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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 furthered dialog among all members and communicates the purposes, goals, advantages, and benefits of the American Medical Writers Association as a professional organization.
FEATURE

ABSTRACT

Biosimilars are a relatively new type of drug category. The rules and regulations surrounding them are evolving. In this primer for medical writers and editors, we define biosimilars and biologics; discuss how they differ from small molecule drug products; differentiate biosimilars from the more-familiar idea of generic medicines; and provide an outline of United States (US) regulatory requirements.

Biosimilars, also known as biosimilarities, are biological products that are not identical to but are highly similar to products that are available to patients, ie, marketed reference products, with minor differences in their inactive components. Biosimilars do not have clinically meaningful differences in terms of safety and efficacy between themselves and the marketed reference product. Biosimilars are not generic drugs.

Interest has increased in the development and approval of biosimilars because many biopharma products have lost or soon will lose patent protection, leading to billions of dollars (US$) in potential sales for the biosimilar sponsor and potential cost savings for health care payers and patients without insurance. Biosimilars are relatively new to the marketplace, and the rules and regulations for necessary documentation to obtain marketing approval are evolving. Also in their infancy are many aspects of the entire approval process, postmarketing surveillance, and pharmacovigilance reporting processes. Unlike traditional biopharma products that are submitted to a regulatory agency with a Biologic License Application (BLA) [351(a)], a biosimilar product submission uses a 351(k) format. Because this is a new and developing area of regulatory writing, medical writers are in a key position to help set standards for documentation.

WHAT ARE BIOSIMILARIS?

To understand what biosimilars are, it is essential to first understand the term biologic. A biologic is a product from a natural source, often animal, human, or bacterial in origin.

Through a series of complex steps that are proprietary, such as cell culture, expansion, recombinant DNA technology, and glycosylation, products are manufactured that are not easily characterized. Biosimilars, also known as biosimilarities, are biological products that are highly similar to a reference biologic product, that is, a marketed product, with minor differences in clinically inactive components. Although biosimilars do differ from the biologic reference product, they do not have any clinically meaningful differences between themselves and the reference product in terms of safety, efficacy, purity, potency, or mechanism of action. A biologic is any pharmaceutical product that is manufactured in, extracted from, or semisynthesized from biological sources, eg, E.coli cells.

It should be noted that biologics differ from small molecule products and that biosimilars are not generic drugs (Table 1).

In terms of data required for marketing authorization, biologics and biosimilars have different requirements. In the United States, biologics require the submission of a BLA [351(a)] with nonclinical (animal) and clinical (patient population of intended use) data that demonstrate safety and efficacy and dosing. A biosimilar requires the submission of an abbreviated document, a BLA 351(k), and the pharmacokinetics requirement may be satisfied with a single-dose study and a clinical trial that demonstrates similarity in dose and response to the reference standard.

Because the manufacturing processes of the biologic remain proprietary, biosimilars are manufactured using independent newly developed exclusive methods. The new biosimilar drug is a complex molecule of biological origin, produced with different steps from the reference biologic, and not chemically identical to the originator. Biosimilars are assessed more rigorously than generics by health authorities, and the regulatory requirements of the European Medicines Agency (EMA) for the approval of biosimilars are more demanding than those for generics.

By Roberta J. Wong, PharmD, and MaryAnn Foote, PhD

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Biosimilars: Basic Information for the Medical Writer
WHY ARE BIOSIMILARS OF SUCH INTEREST?

The loss of exclusivity, ie, patent protection, is the driving force behind the development of biosimilars, with billions of dollars (US$) in potential sales for the sponsor and potential cost savings for health care payers (Table 2).7 Biosimilars may play an important role in reducing the cost of drugs to patients.

