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<tr>
<td>- How to Write Internal E-Mail Messages that Don’t Get Ignored</td>
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<td>- Proper Comment Etiquette (How-to for New Business Team Members)</td>
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<td>- Editorial Self-Test: Checking Your Own Abilities or Those of Others (eg, Applicants)</td>
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<tr>
<td>- Effective Oral Presentation Skills</td>
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<tr>
<td>- Copyright Dos and Don’ts</td>
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<td>- Software Tips and Tricks</td>
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Whatever the format, a Pocket Training should communicate the information and demonstrate any examples within 1 hour or less—ideally to fit into the busy schedule of many medical communication professionals.
Pocket Trainings are developed by AMWA members as an AMWA members-only benefit. As the author of a Pocket Training, you are given a byline, which can include your affiliation, if you so choose. Pocket Training authors retain copyright but grant publication rights to AMWA, as stipulated in a Publication Agreement signed by both parties.

The process for developing a Pocket Training involves review and approval from the Pocket Training Subcommittee of the Web and Internet Technology Committee and administrative support from AMWA headquarters (see box below). If you have an idea for a Pocket Training, please submit a Proposal Form to the chair of the subcommittee. Please complete a separate form for each Pocket Training idea.

**Process for Developing a Pocket Training**

- The author submits a Pocket Training Proposal Form (conveniently available for download from the AMWA Web site), to the chair of the Pocket Training Subcommittee of the AMWA Web and Internet Technology (WIT) Committee.
- The subcommittee discusses and approves/disapproves the topic and title.
- The subcommittee chair contacts the author and AMWA headquarters (HQ) with the subcommittee’s decision. If the topic is approved, the chair sends the “Agreement for a Pocket Training Web Publication” to the author and arranges a due date for the draft copy that is agreeable to both parties.
- The author submits the draft copy of the Pocket Training to the subcommittee chair for review by the subcommittee.
- The subcommittee chair provides input to the author, approves/disapproves the draft Pocket Training, and sends notification to HQ.
- For print publications and slide presentations, the author submits the final copy for the Pocket Training as a Microsoft Word or PowerPoint file to HQ. For podcasts and other multimedia formats, prior to finalizing the copy, the author must submit an advance copy to HQ for review and agree to make any content changes that HQ deems necessary.
- HQ reviews the copy for adherence to AMA style, places it in the approved template, and sends a review PDF to the author and the subcommittee chair.
- When the author and subcommittee chair complete their review, HQ posts the Pocket Training to the AMWA Web site and publicizes it to members.
- If the subcommittee later determines that the Pocket Training information is out of date, the subcommittee chair contacts the author and HQ to establish a timeline for revision. As stated in the Agreement, “if changes are not made as requested, AMWA reserves the right to remove the publication.”
COUNCIL OF SCIENCE EDITORS ANNUAL MEETING

By Hilary Graham, MA
The University of Texas MD Anderson Cancer Center, Houston, TX

The Council of Science Editors (CSE) held its annual meeting on May 1-3, 2011, in Baltimore, MD. The global themes of this year’s meeting included:

- strategies to better communicate science to the general public
- publication ethics and the seeming increased incidence of retractions
- how large data sets and supplemental data should be hosted and what should be made publicly available
- great tips on how to employ technology to work more effectively

Many slide sets from the sessions are available online at the CSE Web site and are packed full of fantastic information. I’ve listed a selection of the presentations that may be of particular interest to AMWA members.

In the first Plenary Address, Darlene Cavalar, The Science Cheerleader, described how she has endeavored to effectively communicate science to the general public while maintaining the integrity of the science and gaining the interest of the audience. Her primary Web site, www.sciencecheerleader.com, promotes the involvement of citizens in science and science-related policy. She is also Principal Investigator for 2 National Science Foundation grants. The first, www.scienceforcitizens.net, links scientists with members of the general public who would like to assist in research projects by collecting data. The second program, Science of Football, is a collaboration with NBC sports and the NFL that promotes the scientific explanations behind the realities of football. These videos can be found at www.nbclearn.com/nfl.

In the second Plenary Address, “The Importance of Reproducibility in High-Throughput Studies: Case Studies in Forensic Bioinformatics,” Keith Baggerly, PhD, a forensic bioinformatician from The University of Texas M.D. Anderson Cancer Center, provided a cautionary tale of scientific misconduct. His quest to validate and reproduce the conclusions from a high-profile research group at Duke University spans several years and unfolds like a CSI episode.

Breakout sessions addressed a variety hot topics that ranged from wading into the social media landscape, to the current issues surrounding supplemental data, to detecting and deterring scientific among others.

The session “Social Media Metrics” gave participants concrete tips on how to evaluate, measure, and track the impact of social media campaigns.

The “Supplemental Data: Questions and Considerations” session, moderated by Carissa Gilman, of the American Cancer Society, presented the pros and cons of publishing supplemental data, highlighted discrepancies in the peer-review process, and gave considerations for storage and archiving large datasets.

The session “Image Integrity” gave participants key information on how to determine if a digital image had been inappropriately manipulated and what action journals can take to deter this form of misconduct.
Dawn McCoy, of the American Society of Nephrology, and Peter Olson, of Dartmouth Journal Services, gave tips in “Build a Better Style Guide” on how to craft a comprehensive, well-structured, user-friendly style guide that will save authors and editors time and frustration.

In “Reproducible Research in Scientific Journals: What’s Needed and Possible?” Keith Baggerly, PhD, Roger Peng, PhD, and Steven Goodman, MD, PhD, discussed the 4 necessary components to facilitate reproducible research: data (analytic data), methods (code and software to execute code), documentation (code, software, and dataset), and distribution. They also suggested the Google Group, Scientist for Reproducible Research, which can be found at http://groups.google.com/group/reproducible-research.

Ivan Oransky, MD, one of the panelists of this session, was one of the most interesting panelists of the entire conference. Dr Oransky is the Executive Editor of Reuters Health and the influential blogger behind Retraction Watch (http://retractionwatch.wordpress.com) and Embargo Watch (http://embargowatch.wordpress.com). Retraction Watch is a must read for all those invested in the scientific community.

In addition to the CSE meeting in Baltimore, the Board of Life Science Editors (BELS) also held their 20th anniversary celebration at the Admiral Fell Inn. John C. Bailar III, MD, PhD (right), former Editor-in-Chief of the Journal of the National Cancer Institute, editorial board member of Cancer Research, and statistical consultant for the New England Journal of Medicine, was awarded an Honorary ELS certification by incoming BELS president Susan Aiello, DVM, ELS. Approximately 50 BELS members were in attendance and thoroughly enjoyed Dr Bailar’s presentation on his professional journey and his first interactions with BELS while it was still in its infancy.
Most of us have had it drilled into our heads that correct grammar is needed in everything we write—medical or personal. Many of us shudder just a bit when we read in a newspaper or magazine some things like “A doctor should treat their patients kindly,” or “A book is judged by it’s cover,” or similar gaffes.

