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FROM THE EDITOR
The Conversation Continues  Victoria J. White

COVER STORY
Five Design Principles for Writers and Editors  Barbara Kristaponis

FEATURE
Conducting a Gap Analysis for a Medical Publication Plan  Stephanie Finucane

FEATURE
Cracking the Medical Writer’s Genetic Code  William Van Nostran

COMMONPLACES
The Medical Writer’s Survival Kit  Ana C. Madani

2014 AMWA ANNUAL CONFERENCE PREVIEW
Let’s Meet in Memphis  Lori L. Alexander

AMWA AWARDS
Golden Apple Award: Thomas Gegeny, MA, ELS  Scott Kober
AMWA Announces 2014 Fellows  Barbara Snyder

ANNUAL CONFERENCE
Posters on Display at the 2014 Annual Conference

AMWA NEWS
Best Year Ever!  Brian Bass
Quarterly Update on Certification  Thomas Gegeny and Marianne Mallia
Take Part in Medical Writing Survey  Victoria J. White

MELNICK ON WRITING
Homophone? Homonym?  Arnold Melnick

FIND
PubMed Commons: A Medium for Commenting on Research  Michelle A. Kraft
136 SOCIAL MEDIA
The Ins and Outs of Google+: An Overview for Medical Writers › Julie L. Phelan

137 CALENDAR OF MEETINGS

138 FREELANCE FORUM
› Brian Bass, Lori De Milto, and Phyllis Minick
How Do You Tell a Good Freelance Writing or Editing Opportunity from a Bad One?
Do You Recommend Giving Clients Gifts at the End of the Year?

140 IN THE SERVICE OF GOOD WRITING
Meanwhile, Back at the Ranch…
› Laurie Endicott Thomas

142 MEDIA REVIEWS
Review of Brain on Fire: My Month of Madness
› Evelyn B. Kelly

143 PRACTICAL MATTERS
Burnout and Renewal › Debra Gordon

Cover: Single leaf from the Arabic version of Dioscorides’ De Materia Medica that was copied in 621 AH / 1224 CE in Baghdad. The leaf depicts 2 doctors preparing medicine. A funnel is set on a tripod over a vessel. Wolters Art Museum, W.675, fol W.675a © 2011 Wolters Art Museum, used under a Creative Commons Attribution-ShareAlike 3.0 license: http://creativecommons.org/licenses/by-sa/3.0/.

AMWA JOURNAL MISSION STATEMENT
The AMWA Journal expresses the interests, concerns, and expertise of members. Its purpose is to inspire, motivate, inform, and educate them. The Journal furthers dialog among all members and communicates the purposes, goals, advantages, and benefits of the American Medical Writers Association as a professional organization.
At some point, belatedly, it dawned on me that a paper’s reference list was much more than a pro forma inventory of sources, there only to adhere to the staid demands of academic publishing. I started to realize that the reference list is an invitation to dive into a subject, a cheat sheet for finding the best thinking on a topic, and a guide for pinpointing the paper’s place in an ongoing conversation.

The reference list serves as a reminder that the paper you see before you was written in some sort of a context. The article does not constitute the first word on the subject and probably does not constitute the last. As a reader, you are eavesdropping on a conversation already in progress.

This issue of the AMWA Journal features several ongoing conversations. William Van Nostran’s contribution, “Cracking the Medical Writer’s Genetic Code,” was inspired by discussions he has had with Tom Lang about the educational background of medical communicators. In his article, Van Nostran offers a vigorous defense of the humanities as a solid foundation for medical writers and takes issue with some of what Lang has written on the subject.

A long-time AMWA member with decades of experience as a practitioner and teacher of medical writing, Lang has published on the topic before and plans to again. He currently has a submission to this Journal under review. From Van Nostran’s reference list, you can track down Lang’s previous contributions. You can also find other gems. In particular, I recommend the article by Patrick Moore: “Legitimizing Technical Communication in English Departments: Carolyn Miller’s ‘Humanistic Rationale for Technical Writing,’” published in 2006 in the Journal of Technical Writing and Communication (2006;36[2]:167–182). The article provides some interesting background on institutional tensions between departments of literature and technical communications.

Also in this issue of the Journal, we have the second contribution to Commonplaces, the new section designed to foster a dialogue among practitioners and teachers of medical writing. In the previous issue, we published “My Little Black Book of Texts for Teaching Medical Writing,” by Lora Arduser. In this issue, Ana Madani contributes “The Medical Writer’s Survival Kit,” which discusses materials she finds useful in her daily work.

In the Journal’s Find section, which provides our audience with the perspectives of a medical librarian, Michelle Kraft discusses PubMed Commons, a recent add-on feature to PubMed that enables certain qualified users to post comments to the PubMed listing of indexed articles. It is not yet clear how popular PubMed Commons will become, but many comments posted so far are of potential interest to medical communicators. For example, one recent comment featured prominently on PubMed was posted by medical writer Karen Woolley, who was commenting on the disclosure of nonfinancial conflicts of interest. Her post is available at http://1.usa.gov/1pw2I3Q.

The Cover
The cover of this issue of the Journal depicts 2 doctors preparing medicine. The image dates from the 13th century Baghdad copy of De Materia Medica by Dioscorides. The 5-volume series, written sometime around 70 AD, discussed “the materials of medicine”—herbs and drugs that could be made from them.

I, for one, cannot read the Arabic script, but I can see the design principles mentioned by Barbara Kristaponis in her article “Five Design Principles for Writers and Editors.” Contrast, white space (negative space), repetition, alignment, and proximity—they’re all identifiable in the image. As medical communicators who organize words on paper or screens, we are following in centuries-old traditions of design.

A Thank You and a Call for Contributors
In closing, I want to thank the contributing writers and editors to this issue and previous issues of the Journal. The Journal couldn’t possibly come together without them. A special shout-out to Randall Fritz, who is stepping down after several years as editor of the Science Series. He has pulled those articles together beautifully, and I am in his debt.

Although I am sad to see him go, that does create an opening for new volunteers to come forward. If you are interested in the Science Series position—or reviewing, writing, editing, or proofreading in any capacity for the Journal, please drop me a line. In the short run, I am also seeking volunteers to cover sessions at the 2014 AMWA Annual Conference. Write to me at JournalEditor@amwa.org.
More than ornate frill, the design of a page can make your words sing or disappear. Readability is at stake here. Readability is the accessibility of the text. How easily can a passage be read or understood? If something is well written, why does it need design help?

As a design practitioner and writer for more than 20 years and a medical writer/editor for more than 10, I would argue that it is not that our writing requires graphic design help, it is that the action of placing words on a page, aka writing, is already designing the page. Would then a random pouring out of words from a bucket onto paper be graphic design? Yes. That bucketload of words would have landed in a design, but no thanks to any conscious attention by a designer. The resulting design may be pleasing to some viewers and unpleasant to others, meaningful to some but meaningless to others.

Graphic design is what we do to words so that they can be read on a page, the means by which words, images, shapes, and symbols convey meaning. By creating numbered lists in our instruction sheets, we are creating hierarchies of action. By grouping like things together in our agendas, we create nuggets of content. We indent paragraphs, capitalize words, place commas, underline phrases, give titles special treatment, and italicize quotations—all elements of graphic design.

How words are arranged on the page determines the legibility and readability of the text. The placement and visual attributes (typeface, color, size) of these words also determines whether a reader will be attracted to the page at all. The “page” could be analogue or digital: housed in a Microsoft Word document, Excel spreadsheet, tablet screen, email, e-book, or LinkedIn post.

In the Middle Ages, monks used gold leaf, color, patterns, and detailed images to create pages of beauty in illuminated manuscripts that would attract their readers, mainly at first other monks who were studying the sacred texts (Figure 1). The images served another purpose: listeners who could not read would have something to look at as monks read the text to them. Since these stories contained the essence of a culture/religion and descriptions of how to live a good life, it was important that these stories be remembered, repeated, and widely known. The images helped them remember the plot, characters, and messages of the narratives and lessons.

This article on C-WRAP (contrast, white space, repetition, alignment, and proximity) provides an introduction to 5 design elements that can inform your writing and editing. You might then more readily embrace, if you do not already, design challenges (opportunities) in your everyday work in the pursuit of communicating meaning through the written word, whether in an email, a chat, or a journal article.

In my 6 years as a managing medical editor at the Memorial Sloan Kettering Cancer Center, I have had those challenges, and as a freelance writer and graphic designer today, I still have them. I may need to create a book cover that will attract readers, craft an annual report that will get a deep read instead of a quick scan, formulate an agenda that people will actually read before a meeting, or write and design an
email that will get a prompt response. To heighten the chance that your words will be given the attention they deserve, these basic 5 elements of graphic design rubrics can be helpful in creating business letters, memos, agendas, blogs, progress reports, evaluations, Web pages, résumés, informational graphics, research posters, patient brochures, slide decks, and long documents.

Like the fundamentals of music, the C-WRAP principles are what one learns at the beginning of design practice and then can spend a lifetime working with—studying with great mentors and experimenting along the way. The basic design principles are the same for novice and expert designers, and writers can use them. Four of these (contrast, repetition, alignment, proximity) are described with great examples in Robin William’s *The Non-Designer’s Design Book,* a much-loved graphic design book now in its third edition. A fifth element, white space, is one that I usually add when I teach my AMWA workshop, *The Good Page: Design and Typography Basics for Writers,* because an awareness of white space is an underlying fundamental for understanding and using the other 4 principles.

**CONTRAST**

Contrast is about comparison, one element noticeably different from another, and it is one of the best ways to attract readers to your page and create a visual hierarchy of the various text elements. There are many ways to create contrast. You can use large type and small type, a bright color and a neutral color, large blocks of text and small blocks of text, large photo and small photo, densely packed lines and widely spaced lines, a decorative typeface and a standard typeface, all caps and sentence case. You also have type, color, size, shapes, lines, images, and white space to work with, plus the meaning of the words. The key to effective contrast is to make the elements VERY different (Figure 2). If you want contrast on your page, make elements very different, not just a little different. Make one element bigger, brighter, darker, or bolder than another. Subtle differences do not often work, eg, 12-point text combined with 10-point text.

**WHITE SPACE**

Like water for fish, white space in design is that element of the layout that we generally don’t notice. That part of the page not marked by text, images, lines, or shapes, it is also called “negative space” and refers to that part of a page left blank, empty.

Writing is a visual thing. We see words. But we also see the spaces between the words, and it is in the placing of letterforms and white space that we achieve readability and then meaning in the mind of the reader. **Negative spaces on pages function much like the rests in musical notation, which are as important as the notes themselves.** The white space between individual words (word space) allows us to read the sentence and not have to decipher this: thewhitespacebetweenindividualwordsallowsustoread

White space can be literally white, or as early rough drafts of the book cover shown below, not white, but light gray (Figure 3). The first row shows the text needed on the cover. The second row emphasizes the shapes of negative space. Each of the 3 book cover versions could be said to contain just one “piece” of negative space, not counting the confined spaces within the letters O, R, A, and P. Of the 3 different shapes of

![Three versions of a book cover](image)

Figure 3. Three versions of a book cover. Same text, same size cover, but different shapes for the negative space. Seeing the negative (gray) space as foreground and the black space as background is helpful. The shape of the negative space in example 1 draws the reader’s eye to the title, while the shape of the negative space in example 3 is more dynamic.

negative space, the first draws attention to the center and appears more “organized” than the second. The second example could be distracting as the 2 words in black could appear to be moving away from the center, and if those 2 words were placed closer to the top and bottom edges of the page, it could look as if they are out of control and about to fall off the page. Since the book is about organization and order, this may not be
what you want in the mind of your potential reader. The third example of negative space has the less predictable and possibly more interesting and dynamic shape. However, there is something slightly off-balance about the whole design so it might require more work to both keep the interesting negative space and also achieve a balanced look to the page.

REPETITION

Our eyes like patterns and rhythms, which create unity and add visual appeal. Repeated visual elements—a line, a logo, a color, a typeface—all of these are pleasing to us on a page and provide consistency in multipage documents. Bold headings, numbered lists, and quotations in italics are repetitive visual elements used daily by many writers.

In the list of design principles (Figure 4), I used the same amount of white space between each category, the same red color for letters and bullets, and the same indent spacing of all bullets, and also used left alignment of all elements except the title. However, what a relief that the line lengths are different! Otherwise, all this visual consistency could become annoying. These repeated elements order the parts and make it easy to see the parallel structure and main ideas. Understanding this design principle can be especially useful at a time when we are all streamlining our texts for blogs, emails, tweets, and web pages. Repetition of design elements can help eliminate unnecessary words by relying upon structure to convey some of the meaning.

Use repetition in a layout to draw readers to your text, speed comprehension, and provide unity for your entire document or project. For example, use the same color scheme and typeface for your business card, stationery letterhead, Web page, and annual report, which will go a long way toward establishing an integrated and positive business identity.

ALIGNMENT

Alignment is about providing a sense of order to your page when you want that, as opposed to the design-equivalent of the messy-desk effect, ie, old coffee cups, newspapers, open books, sticky notes, and pens scattered around. Giving each item a visual relationship with something else (aligning every element to at least one other element) will help provide strength, visual pleasure, and logic to your page. Aligned items are attractive and help the reader to navigate through the text. Align what you can and with intention.

This strategy can be effective even for an outline contained in an email message (Figure 5). You can greatly increase the readability just by using the bullet/number icons on the formatting option toolbar. Usually these icons can be found on a toolbar at the bottom of your email “compose” message screen. This will align all the text, not just the first bullet or number item, and you will have something much easier on the eye and hence more likely to be read.
PROXIMITY

Items relating to each other should be placed physically near one another and apart from unrelated items. Reduce clutter by treating grouped items as one unit. In the 2 business cards (Figure 6), the one on the left looks cluttered, and items are placed in no particular order. By grouping together the name of the restaurant and the type of food and separating that group from the location information, the card becomes easier to read and more appealing to the eye. Editing the text also helps.

When making your design decisions, whether you make these while you are writing the text or when the text is completed, consider starting with the proximity idea. Once you know what information groups you have, it can be easier to make decisions about contrast, repetition, etc.

CONCLUSION

The guides for creating beautiful pages and beautiful lettering have been in the world for centuries. Like all arts, graphic design and typography deserve time devoted to study and practice, but, as with spices in cooking, knowing how to use just one or two good spices can change the whole dish. Notice the exploding world of graphic design savvy all around you. Desktop publishing, color printers for home and office, and the ability to upload pages to the Internet have encouraged much experimentation. Some of this is blatantly awful, but there is much that is truly beautiful. You can borrow some of these ideas, as great designers have always done, to design elegant layouts—whether Web pages, business cards, articles, or article proposals—in the service of meaning.

Barbara Kristaponis is a freelance graphic designer and writer working in New York City. A member of AMWA since 2002, she worked previously as a senior medical editor at Memorial Sloan Kettering Cancer Center and as a senior writer/editor at the New York Hall of Science.

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

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References

RESOURCES


Colophon

In the pharmaceutical and medical device industries, a gap analysis is an integral part of the process for planning publications related to a drug product, medical device, medical procedure, or disease/therapeutic area. A gap analysis assesses how a drug, for example, is represented in the medical literature and at scientific congresses and how current coverage of the drug relates to a company’s internal goals or competitor products. A gap analysis can also uncover whether important information is being delivered to audiences who need it and in a timely manner. The main steps in conducting a gap analysis for a medical publication plan include: 1) identifying the area(s) of focus/rationale, 2) determining a meaningful timeline for analysis, 3) identifying the scope of research, 4) determining search parameters, 5) selecting a format for gap analysis output, 6) conducting the search, and 7) organizing and prioritizing findings to identify trends regarding the topic question. Systematically following these steps will expose knowledge gaps about a drug product, medical device, medical procedure, or therapeutic area in the current literature that can then be addressed with targeted publications as part of a medical publication plan.