In the United States, the Biologics Price Competition and Innovation Act 2009 (BPCIA) provides patent protection for 12 years for new biosimilars, with a potential of an additional 6 months of patent protection for products with pediatric indications. Thus, sponsors of a biosimilar optimally can have lower development costs and up to 12.5 years of patent protection. The reference product must be marketed for 4 years before a sponsor can submit a 351(k), providing some exclusivity for the reference product. The biosimilar may be approved before the expiration of the reference product patent; however, the biosimilar may not enter the marketplace until the patent has expired and any outstanding lawsuits over patent disputes are resolved. If the reference product has applied for and received orphan drug designation, the application for the biosimilar cannot be submitted until after the 7-year market exclusivity or the 12-year patent exclusivity granted by BPCIA, whichever comes later.8

BIOSIMILARS IN THE MARKET

Two biosimilars are marketed in the United States after approval by the United States Food and Drug Administration (US FDA): filgrastim-sndz, a SANDOZ product that is a biosimilar to an Amgen product; and infliximab-dyyb, a Celltrion product that is a biosimilar to a JANSSEN product. Both are in the CDER List in The Purple Book, a listing of FDA-approved biologics and biosimilars and the notation of interchangeability if applicable.9 In contrast, as of April 20, 2015, the

---

**Table 1. Key Terms**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biologics</td>
<td>Also called biological medicines. Biologics contain one or more active substances made by or derived from a biological source, such as <em>E coli</em>. Biologics often have a native counterpart in the human body, eg, insulin, erythropoietin, and growth hormones. Are called “reference product” against which biosimilars are measured.</td>
</tr>
<tr>
<td>Biosimilars</td>
<td>Also called biosimilarities. Biosimilars are biologics that are developed to be similar to an existing marketed biologic, but their manufacturing processes are proprietary and use independently developed proprietary processes. Biosimilars, therefore, are complex molecules of biological origin, produced with different methods, and are not chemically identical to the reference product.</td>
</tr>
<tr>
<td>Interchangeable</td>
<td>A biological product that is biosimilar to an FDA-approved reference product and meets additional standards for interchangeability. An interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the healthcare provider who prescribed the reference product.</td>
</tr>
<tr>
<td>Small molecules</td>
<td>Single molecules with low molecular weight, with a simple well-defined structure independent of the manufacturing process, which is chemical synthesis. Easily characterized and stable and usually nonimmunogenic.</td>
</tr>
<tr>
<td>Generics</td>
<td>Identical or bioequivalent drug to a brand-name product, but can only be manufactured and marketed after the brand-name drug's patent expires; generics are the same as the brand-name drug in dosage form, safety, strength, quality, mechanism of action, indications, and route of administration. Dissolution assays of the generic products are included in the ANDA as are references to the originator's product application.</td>
</tr>
</tbody>
</table>

---

**Table 2. Global Sales (in US$ billion) and European Union (EU) and United States (US) Expiry Patent Protection Dates for Major Biologic Products.**

<table>
<thead>
<tr>
<th>Product/Tradename</th>
<th>Global Sales</th>
<th>EU Expiry Date</th>
<th>US Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalimumab/Humira</td>
<td>9.8</td>
<td>2018</td>
<td>2016</td>
</tr>
<tr>
<td>Insulin Glargine/Lantus</td>
<td>7.9</td>
<td>Expired in 2015</td>
<td>2016</td>
</tr>
<tr>
<td>Etanercept/Enbrel</td>
<td>6.2</td>
<td>2016</td>
<td>2028</td>
</tr>
<tr>
<td>Infliximab/Remicade</td>
<td>4.8</td>
<td>Expired in 2015</td>
<td>2018</td>
</tr>
<tr>
<td>Rituximab/Mabthera</td>
<td>3.8</td>
<td>2016</td>
<td>2018</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>32.5</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ANDA = Abbreviated New Drug Application; FDA = Food and Drug Administration
EMA has granted marketing approval for nearly 20 biosimilars (Table 3).\textsuperscript{10} Biosimilars were introduced into Argentina in 2008; Epomax (epoetin alfa) is manufactured in Tunisia; and the United Arab Emirates (UAE) has manufactured biosimilars since 2012.