But “bad grammar ain’t no sin” when the “error” is deliberate to create humor, emphasize a meaning, make a specific point, or other similar situations; like in the title of this piece, and I’ll bet all the readers understood it at once.

Also, there is leeway for this in signed columns or personal comment.

Ogden Nash was the celebrated icon of humorous poetry. Among his thousands of splendid quotations, one of the most brilliant and famous (and my favorite) was

“A little talcum
Is always walcum.”

A fantastic couplet, but what if some compulsive and erudite but inexperienced editor had “corrected” it to

“A little talcum
Is always welcome.”

Or more simply, “A little talcum is always welcome.”

Trite and unfunny, and Ogden Nash would still be an unknown. Was Nash using poetic license? Absolutely, and it was not a grammatical mistake. It became a landmark of humor.

Another well-known old verse (perhaps also Nash’s) is so expressive:

“A little bit of powder
And a little bit of paint
Makes a woman look
Like what she ain’t.”

Oh, horrors; there’s no such word as “ain’t. That inexperienced editor could have changed it to

“A little bit of powder
And a little bit of paint
Makes a woman look
Like what she is not.”

How many people would laugh? Not I. Literature is full of writers and the entertainment world is rife with comedians who purposely misspeak or misspell the language for hysterical effect. Besides Nash, there are Jimmy Durante and Will Rogers, just for starters.

If I were a national columnist, and a particular public figure mangled the English language, I would be well within my writing bounds to refer to him with “He don’t talk so good.” And everyone would understand.

Further, if writing about the misuse of “ain’t,” I might use that old saw “Ain’t ain’t in the dictionary.” How horrible to “correct” it to “Ain’t isn’t in the dictionary” and have it lose its impact. Readers would understand that it was humor—sarcasm, if you please—and no one would write the newspaper about its poor editing.

So, with a little intelligence (and I think it takes more intelligence to create a grammatically incorrect pun or dramatic point than it does to write it in faultless English)—and with a sense of humor—we are all OK if we use a grammatical error to make a point. Sometimes, “Bad grammar ain’t no sin!”

And, by the way, it’s incorrect to say “Ain’t ain’t in the dictionary,” not for grammatical reasons but (and I looked it up)—ain’t is in the dictionary.
Dear Edie: How did you become involved with AMWA?
Edie: A friend of mine worked for Hahnemann Medical College, and when I came to work there, he said, “The first thing you have to do is join AMWA.” I said “OK!” That was in 1954. And so I’ve been a member since then.

Dear Edie: What types of jobs did you hold in your life?
Edie: I was at the beginning a legal secretary—as opposed to an illegal one. And then I became a medical editor, and that’s what I’ve been ever since.

Dear Edie: Who is the individual that influenced you the most?
Edie: Arnold Melnick, who said, after I’d been a member for some years, “Edie, it’s time for you to become involved nationally, not just with your chapter [Delaware Valley].” I was very active in the chapter. I said, “OK!” He had been president of the chapter, as well as of the national organization. He was a DO, a pediatrician. If it hadn’t have been for him, I don’t know where I’d be today.

Dear Edie: What positive changes would you like to see in the medical communication industry today and tomorrow? Among editors and writers?
Edie: The only thing I would like to see is to have editorship recognized as a profession in its own right. Not as adjunct to writing. It can stand by itself. You don’t have to be an editor to be a writer, but to be an editor, you have to be able to write well. So I’d like to see it stand alone.

Dear Edie: Apart from English, what are your other interests?
Edie: My other interests are music and books. I saw a special about James Levine, the conductor of the Metropolitan Opera. He served for 4 years. And he’s just as excited about it as when he began, 40 years ago. I have the same burning passion about English.

Dear Edie: Did anyone in your family follow the same career path as you?
Edie: My son is also a writer and editor, and also, as if he didn’t have enough to do with that, he’s a computer consultant, and very successful in all of his endeavors. I always joke that I inherited my talents from him. My daughter used to write—she had to—she has a Master’s degree in Public Administration from the American University.

Edie thanks Susan A. Veals, PhD, RN, Seattle, WA; Felicia Del Buono, BS, MT (ASCP), Elverson, PA; and Karen H. Golebowksi, Hoboken, NJ, for their questions.
AMWA Web Site Resources for Chapter Leaders—and Members

By Faith Reidenbach, ELS

2010-2011 Administrator of Web and Internet Technology

One of the best ways to get involved in AMWA is to become active in one or more chapters. Many host dinner meetings or similar events where you can learn more about medical communication, befriend like-minded people, and perhaps make contacts that will lead to a new job or freelance work. Some chapters also hold annual or biannual conferences with opportunities to earn workshop credits toward AMWA certificates. Volunteering for your chapter is particularly rewarding and can help you develop skills directly related to your work—and many chapter leaders build close relationships with people who become lifelong friends and colleagues.

Accordingly, an entire section of the AMWA Web site is devoted to information about chapters. From www.amwa.org, click “Membership” and then “Chapters.” The resources there are intended for 3 audiences: AMWA members, AMWA “evangelists,” and chapter leaders.

AMWA members: Unlike many professional associations, AMWA has a chapter for everyone who lives in the United States (including Alaska and Hawaii) or Canada. When you joined the organization, you were assigned to the chapter that matches your city or town of residence (see the map). You can change that assignment if you wish; for example, someone who lives in southern Oregon might prefer to belong to chapter 16 (Northern California) rather than chapter 18 (Northwest), which usually meets in Seattle. As of early June, 12 chapters have created groups on LinkedIn, and you may join whichever groups appeal to you—or all of them!

Along with the map, the “Chapter Information” section of the Web site gives the names and e-mail addresses of chapter leaders. This comes in handy if you have a question about your chapter’s activities or would like to contact your chapter president and volunteer to help organize a meeting, produce a Webinar, serve as chapter Webmaster, manage a LinkedIn group, and so on.

AMWA “evangelists” spread the word about medical communication and AMWA by speaking to students, postdocs, and corporations in their region. The chapters section contains several resources for such speeches. In the section entitled “Tips, Publicity & Media Kits, Brochures & Presentations, Web Resources,” look under:

- Presentations for a PowerPoint file called “All About Medical Communication”
- Brochures or PDFs of brochures about membership, student membership, the Freelance Directory, the education program, and the self-study modules, and brochures titled “Help! I Need a Writer” and “Career Path: Medical Communication”

This section also features AMWA’s media kit, which tells companies how to become a conference sponsor and/or exhibitor, corporate sponsor, advertiser in the AMWA Journal, or advertiser on Jobs Online.

Chapter leaders can access myriad helpful documents on the AMWA Web site, notably the Manual of Procedures for AMWA Chapters. This 19-page PDF contains sample job descriptions for chapter officers, program suggestions, and helpful hints for managing a dinner meeting. It describes how to take advantage of the travel assistance fund for sending a delegate to Board of Directors meetings and how to get a federal income tax exemption (in the case of US chapters). It also covers accounting procedures and provides a typical budget and balance sheet. A companion manual, the AMWA Chapter Conference Handbook, helps chapters organize a conference in all the meticulous detail that the national conference is famous for.