The gap analysis is a vital step in the development of a medical publication plan. Such an analysis assesses a drug product, device, or procedure, or therapeutic area by comparing its current position in the publication landscape in relation to internal goals, key topic points, future plans, or competitors to expose gaps. A gap analysis helps identify gaps in the type of content conveyed in existing communication efforts, including journal articles and presentations, abstracts, and posters presented at scientific congresses. Any exposed gaps can then be addressed in the medical publication plan.

This article will describe what a gap analysis is and how it is conducted as part of a gap analysis as part of a medical publishing plan. Any gap analysis should be conducted in an ethical manner; guidelines are available to help ensure best practices are followed (Sidebar).

GAP ANALYSIS DEFINED

The gap analysis is the crux of publication planning, says Russell Traynor, CMPP, former president of the International Society for Medical Publication Professionals (ISMPP) and current head of the Strategic Business Unit at Envision Pharma Group. “This can be as simple as giving consideration to whether we have planned for a primary manuscript from each of our clinical trials.” Essentially, according to Traynor (who was interviewed by email), the gap analysis helps publication planners answer the question: “Are we meeting our regulatory and moral obligations in terms of communicating the findings of our clinical trial program?”

Technically, a gap analysis “identifies key topics or educational areas related to a drug product [or device, procedure, or disease/therapeutic area] within a specific therapeutic area or indication” and assesses the extent of coverage of these issues compared with competitors within the publication landscape. A gap analysis does this by investigating what information about a specific drug product is available in the literature, where it is available (eg, medical journals, scientific congresses), what format it is in (eg, type of journal article [primary or review article, secondary analysis, case report, etc], presentation, abstract, poster), which target audience(s) it is reaching (eg, primary care physicians, specialists, nurses, pharmacists), and/or the timing of that information flow in order to expose knowledge gaps and key topic point coverage. This should include looking at any “unmet needs in the target indication” related to claims by competitors. Any topic or subject that is not covered, not covered adequately, or not reaching all...
of the appropriate audiences as compared with internal standards or to a competitor(s), would be considered a knowledge gap. A gap analysis may be conducted several times throughout a drug product’s life.

A gap analysis looks at “whether we are reaching the correct people, with the information they need, in a timely manner,” says Traynor. “Timeframe is an important part of looking at whether there are gaps in what we are planning. If the people who need the information we are providing are not getting that information when they need it, then there is a big gap in our plans as if we weren’t communicating that information at all.” For example, a gap analysis may demonstrate that Brand X has been targeting specialist audiences by selectively presenting data at meetings for specialists only, while competitors A and B have expanded their coverage to include meetings for nurses and primary care physicians (PCPs). A knowledge gap about Brand X, therefore, would exist among the nursing and PCP audiences. Findings from this gap analysis may be used to recommend that the publication plan include presentations, posters, and abstracts to be submitted to meetings specifically targeting PCPs and nurses. The publication plan also should include targeting articles to journals catering to PCP and nursing readership (Journal of Internal Medicine, American Journal of Nursing). Similarly, a gap analysis may reveal that most of the reviews and articles on randomized trials on Brand X are targeted to one journal category (eg, endocrinology) while competitors target multiple journal categories (eg, general medicine, cardiovascular, pharmacology, obesity, managed care, and health technology). These findings may be used to recommend targeting future publications to a broader array of journal categories to reach these other specialized audiences.

What Can be Analyzed in a Gap Analysis?

A gap analysis of publication activity can be numeric (quantitative) and/or interpretive (qualitative). A quantitative assessment of the publication landscape may look at the number of publications on a drug product or medical device (alone or compared with competitors) according to specific categories, such as:

- year or timeframe of publication
- therapeutic indications covered in publications
- key words, such as population subgroup or efficacy endpoint
- types of publications:
  1) for a journal publication: primary clinical manuscripts (efficacy/safety, pharmacokinetics), review, secondary analysis, editorial, letter, case reports, health economic analyses, meta-analyses, treatment guidelines
  2) for scientific congress proceedings: abstracts, posters, presentations

Ethical Guidance For Publication Planning

Once the findings of a gap analysis are interpreted, recommendations may be made for the publication plan. Below is a listing of links to relevant publication planning guidelines and organizations that may help ensure that the publication planning process is conducted in an ethical manner. Ethical considerations for publications generated by gap analysis recommendations include the freedoms and responsibilities of authors, criteria for authorship, how to report data, and disclosure of conflicts of.

Guidances

- Good Publishing Practices II (GPP2) (www.bmj.com/content/bmj/339/bmj.b4330.full.pdf)
- International Committee of Medical Journal Editors (ICMJE) (www.icmje.org)
- Committee on Publishing Ethics (COPE) (http://publicationethics.org)
- Consolidated Standards of Reporting Trials (CONSORT) (www.consort-statement.org/consort-2010)
- Transparent Reporting of Systematic Reviews and Meta-Analyses (PRISMA) (www.prisma-statement.org)

These and many more guidelines are listed by the US National Library of Medicine on the Research Reporting Guidelines and Initiatives page (www.nlm.nih.gov/services/research_report_guide.html).

Professional Associations

- International Society for Medical Publication Professionals (ISMPP) (www.ismpp.org)
- American Medical Writers Association (AMWA) (www.amwa.org)
- The International Publication Planning Association (TIPPA) (www.healthcare-conferences.com)

- types of journals, which can be stratified by audience, area of specialty, or geographic region
- number of mentions of key topic points
- competitor claims
- patient population
- number of times selected articles were cited in other publications within a specified time period

Figure 1 presents 3 examples of the output from a quantitative gap analysis that could be used for a publication plan.

Figure 1A depicts the total volume of publications on a drug product, stratified by the type of article. This gap analysis exposed the lack of case reports and coverage in treatment guidelines. Therefore, the resulting publication plan can include a recommendation for increasing the number of these types of publications.
Figure 1B focuses on 1 drug product, calculating the number of times this drug product's publications were cited over 8 years. Publication planners can use this information to incorporate steps to increase production of citable publications.

Figure 1C takes the gap analysis one step further by comparing the number of publications produced on 1 drug product to the number produced for competitor drug products over 8 years. As the figure shows, the featured drug product has consistently trailed the competitors in the number of publications. This gap analysis exposes the need for publications and data about Brand X in relation to competitors in the interest of fair balance as well as of providing transparent access to available evidence. In other words, it is not just a matter of increasing the information output on Brand X but, rather, the producer of Brand X also is responsible for making evidence available to the medical community so they can make informed medical decisions based on all available evidence.

This issue of fair balance and transparent access to available data “is at the heart of everything we do in communication planning nowadays,” says Traynor. “The aim of a communication plan should be to ensure that health care professionals are getting the information they need, be it on new treatments, techniques, devices, in a timely manner and a form they can easily access and digest in order to enable them to treat their patients as best they can. A big part of that is ensuring fair balance and access to data. As such, any gap analyses undertaken as part of the planning process need to focus on whether there are gaps in providing that information in a way that ensures transparent access to data and provides fair balance. Ultimately, the end goal is to improve the lives of patients around the world. Our part as publication professionals in striving towards that goal is to ensure that there aren’t any gaps in the provision of transparent, balanced and timely information to health care professionals.”

An analysis of clinical trials (completed, ongoing, recruiting) can yield important information that may be helpful for planning future publications. An examination of competitor clinical trials (eg, by exploring ClinicalTrials.gov for US trials) will reveal the number and status of registered studies, study designs, established and evolving endpoints/outcomes, indications being investigated and in what patient populations, etc. Recently completed, in-progress, or planned trials can serve as an indicator of potential future competitor publications. As an example, a gap analysis could compare the endpoints across the planned clinical trials for Brand X to determine whether they will “provide relevant data to support” the drug’s key topic points and provide a comparable degree of information compared with trials of other products or competitors. If not, the gap analysis will help determine what endpoints or analyses are needed to support these key topic points by communicat-
A qualitative method of gap analysis involves looking at the tone with which key topic points or data are presented for a brand versus competitors (Figure 2). This type of assessment may ask if the publications present the drug product’s key topic points within a positive or negative context, and how this perspective compares to that of competitors. The tone of the language used to describe scientific evidence can also be compared between a drug product and its competitors.

The interpretive part of the gap analysis involves a qualitative assessment of publications in search of key developments and trends that may expose gaps. In this regard, a gap analysis may investigate the quality of the data/information featured in publications on a drug product, stratified by the following categories:

- integrity of data or strength of evidence based on quality of the trial design
- extent of exposure of key topic points
- extent of exposure of key data
- inclusion/exclusion in treatment guidelines
- developments in that therapeutic area

Stratifying publications on a drug by the quality of a study design or the consequent strength of the evidence will help expose how the integrity of data on a drug compares to that of competitor drugs. Such comparisons will reveal where evidence may be strong, weak, or lacking, and areas for potential improvement. This information can be used to plan publications that emphasize any existing evidence that is considered strong. Studies that previously produced weak results or were lacking evidence may be reevaluated to suggest future studies with improved design.

Likewise, evaluating publications according to the extent of exposure of key topic points may help to highlight the strength, or lack thereof, of messaging for a drug or device product in reference to competitor drug products. For example, a gap analysis may survey key topic points A, B, C, and D pertaining to Brand X versus Competitors 1, 2, 3, and 4 within the publication landscape. The gap analysis results may demonstrate the consistently abundant exposure of Brand X’s 4 key topic points compared to competitors but may also expose the need for Brand X to increase coverage of Topic Point B compared to Competitor 1. This information can be used to plan more publications emphasizing Topic Point B to build up coverage to equal or surpass that achieved by Competitor 1.

Other qualitative aspects of a gap analysis may include whether or not the subject of the gap analysis is included in current treatment guidelines. For example, if the drug product is not included in treatment guidelines, is this due to a lack of available data or insufficient coverage in the publication landscape informing the medical community? Has the drug product been newly added in the most recent guideline update? Or is the drug product included but not at equal standing to competitor treatments? In any case, the gap analysis will help reveal where the product and pertinent data may benefit from additional exposure in the literature.

While the addition of a drug product in a guideline update is one of the various developments in a therapeutic area that a gap analysis might look at, other key developments may include the expansion of an indication, the recent publication of a meta-analysis or population-based study, or the availability of new data on disease progression or pathogenesis. A gap analysis may look at how Brand X is covered in the publication landscape in relation to these developments and compared to competitors. For example, if Brand X received its pediatric indication after the competitor product did, a gap analysis could examine the extent of the competitors’ coverage on this indication in the publication landscape and any associated claims regarding the indication to reveal where Brand X may be lagging in coverage. These findings may be used to recommend a series of articles to report and discuss relevant study findings with Brand X that might relate to the claims of its competitors. Likewise, if a new meta-analysis or population-based study has been published, the findings can be included in a gap analysis as part of the assessment of available evidence and major conclusions or opinions derived from the literature. For example, does the meta-analysis reveal any important differences...
in safety or efficacy (or other aspects of differentiation) with Brand X compared to competitors? Does it reveal differences in chosen endpoints or study designs in clinical trials? Lastly, if new data are available about disease pathogenesis or progression, these findings may be applicable to future publications about Brand X. These findings also could be used, for example, to recommend new epidemiologic or clinical studies (which would be followed by publications including abstracts, posters, presentations, and journal articles) to investigate the effect of Brand X in light of these new data.

Likewise, if a new meta-analysis or population-based study has been published, the findings should be assessed in a gap analysis to reveal where Brand X may be lacking or leading compared to competitors. For example, does the meta-analysis reveal a shortage of publications referring to Brand X compared to competitors? Does it reveal differences in chosen endpoints in clinical trials?

If new data are available about disease pathogenesis or progression, the findings of a gap analysis will reveal whether this information has been made available in the context of Brand X. If not, these findings could be used, for example, to recommend new epidemiologic studies (followed by publications including abstracts, posters, presentations, and journal articles) to investigate the effect of Brand X in light of these new data.

**Using the Findings of a Gap Analysis**

The findings of a gap analysis on a drug product will ideally provide an overview of a therapeutic area from the perspective of scientific publications. This overview may be used to compare a drug product to its previous publication performance or to compare a drug product to competitor products, in order to identify gaps in the evidence base, scientific or medical themes, and audience reach as depicted through the existing communications. Trends may emerge if knowledge gaps are identified in the literature where data or expert opinion are missing about Brand X.

To help identify trends, it is useful to look for:

- key topic areas that set the drug product apart from the competition
- key topic areas that are central to the drug product’s role or identity in the therapeutic landscape
- common themes in the literature, particularly trends in positive, negative, or neutral statements or depictions of the drug product compared to competitors
- any coverage of data regarding the safety and efficacy of the drug product and competitors’ efficacy and safety
- any coverage on specific symptoms and special populations relating to the drug product’s therapeutic area

A review of the findings of a quantitative or qualitative assessment of publications, for example, may reveal such trends as:

- the most common endpoint used in clinical trials
- certain journals or types of journals that are targeted more frequently than others (such as specialty versus general)
- a few authors frequently serving as lead authors on publications
- the percentage of articles on Brand X that are reviews, primary reports of data, or secondary analyses
- the absence of primary manuscripts for some of Brand X’s clinical trials

Identifying these trends and various others will help formulate recommendations for the publication plan. For example, the gap analysis findings may include recommended endpoints for future clinical trials depending on where the drug is in its lifecycle. The findings may also help to determine whether any exposed gaps can be addressed by any existing or forthcoming trial data. Or, if a gap analysis reveals that competitor drug publications are authored by a particular scientific or medical expert, one recommendation may be to seek that person’s involvement in future studies.

**BASIC STEPS TO CONDUCTING A GAP ANALYSIS**

The following are the basic steps to conducting a gap analysis of a drug product for a medical publication plan.

1. **Identify the areas of focus/rationale.**

A gap analysis needs a defined and limited focus or rationale before it can be initiated. Having a comprehensive understanding of the drug product’s therapeutic area, including any competitor products, will help in the task of formulating the rationale for the gap analysis. What knowledge gap(s) will the findings from the gap analysis fill? Define the focus by forming a topic question, such as “What was the nature of the postlaunch medical journal coverage of Brand X compared to competitors A, B, and C?” The findings of such a gap analysis will answer such questions as: Which drug had the most publication activity? What kind of evidence and data were featured in those medical journal articles? What were the common endpoints of trials?

2. **Determine a meaningful timeline for analysis: historical, current, or milestone snapshot.**

In order for a gap analysis to be manageable, a reasonable timeline needs to be chosen. The timeline will limit the years within which publication activity will be considered. Typically, gap analyses adopt a historical, current, or internal/external milestone perspective. A gap analysis with a historical perspective will limit its timespan to a certain period that is meaning-
ful to the analysis. For example, a benchmarking gap analysis may compare the publication activity of a drug product versus a competitor during a particular phase of a product’s lifecycle, such as prelaunch, perilaunch, or postlaunch over the last 5 years. A historical perspective can be useful also to search for trends over time to predict future trends. Alternatively, a gap analysis may be limited to a shorter and more recent timespan. Choosing a brief time period, such as the last 12 months, will help shed light on what issues are relevant today regarding a drug or device product compared with its competitors. It may also allow for a much more in-depth examination of publication activity.

A third option blends the historical and short-term perspectives by focusing on a specific period within the lifecycle of a drug or device product, such as the prelaunch, perilaunch, or postlaunch. This type of perspective provides a “milestone snapshot” of the publication activity of a drug product and competitors. By looking at these “snapshots” in time, trends may become obvious.

3. Identify the scope of research.
Another preparatory step for a gap analysis involves delineating what types of research materials will be considered and what databases will be searched. The types of publications that are commonly considered for gap analyses in medical publication planning include peer-reviewed articles published in indexed journals, and abstracts, posters, and presentations from scientific meetings and congresses.