In the section “Tips, Publicity & Media Kits, Brochures & Presentations, Web Resources,” chapter leaders are invited to read “Tips for Chapters in the AMWA Journal,” a compilation of articles on topics such as setting up a chapter Web site, cultivating chapter leadership, and organizing a chapter or regional conference. That section also has a publicity kit (PDF and Word versions) that includes a sample news release and tips for getting local press coverage.

Two of the newest additions to the chapters section are widgets that chapters can add to their Web sites to advertise the Freelance Directory and Jobs Online. For additional ideas about improving your Web presence, visit other chapters’ sites (the Chapters Information section provides links). Don’t forget to revisit the national site occasionally, too. Thanks to the creativity of AMWA members and staff, nothing stays static for long!
Social Media or Social Networks?
There's No Simple Semantic Solution!

By Cyndy Kryder, MS, CCC-Sp
Freelance Medical Writer, Phoenixville, PA

Much online and offline buzz appeared following an April 2011 blog post on Social Media Today (http://socialmediatoday.com/rohnjaymiller/287465/stop-its-not-social-media-its-social-networks) that advocated using the term “social network” rather than “social media.” Perhaps advocated is the wrong term, since the author began his post with “We have to stop using the term ‘social media.’ Everybody. Stop. Now.”

His argument was primarily that senior management in organizations that do online marketing continues to misunderstand what’s happening with platforms such as LinkedIn, Twitter, and Facebook. It views social media as clutter or fads, or simply as just another way to market and get customers to buy its products, rather than a way to connect with customers and find out what they are saying about a product or service. In the author’s opinion, the term social networks better describes engagements that occur with the listening and sharing of ideas, videos, and links on social networking sites.

It’s an interesting discussion, and one for which there is no simple semantic solution. In my opinion, the term social media implies something much larger than a social network. The term media in the context of social media refers to another form of mass communication. A social network such as LinkedIn is simply the tool we use to communicate.

So social media comprise social networks, but not vice versa. Our social media strategy should drive the social networks on which we become active because it will identify the colleagues, customers, and potential clients with whom we want to communicate.

I’m not sure what value the online debate over the proper terminology brings to the social media/social networking discussion. Certainly words matter, but more important than using the right word to describe what we’re doing is actually doing it. I agree that the term social media can be misperceived as marketing. For medical writers, however, it should be about the connections we make, the conversations we have, and the value we bring to those conversations. Along the way, we should strive to become part of the message rather than add to the noise.

The Voices of Experience Share Ideas in AMWA’s LinkedIn Group

By Mali R. Schantz-Feld, MA
Freelance Medical Writer, Seminole, FL

AMWA’s LinkedIn group is always ready with advice, stories from past experience, and “caveats” from lessons learned. New freelance Kristie Boehm benefitted from such wisdom when she asked for advice about her situation. She had been coaxed into providing some writing assistance. While her gut was telling her to flee, her kind spirit made her accept the offer. With only an oral agreement, she started the preliminaries but received no follow-up from the client. She asked for advice, noting, “I hate burning bridges but might consider a bit of scorching in this case!” Many of us have had that same feeling after reluctantly accepting a client—the feeling that one usually gets after eating the remnants of a day-old burrito that may or may not have been sufficiently refrigerated. The discussion produced many helpful suggestions: Bailing out was unanimous, but how? Without a contract to seal the deal, Kristi was advised to write a cordial note thanking them for their business but politely declining the assignment. One member said to offer names of other freelances, but another noted that was not necessary and was passing on a potential problem. Another member noted the importance of including a definite timeline based on deliverables from both sides so the client will understand what it takes for the assignment to be completed.
Another question, from Laurie LaRusso, involved manuscripts and whether medical editors should help in contacting journals to get the placement and the paperwork in place for clients. Some suggested guiding authors to choose the right journal, others said they make it a policy never to contact the journal, and some said they collate all the necessary forms, shorten the abstract to the appropriate word limit, and submit the manuscript for the client. One response noted that this service is particularly appreciated by authors whose first language is not English. This discussion showed the variety of services and policies of AMWA editors and illustrates that there’s more than one way to run a business.

Our very own Journal Editor Lori Alexander also invited members to read about medical communicators’ salaries on the AMWA Journal Blog. Also, now is the time to help guide AMWA leaders in a constructive direction. Annual conference session moderators, roundtable leaders, and the like are asking members what they’d like to see covered in their sessions, roundtables, etc. Reach out to them with your suggestions, and facilitate the exchange of information and discussions that will increase medical writing “know-how” and improve business. A continuing thank you to all who read our discussions, to all who ask questions, and to all who supply answers. Our group continues to grow in numbers and knowledge. Looking forward to connecting with you on LinkedIn!

**Blog Log**

**Blogging about . . . Oncology**

I attended my first American Society of Clinical Oncology (ASCO) meeting this year. In honor of that, the focus of this issue’s Blog Log is cancer research.

Wall Street Journal’s Health Blog:
http://blogs.wsj.com/health

Ok, it’s not a cancer-only focus, but the WSI’s health blog is chock-full of interesting tidbits about a variety of health-related issues. It popped up on my search because of the coverage it provided on ASCO; far more than you would have learned reading the print version. Plus, the blog is free!

Pharmahororum:
www.pharmahororum.com

Another one of those it’s-not-just-about-cancer-but-is-worth-following-for-cancer news blogs. The blog came up on my search because it, too, had great coverage of ASCO, albeit from a pharmacentric perspective. Search here for companies to target for potential oncology work.

GenomeWeb’s Cancer Minute:
www.genomeweb.com/newsletter/cancer-minute

This blog aggregates a variety of cancer-related news. Recent posts: controversy at a Spanish cancer institute; comment on articles in the week’s *Lancet Oncology, New England Journal of Medicine*, and *Journal of the American Medical Association*; and coverage of some interesting research, including another link between obesity and cancer risk. You do have to register for access, but it’s free.

Cancer Research UK:
http://scienceblog.cancerresearchuk.org

Get the Brit perspective on ASCO and learn about cancer research on the other side of the pond. Yes, shocking, I know, but not all medical research occurs in the United States.

Penn Medicine’s Focus on Cancer:
http://penn-medicine-focus-on-cancer.blogspot.com

I’m sure most large academic centers have their own blogs these days (and if you find one that doesn’t, call them up and offer to write it for them—for a fee). This is just one such blog. A recent post gave the blog over to a cancer survivor to provide a unique perspective on a melanoma conference.

Pharma Strategy Blog:
http://pharmastrategyblog.com

I stumbled onto this one by accident. Written by a biochemist who works for Icarus Consultants, it grabbed my attention because she writes it in her spare time “when not playing fantasy football.” She also attends nearly every major cancer-related conference and posts her thoughts and impressions here. Recent posts include the thorny question of whether maintenance therapy with chemotherapy improves progression-free survival in non-squamous lung cancer and an update on PARP inhibitors.

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President’s Message
Melanie Fridl Ross, MSJ, ELS, 2010-2011 AMWA President

In our line of work, transitions are used to permit the reader to pass smoothly from one part of text to another. They strengthen connections between thoughts. They link ideas.

AMWA is about to embark on one of its most significant transitions in a decade. By now you’ve heard the news that after 35 years in association management and a decade of leadership with AMWA, Executive Director Donna Munari, CAE, will retire at the conclusion of the annual conference in Jacksonville this October. She will be succeeded by Susan Krug, CAE, who joined AMWA July 29 (see page 142). And while the change that comes at times like this can bring mixed feelings, I am confident that AMWA will easily weather this transition.

Many of you may not know that Donna is a master gardener. Master gardeners undergo hours of horticultural training and often give back through volunteering, sharing their knowledge with others. Donna’s green thumb extends to AMWA headquarters, where her office is dotted with several healthy specimens. But you might say that the same spirit embodied in her love for growing things has extended to AMWA as well. She has worked with volunteer leadership on many projects that have taken root and blossomed during her tenure.

Our organization has reached new heights during this time, and her business acumen and assistance with our strategic planning process have been extremely valuable. Through her efforts on AMWA’s behalf, Donna has helped to usher in a new era in the organization’s history. Membership reached an all-time high of 5,652 and AMWA’s online presence was solidified. She also assisted with the implementation of many important new initiatives, including the restructuring and expansion of AMWA’s education curriculum. In addition, attendance at the organization’s national annual conference grew, consistently averaging almost 900 attendees and even recently topping 1,000. And the conference registration process was moved online.

A long-range plan was developed during this time, and an e-newsletter was unveiled. AMWA’s first meeting planner and marketing coordinator were hired. The headquarters office moved to larger space. The coffee klatches and chapter greet-and-go were begun. Self-study modules were expanded to include a suite of 8 offerings. AMWA ushered in a code of ethics and launched related workshops. And, as you will read elsewhere in this issue of the Journal, the seeds of an effort to launch a certification in medical writing were planted under her watch. This initiative represents a major milestone in AMWA’s history, and you will hear more about it in the months ahead.

A Certified Association Executive, Donna has collaborated with the member volunteers who make up the Executive Committee and the Board of Directors on policy matters, major decisions, and initiatives. In addition, she has worked closely with AMWA officers, department administrators, and other volunteers to implement established goals and has sought to continuously improve AMWA’s service to its members, evaluating programs and services on an ongoing basis while promoting and supporting the association.

Many transitions are bittersweet. We will miss Donna, but she leaves AMWA better than she found it. And we are excited to welcome Susan Krug, CAE, who will very capably take the reins and work with us on helping AMWA realize its full potential.

I’d also like to take a moment to thank you for the opportunity to serve you as president this past year. Soon I will be making a transition of my own, and Barbara Snyder will assume the position. I know she will do an outstanding job. AMWA will be fortunate to have her at the helm!

Please join me in thanking Donna for her years of service, and in wishing her all the best as she enters this next phase of life. And be sure to welcome Susan and Barbara into their new roles when you have a chance. To close on the gardening theme, I offer them all a bouquet, starting with Donna’s favorite flower, the iris. In a florist’s lexicon, the iris represents wisdom, success, and knowledge. And I add a little amaryllis, for determination; bouvardia, for enthusiasm; lisianthus, for appreciation; pink roses, for gratitude; and anemone, for anticipation, as we look forward to another successful decade ahead.
Susan Krug Joins AMWA as New Executive Director

By Barbara Snyder, MA
Chair, Executive Director Search Committee, and AMWA President-Elect

A fter screening more than 200 applications, we are delighted to announce that Susan M. Krug, CAE, joined AMWA on July 29, 2011. Susan will succeed Donna Munari, CAE, as Executive Director upon Donna’s retirement in October, right after the 2011 Annual Conference in Jacksonville.

In accepting the position, Susan said: “The medical communications profession has a solid record of growth and success, and tremendous potential for the future. It is an enormous privilege to serve AMWA as executive director in the years to come.”

Susan brings a wealth of highly relevant experience to AMWA, which will be a tremendous asset to our organization going forward. As a communications specialist before becoming an association executive, Susan has overseen the implementation of online technologies to give members greater flexibility and easier access to professional resources. She has cultivated successful partnerships and strategic alliances for organizations, and she has been instrumental in the initiation, development, and implementation of strategic plans.

Krug’s most recent position was as Associate Executive Director of the American Dental Education Association, where she led the $5 million member services division that included meetings, professional development, publications, and membership service. Previously, Susan was the Executive Director of the Child Life Council, a 501(c)(3) organization dedicated to empowering children and families to master challenging life events. She also served as Vice President of the Convention Industry Council at the Association Management Group.

Other positions Susan has held include Communications Manager for the National Council for Interior Design, Project Administrator for the American Society of Association Executives (ASAE), and Public Affairs Project Manager for the World Wildlife Fund, the world’s largest private conservation organization.

A Certified Association Executive and Certified Meeting Professional, Susan has been a featured speaker and writer on association management, as well as meeting industry and certification best practices. She has served on the Meeting Professionals International (MPI) board of directors, including service on the executive committee as vice chairwoman of administration. Other volunteer leadership positions include service on the Governance Committee of MPI, the Executive Management Council of ASAE and The Center for Association Leadership, and the Hospitality Sales & Marketing Association International and San Diego Convention and Visitors Bureau Advisory Boards.

On the phone and in person, Susan impressed our Search Committee as competent, professional, energetic, person-able, and passionate about finding an organization precisely like AMWA. She showed good insight into AMWA’s past and present, and an eagerness to help move the association forward in the future.

AMWA members will have many formal and informal opportunities to meet Susan in Jacksonville at the annual conference. If you’re there, please introduce yourself and make her feel welcome to our organization.

Q: What are some distinctive features about AMWA, compared with other organizations you’ve worked with?
A: I’m fascinated by AMWA’s chapter structure. It’s a great way to educate members and to encourage involvement in the organization, at different levels. What’s more, it has enormous potential as a way to invite new members into the AMWA community.

Q: What do you see as a key strength of AMWA?
A: Without question, the degree of member involvement. To have such a high degree of volunteer participation is both unusual in associations I’ve seen, and a great indicator of continued strength for the future. Just by itself, the commitment members make to design and lead workshops at the annual conference is a remarkable statement of the value they attribute to AMWA, and its importance in their professional lives.

Q: Where do you see AMWA going in the future?
A: As for every other professional organization, the use of the Internet as a networking tool, source of information, and “virtual face” to the world will be a key part of the future. I’m also very excited about the certification process that AMWA has embarked on, and how that initiative could solidify AMWA’s desired position as the premier association for medical communicators. We will explore new ways to carry out our mission, and I’m looking forward to being part of that process. I am eager for AMWA members to share their vision for the organization’s future, and how together we can achieve our goals for success.
By Bettijane Eisenpreis, New York, NY

In 1990, Jude Richard’s future mother-in-law, a volunteer at The University of Texas MD Anderson Cancer Center in Houston, TX, happened to tell a co-worker that her daughter’s boyfriend was looking for a job in medical writing. Unaware that Richard had already been rejected by MD Anderson for lack of experience, the co-worker said, “Give me his resumé; I’ll give it to my husband, Kevin.” Kevin Flynn, who remembered Richard from graduate seminars at the University of Houston, passed the resume on to his superior in MD Anderson’s Scientific Publications Department, and a career was born.