Indexed journal article search
A gap analysis limited to indexed journals needs to establish in advance which databases will be searched, such as PubMed, EMBASE, the Cochrane Library, Google Scholar, CINAHL, PsychINFO, and the Thomson Reuters Web of Knowledge. Determine ahead of time if only full articles will be considered for the gap analysis, and if abstracts will be considered if full articles are not available.

Scientific abstract, poster, and presentation search
The online archives of relevant medical organizations may be searched for abstracts, posters, and presentations from previous scientific congresses and meetings. Establish in advance which scientific meetings/congresses will be considered for the gap analysis.

Search of other sources
National databases of clinical trials, such as Clinicaltrials.gov, hosted by the United States National Institutes of Health, may provide useful information for a gap analysis. Additionally, the content of websites associated with government offices, medical organizations, or disease associations are typically considered acceptable for gap analyses on drug products. Press releases may be used as starting points for understanding more qualitative aspects or identifying key targets or audiences. These can be searched for in press release databases and through general search engines such as Google and Google Scholar.

4. Determine search parameters.
Having a clear idea of the focus/rationale, timeframe, and scope of the gap analysis will help in identifying the appropriate search methodology (eg, data sources, key words, and filters/limits). A full analysis may involve several sets of analyses of data (eg, grids), with some being more drug-specific and others more disease-specific or patient-related, so this all has to be taken into account when considering search parameters. The search parameters chosen for the gap analysis will determine what publications are produced in the search. Therefore, search terms must be chosen carefully and should be directly related to the goal(s) of the gap analysis. Search terms must be established before any research begins and must be adhered to rigidly throughout the gap analysis to ensure that the publication results will be reproducible. The rationale for inclusion and exclusion of relevant search terms should be provided.

For the purposes of a gap analysis on a drug product, the designation of search parameters would start with including the name of the drug product of interest and any relevant competitors. Other keywords that may be considered include those referring to the target disease, treatment type, and data of interest (eg, quality of life versus efficacy data).

In addition to search terms, selecting limits for the search will help filter out unwanted results. Limits may include which fields to search such as text availability (eg, abstract only, full-text, or free full-text), languages (eg, English only), types of articles (eg, clinical trials, case reports, reviews or meta-analyses), age of study population (eg, all ages, or pediatric or elderly populations), and publication dates (eg, occurring during the last 12 months versus the last 5 years).

5. Select a format for gap analysis output.
The last step before starting the gap analysis is deciding in what format to present and organize the results of the gap analysis. Table 1 is an example of how data from a literature search can be tracked on a grid, which can be easily created in Microsoft Word or Excel. Information from both programs also can be imported into a PowerPoint slide to create a presentation of gap analysis findings.

6. Conduct the search.
Adhere strictly to the pre-established key words while search-
ing the databases. Carefully populate the output format with data on publication coverage.

7. Organize and prioritize findings to identify trends regarding the topic question.

Keep track of publications by creating a grid in an Excel spreadsheet or a Microsoft Word table (Table 1). Use column headings matching the search parameters. Column headings can include such parameters as citation, journal/congress, title, type of publication, name of drug, study endpoints, key topic points, key data points etc. The research findings will also suggest column headings not previously considered. For example, if the identified publications are spread over a variety of audiences opposed to just one audience type (eg, general medicine), the grid will benefit from adding a heading such as Target Audience, Journal Type, and/or Scientific Meeting Type. Alphabetizing the contents of columns in both Word and Excel is a simple way of organizing findings.

Trends about publication coverage should become apparent as the publications are organized into categories according to the column headings and interpreted. For example, as Figure 3 shows, change in HbA1C tends to be the most common endpoint in publications on exenatide and/or liraglutide. If Brand X were a competitor of these diabetes treatments, this information could be compared to the endpoints in Brand X trials to see if they align. If Brand X is using different endpoints, the recommendation could be made to design new studies (and then publish companion abstracts, posters, articles, etc) that use HbA1C as a primary endpoint.

CONCLUSION

A gap analysis is an integral part of the publication planning process. It takes a comprehensive look at the publication landscape to determine the position of a drug product, medical device, medical procedure, or therapeutic area in relation to internal goals, key topic points, plans, and/or competitors to identify any knowledge gaps. By demonstrating where the holes are in the publication landscape, a gap analysis will reveal opportunities to increase publication coverage in terms of which data to focus on in the publication plan, which target audiences such data should be directed to, which of the available journals and scientific congresses and meetings should be targeted for submission, and when these targeted submissions should occur. These gaps can then be resolved with targeted publications via a medical publication plan. Ideally, a gap analysis will help maximize the impact of publications related to a specific drug or device product and may be conducted several times throughout a product’s lifecycle. It is essential that any gap analysis be conducted in accordance with existing ethical guidelines that cover authors’ freedoms and responsibilities, criteria for who merits inclusion in the authorship group, the reporting of data, and disclosure of conflicts of interest, among other criteria.

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

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References


Table 1. Abbreviated Sample Grid for Tracking Publications on Specific Drug and Competitors.

<table>
<thead>
<tr>
<th>Drug</th>
<th>First Author</th>
<th>Journal</th>
<th>Journal Type</th>
<th>Article Title</th>
<th>Article Type</th>
<th>Endpoints (for RCTs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exenatide vs liraglutide</td>
<td>Buse JB</td>
<td>Lancet</td>
<td>General</td>
<td>Exenatide once weekly versus liraglutide once daily in patients with type 2 diabetes</td>
<td>Randomized clinical trial</td>
<td>Change in HbA(1c)</td>
</tr>
<tr>
<td>Exenatide and liraglutide + Liraglutide vs sitagliptin (DPP-4 inhibitor)</td>
<td>Russell-Jones D</td>
<td>Clinical Endocrinology</td>
<td>Endocrinology</td>
<td>Recent advances in incretin-based therapies</td>
<td>Review</td>
<td>N/A</td>
</tr>
<tr>
<td>Pratley RE</td>
<td>Diabetes Care</td>
<td>Endocrinology</td>
<td></td>
<td>Efficacy and safety of switching from the DPP-4 inhibitor sitagliptin to the human GLP-1 analog liraglutide after 52 weeks in metformin-treated patients with type 2 diabetes: a randomized, open-label trial</td>
<td>Randomized, open-label trial</td>
<td>Change in HbA(1c), reduction in FPG, change in body weight after switching from sitagliptin (DPP-4 inhibitor) in metformin treated adults</td>
</tr>
</tbody>
</table>
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ABSTRACT
By the mid-20th century, it became increasingly apparent that many scientists and medical researchers lacked sufficient English writing skills to communicate original research findings effectively—either to their peers or a wider audience. As the pace of technology and scientific discovery quickened, technical, medical, and scientific writing and publishing standards required specialized compositional competencies. As these scientific writing genres advanced, some technical and medical writers became disenchanted with the value of English writing instruction as taught within the humanities. To them, writing in the humanities fails to provide a suitable orientation for success as scientific and medical communicators.

Drawing on authorities in the humanities, sciences, engineering, and medical writing, I argue that writing in the context of the humanities is equally pertinent to success as a professional medical writer. I offer several “propositions” to challenge the claims of those who contend learning to write in the humanities is detrimental to a medical writer’s career development. I conclude that fine writers and expert teachers of writing in the humanities possess the erudition and tools to make significant contributions to the medical writer’s repertoire of relevant skills.

The expense of a college education, with its tsunami of graduation day debt, has made incoming freshmen and their parents leery of majors that appear to have dismal employment prospects. The humanities, as a result, are under pressure to justify their value, not only as a return-on-investment, but also as academic equals to science, engineering, and technology.  

The gulf separating science and the humanities is mirrored in medical writing. Some technical and medical writing practitioners have long questioned the value of English department composition courses. “There is so much wrong with freshman English and so much right about technical writing that I suggest they trade places in the academic scene,” wrote W. Earl Britton as far back as 1974. More than a decade later, Tom Lang echoed Britton, writing: “I believe my authors and students are such poor communicators because they were taught writing in the tradition of the humanities, and they have applied this orientation to technical writing, which requires a fundamentally different orientation.” More recently, Lang wrote: “…the single largest impediment to the development of our profession [is] the belief that writing ‘belongs’ to the humanities.” From the opposite perspective, humanities faculty have been described as regarding technical communication as “vocational training” antithetical to the goals of academia.

Obviously writers schooled in liberal arts cannot simply flip a switch and meet the editorial rigor of scholarly medical publication overnight. The assertion, however, that writing as taught in the humanities lacks the orientation required for medical writing is an unnecessary exercise in fence-building. I propose, like DNA’s double-helix, the two are complementary and closely interwoven.

To place this analysis in context, Figure 1 illustrates a spectrum of medical and health care communications. This article addresses scholarly writing directed to highly literate health care readers. Within this context, then, what takes place in contemporary college English composition classrooms? Does writing in the humanities possess any value to medical writers?

Proposition 1: First-year composition in 2014—not dad’s freshman writing class.
In freshman English composition, wrote Britton, “…the flow of information proceeds from an ill-informed freshman to a well-informed instructor, primarily because the instructor insists

* For the record, I find Lang an insightful, credible commentator on medical writing matters save for this topic.
that it be that way. He argues that he can assist the student only by knowing more about the material than the writer does."  

Course catalogs demonstrate this is no longer the case. “English 110 on the Columbus Campus positions students in a Research I university setting by asking them to learn the conventions of academic research and writing while gaining expertise in a particular course topic. Students enrolled in English 110 focus on a single research topic throughout the quarter. ... students produce a series of academic texts, including abstracts, annotations, critical responses, proposals, and, of course, traditional academic papers.”

Ohio State’s First-Year Writing Program is hardly unique. Stanford University’s Program in Writing and Rhetoric is not taught within the English department milieu. Instead, courses are “designed to offer richly diverse intellectual experiences based on shared assignments, goals, and learning outcomes.” Each instructor builds on this core to develop a unique introduction to disciplined writing. A sampling of the program’s course topics illustrates the connective tissue linking content and structured writing (Box 1).

Figure 1. Depiction of the relationships between target audiences, typical medical writing projects, the distribution medium and levels of health care literacy. The middle band lists typical writing projects associated with varying audiences. In addition to differing audiences and objectives, today’s medical writers employ a wide range of media influenced by how the intended audience is most effectively reached. The examples are not all-inclusive and subtle gradations exist between and within these categories.

Box 1. A Representative List of First Year Writing Unit Courses from Stanford University’s Required Program in Writing and Rhetoric (PWR).

Writing & Rhetoric 1: Writing Nature: Discourses in Ecology, Culture, and Technology
Writing & Rhetoric 1: Body Politic: The Rhetoric of Transhumanism
Writing & Rhetoric 1: The Shape of Things: The Rhetoric of Design
Writing & Rhetoric 1: Are you Fuzzy or Techie?: The Rhetoric of Art and Science
Writing & Rhetoric 1: Ladies, Tramps, and Other Furry Friends: The Rhetoric of Pets
Writing & Rhetoric 1: The Politics of Difference, Identity, and Harm: The Rhetoric of Hate Crimes
Writing & Rhetoric 2: All That Jazz: The Rhetoric of American Musical Theater
Writing & Rhetoric 2: The Power of Political Photography
Writing & Rhetoric 2: Red Pill or Blue Pill?: The Rhetoric of Drugs
Writing & Rhetoric 2: Illness Narratives: Attention, Empathy, and Storytelling

Proposition 2: When writers became writing teachers, the focus shifted from “product” to “process.”

In the 1970s, teachers of writing began asking if the writing process employed by successful writers could serve as a paradigm to improve writing by children, students, and adults.\textsuperscript{9,10} A deeper appreciation of the relationship between writing process and quality of the written product emerged. Observing experienced writers at work birthed the pre-writing, drafting, revision, and editing stages we now take for granted.\textsuperscript{9,10}

Cleveland State University’s Writing Center website, for instance, offers this advice: “Writing is a task that no two people do the same way. However, there are some logical steps that every writer seems to follow in the creation of a paper. The process described here outlines those basic steps. Keep in mind that these steps are not exclusive of each other, and at times they can be rather liquid. Also, writers will notice that most of these steps are reciprocal; that is, work done in one area may necessitate returning to a step that you have already ‘completed.’”\textsuperscript{11}

By assessing a student’s portfolio of accumulated drafts, instructors do not simply evaluate a finished piece of writing—but trace each writer’s passage from initial idea to final draft and how reader feedback influenced evolving drafts. Applying the work habits of highly successful writers in all content areas can dramatically improve a student’s written product.

Proposition 3: Writing is a private act with a public intent.

Donald Murray, Pulitzer winner and highly regarded teacher of the theory and practice of writing, elucidates the dual roles every writer confronts: “Writing is a private act with a public intent.”\textsuperscript{12} Technical writer Carolyn Miller maintains that communication occurs in communities.\textsuperscript{13} “Scientists form an epistemic community, consisting of smaller and overlapping disciplinary sub-communities. We can define scientific writing as written communication based within a certain community and undertaken for certain communal reasons.”\textsuperscript{13}

Linda Flower, Carnegie-Mellon University English professor and recognized authority on composition, stated: “You want the reader to share your knowledge and your attitude toward that knowledge … a good piece of writing closes the gap between you and the reader.”\textsuperscript{14} The first step is to “gauge the distance between the two of you.” Good writers design their writing to reduce these differences.\textsuperscript{14} Flower’s “English teacher” perspective is consonant with Britton’s assertion that “technical writing places the emphasis where it should be: on the reader rather than the writer.”\textsuperscript{3}

Murray offers English composition instructors essentially the same advice: “An effective piece of writing answers a reader’s question, and to do that the writer must learn to anticipate the reader’s concerns.”\textsuperscript{12} Writing is a conversation between author and reader within the context of a community. It little matters whether the reader wishes to learn a scientific hypothesis or the history of musical theater.

Proposition 4: Substance, form, and style are inseparable.

In the humanities, Lang has asserted, the written word “is intrinsically valuable; that is, it should be studied and valued for its own sake…”\textsuperscript{4} He cites “the well-turned phrase, the moving speech, the enchanting story…”\textsuperscript{4} However he defines a so-called “well-turned phrase,” authors in the varied domains encompassed by the humanities do not dedicate a lifetime of writing to turn a phrase as if it were a wood screw. Novelist and critic Martin Amis asserts that style “is not something grappled on to regular prose; it is intrinsic to perception.”\textsuperscript{15} In a similar vein, Ben Yagoda writes, “Content does not exist separate from the words in which it is expressed. Each depends on the other. When you remove the wrapping of language, you see that the box is empty.”\textsuperscript{16}

Lang’s reference to a “moving speech, the enchanting story” evokes the playwright’s craft. I have participated in several playwriting workshops but never heard a fellow dramatist say, “my goal this session is to write a moving speech.” Dramatists don’t think that way. They create vivid characters, then insert them into situations of conflict and see what happens. Although it is possible to admire Shakespeare’s language intrinsically, his work is best appreciated in the context of live performance where speeches grow organically from the interaction of character, plot, and dramatic conflict. Shakespeare’s soliloquies reveal Hamlet’s irresolute state of mind or Iago’s intent to arouse Othello’s jealousy. Going to the theater simply to hear a moving speech is to miss the point of buying a ticket.