Richard, who holds a BA in philosophy from the University of St. Thomas in Houston, never thought of a writing career until he was in graduate school at the University of Houston, where he earned a Master’s degree in English literature in 1989.

“While getting my graduate degree, I began to think about a career as a writer. I heard about this job called technical writing and began to look around Houston for jobs like that,” he says.

Shortly after his arrival at MD Anderson, Richard became staff editor of Molecular Carcinogenesis, a new basic science journal managed by the Scientific Publications department. Soon after that, the journal’s managing editor left and Richard brought 1 issue to press while a new managing editor was being sought. For the next 10 years, he continued to take on similar ambitious assignments and learn from them. Also, he joined AMWA, at the urging of MD Anderson’s Director of Scientific Publications, Walter Pagel.

In 1991, Richard attended his first AMWA Annual Conference, held in Toronto. “I went with Kevin Flynn, and the city was electric because the conference coincided with a visit by Prince Charles and Princess Diana to Canada,” he reports. “Just the fact that it was in Toronto whetted my appetite. The next year it was in Houston, so I became even more involved.”

After a decade at MD Anderson, he accepted a position as writer-editor at Texas Heart Institute (THI), where Marianne Mallia, ELS, AMWA’s 2010 Swanberg Award recipient, was Manager of Scientific Publications. She strongly encouraged department members to participate in AMWA, so Jude became even more active.

In 2005, Richard and his wife decided to move their family to Austin. After a stint as a freelance, he joined Premier Research Group Limited as a regulatory medical writer, carrying out a wide range of writing, quality control, and supervisory duties.

Meanwhile, he earned his AMWA core curriculum certificate in editing/writing and certification as an Editor in the Life Sciences (ELS) from the Board of Editors in the Life Sciences (BELS). In 2003, he and Christina Chambers agreed to team-teach a basic grammar workshop at the AMWA Annual Conference in San Diego.

Since then, AMWA’s basic grammar course has been divided into 2 levels, and Richard and Chambers have regularly taught Basic Grammar I at annual conferences. In 2011, at the Asilomar Conference in California, he taught both Basic Grammar I and Basic Grammar II alone. From 2003 to the present, he has also led a roundtable on “Publishing a Physician-Targeted Newsletter.” He also served as moderator for a panel on “Becoming a Medical Writer: Why? How?” at the AMWA Southwest Chapter meeting in Dallas in April 2009.

“Over the years, AMWA has filled many gaps, seen and unforeseen, in my working knowledge of the medical writing process,” says Richard. “It pointed me to the many possible career paths out there. It has helped equip me for work at all points along the research and development continuum, from bench to clinic to market. And it has also put me in touch with people who love words and clarity and relish what they do.”

Kevin Flynn, says, “Whether it’s Milton or medicine, Jude is a talented wordsmith and a great AMWA workshop leader. AMWA is lucky to have such a craftsman.”

“Jude’s successful career is testimony to his editorial skills, and he regularly shares his knowledge with others through his work in AMWA,” says Marianne Mallia. “He has taken a leadership role in the Southwest Chapter, regularly driving 150 miles from Austin to Houston for meetings. He has also participated actively in annual conferences. This year, he’s teaching the Basic Grammar workshop, chairing the klatches, leading a roundtable discussion, and moderating a general session.

“But it’s Jude’s character that has always impressed me the most,” she continues. “He is kind, honest, and caring. He is devoted to his family and believes in living a balanced life. And, he has a great sense of humor. He has this black, worn-out Timberland fleece pullover, which he wore almost every day that we worked together. We all kidded him about it. When I saw him at the first AC function last year, he gave me a big smile, pointed with both hands toward his chest, and mouthed the words, ‘It’s the fleece.’ Once again, he made me laugh.”

Photo courtesy of Jude Richard.
"Owning an old brain, you see, is rather like owning an old car....
Careful driving and maintenance are everything."
George Vaillant, MD. Aging Well

My Inheritance
By Eleanor Vincent

In a recent phone conversation I reminded my father that he was about to turn 91, and he replied, "I am?"
"Yes, Dad," I said, "you are."
"Why that's amazing," he said, surprised and delighted, wrapped in a protective blanket of dementia. My father's only choice is to be here now.

This man smoked 2 packs of cigarettes a day until he was 62 years old, ate hot fudge sundaes and beef stroganoff, never exercised, worked like a fiend, and kept the irregular hours of a professional actor until his mid-70s. Both of his parents died young.

How does he defy the odds? In a word: resilience. When life hands him lemons, Dad makes lemonade – and then makes darn sure everyone around him appreciates it! Psychologists call this "adaptive coping."

My father passionately loved his life in the theater as well as teaching acting to his students. He still delights in movies, plays, and music. He loves life despite circumstances that would depress many. He survived colon cancer surgery in his late 80s and a broken hip a year later. These days, Dad tools around the halls of the Actors Fund Home in Englewood, NJ, in an electric wheelchair. He doesn't know how old he is or even today's date, but he still recognizes my voice in our weekly phone calls.

Some forms of dementia lead to paranoia and anger. My father's has made him a kinder, gentler human being. He loves dark chocolate and his 3 children keep him amply supplied--he recently consumed an entire box of Godiva's finest in one sitting. After a bout of violent nausea and vomiting, he vowed not to do it again. Now, the nursing home staff parcels out his drug of choice in small amounts.

The geriatric psychiatrist Helen Lavretske, MD, writing in *Psychiatric Times*, says resilient people are characterized by commitment, dynamism, humor in the face of adversity, patience, optimism, faith, and altruism. My type-A father was naturally gifted with 6 of the 7 traits – and his physical and mental limitations have forced patience upon him – so now he exhibits all of them.

I'm not one to sugarcoat the challenges of aging, but I look for the bright spots. My father's ability to laugh in the face of adversity inspires me. Dad has passed on the characteristics of resilience to his children. Whether by nature or nurture, I have followed my father's example by handling setbacks with renewed determination. My default setting is always humor and a belief that I'll do better next time.

When I told Dad I had recently celebrated my 63rd birthday, he gasped.
"No. You didn't!"
"I did, Dad," I said.
"Well you don't look it," he said.
"And you don't look a day over 85," I quipped. He guffawed.

I can still make my father laugh, which brings me joy and a measure of hope for my own old age. Dad has no money to leave his children, but I've received gifts from him that you can't put a price on – an ability to bounce back and a firm conviction that hot fudge cannot be bad for me.

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She lives and writes in Oakland, CA.
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Three well-known, long-established AMWA freelance members presented an open session on increasing business productivity to a full house during the 2010 Annual Conference in Milwaukee. This article presents highlights from this session to help established and newer freelance members examine various ways to increase their productivity and, ultimately, their bottom line.

**Evaluating Your Business**

Periodically, you need to evaluate your entire set of business operations to increase your productivity as a freelance. To accomplish this goal, you need to know your clients, know your projects, and know your deadlines. The purpose of this evaluation is to work smarter, not harder! You want to spend your marketing time and money only on those clients and projects that meet the goals you have set for yourself and your business.

**Know your clients**

When planning for greater productivity, it is important to remember the 80/20 Rule: A full 80% of your freelance business will come from 20% of your clients or contacts. Your client evaluation, therefore, should focus on identifying which of your clients are—or could be—counted among that important 20%. To do this, list all of your clients within the last year or two and rate them by several factors that are important to you. Factors could include the amount of business given quarterly or yearly, the types of projects, the working relationship, appropriate deadlines, payment schedules, or any other criteria you establish as important to your business. Assign each client a numerical or letter grade for each factor.

Next, list your clients in priority order. Your top tier clients are those who meet or exceed all points in your evaluation and are the ones on whom you should focus most of your attention and marketing efforts. Your second tier clients are those who meet most of your evaluation points and should merit slightly less marketing efforts—unless you desire to raise them to top tier status. For the remaining, lower tier clients, you need to decide if you want to continue with the working relationship. If you decide to keep them, determine how you can improve your relationship with them. It may be as simple as telling them what your other clients provide or do to make them more favorable to your business. If that approach does not yield positive results, or if you decide to drop them from your client mix, you could research other clients to replace them or work to increase the business gained from your other, higher ranked clients.

**Know your projects**

In addition to knowing your clients, you need to know and evaluate your project mix. List all of the different types of projects you have undertaken, such as regulatory writing, journal supplements, advisory board executive summaries, continuing medical education programs, sales training modules, product monographs, or other categories. Rate this mix according to your priorities. Do you enjoy all of these projects? Do you enjoy one type of project more than another? Are there any recent projects you totally disliked (either by type, subject matter, or client)? Can you increase work in your favorite types of projects and reduce your involvement in others? Which clients give you these favorite types of projects?

Ideally, the types of projects you most enjoy should be those that come from your top tier clients. If not, you will need to reevaluate your criteria and workload to make the match work in your favor.

**Know your deadlines**

In our business, deadlines are sacrosanct. To stay focused and productive, you may need to establish daily or weekly to-do lists. Some writers try to work on only one project at a time. Others devote the morning to one and the afternoon to another. You may have to work occasionally some nights or weekends to meet a client’s deadline. Be sure to stay focused on the project in-hand, take frequent breaks, and only check e-mail occasionally during the day.

Finally, for your own sanity, it is important to balance your work and leisure time. Attempt to forget about your
projects during nonbusiness hours. Remember to exercise, do fun activities, relax, see friends, and get a good night’s sleep. By providing a balance in your life, you will be more relaxed and rejuvenated when you return to the projects in hand.

Coordinating Multiple Projects and Writers

Coordinating multiple projects and writers can be as difficult as herding cats, but it is also a great way to increase your productivity and, thereby, your profitability as a freelance.

There are a number of reasons why a freelance medical writer would want to take on the challenge of coordinating multiple projects. First, opportunity literally calls (or e-mails) every day, and if you do not answer, it will not call back. This is because clients and potential clients only call a freelance when they need one. If you get the call and you don’t answer, clients are forced to call someone else, and the freelance they worked with last is likely to be the first freelance they will call the next time as long as that person delivered on time, on target, and on budget.

The second reason for putting yourself in the position of handling multiple projects is that when you say “yes” to everything, it is unlikely that everything will actually come through at once. Once the writer is brought on board, projects often get delayed or cancelled. The third reason is that freelances do not get paid if they do not work. If a project you have committed time for gets postponed or cancelled, the resulting void can make it difficult to pay your bills.

But then, what do you do on those rare but very real occasions when all the projects you have committed yourself to doing come through at once? You can panic; you can work harder by putting in evenings and weekends to get it all done; or you can work smarter by applying some simple but effective strategies to coordinate your multiple projects, and possibly by bringing in other freelance writers to work with you. Of course, engaging other writers is something you should never do without the knowledge and consent of your client.

There are also a number of reasons why a freelance medical writer may want to take on the challenge of coordinating multiple writers. Coordinating multiple writers can help you meet increased demand, as long as those writers are equally committed as you to quality, timing, and budget. It also increases your productivity because more writers can get more work done, and you can continue to earn money by having other writers working for you even when you are not writing yourself. There may even be an opportunity to increase your income by coordinating multiple writers—but here you need to be careful because when you write, you earn 100% of the fee whereas when another writer writes for you, that writer earns nearly all of the fee.

If you choose to take on multiple projects or writers, these tips will help you overcome some of the challenges you will likely encounter.

Tips for coordinating multiple projects

• Take deep breaths. As the number of projects you are working on at one time increases, it is important to keep your stress level low and maintain your perspective. Whether you do yoga, take a walk, go to the gym, or get a good night’s rest, that you do something is more important than what you do to keep yourself calm and in control.

• Keep organized. Consistent use of systems can help you stay on top of all the projects you have going on at once. Use job numbers and good physical and electronic filing systems to keep track of projects, and use a white board or other visible calendar system to keep track of deadlines. Do not underestimate the value of sticky notes and notes to remind you to look at those sticky notes. Make sure you clean up after every project so you do not get lost in an avalanche of paper.

• Be realistic. Not being afraid to overcommit is a vital survival skill for successful freelancers, but it is equally vital to your survival that you know the difference between an “impossible” deadline (one that will take a lot of doing to get done) and an IMPOSSIBLE deadline (one you really, truly cannot make without sacrificing quality, your health, and/or your sanity).

• Set priorities. Setting priorities can be an overwhelming task when there seems to be a frenzy with every project, but with a little deep breathing to gain perspective, it is usually possible to rank the frenzy before the fire, the fire before the panic, the panic before the urgent, the urgent before the rush, and so on.

• Be flexible. When you are a freelance medical writer coordinating multiple projects, the only constant is change. Be prepared for it, embrace it, and you can eventually learn how to profit from it.

Tips for coordinating multiple writers

• Hire experts. Writers with less experience charge less than experts, but you’ll end up paying for it in the long run with your time to make revisions and deal with problems. Do not be afraid to do the same thing you want your clients to do, that is, pay the freight for the expertise you need to get the job done right the first time.

• Trust them to do their job. The writer is the content expert, which makes you the project expert. Provide guidance and support and troubleshooting the logistics so the expert writer you have hired can do his or her job.

• Maintain total control. When coordinating multiple writers, it is crucial to remember that the client is yours, not the other writers’. Your reputation is on the line.
with every project you deliver. When things go right, you share the glory with the writer who assisted you; when something goes wrong, you take full responsibility.