An “enchanting story” alludes to structure. Story results from an author’s conscious sequencing of events. Many scientific writers describe...
their reports of original research as telling a story. Statisticians refer to the story the numbers convey. In a talk titled “The Way We Live Our Lives in Stories,” Jonathan Gottschall, a distinguished research fellow in Washington & Jefferson College’s English Department, said:

Scientists are telling stories, too. That’s what a hypothesis is. You have the question, and you make up a story about how to account for the phenomenon. The advantage that sciences have over the humanities … is that science has methods for helping winnow down the field of competing hypotheses.17

Proposition 5: Writing often begins in chaos.
When we write about a complex subject, we first explain it to ourselves. In a video interview in which she described the value of her nascent writing, the director of Stanford’s Institute for Computational and Mathematical Engineering said: “I never write only at the moment when I fully understand the problem. So I don’t work on the problem and then when I say I have 100% comprehension—okay now I’m just going to write up that story and I know exactly what I’m going to write. Writing is part of the scientific discovery.”18

Similarly, Stanford University Environmental Earth System Science Professor Julie Kennedy says, “The more that you take care with your writing, the more you might explore uncertainties in your thinking. And the more you explore those uncertainties in your thinking, the clearer you will be in your writing and communication.”19

Professional medical writers rarely communicate their own scientific research. When a project begins, we may lack knowledge of the medical specialty, disease state, or therapeutic intervention. As with Britton’s lowly freshman, we start from a position of ignorance. Pre-writing and the trial and error of rehearsal help us accumulate and synthesize new information in order to develop a precise research protocol or informative patient pamphlet.

Proposition 6: Rhetorical devices considered poetic are equally available to medical writers.
In Metaphors We Live By, Lakoff and Johnson ponder mistaken notions about poetic metaphor. “The generalizations governing poetic metaphorical expressions are not in language, but in thought: They are general mappings across conceptual domains … most of our ordinary conceptual system is metaphorical in nature.”20 The authors provide numerous examples, such as the mental construct that “argument is war.” Our daily vernacular is rife with allusions derived from the overarching metaphor (Box 2). Other metaphorical constructs arise from our physical and cultural experience.20 We intuitively associate emotional states (happy/sad) with physical space (up/down).

We intuitively associate between emotional states (happy/sad) and physical space (up/down).

ARGUMENT IS WAR
Your claims are indefensible.
He attacked every weak point in my argument.
His criticisms were right on target.
I demolished his argument.
I’ve never won an argument with him.
You disagree? Okay, shoot!
If you use that strategy, he’ll wipe you out.
He shot down all of my arguments.

HAPPY IS UP; SAD IS DOWN
I’m feeling up.
That boosted my spirits.
My spirits rose.
You’re in high spirits.
Thinking about her always gives me a lift.
I’m feeling down.
I’m depressed.
He’s really low these days.
I fell into a depression.
My spirits sank.

Writing who eschew metaphor in an attempt to make their prose completely transparent labor under a false assumption rooted in a positivist perspective** that the world consists of objects independent of any people who experience them. The standard dictionary-maker’s view of “definition” assumes that experiences and objects have inherent properties and that people understand them solely in terms of these properties.20

By adopting names of familiar objects to identify anatomical parts, “medical language was originally highly metaphorical,” Robert Bjork points out. Bursa, Medieval Latin for purse, came to signify the pouch lined with synovial fluid near a joint, as 1 example.21

Lakoff and Johnson describe fallacies stemming from a positivist** conception of language and reality: 1) that metaphor is a matter of words, not concepts, 2) that metaphor is based on similarity, 3) that all concepts are literal and none

**The positivist movement held that all meaningful statements are either analytic or conclusively verifiable, confirmed only through observation and experience.
can be metaphorical, and 4) that rational thought is in no way shaped by the nature of our brains and bodies.20

Their book illuminates how sophisticated concepts are made clear by deeply structured interacting metaphorical thought processes. Readers grow to understand why Lakoff and Johnson reject that “metaphors are nothing but linguistic expressions—a mere matter of words.”20

**Proposition 7: Literary invention can clarify abstract scientific concepts.**

In contemplating physical phenomena, some scientists find personification apropos. Richard Dawkins describes hearing the molecular biologist Jacques Monad talking about creativity in science:

> When trying to think through a chemical problem, he would ask himself what he would do if he were an electron. Peter Atkins ... uses a similar personification when considering the refraction of a light beam, passing into a medium of higher refractive index which slow it down ... Atkins imagines it as a lifeguard on a beach racing to rescue a drowning swimmer. Should he head straight for the swimmer? No, because he can run faster than he can swim and would be wise to increase the dry-land proportion of his travel time. Should he run to a point on the beach directly opposite his target, thereby minimizing his swimming time? Better, but still not the best. Calculation (if he had time to do it) would disclose to the lifeguard an optimum intermediate angle, yielding the ideal combination of fast running followed by inevitably slower swimming.22

Dawkins believes original use of language can yield greater insight than a more prosaic approach: “...push novelty of language and metaphor far enough, you can end up with a new way of seeing.”22 As medical writers do we push novelty of language sufficiently to help readers understand complex content?

**THE MEDICAL WRITER'S GENETIC CODE**

Although related, medical and technical writing do not share matching genetic material. Technical communicators create user instructions and technical manuals; they document complex processes or management systems. The currency of biomedical research, however, is accumulation and dissemination of knowledge spun in an evolving communal dialogue of breakthroughs, course corrections, and clinical applications. Referring to his role as a technical communication teacher, Jeff Todd warned against a “tendency to conflate scientific writing with technical writing.”22

Although Britton declares that technical writing “differs from literature in that more than one interpretation is unacceptable,”23 Gopen and Swan contend that “we cannot succeed in making even a single sentence mean one and only one thing; we can only increase the odds that a large majority of readers will tend to interpret our discourse according to our intentions.”24

Gopen comes from the humanities; he has a PhD in English from Harvard and a JD from Harvard Law School. While a sought-after consultant in legal and scientific writing, he simultaneously taught Chaucer and Shakespeare.25

Among scientists, noted marine biologist Rachel Carson peered into the ocean depths for subject matter and found it a world of poetry.26 Astrophysicist Carl Sagan cast an upward glance to wonder at the night sky. Both were masterly communicators: Carson in nonfiction and Sagan as a writer of television documentaries and author of many books.

Writing is too diverse an enterprise to be owned by a single academic discipline. Neither English department nor the engineer’s technical writing classroom can contain it all. The writer's craft is essential to participate in journalism, public relations, and digital media communication. Historians must be skilled researchers and imaginative writers to illuminate the past. We are deprived of future playwrights, screenwriters, even video game writers, without fulfilling their need for instruction in how to tell stories using sight, sound, and motion.

To erect parochial barriers between genres and plant a “no trespassing” sign becomes self-defeating to any writer striving to fulfill his or her potential. To disregard the synergy between medical writing and composition within the humanities fails to acknowledge the genetic code all writers share.

**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**

When I was attending graduate school, the concepts of medical and even technical writing were still learned on the job. As a medical writer who came in through the back door, without the benefit of professional training available today, I developed my writing skills on the job. Before getting into medical writing, I had been a technical communicator in the automotive, defense, and environmental industries. Learning new concepts and terms was not alien to me, and I enjoyed expanding my knowledge.

My start in medical writing was in a dermatology lab, transcribing recorded diagnoses. Although the task sounds mundane, I made the best of it by editing the transcriptions for clarity and showing them to the physicians. I was then able to work with a programmer, and we developed standard language for diagnoses for a database. This saved time for all of us because the physician could simply provide a diagnosis, such as “dermal nevus,” and I could import the standard language for this diagnosis from the database. If necessary, we could then provide further details.

From there, I moved on to researching regulations in various US states and territories on pharmaceutical distribution. Many states not only have slightly different laws and rules governing the manufacture of drugs and devices but also the distribution of these items. There are also federal regulations to consider. At that time, physicians could write prescriptions in all states or territories, but advanced practice nurses could not. Therefore, the pharmaceutical companies wanted to know who could prescribe their products in different parts of the country. I also researched licensing laws and regulations for medical professionals in different states/territories. The experience provided a valuable introduction to pharmaceutical operations and clinical trial regulations.

I also worked in a surgery department where I offered to edit the department’s annual report. It certainly needed updating, and there was much repetition and extraneous material that could be deleted. It also lacked illustrations to help readers recognize the kinds of innovative research being conducted in the department. For instance, including a photograph of a room used to simulate attending to wounded soldiers while in flight helped reinforce the challenges military medical professionals face on the front lines. My revision was so well-received that I was then invited to edit research papers and book chapters. From there, I went on to writing morbidity and mortality reports and serving on committees (such as ethics and continuing medical education).

Today, the field of medical writing is as diverse as medicine itself. As a writer, you may find you specialize in a particular area, such as surgery or infectious diseases. My perspective comes from being a medical writer who works with physician-scientists and clinical researchers in hospital or laboratory settings.

What connections can you make and what resources should you have on hand to make your job easier and deepen your understanding of your subject? The answer to the former is to get acquainted with people in support areas, because getting your job done is likely to require more than just producing clear prose. In my work setting, such support offices include:

- Grants and contracts. Most organizations have a point person who works closely with each division, and larger organizations often have a team; they will rely on the medical writer for research abstracts and progress reports. The medical writer, in turn, relies on the grants and contracts points of contact to ensure grant-supported research complies with the intricate rules and policies from each agency.
- Public relations. Yes, what the medical writer does is often vastly different from what the PR department does, but collaboration between the two can benefit both sides.
Dissemination of research results to targeted audiences or the general public may be a shared objective.

- The institutional review board. The IRB can be a treasure trove of information and resources that can help medical writers educate themselves on federal regulations, research project design and ethics, and institution-specific policies.

**Recommended Resources**

**Textbooks**

To deepen my subject knowledge and improve my medical communication skills, I also keep a small personal library and bookmark helpful websites. While others’ individual requirements may differ, here are some resources that I have found helpful across all projects.

Acquiring all these resources may seem like an expensive undertaking, but I have found it well worth the investment. Slightly older editions of the textbooks can be obtained for a fraction of the new retail price, and they may suffice to aid your basic understanding. If you are affiliated with a university, consult the medical library staff, as the library likely provides some electronic textbooks through an institutional login.

**Basic & Clinical Pharmacology**


This book is now in its 12th edition. As the title suggests, this book is an excellent introduction to pharmacologic concepts, and it can help even those not directly involved in writing for the pharmaceutical industry. Obviously, much medical research is aimed at finding the underlying causes of diseases. The medical writer’s understanding of the pharmacologic process (ie, exactly what drugs do once they enter a human body) will aid in understanding what scientists hope to achieve when developing new therapies.

**Contemporary Project Management**


This book covers all the aspects of project management—in short, how to do all the myriad tasks so that your research team can do what they do best (research) and the medical writer can take care of the rest. New editions come with a Microsoft Project CD.

**Explaining Research: How to Reach Key Audiences to Advance Your Work.**


A scientific writing veteran, Meredith discusses research articles and posters as well as the increasing demand for digital scientific communications, including blogs, video presentations, and podcasts. Meredith also provides valuable advice on how to get research support from stakeholders and how to give inspiring oral presentations.

**Human Anatomy and Physiology**


One of the best ways to improve your ability to write about scientific research is to educate yourself on the basics. This text is not only comprehensive, it is also very readable; it contains dozens of helpful illustrations and explains scientific principles in a clear and concise manner.

**Intercultural Communication in the Global Workplace.**


Working with research scientists and clinicians from different cultural backgrounds is now the rule rather than the exception. Although this book is oriented more to business than to scientific colleagues, the principles of how individuals communicate, and the cultural reasons behind it, are worth investigating.
Medical Terminology Simplified: A Programmed Learning Approach by Body System
I acquired an earlier edition of this book when I took a medical terminology course, and I have often found it essential. The book takes much of the mystery out of medical terminology by explaining the roots of seemingly arcane words. It also contains many helpful diagrams and illustrations that can help with retention. When used together with the anatomy and physiology textbook referenced above, even those without a scientific background can have a solid grounding in basic medical concepts.

The Merck Manual of Diagnosis and Therapy
This remarkable guide is indeed published by the pharmaceutical company bearing its name, but it is definitely not a mere advertisement for its drugs and devices. Rather, it presents information on nearly all medical conditions, both common and rare, with objective details on currently accepted therapies. This book will help medical writers understand where treatments fall short so they will know how research projects may make a difference to future patient health.

On Being a Scientist: A Guide to Responsible Conduct in Research
This little book provides excellent guidance on sometimes-thorny issues such as intellectual property, data management, conflicts of interest, allocation of author credit, and other important considerations. It includes case studies to help readers apply the concepts.

Writing Scientific Research Articles
Medical writers who think how-to books are somehow beneath them really ought to think again. Books like this are crucial to continuing professional development as a writer and editor. This one contains many helpful examples and uses actual scientific journal articles as case studies.

Health News Sources
I’ve also made a habit of reviewing science and health news from reliable sources, such as Nature, Scientific American, and Discovery Medicine. As most graduate students know, there is much to be learned from other writers, both from the content and its presentation. I also highly recommend the Best American Science Writing books, published annually by Mariner Books.

Writing Guides
For someone getting started in medical writing, there are many other useful resources available. It is impossible to list them all, much less read them all. The individual’s choice of style and writing guides may vary according to both preference and the specific rhetorical requirements of the task at hand. With that stated, here is a short list of general references, both paper and electronic.

Much like the MLA and APA, the medical writing world has its own conventions and rules. There are print versions available as well, but the website provides handy search tools and updates along with helpful tips. AMWA members are eligible for a 20% discount to the website or print versions. If you’re affiliated with a university or other institutional library, an institutional log-in may be available.

Author Aid (www.authoraid.info)
This website provides instructional resources for researchers in developing countries who are seeking to publish their work. It also provides a way for aspiring and new medical writers to make connections with scientists. Many of these scientists speak English as a second language. Medical writers can volunteer as mentors.

How to Write, Publish and Present in the Health Sciences: A Guide for Clinicians and Laboratory Researchers
Like the guide by Cargill and O’Connor mentioned previously, this book by Lang, an experienced medical writer who has taught many AMWA workshops, emphasizes the importance of clear prose and well-designed papers.

How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors and Reviewers
Lang provides practical guidance on preparing written reports for publications in journals, using examples to help others understand and apply the presented concepts. He also helps medical writers cope with the sometimes challenging process of interpreting statistics.
Common Places

National Institutes of Health Grant Application Basics (http://grants.nih.gov/grants/grant_basics.htm).
This website provides extensive details and instructions on what to do (and not to do) to get research projects funded by NIH organizations. In the increasingly intense competition for dwindling research funds, a well-written grant application provides a distinct advantage.

Scientific English: A Guide for Scientists and Other Professionals
This book provides overviews of basic grammar and style, self-editing, and writing for electronic media. It may be especially useful for people who are not fluent in English.

Scientific Style and Format: The CSE Manual for Authors, Editors and Publishers
The latest edition incorporates changing requirements for publishing in print; it is also an excellent guide to the evolving world of online content delivery. This includes blogs, social networking, e-books and podcasts/webcasts. There is also a subscription version available at www.scientificstyleandformat.org with the most up-to-date tools and tips. AMWA members are eligible for 20% discounts.

Presented by the International Committee of Medical Journal Editors, this site provides news and opinion pieces along with free downloads and recommendations. Those who are serious about medical writing and editing should definitely bookmark this site. (The recommendations were previously known as the Uniform Requirements for Manuscripts Submitted to Biomedical Journals.)

Resources Near You
In addition to offering print and online resources, many institutions also offer seminars and other learning opportunities for continuing professional development. Although most are oriented toward clinicians, medical writers may be able to take advantage of them. For instance, the University of Cincinnati will soon offer a 1-hour session on writing a letter of intent. This can be a vital step in applying for research grants and can often be the deciding factor in whether researchers are invited to apply. I have attended seminars, such as “Writing for Biomedical Publications” and “Write Winning Grants,” which provided useful exercises as well as print guides for reference. These kinds of live presentations are usually free or offered at a nominal cost.

Another resource you shouldn’t overlook: your computer. Online seminars and training sessions, often self-paced or recordable for repeat viewing, can help medical writers stay connected with one another, exchange ideas, explore trends, and get updated information—all from the comfort of office or home. Employers often cover the costs of professional development activities. Finally, look for local chapters of medical writing organizations such as AMWA or start your own informal group! There are also online discussion groups and social networking sites dedicated to medical writing. These groups will not only stimulate your intellectual pursuit of medical writing excellence, but also be a resource for valuable contacts and additional reference guides, examples, and useful tips and tricks.

Author disclosure: The author notes that she has no commercial associations that may pose a conflict of interest in relation to this article.
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AMWA Resources for Medical Communicators
The AMWA Amazon Store lists suggested books for medical writers. The website includes resources for beginners, books written by AMWA member authors, and books that have received AMWA awards.
http://astore.amazon.com/wwwamwaorg-20

Past issues of the AMWA Journal are online at www.amwa.org/issues_online.

An index of journal articles and a separate index of “Dear Edie” columns are available at www.amwa.org/journalindexes.

AMWA pocket trainings (members-only) are mini tutorials on a variety of topics useful to medical communication professionals.
http://www.amwa.org/pocket_trainings

AMWA offers Self-Study Modules (www.amwa.org/self_studies) for sale on a variety of workshop topics:
• Basic Grammar & Usage
• Elements of Medical Terminology
• Essential Ethics
• Punctuation for Clarity & Style
• Sentence Structure & Patterns
• Statistics
• Tables & Graphs

Through AMWA, members have access to a variety of discounted resources. The discounts are listed at:
www.amwa.org/memberdiscounts
Tweet Your Way to a Prize!

The 2014 Conference Tweet Away is designed to heighten awareness of the AMWA conference and to encourage participation in social media, which can be of great value to medical communicators. The Conference Tweet Away involves using Twitter to promote the annual conference before it happens and to highlight important activities during the conference. Since the middle of August, AMWA has engaged members and nonmembers alike to highlight reasons to attend the conference. There's still time to get involved in that competition if you act fast. You'll also be able to participate in the Tweet Away during the conference, with 3 prizes given through a random drawing and 1 prize given to encourage Twitter users to send meaningful messages—ones of value to medical communicators inside and outside of Memphis.

AMWA has also planned ways to acknowledge all conference tweeters, from free drink vouchers to an informal TweetUp event. Learn more about these and other opportunities at www.amwa.org/events_annual_conference.

If you have a Twitter account, get ready to tweet your way through the annual conference! If you don't have a Twitter account, sign up—it's easy. You can even learn how to set up and use Twitter to your advantage at the conference and beyond. Check out the AMWA tutorial at www.amwa.org/events_annual_conference.

Help AMWA Give Back

AMWA has a tradition of using the conference as an opportunity to give back to the local community. This year, the Southwest Chapter, led by Michelle Saur, has organized a program to help at both the local and global levels. When you're packing, be sure to include travel-size toiletries (shampoo, conditioner, toothpaste, shower gel, etc) to donate. The toiletries will be used to create hygiene kits for the Memphis Family Shelter (www.memphisfamilyshelter.org), which provides transitional housing and support services for homeless women and their children. Bring bar soaps (any size) to donate to International Medical Relief (www.internationalmedicalrelief.org); the soaps will be used to teach hand-washing classes in clinics all over the world. These travel-sized toiletries are easy to pack and will be such a valuable contribution to these two worthy causes. Donations will be accepted at the AMWA Southwest Chapter table near the registration area.
AMWA’s in Memphis
(Sung to the tune of Midnight in Memphis*)

It’s AMWA in Memphis
And all the med writers are out tonight.
Oh, AMWA’s in Memphis
All our colleagues look so fine.
The conference is happening,
Just follow that welcome reception sign.

I’m following my footsteps
trying to find myself a session.
Oh, baby! Following my footsteps
trying to see where they might end.
I’m tryin’ to break my writing blues
at the workshop ‘round the bend.

Oh, AMWA’s in Memphis,
Shake, rattle, and write.
AMWA’s in Memphis,
Where we’ll learn all day
And play at night.

Dinner down on Beale Street
Care to join your chapter now?
Yeah, yeah, yeah, yeah
Runnin’ down to Graceland
Look around you and say “wow.”
Yeah, it don’t matter what you like
There’s something for everyone in town.
Play it for me one time, boys.

I’m hearing the best speakers
And they’re filling up my brain.
Yeah, I’m hearing the best speakers
Oh, the skills that I will gain.
I don’t need another conference
AMWA runs through my veins.

Oh, AMWA’s in Memphis,
Shake, rattle, and write.
AMWA’s in Memphis,
Where we’ll learn all day
And play at night.

Whoa, oh, oh, oh, AMWA’s in Memphis
AMWA’s in Memphis
AMWA’s in Memphis,
Where we’ll learn all day
And play at night.
And play at night.

*Midnight in Memphis was written by Tony Johnson
for The Rose.
©AMWA’s in Memphis, Lori Alexander.

Time is running out.
Register now on www.amwa.org!

2014 AMWA Annual Conference Committee
My thanks to an amazing group of people who helped
develop the annual conference program.

Noelle Demas, MS, conference administrator-elect;
Panorama MedWriters Group Inc, San Diego, CA
Keightley Amen, ONS: Edge, Pittsburgh, PA
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Scott Thompson, ELS, Medtronic, Spinal Business,
Memphis, TN
Christine Welniak, Upside Communications,
Brooklyn, NY
Wendy Wippel, Medtronic Inc, Memphis, TN

*I am sad to note that David passed away in June. The committee
was happy to have known him, even if only for a short time.
Golden Apple Award:
Thomas Gegeny, MA, ELS


In the late 1990s, Tom Gegeny was working in the Texas Medical Center Library in Houston and was often asked to give lectures on this newfangled thing called “the Internet.” Knowing how important online resources were going to be to the future of medical writing, members of AMWA’s Southwest chapter got wind of Gegeny’s expertise and asked if he would be interested in developing a workshop course.

Since his initial development of that workshop—Using the Internet for Effective Medical Research—Gegeny has become a regular contributor to AMWA’s education program, both updating and refining his original presentation annually at the national and chapter conferences and adding workshop topics to his repertoire. For his dedication and excellence as an educator of AMWA members, Gegeny was selected as the recipient of AMWA’s 2014 Golden Apple Award.

The Golden Apple is awarded annually to a workshop leader who has demonstrated excellence in teaching in the AMWA education program. The award winner is selected by AMWA’s Education Committee on the basis of both the quality and quantity of workshops developed and delivered.

“In my first professional job, I was teaching sessions to medical center students, faculty, and staff 3 or 4 times a week, so that got me comfortable speaking in front of groups of people,” said Gegeny, AMWA’s president in 2009–2010. “I learned very quickly that you don’t always have to be so serious when you are standing in front of other people. You can have a dialogue, and even if a question comes up that you can’t answer, that doesn’t mean you aren’t a good presenter. Teaching workshops keeps me on my toes and forces me to keep learning.”

The evolution of Gegeny’s original workshop to the current day largely follows the path of the online world. Initially, he focused on research tools available on the Internet. In 2004, he added a second workshop focused more on the use of online databases. Today, he blends a number of different concepts into his workshops to reflect the lightning-speed evolution and diversity of the Internet.

“I’m always on the lookout for something new that I can incorporate into my workshops,” Gegeny said. “If you can find an interesting article or blog posting, that brings a level of currency to things and lets people know that you are keeping up with the topic.”

Along with his Web-focused workshop, Gegeny helped develop a new workshop, Introduction to Basic Virology, in 2009 and is debuting a new workshop in 2014, Introduction to Basic Bacteriology, which he will co-lead with a colleague, Becky Jarvis. Gegeny also was voted in recently as the president-elect of the Board of Editors in the Life Sciences. As he says, “It’s the old adage—if you need something done, ask a busy person.”

Gegeny’s advice to those interested in developing new workshops in the future?

“Be prepared,” Gegeny said. “Make sure you have done your homework. Practice in front of other people or just by yourself. Have other sets of eyes look over your content. Every year, I always check the links and sites I have included in my presentation to make sure they are still active and still contain the relevant content. You don’t want to put something out there for your peers where a URL, for instance, is out of date. Our members are very savvy, and they deserve the best from workshop presenters.”
AMWA Announces 2014 Fellows

By Barbara Snyder, MA / Chair, 2014 AMWA Fellowship Committee

Each year, AMWA presents up to 3 fellowships to members who have made significant contributions to the goals and activities of the association. Awardees of active fellowships must have been consistently active in AMWA during at least the previous 5 years and must be currently active. Nonmembers of AMWA are eligible for honorary fellowships, which recognize distinguished contributions in an area of communication in the medical or allied professions and sciences.

When it met this spring, the Board of Directors voted to accept the Fellowship Committee's recommendation to present well-deserved active fellowships to Lori De Milto (Delaware Valley Chapter), Joanne McAndrews (Mid-America Chapter), and Deb Whippen (Florida Chapter) and an honorary fellowship to Justina Molzon of the US Food and Drug Administration. The awards will be presented at AMWA's 74th Annual Conference in Memphis.

ACTIVE FELLOWSHIPS

Lori De Milto, MJ
Since joining AMWA in 1997, Lori has left a lasting impression at both the national and chapter levels. For the AMWA Journal, she has been an article author, Editorial Board member, and panelist for the Freelance Forum. She wrote the Toolkit for New Medical Writers, which is featured on AMWA's website. She has served as a member of the Annual Conference Committee, roundtable coordinator and leader, session chair and panelist, and Eric Martin Award judge. In addition, Lori has been a dedicated leader of the Delaware Valley Chapter, where she has been secretary, president-elect, president, immediate past president, chair of various committees (membership, freelance workshop, and e-communications), founder of the annual freelance conference, and chapter delegate to the national Board of Directors. She received the President's Award from the Delaware Valley Chapter in 2003 and from national AMWA in 2012. In her day job, she is a freelance writer who delivers targeted medical copy and content for patients, consumers, and health care professionals. She has master's and bachelor's degrees in journalism from Temple University.

Joanne McAndrews, PhD
Joanne has been an active member since joining AMWA in 2004. In the Mid-America Chapter, she has served in numerous leadership roles, including treasurer, president, immediate past president, and membership officer, and for several years as the co-chair of the St. Louis Area freelance luncheon. Since 2006, she has contributed each year to the AMWA annual conference in roles that include workshop developer, workshop leader, roundtable leader, session moderator and speaker, and member of the Annual Conference Committee. She has been contributing articles to the AMWA Journal since 2009. Joanne has been a freelance medical writer since 2000, preparing manuscripts, medical textbook chapters, literature reviews, white papers, webcast scripts, protocols and reports for clinical studies, and General Recognition of Safety regulatory dossiers submitted to the FDA. She has a BS in biology from Union College, an MS in physiology from Penn State, and a PhD in neurobiology and physiology from Northwestern University.
Deborah Whippen
An AMWA member since 1989, Deb has been a driving force in the Florida Chapter for the past several years, including serving as president-elect, president (2 terms), immediate past president, multiple terms as publications director and Web chair, and chapter delegate. In addition to serving in a variety of roles with the AC (roundtable leader, coffee klatch leader, local host committee co-chair, Book Awards Committee member), she has been a member of the Web and Internet Technology and Budget and Finance committees, and Endowment Fund Subcommittee. She served as administrator of the Department of Awards on the Executive Committee in 2012–2013 and is currently administrator of the Department of Publications. She is the senior managing editor for the *Annals of Surgical Oncology*, the managing editor of GeriatricsCareOnline.org, and publisher and editor at Editorial Rx Inc.

HONORARY FELLOWSHIP

Justina Molzon, JD
For many years, Justina has been coordinating the efforts of the Food and Drug Administration’s Center for Drug Evaluation and Research (CDER) related to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (also known as ICH). ICH is the global group of regulators and pharmaceutical industry representatives that develops guidelines on scientific and technical aspects of drug registration. One such guideline is the Common Technical Document (CTD), which describes a common format for the summary documents required for submission to regulatory agencies in the United States, Europe, and Japan. Although not a writer herself, Justina recognized from the beginning that medical writers would be the group perhaps the most affected by the new guideline, and she has worked tirelessly to educate regulatory writers about the CTD and other relevant guidelines. A pharmacist, attorney, and commissioned officer in the US Public Health Service, Justina is currently the Associate Center Director for International Programs at CDER. She received her BS in pharmacy and MS from the University of Rhode Island and her JD from the Chicago-Kent College of Law.

This year’s Fellowship Committee consisted of Sharon Nancekivell, Melanie Fridl Ross, Michele Vivirito, Anne Marie Weber-Main, Rachel Spassiani (ex officio), and Barbara Snyder (chair).

Deadlines, Deadlines, Deadlines

**October 27, 2014:** AMWA Journal submission deadline for articles covering the 2014 AMWA Annual Conference.

**December 8, 2014:** Submission deadline for Spring 2015 special theme issue that will provide narrative updates on a variety of topics of interest to medical communicators. Potential topics include authorship criteria, continuing medical education, job outlook for regulatory writers, and advances in editing software.

Email JournalEditor@amwa.org to volunteer to cover a conference session, propose an article for the special issue, or inquire about other volunteer opportunities with the AMWA Journal.
Evaluation of Improvement Recommendations to the 510(k) Program
Emily E. Campbell, Graduate Student in Biomedical Writing, University of the Sciences, Philadelphia, PA

In 2011, the US FDA began implementing changes intended to address critical challenges to the 510(k) program and enhance 510(k) decision-making. This poster will present a summary of the Plan of Action and a comparison of the FDA’s Plan of Action to the implemented changes, as well as an assessment of 510(k) review times from 2008 through mid-2014. This information will provide the audience with both an overview of how the 510(k) program has changed as a result of the implementation of the Plan of Action, as well as how effective the Plan of Action has been in terms of FDA follow-through and effect on 510(k) review times.

From R&D to Clinical Trials: Medical Writing Strategies for Global Teams
Angela N. Johnson, BFA, MSE, PMP, Senior PB Clinical Writer, and Catherine Cadogan, BS, Senior PB Clinical Writer, GE Healthcare, Waukesha, WI; and Yolanda Wang, PhD, Senior PB Clinical Writer, GE Healthcare, Beijing, China

Global collaboration poses unique challenges and opportunities for medical writers working with researchers developing new device, pharmaceutical, and combination products. Contemporary medical writers must work effectively through telecommunication channels, assess and incorporate cultural values, and seamlessly navigate input from a variety of stakeholders with competing priorities to generate comprehensive and accurate documents. As a result, medical writers who can effectively interact with global stakeholders are increasingly in demand in both industry and as freelance medical writers. This poster and corresponding panel discussion (OS-19) will present strategies and lessons learned from a group of medical writers with extensive experience in diverse global research teams, generating documents ranging from pre-market protocols to post-market publications. Key strategies for improving relationships with project managers, regional regulatory experts, biostatistics groups, research and development teams of engineers and laboratory scientists, and medical investigators to build a documentation knowledge base will be addressed. In the dynamic landscape of contemporary telecommunication tools and expanding global medical device and pharmaceutical markets, we tackle global collaboration as a learned and measurable medical writing skill critical for success in global research teams. Building on these lessons learned can allow medical writers of all experience levels to advance their careers by working more effectively with global teams.

Hey RNA—Writers Don’t Like Transcription Errors Either
Linda A. Landon, PhD, ELS, President, Research Communiqué, Jefferson City, MO

Increasingly, writing consultants are required to wear many hats. A writing consultant may be required to communicate complex statistical output created by statisticians, who communicate in mathematical notation and statistical terms, to clients whose eyes roll back in their sockets when they hear statistical phrases. Wearing so many hats, to borrow a statistical phrase, increases the probability for error to greater than might be expected to occur by chance. One source of error is transcription error, where errors are introduced during hand copying and/or initial computer inputting of data. One way to reduce error is to refine the production process to reduce transcription of data and results. Practically, to achieve client expectations and to reduce error, the writing consultant must understand how to use the built-in tools of disparate software packages to create processes to transfer information efficiently and with high fidelity. This poster will describe a step-by-step process of creating tables, graphs, and figures without transcribing data or statistics after the initial data entry step. The process is designed to accomplish transferring data and results into and between SAS, Microsoft Word, and Microsoft Excel without transcription. Error-checking strategies at each step, including the initial data entry step, will be described.