- Keep it all straight. To maintain an efficient freelance business coordinating multiple projects and writers, you must keep every detail straight, including knowing which writers are best for which types of projects, when writers are available and when they are busy, which projects are currently in-house and which are pending, and the vacation and travel schedules of everyone on the team.

Celebrating Project End: What to Do When the Project’s Over
The end of a project is often time for celebration, especially if the project was long, drawn out, or fraught with problems. Even when the project had no surprises or complications, many freelances still feel like popping the champagne cork and doing the happy dance after pushing the deliverable out the door. But don’t party too long. Once you have met a deadline, it’s time to concentrate on 4 issues to help you maintain your productivity: client satisfaction, invoicing, getting the next project, and professional development.

Client satisfaction
Client satisfaction is a combination of 3 variables: quality, delivery, and cost. If you produce a high-quality product that’s on target, deliver it on time (or even earlier than expected), and provide outstanding value, you will have a satisfied client. Fail short on any one of those variables, and you could have an unhappy client.

Never send a project out the door without follow-up or assume your client is thrilled with your work. Always inquire about the client’s satisfaction via e-mail or telephone, followed by your next question, “What else can I do for you?” Remember, it takes less time and energy to maintain clients than it does to cultivate new ones. Don’t hesitate to remind your clients when you’ve delivered on time, on target, and on budget.

Invoicing
Timely invoicing is the key to maintaining adequate cash flow. It’s not a good idea to wait 20 days after you have delivered the project to send out the invoice. If the client takes 60 days to cut your check, which is not uncommon these days, then you will not get paid until 80 days after you completed the project. Progress invoicing is one tactic that can improve cash flow. With this method, you establish benchmarks with your client to determine when you will send interim invoices, usually after you’ve supplied a specific deliverable. Progress invoicing works best when you work on a large project with multiple deliverables.

Some freelances also invoice a portion of the estimate at project initiation, which can amount to 10% or 20% of the total estimate.

Always invoice for the agreed-upon price unless there have been scope changes or other surprises that were not part of your original estimate. If the project was a victim of the dreaded “project creep,” you should have discussed this with your client as soon as the project went out of scope and provided a second estimate that took into account the unplanned changes. If you did not, and the project simply took longer than you estimated, then you need to invoice for the original amount and estimate more accurately next time.

Getting the next project
The time to look for work is not when you need it. Because you never know when a project you expected will be postponed or cancelled, you need to engage in constant marketing to avoid down time. Concentrate your marketing efforts in 4 areas:

- Social media via LinkedIn, Twitter, and other networks. Social media marketing is all about building and nurturing relationships. After you have finished a project, send out a tweet telling your followers you’re available for the next one. On LinkedIn, leverage your group memberships and ask members for leads to new projects. Always ask clients to supply recommendations via LinkedIn so you can easily direct prospective clients to your online references.

- Previous clients who were happy with your work. A job is not finished until it starts working for you. Leverage each project so it helps you get the next one. Your previous clients might be interested in learning about the project you just completed. A short e-mail like this points them to your latest work and reinforces your capabilities: “I just finished a project on topic X and thought you might be interested. Here is the link…”

- Potential clients you want to cultivate. Thinking you have an unlimited number of prospects can be a comfortable illusion. But in reality you can’t be everything to everybody. It is much easier to build a reputation within a specific niche. Focusing your marketing efforts on a specific target audience enables you to reach your market with less effort. Think about it. People in the same niche go to similar meetings and talk with one another. Once you build credibility with one of them, your name and reputation will spread quickly.

- Colleagues. Marketing to colleagues who do similar work as you may seem counterintuitive, but busy colleagues may be interested in funneling you their overflow work.

Keep in mind that good news travels fast, but bad news travels faster. Clients who are happy with your work will
come back to you with more work. They might even pass your name on to colleagues (if they don’t want to keep you to themselves). In contrast, unhappy clients will not hesitate to tell others about the bad encounter they had with you. The key to getting the next project is keeping your clients happy.

**Professional development**
At the end of each project, ask yourself, “What did I learn from this project?” Perhaps you learned how to use a new software program or you improved skills already in your repertoire. Maybe you were introduced to a new program you never used before and discovered you really weren’t that good at it. Learning what you did not know is a helpful reality check that shows you where you need to go with regard to professional development. You are your best resource. Do not hesitate to invest in yourself if you want to grow your business.

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

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National Human Genome Research Institute (NHGRI): Educational materials about genetics and genomics
www.genome.gov/Education

With National DNA Day (April 15, 2011) having come and gone, we are now in the 8th year since the Human Genome Project (HGP) was completed in April 2003. Given the significance of this monumental feat, the NHGRI has created an Education Web portal on its Web site to aid viewers in sifting through the mounds of genomic data gathered from the HGP. I explored the site and was impressed with the wealth of information, much of which could be of use to medical communicators who either specialize in genetics or simply want to learn more about the Human Genome.

Within the site’s main section, All About the Human Genome Project, you can access pages on Educational Resources, General Information, Research, and Model Organisms. Other sections of interest to medical communicators:

- Fact Sheets
  - About the Institute
  - About the Science
  - About Ethical, Legal and Social Implications (Research)
- NHGRI Webinar Series (listen to current topics on genomics, health and society)
- Understanding the Human Genome Project—an online education kit (CD) (download in its entirety or by individual module)
  - Dynamic Timeline
  - Genes, Variation and Human History
  - How to Sequence a Human Genome
  - Ethical, Legal and Social Implications
  - Bioinformatics
  - Exploring Our Molecular Selves
- Talking Glossary of Genetic Terms (site reviewed at AMWA’s 2010 conference in the “Mining the Internet” Open Session).

Aside from these great resources, viewers can click on the Online Genetics Education Resources tab for a page of separate links (www.genome.gov/10000464) and access information on virtually every facet of genetics and the Human Genome. These links provide data ranging from classical subjects such as MendelWeb and Online Mendelian Inheritance in Man (OMIN database), to more specific topics, such as Your Genes Your Health and the Human Genome Epidemiology Network (HuGENet).

When The Scientist Presents
http://scientific-presentations.com

If you are lucky enough (yes, lucky is the right word!) to be giving a workshop presentation or participating in an open session at this year’s AMWA conference in Jacksonville, this Web site is just what you need. The site is actually a blog written by Jean-Luc Lebrun, an author and expert in scientific writing/communications who is based in Singapore, but is French in nationality. Lebrun has trained scientists throughout the world on the science of writing scientific papers and grants and gives seminars on the sci-
ence of communicating to both scientific and lay audiences. He also has a personal Web site, Scientific Writing: A Reader and Writer’s Guide (www.scientific-writing.com).

Lebrun is a talented writer and presenter with a captivating blogging style that lends a bit of humor to his commentary, enticing you to explore the site further. On Web page after Web page, his passion for perfecting scientific writing and his expertise in presenting such communications is evident. In his blog, he covers everything you need to know about presenting scientific data: the basics of constructing effective slides, creating compelling introductions that engage your listeners and ending with thought-provoking conclusions that keep your presentation in the minds of your audience long after it’s been given, plus legal issues related to images or copyrighted material and all the nuances of presenting, such as body language and “body noise” distractions.