Meta-Analyses and Systematic Reviews—the Literature Reporting Panaceas in an Evidence-Based World?
Karen Sedacki, Senior Medical/Technical Writer, MicroPort Orthopedics, Arlington, TN

Introduction: With the ability to condense and synthesize data from multiple studies into 1 document, systematic reviews and meta-analyses are important tools in the medical decision-making process. The ever-increasing number of clinical treatments also makes them very desirable to understand and utilize. While the quantity of published meta-analyses has risen in recent years, there is question whether high-quality techniques are used. The purpose of this poster is to detail the essentials and considerations for reporting meta-analysis results.

Essentials and Considerations: Creation of the PRISMA statement in 2009 spurred journals to use this guideline as a criterion standard for reporting. Although the aims of systematic reviews and meta-analyses are to reduce the amount of bias through a methodologic manner, inherent bias exists. In the ideal world, individual study assessments of quality biases are performed and reported. Additional considerations include whether enough evidence exists to provide meaningful answers to
Streamlined Approach for Preparing Multiple Country-Specific CMC-Dossier Sections to Support Worldwide Clinical Trials

R. S. Robin Robinett, PhD, Director, Merck & Co., Inc., West Point, PA

Due to authoring, reviewing, and auditing cycles, preparation of multiple county-specific Chemistry, Manufacturing, & Control (CMC) dossiers can be a long process. Using a so-called nose-to-tail approach with each country’s dossier treated as an individual document can delay the start of clinical trials in many countries. A streamlined approach to CMC dossier preparation was devised that eliminates the need for multiple cycles, thereby reducing preparation time from approximately 4 years to about 6 weeks. This poster will provide schematics comparing a typical nose-to-tail document preparation lifecycle with documents prepared using this streamlined approach. Details of the process will also be provided to show how a single master dossier, which includes information needed for all countries, can be used to efficiently prepare multiple country-specific versions. In addition, set-up requirements and process advantages will be described. Comparison of these timelines shows that implementation of this new system has not only significantly reduced document preparation time but has also reduced auditing resources by 90% while maintaining the 100% data auditing standard. More than 150 CMC dossiers have been prepared using this process since 2010. This concept can be applied whenever multiple, similar documents need to be created.

Successfully Onboarding a Medical Writer: Filling the Gap between Orientation and Integration

Yeshi Mikyas, PhD, ELS, CMPP; Publications Lead, Baxter Healthcare, Thousand Oaks, CA; and Caryl Burke, MS, PMP; Medical Writer, Medpace, Cincinnati, OH

The onboarding process is a long-term systematic process that allows a new or transitioning medical writer to successfully integrate into an organization. Onboarding done well results in increased efficiency, productivity, confidence, credibility, compliance, and greater work quality. The process is one of the strongest drivers of employee engagement, bringing significant benefits to both the organization and the new hire. The onboarding process allows the writer to develop credible and effective relationships and to gain a clear understanding of the quality, timeline, and processes required of him or her. A successfully onboarded writer will have a clear definition of what constitutes success in being a productive member of the team and a timeline for getting there. The onboarding process takes effort and targeted planning; investing a little time and energy to help a new or transitioning medical writer facilitates success at multiple levels. The manager and the mentor are important partners whose engagement can make the onboarding process a success. This poster will describe the people and processes that are important in the onboarding and successful integration of a medical writer to the team.

A Systematic Process to Creating High-Quality Developmental Safety Update Reports

Roshawn Watson, PharmD, PhD, Senior Regulatory Writer, Synchrogenix Information Strategies, Cambridge, MA

Regulatory agencies use Developmental Safety Update Reports (DSURs) to periodically assess the ongoing safety profiles of investigational drugs and whether their current benefit:risk ratios warrant continued subject exposure. It is thereby crucial to prepare DSURs that accurately characterize important clinical and preclinical safety events, safety actions, class related toxicities, and new and significant literature reported during a review period. DSURs must also place these data within the appropriate context of the entire program. Regulatory medical writers can play pivotal roles in the creation of DSURs beyond providing technical expertise. This poster will describe a methodology medical writers can use to collaborate with clinicians in creating high-quality DSURs. The poster will also characterize the necessary conditions, particularly team structure and resource availability, whereby medical writers can successfully apply this process. This approach is based on the DSUR guidance and best practices developed through years of experiential learning. This process specifies the medical writer’s role in authoring DSUR content, evaluating literature, assessing pertinent safety actions, reviewing cases, reconciling comments, driving consensus between functional areas, synchronizing the DSUR with other safety documents and aggregate reports, and assessing the utility and proper placement of tables, figures, and listings.

Writer/Editor Relationship: Reflections on Current Practice

Charlotte A. Kenreigh, PharmD, CMPP; Principal Medical Writer; Linda T. Wagner, PharmD, CMPP; Principal Medical Writer; Tabatha L. Cannata, Editorial Manager, Editorial Solutions; and Elizabeth Wassmer, Editor, Editorial Solutions, Envision Pharma Group, Southport, CT

Background: Writers and editors bring different skill sets to the development of publications. We sought to gain a better understanding of the nature of this relationship within the medical writing environment.

Methods: We distributed a brief survey to members of the International Society for Medical Publication Professionals (ISMPP) and AMWA. ISMPP members received the survey via an email communication, and AMWA members had access to the survey via the AMWA LinkedIn page. Survey participants were required to be a medical writer or editor as their princi-
Laurel E. Riemann, PharmD, President, PharmIJAD, Inc, Savannah, GA; and James B. Lutz, MS, CCRA, President, Lutz Consulting, LLC, Buellton, CA

All medical devices marketed in the European Union, Switzerland, Norway, Liechtenstein, and Iceland require a Clinical Evaluation Report (CER) as part of the device technical file regardless of device classification. A CER is required to obtain a “Conformite Europeene” or CE Mark, which indicates the device is approved for marketing. Further, the CER must be reviewed at least every 5 years as part of the CE mark renewal. While the CER is technically a series of related documents, it is best described as a process by which these documents are generated. Medical writers may become involved in the generation of these documents, so it is beneficial for the writer to have a basic understanding of the process. CER best practices are systematic and transparent reviews of the clinical evidence and should be conducted in a scientific and replicable manner and follow a well-defined standard operating procedure. Often, a first step in the CER process is a methodologic review of the relevant published literature, which requires generation of a literature review protocol and summary report. These data feed into the CER document, where they are combined with unpublished safety and efficacy data, as well as postmarket surveillance data relative to the device.

Becoming a Workshop Leader: the How-to Guide
AMWA Education Resources and Support Subcommittee

Background: AMWA always welcomes and encourages individuals to share their knowledge with colleagues. This poster presentation will outline the requirements for leading workshops that current and future volunteers can use as resource material.

Process: All new workshop leaders for credit workshops are approved by the AMWA Workshop Subcommittee. The basic requirements for a workshop leader is that he or she is an AMWA member, has demonstrated expertise in the subject matter, and has experience in teaching or presenting.

Expectations of Workshop Leaders: AMWA workshop leaders develop and lead interactive workshops, develop handouts, and create and review homework assignments. AMWA asks that leaders be willing to teach the workshop more than once. Before becoming a workshop leader, we encourage you to attend several current workshops to see how they are done and to talk to current instructors about co-leading (if you have interest in a specific workshop) or being mentored.

AMWA is highly appreciative and fortunate to have dedicated professionals who continue to add incredible value both to the organization and to fellow AMWA members in their professional journey as medical communicators. We hope this presentation will be of value to all who aspire to volunteer as workshop leaders.

Getting Ready for the AMWA Medical Writing Certification Examination
Tom Gegeny, MS, ELS; Marianne Mallia, ELS; David Clemow, PhD; James Cozzarin, ELS; Barbara Gastel, MD, MPH; Bart Harvey, MD, PhD; Sue Hudson, and Karen Klein, MA, ELS; on behalf of the 2013–2014 Medical Writing Certification Commission

At the 2015 Annual Conference in San Antonio, the American Medical Writers Association (AMWA) will launch a medical writing certification program. This poster will describe the application process for certification, the certification candidate handbook, and key characteristics of the examination. Membership in AMWA is not required for obtaining certification, nor is completion of educational certificates in AMWA’s workshop curriculum (although the resulting knowledge may help in preparing for the examination). The certification program will include an application process to demonstrate appropriate background and experience in the profession, along with an exam to test knowledge considered fundamental to the profession. The content outline for the examination was determined by using survey data from 1,177 medical writing professionals who ranked the importance of various topics and tasks requiring certain knowledge, skills, and abilities. Individuals seeking certification must complete an application form and provide all requested documentation. Successful application will qualify an individual to take the exam. A certification handbook will give candidates information about the exam’s content and format and will include a few sample questions. The handbook also will recommend resources and references for preparing for the exam, and it will present details of the overall certification process (including recertification, which will be an option after each 5-year certification period). Passing the exam will result in certification and confer a credential that certificants can use as a professional designation. Although exam performance alone cannot indicate how well one performs as a medical writer, it will provide insight into each candidate’s level of knowledge in core content areas. Thus, certification in medical writing adds to the tools available to help individuals demonstrate knowledge relevant to the profession. This certification program will help define and establish standards for essential competency in medical writing.
When I became president of AMWA last October, I knew it would be exciting, challenging, and exhilarating. I knew it would be rewarding and exhausting. And yet, it turns out I had no idea! Every year I’ve been in AMWA has been a great year. But this is the best year ever!

I joined AMWA in 1994, and, soon after, I got involved at the chapter level. I welcomed people to our chapter dinner meetings, worked the meeting registration table, helped promote chapter events, and represented my chapter as a delegate and a member of the Board of Directors. Because of the confidence my AMWA friends and colleagues had in me, I found the courage to get involved in our chapter conference—a relationship that lasted 17 wonderful years. I was also chapter president and served on numerous national committees. Then I was invited to join the Executive Committee (EC) and have a role in national leadership.

I am currently serving my fifth year on the AMWA EC. Next year will be my last year on the EC, when I serve as immediate past president. Afterward, I cannot serve on the EC again, which ensures there is always a place for new volunteers to find their confidence, their voice, and to lead our great organization. I’m going to miss the EC, but there are many committees at both the chapter and national levels where I can continue to serve.

Yes, I have been active in AMWA for a long time. But I’m not boasting. This isn’t about me. It’s about you.

I’ve been thinking a lot this year about why professional medical communicators join AMWA. Why did you join AMWA? Why did I join AMWA? For me, AMWA presented an opportunity to become a part of the profession to which I had committed my career, to meet other people like me, and to learn and become better at my craft. I also joined AMWA to make sure I was doing my job properly, upholding the highest ethical and professional standards of our industry. Along the way, I discovered something I wasn’t expecting. AMWA has so much to offer passive members: resources, knowledge, camaraderie, and professional development. But AMWA has so much more to offer active members: confidence, connections, challenge, personal development, and the opportunity to help shape the future of medical communications.

Without a doubt, I am the professional I am today because of my active involvement in AMWA. As someone long ago wisely said, “I am a great believer in luck. The harder I work, the more I have of it.” This is how I feel about my relationship with AMWA, and this is how I would like every member to feel about the organization. By being active members of AMWA, we have the opportunity to shape ourselves personally and professionally. And together, we have the opportunity to shape our industry.

This year, I have had the great pleasure and honor of working directly and indirectly with scores of volunteers who have given their time, energy, and expertise, in varying degrees as they could, to help AMWA achieve its mission. You know who you are, and I thank you from the bottom of my heart. Whether you gave an idea or an hour or a year of your time or more, your commitment is valued. No matter how much time a volunteer has committed to being active in AMWA, we all seem to say the same thing: “I’ve gotten much more out of it than I put into it.” So let’s see what we’ve accomplished this year.

Webinars. AMWA has launched into e-learning with a webinar series that includes events that are free to AMWA members as well as fee-based events.
Learning Management System. AMWA has begun exploring the purchase of a software system that will provide a robust platform for online education. The system will enhance and expand the user experience and enable members to participate in and track their educational activities for professional development, certification, and recertification.

Certification. AMWA is progressing steadily toward its goal of offering its first certification exam, which is scheduled for the annual conference next year in San Antonio, Texas. Study guides and other materials needed to launch certification are well under way.

Strategic Collaboration. AMWA’s EC is working more strategically than ever to help guide our organization into the future. At EC meetings we’re brainstorming how AMWA’s priorities can be implemented across departments and committees, and committees are empowered more than ever to work together collaboratively to achieve their goals.

Communication. AMWA’s leadership opened the new Lines of Communication blog this year to keep you informed and engaged in organizational efforts. My personal blog, From the President’s Desk, is accessible from the AMWA home page. This is where you’ll find me writing about interesting and important behind-the-scenes efforts that will benefit our members, our organization, and our industry. The AMWA Online Forums continue to offer excellent opportunities for members to engage one another in helpful, meaningful, insightful, and respectful discourse. The AMWA Journal introduced a bold new look and full-color printing this year.

Resources. AMWA chapters have created amazing resources for their members, ranging from webinars to newsletters, and committee volunteers have been working to identify and capture these chapter gems and share them through the AMWA website so that all members can benefit.

Medical Communications Inter-Organizational Summit. AMWA pioneered a collaboration with sister organizations to share ideas and resources. The Medical Communications Inter-Organizational Summit met for the first time in Bethesda, Maryland, this past April, and we had our first follow-up teleconference in July. The sister organizations include DIA, the International Society for Medical Publication Professionals (ISMPP), and the Society for Technical Communication (STC). We’re now coordinating a portal through which organization leaders can inform each other about the resources we have to share with one another and resources we are seeking to obtain to share with our own members. This is an exciting step forward for all of us!

Budapest Working Group. AMWA has joined the Budapest Working Group, a collection of individuals and organizations that the European Medical Writers Association formed to review the E3 guidelines and the protocol portion of the E6 guidelines governing the structure and content of clinical study reports and good clinical practices and to recommend updates.

Of course, there are a lot of other exciting efforts, activities, and plans in the works than what I’ve already mentioned. Volunteers are working with AMWA headquarters, EC members, and committees to plan for celebrations this year in Memphis, next year in San Antonio, and throughout the coming year in honor of AMWA’s 75th anniversary. And AMWA continues to benefit from the wisdom and experience of our past presidents. I have sought their opinions and recommendations on several occasions this year. It’s wonderful to be supported by the wisdom of several decades of past leaders who continue to share their passion for AMWA’s continued success.

I want everyone reading this article to become an engaged and active member of AMWA—whether you’re introverted or extroverted, new to the organization or already have several longevity pins, and regardless of what facet of medical communications you call home. I want you to have your best year ever as an AMWA member. We all have something to offer each other and our industry through AMWA, and so much to gain from doing so. I’m living proof.
Quarterly Update on Certification—Fall 2014

By Thomas Gegeny, MS, ELS, and Marianne Mallia, ELS
2014 Certification Commission Co-Chairs

The Certification Commission will be busy at the upcoming conference in Memphis spreading the word about the certification examination for medical writers, which will be launched at the 2015 Annual Conference in San Antonio, Texas. To learn more about certification, stop by the certification information table near the registration area, which will be staffed by commission members at the times listed below:

- Wednesday, October 8, 6:30–8:00 PM
- Thursday, October 9, 5:00–6:00 PM
- Friday, October 10, 7:30–9:00 AM

The Certification Commission will also present a poster presentation entitled “An overview of AMWA’s Medical Writing Certification.” You can meet the poster presenters on Friday, October 10, from 7:30–9:00 AM.

Much has happened this past quarter. The commission finalized the Policies and Procedures Manual. By the end of the year, the Candidate Handbook will be completed. We still anticipate that these materials and the examination application will be available online in the first quarter of 2015, which is the anticipated timing for the opening of the application process. To learn more about the eligibility requirements for applying for the examination, see the AMWA Journal (2014;29[1]:47). The Exam Development Committee is busy completing work on the first exam form.

Much more information about the certification examination will be coming your way soon. Watch for news in AMWA Updates and in the AMWA Journal.

Take Part in Medical Writing Survey

AMWA members, watch your email inbox in November for a link to participate in a survey of practices by medical writers who make substantial contributions to manuscripts submitted to medical journals.

AMWA has adopted a formal position that biomedical communicators who contribute substantially to the writing or editing of a manuscript should be acknowledged with their permission and with disclosure of any pertinent professional or financial relationships. The survey was previously conducted in 2005, 2008, and 2011 to identify trends in the industry.

“Ghostwriting” of medical manuscripts has received considerable media attention during the past decade out of a concern that unacknowledged contributors to medical manuscripts may be biasing the information presented. Organizers of the survey hope to attract a large number of participants to gauge the prevalence of ghostwriting and other unethical practices among members of AMWA and the European Medical Writers Association.

—Victoria J. White
Homophone? Homonym?

By Arnold Melnick, DO / Aventura, FL

Most of us get stuck occasionally on deciding between 2 words and choosing the proper one—especially if the words are homophones (words that sound alike but have different meanings) or homonyms (words that sound alike but are spelled differently)—and some pairs of words are both homophones and homonyms. Or sometimes, confusing pairs may be related words that have slight differences in meaning. Not that this is a crisis for good writers, but it does make us pause briefly and make a conscious effort to choose the right word—and get annoyed at having to do so. (Of course, when really stymied, a brief visit to a dictionary will solve the problem.)

There are a large number of such word pairs and they occur rather frequently. I’ve tried to pick here a few that often occur in medical writing.

First, let’s look at a few sound-alike pairs. The first 3 are homophones. The definitions are mine; they are not all-inclusive but are my attempt to make clear the practical differences by sometimes modifying the exact dictionary definitions.

**Chord—cord**
We know that a chord, in general, is a musical sound. But sometimes vocal cord confuses us because it is associated with sound in both instances. The dictionary says a cord is a long, rounded, flexible body or organ. Spinal cord fits that description so it rarely gives us problems.

**Breech—breach**
The dictionary says that breech has definitions all relating to the hind end of the body, and it is mostly used in obstetrics as breech presentation. Breach, on the other hand, means a temporary break in continuity of something or a broken or torn condition, like breach of contract or breach of promise.

**Callus—callous**
A hardened or thickened area on skin or bone is called a callus (a noun), while callous is an adjective meaning, in most common usage, indifference to something personal, and, in medicine, meaning hardened and thickened. Sometimes thinking about the part of speech you are using will tell you which one to use.

The rest of this list consists of commonly confused word pairs.

**Principal—principle**
The noun principle represents a fundamental law or rule. On the other hand, principal can be used as a noun or adjective, for example, “The principal met all the teachers,” or “The principal argument was lost on the crowd.”

**Regime—regimen**
A ruling party or political tenure or a mode of management is called a regime, as in “The regime of President Mubarak ended with the Egyptian revolt,” while regimen describes a systematic plan, as “The injured man was placed on a regimen of neurological care.”

**Criteria—criterion**
The first is plural and the second is singular. Mainly, confusion arises when we write about criteria and wind up mentioning one item, making it singular or criterion.

**Specious—spacious**
The usual meaning of specious is showy or deceptive, or looking false. Unlike that, spacious simply means roomy.

**Autopsy—biopsy**
The postmortem examination of a body is called autopsy, but biopsy is the removal of some tissue from a living body for examination and study.

Although there are some differences among authorities in the definitions of homophone, homonym, and oronym, the resultant problems—and humor—remain.

To make the point clearer, here’s a poem (source unknown) that was run through a spell-checker:

Eye have run this poem throw it
I am shore your pleased to no
Its letter perfect in it’s weigh
My chequer tolled me sew.

All I can add is this: Sew they’re, now I no that you no how to handle word pears.
PubMed Commons was created by the National Center for Biotechnology Information (NCBI) to give researchers the opportunity to post comments on abstracts within the PubMed database. It is intended as a kind of postpublication peer review system for articles indexed in the database.

Online postpublication review is not an entirely new concept. Some publishers have experimented with allowing comments to be posted directly on articles in accordance with their established rules. The *New England Journal of Medicine* allows registered users to comment on articles that are not indexed and only viewable on the journal’s website. *BMJ* allows “rapid responses,” which are essentially brief letters to the editor that are posted online almost immediately after editors have deemed them appropriate. Selected rapid responses appear in the weekly journal; these responses are indexed in PubMed.

Aside from these efforts by *BMJ* and a minority of other publishers, however, there was no central site on the web for commenting on a particular article until the advent of PubMed Commons. Online postpublication review is spread out and disjointed with reviews and comments appearing on blogs or Twitter. According to the NCBI, PubMed Commons was created “in response to repeated requests by the scientific community for such a forum to be a part of PubMed.”

It is intended to be a centralized area for researchers to engage in constructive criticism and discussion regarding scientific issues within the articles found in PubMed.

Although anyone can see comments made to PubMed citations, posting to PubMed Commons is only open to recipients of NIH or Wellcome Trust grants or authors of any article listed in PubMed. Anonymous accounts are not permitted, and people must post using their real first and last names. Commenters must abide by certain guidelines; comments can be removed if they are deemed inappropriate, and NCBI reserves the right to suspend or cancel the accounts of members who do not adhere to the guidelines.

Restricting the ability to post to PubMed Commons and disallowing anonymous comments were 2 topics of great debate as the system was being established and continues to be so. Some worry the commenting restriction is too narrow, preventing graduate students, patient advocates, science journalists, and others within the health care and health information community from participating. Rob Tibshirani, a Stanford University professor who was a leader in the development of PubMed Commons who also organized the group of scientists who beta tested the system, said the group remained divided on the issue of anonymous comments. Some feared junior researchers and other scientists would be reluctant to write critical comments or questions.

Although PubMed Commons was created for researchers to engage in discussions, authors of papers are also using PubMed Commons to include supplemental research and material. According to the PubMed Commons Blog, almost 1 in 5 comments made have been by the authors themselves. The most common types of comments made by authors

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**Box 1. Resources with More Information on PubMed Commons**

PubMed Commons Twitter account – [https://twitter.com/PubMedCommons](https://twitter.com/PubMedCommons)
were to add study data or link to free full text, additional materials, or updates related to that article. PubMed Commons members can also rate these comments for their helpfulness. A permalink was created for each comment, which makes it easy for people to share or cite it. PubMed Commons is very new. It went live October 2013 and is currently in pilot phase. As of February 2014 the PubMed Commons team reported over 3,000 members and over 1,000 comments made. While this is a good start, there are over 23 million articles within PubMed so even if PubMed Commons is successful, it may still be a while before comments are regularly seen on retrieved PubMed citations. PubMed Commons is not the only site for online postpublication review. There are also blogs and websites such as PubPeer.com and ResearchGate that provide people with the opportunity to write reviews on research. It remains to be seen whether the advantage of having comments embedded in the already established product of PubMed will be enough to outweigh any limitations in the commenting system and sway researchers away from competing methods of online review.

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

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References

Box 2. Examples of Comments in PubMed Commons

- Amanda Capes-Davis uses PubMed Commons to annotate publications that misreport identities of known cross-contaminated cell lines (www.ncbi.nlm.nih.gov/myncbi/amanda.capes-davis.1/comments/).
- Several commenters use PubMed Commons to link to information in blogs and in the media. Dorothy Bishop included links to blog posts, including hers, as well as an article in Nature providing additional information about the original PubMed article on research misconduct (www.ncbi.nlm.nih.gov/pubmed/24372677). For an article on peer review published in Science, there is a PubMed Commons link to a blog post on the same topic (www.ncbi.nlm.nih.gov/pubmed/24092725).
- Allison Stelling’s comment (www.ncbi.nlm.nih.gov/pubmed/23142680) and Ivan Oransky comment (www.ncbi.nlm.nih.gov/pubmed/18818438) are good examples of using PubMed Commons to note that an article has been retracted and to provide background on the circumstances surrounding the retraction.
- Anne Marie Cunningham has used PubMed Commons to provide supplemental information to her own articles (www.ncbi.nlm.nih.gov/pubmed/24528392 and www.ncbi.nlm.nih.gov/pubmed/24458338).
- PubMed Commons can be used as a method to ask the author questions, as the exchange between Christopher Haggerty and Brian Bostick illustrates (www.ncbi.nlm.nih.gov/pubmed/24933400).
With the advent of online technology, various social media platforms have been developing rapidly during the past decade. Given the numerous entities, it has become increasingly difficult to decide into which platforms to invest time and energy learning, building relationships, and contributing content. Herein, an overview of Google+ will be presented, along with the benefits and concerns of using this social media platform, specifically for medical writers.

**What is Google+?**

Google+ is an online social networking site that links well with other Google programs and platforms and enables the sharing of posts and Internet content not only with your followers but also with the general public, if you choose to do so. If you do not already have a Google account, you can sign up for a Google+ account, which is free for individuals and businesses, at the following link: [http://plus.google.com](http://plus.google.com). New users of Gmail accounts are required to create a profile, a move that automatically creates a Google+ account.

**Why sign up for a Google+ account?**

While other social media platforms allow various levels of sharing content with the public, it is especially easy in Google+ to choose with whom to share by using “circles,” which are groups of contacts developed by the user. Such circles might include friends, family, acquaintances, or professional colleagues. Circles also help segregate the kind of news and updates you see based on your selected preferences. For example, if you are in the mood to see updates from medical writers, you can click a circle that you have populated with your medical writing friends and colleagues.

Additionally, as you search the Internet using Google, you can easily share content such as YouTube videos, news stories, and maps by selecting the “Google +1” button (a “+1” on Google+ is similar to a “like” on Facebook). As with Twitter, you can perform a search using a hashtag and see Google+ posts on the right side of your Google search results. These hashtag searches could help in researching and writing medical manuscripts or learning about new health topics.

Google+ has experienced increasing traction among individual users, corporations, hospitals, and nonprofits. The number of active monthly users increased from 190 million in May 2013 to 300 million in October 2013. Consequently, Google+ members who had interacted with any of Google’s services comprised 390 million users in May 2013 and 540 million users in October 2013.

Each social media platform attracts a different audience. Given that Google+ is still in its nascence and building traction, the audience for this platform has yet to be determined. Google+ might provide unique networking opportunities. For those medical communicators seeking to change positions or are freelances, Google+ offers another avenue to market your skills, services, and interests.

The *Financial Times* attracted Google+ followers by emphasizing original reporting and highly visual content on its page. “Google+ is a hugely visual platform for the FT and that is where we see the highest degree of engagement,” according to *Financial Times* Community Manager Rebecca Heptinstall. “Whether it is a video, image or infographic, the interface of Google+ just works well.”

By August 2014, the *Financial Times* Google+ site had attracted almost 3 million followers.

With the popularity of Google as a search engine, using Google+ could increase the visibility of your blog or posts because they appear in Google searches. In a post on Search Engine Watch, Eric Enge suggests it is also possible that
Google+ sharing might affect search rankings because of the way Google personalizes search results.\(^5\) Google discloses little information about its algorithms for ranking pages.

In the interests of privacy, a user can select how much or little of his or her profile is shared with the public, extended circles, or particular circles, and a user can even select whether a profile is indexed by search engines including Google.\(^6\) In the user profile settings, you can select whether to share photographs, reviews, or “+1” tabs by changing the Google+ settings for a profile. Finally, Google+ could be seen as a convenience: If you already use other Google services such as Gmail and Hangouts (a video chat application), only a single log-in is required to access all Google services.

**What are the potential drawbacks?**

Google+ is yet another social media platform to learn, and upon which to develop a network, followers, and content. For medical writers, there are always privacy concerns and issues to consider. As with all social media platforms, medical communicators should read the legal disclaimers to determine whether an Internet platform is right for you, your employer, or your business. Additionally, on Google+, certain information is always public, including your profile name, your profile and cover images, and your YouTube channel link (if it is linked to your Google+ profile).

Google+ is a growing social media platform that could help increase the visibility of your blog and posts through Google searches or could help you research content for your work.

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

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How do you tell a good freelance writing or editing opportunity from a bad one?

First and most importantly, trust your gut instinct. If something doesn’t feel right about the project, politely decline it. If the project seems too good to be true, it probably is.

Good opportunities pay well and don’t have unreasonable deadlines. Expectations for what you’ll do and what the client will do, and when, should be clearly defined in writing. Asking colleagues what they know about various organizations is also helpful in sorting good opportunities from bad.

Sometimes a seemingly good opportunity can turn into a disaster. Learn what you can from the experience and move on. For example, once, after providing a very clear scope of work for covering a meeting, I arrived and found that the client (who had approved the scope of work in my estimate) expected me to work 15 hours 1 day and 13 hours the next (instead of 10 and 8 hours as per my estimate). I did charge them for the extra time, but it wasn’t worth it. After this experience, I added a clause to my estimate template that any project that required more than 10 hours of work a day would be billed at 2.5 times my normal rate for the additional hours. If I find myself in this type of situation again, at least I will be well compensated.

—Lori De Milto

Securing a client who agrees to sign your (lawyer-approved) contract is 1 way to distinguish a good opportunity, at least 1 that gives the freelance an opportunity to collect in court should the client default. Such a contract, at the very least, includes project type and name, client name, designation of specific person(s) responsible for approvals and payment, timing (eg, due dates), provisions for overtime, and limits of uses for the finished product.

Your contract should include a “hold harmless” clause. My clients have signed this statement: “I hold him/her (freelance’s name) harmless and free from expenses if any legal claim results from a third party for the use of this material.” If your client’s company is later sued, for example, because of incorrect information in a package insert, you as the writer are unlikely to be liable. An AMWA freelance actually was sued in such a situation.

—Phyllis Minick

You have to kiss a lot of frogs to find a prince or princess. Fortunately, it’s not quite as difficult to find a good freelance opportunity. But there are still frogs out there.

Good freelance opportunities come from good clients with whom you have a good partnership. This is because you know what to expect from them, they know what to expect from you, and your experience with each other enables you to communicate at a deeper level of understanding. It’s like twins who share their own special language.

Then there are clients with whom you’ve already worked and had a difficult or unrewarding experience. If you’ve had a bad experience with a client, don’t expect a better experience the next time around. You might get lucky, but more likely you will get another reminder of why you don’t want to work for that client. I usually give clients like this a second chance, and I usually kick myself for having done so. After 2 strikes, they’re out.
The challenge is learning how to tell whether a new client will be a good opportunity or a bad one before you start the first assignment. Here are some warning signs I look for to identify a potentially bad freelance opportunity and steer away from it.

- I receive a message like this: “You don’t know me, but I have a quick project with a crazy deadline and no budget.”
- The introductory call or email comes at the end of the business day, at the end of the business week, just before a holiday weekend. Nothing reeks more of desperation and poor planning, which are hallmarks of a bad client.
- Early in the relationship, the new client shows no respect for your personal time by calling you or expecting you to attend teleconferences at night or on the weekend.
- The client can’t tell you much about the project but thinks that’s enough for you to get started.
- “I know it’s a small-budget project, but we can give you a lot of them.”
- Although the client doesn’t know you or your work, and you don’t know the client or what the working relationship will be like, the client nevertheless insists your estimate is too high and demands a sizable reduction.