On the blog site, visitors can select from a list of “Funcasts” or “Profcasts” and listen to the corresponding podcast, browse through the long list of presentation tips, or view videocasts about the audio and visual technology aspects of presenting. All and all, “When The Scientist Presents” is a comprehensive, informative, and entertaining blog site worth bookmarking by veteran and newbie presenters alike.

The Hastings Center
www.thehastingscenter.org

Despite the industry’s call for better transparency, allegations of unethical conduct or questionable ethics by pharmaceutical and medical communication companies are still being bantered about in the press by those who may or may not have a political manifesto. As medical communicators, we can defend the integrity of our profession by utilizing our resources to educate these dissenters and advocate for the many organizations that promote bioethics research. One such organization is The Hastings Center, an independent, nonpartisan, and nonprofit bioethics research institute founded in 1969, whose mission is “. . . to address fundamental ethical issues in the areas of health, medicine, and the environment as they affect individuals, communities, and societies.”

The Hastings Center Web site offers resources on a selection of topic areas, many of which have been discussed on the AMWA listserves (eg, clinical trials and human subject research and conflicts of interest in research). The Center publishes The Hastings Center Report, a bimonthly journal promoting ethics in health, medicine, and the environment, and IRB: Ethics & Human Research, a peer-reviewed, print-only journal (some past issues are available online) exploring issues in research with human subjects, including findings and analyses of empirical studies. The Web site also hosts two forums, The Bioethics Forum, which is a commentary between invited guests and visitors who discuss timely issues in bioethics, and The Health Care Cost Monitor, which provides commentary and opinions on cost control as part of the implementation of health care reform.
Stroke
Louis R. Caplan
New York: Oxford University Press, 2011

In this short book with the one-word title, Louis Caplan has written a valuable tool for the clinician for evaluating and treating people with cerebrovascular disease. Medical students, residents, and early-stage practitioners, as well as medical writers, can especially benefit from the organized presentation.

The book addresses 26 different kinds of stroke, with chapters written by several stroke specialists, including the author. The format makes the book very readable. First, a case history is provided, followed by a discussion of the case and the type of stroke the case illustrates. For example, the case of a 64-year-old man who came to the emergency room describing sudden “graying of vision” is used to study transient monocular vision loss. Further enhancing the case is an illustration that shows how an embolus blocked the vascular supply to the eye. The question “What do you do now?” is included after each case study, and the key points emphasizing the essence of each case are especially valuable.

This book is useful for medical writers who need to quickly research the more technical aspects of cerebrovascular disease. The case histories, clear explanations, illustrations and photos, and bullet points of salient information make Stroke is a fine volume for quick reference to answers about neurologic events.

—Evelyn B. Kelly, PhD

Evelyn is a freelance writer living in Ocala, FL.
AMWA Puzzler
Developed by Laura J. Ninger, ELS, Rutherford, NJ

Across
1. Thing that is gratis
5. Move like a bird
9. Spud state
14. Blanc-cassis
17. Fruit dessert
19. Carson’s successor
20. A key might be
22. A weighty novel?
26. Chemical suffix
27. Vinegar vessel
28. Country south of China
29. Savage human of “Firefly” TV series
31. “Lions for Lambs” director
33. Fragrant resin
35. Covered entry
36. When repeated, a patriotic chant
37. What Chrissie Hynde is
39. Aware of
40. Bridle extension
43. Semblances
45. Many-toothed fishes
46. It holds a yard
47. Govt. workforce agency
48. Owner of the LA Lakers
49. Clogs
52. Aquatic appendage
53. Live ___ (1985 musical fundraiser)
54. Beasts of burden
56. Dainty laughter
57. “___ and the Swan”
59. Filthy place
60. Turtle shell, e.g.
61. Guatemalan language
62. Fit to eat, or otherwise legitimate
64. 2000 pounds
65. “...the raveled ___ of care...”
67. Emasculates
70. Mineral
71. Coin
73. ___ long (shortly)
75. Greek liqueurs
76. Prevent from use
77. Info. about flights
78. Embryonic membranes
80. Email, nowadays
81. Heat meas.
82. Crumb
83. Puff pastry has many
85. Jewish month
86. Exclamation of fear
87. Water walls
89. Shrek, e.g.
90. More skillful
92. “___ quam videri” (North Carolina’s motto)
93. Sword
94. Rectories
97. “___ Pray Love” (2010 film)
99. Woolgathered, in a way
101. Of the monarchy
102. Recent war zone
106. Rapid speech
107. 2009 Rob Marshall movie
108. Tibetan city
110. “...the sound of ___ hand clapping”
111. Word with bin or wood
112. Light in the distance?
117. First name of man whose last name is a scientific measure
118. A “Christian” name
119. With politesse
120. St. Louis player
121. Extra inning
122. Current units
123. Give up

Down
1. Nickname in “Top Gun”
2. Mildly annoyed
3. Law enforcement org.
4. Phone or communication orgs.
5. Floating ice
6. Orator’s spot
7. Word with invisible or India
8. Another word for personal grooming
9. Announcement upon leaving?
10. Claims, with “on”
11. Singer DiFranco
12. “Little Shop of ___”
13. It may be tall
14. Comic strip about a boy and his tiger?
15. Gnats, e.g.
16. Pigweed
17. It is born, or searched for
18. Exercised to excess?
23. ___ pie (chocolate treat)
24. “The ___ of the Rose” (Eco novel)
30. Motes
32. Source of mirth
34. Word commonly misused for “fewer”
35. As such
37. 100 centimos
38. Word with cheap or play
40. Slow-cooker items
41. Antibody-binding region
42. What she states before dates?
44. Germane consideration
45. John Entwistle of The Who, e.g.
46. Green giver: Abbr.
47. Smith
48. Another cause of 18 Down
49. Wool, in a way
50. Green giver: Abbr.
51. A Bridges
52. Dental practitioner?
55. Marriage hazard?
56. Preps a lawn, perhaps
62. Poor excuse?
63. Zap again
66. “...15 miles on the ___ Canal”
68. Wall works
69. Chemical with three nitrogen atoms
72. It has a belt
74. Word with dog or tin
78. Chilly
79. Word with dog or tin
81. Heat meas.
84. It’s a long story
87. A sign of depression, perhaps
88. Language disorder
91. Hotel porter
92. African entry
95. A gambling town
96. Ulterior motive
97. Undiluted
98. Umbrella-shaped fungus
99. XX genotype possessive
103. Used heavy equipment, informally
104. Chameleon
105. Contradict
107. Undiluted
109. XX genotype possessive
113. XY genotype adult
115. Word with black or Italian

Answers on next page

Measure Up
17 22 26 31 32 33 34 35 36 37 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100 101 102 103 104 105 106 107 108 109 110 111 112 113 114 115 116 117 118 119 120 121 122 123