It’s better to misread a good freelance opportunity as a bad one and miss out, than to misread a bad freelance opportunity as a good one and wish you had missed out. Best of all is to read every opportunity properly and realistically. Trust your instinct. If it looks like a frog, hops like a frog, and croaks like a frog, it’s a frog.

—Brian Bass

**Do you recommend giving clients gifts at the end of the year?**

**Absolutely! This is a great and easy way to thank and impress your clients. Many years ago when I was a client, one of the printers I worked with gave me a tin of Danish cookies at the holidays. This didn’t cost much, but I appreciated the gesture, which made me want to give him more business than other printers. And, of course, I enjoyed the cookies.**

I live near Philadelphia, so I send my clients gift trays of luscious homemade chocolate-covered pretzels from Anthony’s Chocolate House in Philadelphia’s famous Italian Market. They look forward to getting these each year.

For maximum impact, send your holiday gift early—between the Monday after Thanksgiving and the end of the first week in December. Make sure, though, that your clients are allowed to accept gifts. One of my clients, a foundation, is legally forbidden to accept gifts. The first year I worked with them I didn’t know this and sent them a gift tray. They let me know about their policy, and now I just send them a card each year.

**Impress clients even more when you send a gift for a special occasion such as a promotion, wedding, or birth of a baby. I like to send something motivational for a promotion (e.g., a desktop print or gift book) or a photo frame for a wedding or a new baby.**

—Lori De Milto

I do give most of my clients an end-of-year gift by using a model I learned from Lori Alexander, *AMWA Journal* editor emeritus. One online contribution to Make-A-Wish Foundation (http://wish.org) enables you to send as many acknowledgements as you choose. I usually contribute at least $100 for up to 10 gifts. Other organizations have similar arrangements.

—Phyllis Minick
Grammer is the study of how words are altered and combined to form sentences. Thus, a solid understanding of grammatical principles helps you identify and solve problems within sentences. Yet nearly any piece of writing consists of more than 1 sentence. Thus, writers need to show how sentences relate to each other. Conjunctive adverbs and conjunctive adverbial phrases help you do that. For example, the conjunctive adverb meanwhile tells you that the action or state of being described by that sentence is simultaneous with the action or state of being that was described by the previous sentence. The adverbial phrase back at the ranch alerts you to a shift in scene from 1 sentence to the next.

Conjunctive adverbs can be distinguished from 2 other kinds of adverb: adjuncts and disjuncts. Adjuncts are adverbs that modify a particular element within the sentence, such as a verb. Disjuncts (sentence adverbs) don’t modify an element within the sentence; instead, they are used to express the speaker or writer’s opinion about the content of the clause or sentence (eg, fortunately, obviously). I discussed the difference between adjuncts and disjuncts in the fall issue of AMWA Journal last year.1

To use a conjunctive adverb or conjunctive adverbial phrase correctly, you must first think clearly about the relationship between the clauses and sentences that you wish to connect. For example, you can use the conjunctive adverbial phrase for example to indicate that you are about to give specific examples of some general principle that you have just stated. The word however is used to introduce a statement that conflicts with or seems to contradict something else that you have just said. Therefore is used to mark the conclusion of an argument, after the premises that support that conclusion have already been stated. You can also use the words first, second, third and so on as conjunctive adverbs to show how the minor sentences in a paragraph relate to the topic sentence:

- There are 3 reasons why we need to buy a new computer. First, our current computer is slow. Second, ....
- The rules for word order and punctuation for conjunctive adverbs are simple. If the conjunctive adverb occurs at the beginning of the sentence or clause, it should be set off with a comma:
- We’re out of baking powder. However, we can use baking soda and cream of tartar as a substitute.
- Use a semicolon and a comma if the conjunctive adverb or adverbial phrase is linking 2 independent clauses:
- We’re out of baking powder; however, we can use baking soda and cream of tartar as a substitute.
- The conjunctive adverb may need to be set off with commas if disrupts the flow of a clause:
- There are, however, several exceptions to the rule.
- You don’t need commas if the conjunctive adverb doesn’t disrupt the flow of the sentence, especially if it is placed between the auxiliary and stem of the main verb:
- It would therefore be impossible to fly at a speed faster than the speed of light.
- Of course, some words that can be used as conjunctive adverbs aren’t always used as conjunctive adverbs. The word however can be used as a conjunction (as in “You can decorate it however you like”) or as a conjunctive adverb. Also, there are some words (eg, thus) that can function as adjuncts or as conjunctive adverbs.

Conjunctive adverbs enable you to connect clauses and sentences. Thus, you can use them to show how your ideas are connected to each other. Careful use of conjunctive adverbs can help you to improve the coherence of your writing and even of your thoughts.

One useful exercise for improving your writing skills is to compile your own list of conjunctive adverbs and adverbial phrases. Classify them according to their function, such as showing temporal relationships or logical relationships. Keep the list handy when you are writing. Here is a short list to get you started:

**Addition:** furthermore, moreover, in addition, likewise

**Apposition:** for example, for instance, that is, namely

**Cause and effect:** consequently, as a result

**Concession:** nevertheless, however, of course

**Contrast:** in contrast, rather, on the other hand

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Laurie Endicott Thomas, MA, ELS

Meanwhile, Back at the Ranch...
Logical relationships: therefore, thus, ergo
Reinforcement: indeed, in fact
Summary: in conclusion, in short
Time: meanwhile, subsequently, thereafter, henceforth

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References

Glossary
adverb—a member of a class of words that typically serve as a modifier of a verb, an adjective, another adverb, a preposition, a phrase, a clause, or a sentence. Adverbs express some relation of manner or quality, place, time, degree, number, cause, opposition, affirmation, or denial. In English, adverbs can be used to connect clauses and sentences and to express the speaker’s or writer’s view about what the clause or sentence is saying.

clause—a string of words that contains a subject and a predicate and that functions as a member of a complex or compound sentence.

complex sentence—a sentence that contains at least 1 independent clause and at least 1 dependent clause.

compound sentence—a sentence that contains more than 1 independent clause.

compound-complex sentence—a sentence that contains at least 2 independent clauses and at least 1 dependent clause.

conjunction—a member of a class of words that are used to connect words, phrases, clauses, or sentences to each other. Coordinating conjunctions (and, or, but, nor, for, yet, so) connect elements that are coordinate (ie, of equal rank within the sentence). Subordinating conjunctions (eg, if, then, while, whereas) connect a subordinate clause to an independent clause).

conjunctive adverb—an adverb that connects two or more clauses or sentences.

independent clause—a clause that could stand on its own as a sentence because it expresses a complete thought.

sentence adverb—an adverb that is used to express the speaker’s or writer’s opinion about the content of a clause or sentence; also called a disjunct (see “Editorialize with Sentence Adverbs” AMWA J. 2013;28(3):128–129).

subordinate clause—also called a dependent clause, a clause that cannot stand on its own as a sentence because it expresses an incomplete thought. Subordinate clauses typically begin with a subordinating clause or a relative pronoun.
In the book *Brain on Fire: My Month of Madness*, Susannah Cahalan recounts her experiences with anti-N-methyl-D-aspartate (anti-NMDA) receptor autoimmune encephalitis, a condition thought to be rare but may not be. In early 2009, as an ambitious 24-year-old cub reporter at the *New York Post*, she was working at her desk when she inexplicably began to cry hysterically. When she recovered, she brushed it off as if nothing had happened. However, she knew something was not right and made an appointment to see her doctor. He told her it was nothing—maybe mononucleosis or another virus.

A few weeks later, she was watching television with her boyfriend, and suddenly she started grinding her teeth and biting her tongue, and then passed out. That was the last thing she remembered for a month. A series of bizarre incidents followed. She had serious paranoid delusions. She imagined her father had murdered his wife. On the ride to the neurologist, she tried to jump out of the car as she screamed hysterically. She had several grand mal seizures and was placed in the epilepsy ward at NYU Langone Medical Center. When they tried to attach the electrodes for an electroencephalogram, she ripped them off. When a night nurse came in to take her vital signs, she slapped her across the chest. As the days passed, there were no answers to what was happening to her. Her parents and friends sat by hopelessly as she catapulted from psychosis to catatonia to near death. Teams of doctors came to diagnose; they too were baffled.

Finally, her doctors called in Dr. Southel Najjar, a neurologist at NYU. When they tried to attach the electrodes for an electroencephalogram, she ripped them off. When a night nurse came in to take her vital signs, she slapped her across the chest. As the days passed, there were no answers to what was happening to her. Her parents and friends sat by hopelessly as she catapulted from psychosis to catatonia to near death. Teams of doctors came to diagnose; they too were baffled.

Nijjar started the treatments immediately: first, the intravenous immunoglobulin to reduce inflammation and then high levels of steroids. He then brought in the plasmapheresis machine to flush out the harmful antibodies.

Cahalan had become the 217th person in the world to be diagnosed with the disease. In 2005, Dr. Josep Dalmau at the University of Pennsylvania had studied 4 patients and found these women had a rare disorder in which NMDA receptors, especially in the hippocampus, were being attacked by the body’s own antibodies. The NMDA receptors are essential for memory, learning, and behavior. In 2007, Dr. Dalmau added another dimension. He found that the women had ovarian teratomas, monster tumors that may have random tissues and body parts from hair and teeth. The tumors may be the source of the antibodies that break through the blood-brain barrier and attack the brain. Although the tumors have been found in other women, none were found in Cahalan’s case.

Six months later, Cahalan is back at work and back at home. While she was ill, her father took notes in a spiral notebook. That along with the accounts of her boyfriend and other friends helped her to write a book about the many events she had no memory of. When she thumbs through the pages of her father’s notes, she marvels at the lost month of her life and feels like she is reading about some stranger rather than herself.

This book is especially readable and well written. However, I think it is an important book not because it so beautifully tells about a person’s encounter with a rare disease but because of some of the potentially broader implications. According to the researchers, the condition may not be as rare as initially thought. They surmise that there are people—some in asylums or incarcerated—who have been misdiagnosed with mental illnesses such as schizophrenia but who actually have this autoimmune disease. Sadly, they are going without an effective treatment.

— Evelyn B. Kelly, PhD

*Evelyn Kelly is a freelance writer in Ocala, Florida.*
Not long ago, I was taking a yoga class when the instructor talked about the importance of alignment and balance in our practice. Suddenly, the proverbial light bulb went off. While both are important if I’m to do a proper standing tree or bow, they are absolutely critical if I’m to have a healthy life.

I wish I’d learned this lesson years ago. For, you see, for most of my career, particularly most of the last 14 as a freelance, I had neither. I was the classic workaholic, despite the fact I had 3 children, who were 4, 7, and 12 when I started freelancing, and a husband who traveled extensively. Oh, I got the children to school and soccer practice and did all the necessaries. But field trips? Volunteering in their schools? Sending home-baked cookies in for the class party? Um…not so much.

My career thrived. I was earning more money than I’d ever expected to earn in my life, doing work I loved, and slowly burning out. I was 37 when I started freelancing, and in those early years I was able to keep all the balls in the air.

I’m 51 now, and a couple of years ago I started dropping the balls. With the kids older and independent (and two out of the house), my husband still traveling, and no “hard stops” at the end of most days for soccer practices and dinners, I was like an alcoholic let loose in a liquor store. I worked and worked and worked. We’d go to our weekend house on the Chesapeake Bay and I’d sit on the screened porch and work. A “break” was taking a Saturday off.

It all came to a head during a long-planned trip to Barcelona in April 2012. I’d worked nonstop the 2 weeks before to meet my deadlines, including 1 long day from 2 AM to 11 PM. I had also subcontracted out some work I wasn’t able to do but still wanted to keep. That project was supposed to be delivered to me from the subcontractor a few days before I left, but I never received it. I got on the plane to Barcelona exhausted, stressed, angry, worried, and frustrated—everything but excited.

As you might imagine, the trip was a disaster. I cried most of the week, snapped at my husband and son, and wanted nothing more than to curl into a fetal ball under the covers.

When we returned home, I sat down to figure out my schedule for the following month. For the first time in 12 years, I made a spreadsheet and tried to assign days to the
projects according to how long I knew each would take. I started crying when I realized there simply weren’t enough days for all the projects—even if I worked every weekend.

That’s when I knew I needed help. I found it through a wonderful therapist. We started working on my workaholism and for a few months I was better. That summer, I didn’t work weekends (well, not many), took a couple of vacations that really were vacations, and started to feel much, much better.

Then, in August 2012, I wound up in the hospital with an infected tooth that had turned into an abscess that required days of intravenous antibiotics and, eventually, surgery. Need I tell you that the nurses often found me working at 2 AM when they came in to change my IV?

And so the pattern began again until I got to the point that I was fantasizing about getting sick or breaking my wrists so I couldn’t work. I simply didn’t know how to stop. One day in March 2013 I said to my therapist, “Why isn’t there a rehab center for workaholics the way there is for alcoholics and drug addicts?”

“There is,” she replied. “It’s called a sabbatical.”

I was finally ready to enter rehab.

That day, I went home and announced to my family that beginning June 1, I was taking the entire summer off. When they finished laughing, they looked at me with pity and said, “Good luck with that.” I got pretty the same reaction from my friends and even my AMWA colleagues, one of whom told me there was a pool as to how long I would last. (I think she was kidding.)

I stopped taking on new work that very day. I was already booked through May with a book to finish as well as other projects. I arranged for friends to take over my regular clients while I was out, an arrangement my clients were fine with. I started a countdown of the days on a white board propped up on my desk.

I spent the next 2 months finishing projects but at a much saner pace than usual. And on Memorial Day 2013, I hit “send” on the last project and put an out-of-office message on my email. I was free.

That summer, the first extended time off I’ve had in my life, was wonderful. I didn’t do anything major. We had a couple of trips planned (wonderful to get on an airplane feeling calm and relaxed and not obsessing over what you didn’t get done). I organized an engagement party for my son. I weeded the garden. I sat on the screened porch and watched the birds and wrote in my journal. I learned to knit. I hit the gym every day and took the dog for walks. Current and potential clients who contacted me during the summer were supportive and, in most cases, envious.

I rebooted.

By the time Labor Day rolled around, I felt really good. I felt good about the time off, and good about returning to work. And here’s the thing: My September was already booked.

It’s been exactly one year since I started my sabbatical and I can tell you that it changed me. I rarely work weekends. I still get to the gym every day and still write in my journal several times a week. I keep my in-box below 100 messages (which helps me feel in control), and I knit at night instead of work. I ended therapy and now see my therapist every couple of months for “maintenance.” Plus, the break cleared my mind enough to enable me to take my business in new directions, including teaching, speaking, and conducting webinars.

I adhere strictly to what I call my “magic spreadsheet,” on which I assign days to every project and track how much business I booked. I set a monthly financial goal (no, I’d never done this before!), and, once I reach it, I feel comfortable turning down work even if there is room on the schedule.

The best part? I’m working less and earning the same if not more. Why? I realized my worth and increased my prices. I stopped taking on small, one-time projects that, while lucrative, were time sucks. I put the time into getting more work from existing clients rather than taking every new client who came my way. (The more you work for someone, the easier the projects become.)

I’m not perfect, and sometimes I backslide (hence the maintenance visits to my therapist). But even that is different because I’m aware of it when it happens and can take immediate action. It’s kind of like weighing yourself every week and, when you see you’ve gained 5 pounds, cutting out dessert.

I’m able to do this, I think, because I realized that, not only was there life beyond work, but that I had a worth beyond work.

I realized, as the panelist on our work/balance panel at the AMWA national conference in 2013 said, that sometimes money costs too much.

I’m sharing this with you all in the hope that it doesn’t take you 13 years to learn that lesson.

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