**INFORMATION TO BE INCLUDED IN A 351(k) SUBMITTED TO THE FDA AND PATENT LITIGATION PROCESS**

Section 351(k)(2)(A)(i) requires manufacturers of 351(k) products to submit an application for FDA review and licensure before marketing a biosimilar product. The application must include specific information:

- Data that demonstrate that the biological product is bio-
  similar to a reference product. These data are obtained from animal studies (including toxicity) and a clinical study or studies (including immunogenicity and pharmacokinetics or pharmacodynamics). The secretary of Health and Human Services (HHS) holds the option to determine if any of these elements is unnecessary;

- Both the biosimilar and the reference product use the same mechanism of action for the condition of use prescribed in the proposed labeling, but only to the extent the mechanism of action is known for the reference product;

- The condition or conditions of use prescribed, recom-
  mended, or suggested in the labeling proposed for the biosimilar have been previously approved for the reference product;

- The route of administration, the dosage form, and the strength of the biosimilar product are the same as those of the reference product; and

- The facility in which the biosimilar product is manufac-
  tured, processed, packaged, or held meets standards of the reference product to ensure safety, purity, and potency. The application must include publicly available information that the reference product is safe, pure, and potent.

Under section 351(k)(2)(B) and (k)(4), a manufacturer may include information demonstrating that the biological product meets the standards for interchangeability either in the application to show biosimilarity or in a supplement to such an application. The information submitted to meet the standard for interchangeability must show that:

- The biological product is biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient; and

- For a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

Once the 351(k) has been submitted, the FDA has 20 days to notify the biosimilar applicant if the application has been accepted for review. At this time, the applicant must provide the reference product sponsor confidential access to their biosimilar application, including information describing the manufacturing process. Within 60 days, the reference product sponsor must provide the biosimilar applicant a list of patents that it believes are infringed by the 351(k). Within another 60 days, the biosimilar applicant may provide the reference product sponsor a list of patents and provide a statement on each

**Table 3. Biosimilars Approved by European Medicines Agency for Marketing as of April 20, 2015.\textsuperscript{10}**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Active Substance</th>
<th>Biosimilar MA Holder</th>
<th>Year Granted</th>
</tr>
</thead>
<tbody>
<tr>
<td>abasaglar</td>
<td>insulin glargine</td>
<td>Eli Lilly</td>
<td>2014</td>
</tr>
<tr>
<td>accofil</td>
<td>filgrastim</td>
<td>Accord Healthcare</td>
<td>2014</td>
</tr>
<tr>
<td>bemfola</td>
<td>follitropin alfa</td>
<td>Finox Biotech</td>
<td>2014</td>
</tr>
<tr>
<td>grastofil</td>
<td>filgrastim</td>
<td>Apotex</td>
<td>2013</td>
</tr>
<tr>
<td>inflectra</td>
<td>infliximab</td>
<td>Hospira</td>
<td>2013</td>
</tr>
<tr>
<td>ovaleap</td>
<td>follitropin alfa</td>
<td>Teva</td>
<td>2013</td>
</tr>
<tr>
<td>remsima</td>
<td>infliximab</td>
<td>Celltrion</td>
<td>2013</td>
</tr>
<tr>
<td>nivestim</td>
<td>filgrastim</td>
<td>Hospira</td>
<td>2010</td>
</tr>
<tr>
<td>filgrastim hexal</td>
<td>filgrastim</td>
<td>Hexal</td>
<td>2009</td>
</tr>
<tr>
<td>zarzio</td>
<td>filgrastim</td>
<td>Sandoz</td>
<td>2009</td>
</tr>
<tr>
<td>biogratstim</td>
<td>filgrastim</td>
<td>AbZ–Pharma</td>
<td>2008</td>
</tr>
<tr>
<td>ratiogratstim</td>
<td>filgrastim</td>
<td>Ratiopharm</td>
<td>2008</td>
</tr>
<tr>
<td>tevagratstim</td>
<td>filgrastim</td>
<td>Teva</td>
<td>2008</td>
</tr>
<tr>
<td>abseamed</td>
<td>epoetin alfa</td>
<td>Medice Arzneimittel Pütter</td>
<td>2007</td>
</tr>
<tr>
<td>binocrit</td>
<td>epoetin alfa</td>
<td>Sandoz</td>
<td>2007</td>
</tr>
<tr>
<td>epoetin alfa hexal</td>
<td>epoetin alfa</td>
<td>Hexal</td>
<td>2007</td>
</tr>
<tr>
<td>retacrit</td>
<td>epoetin zeta</td>
<td>Hospira</td>
<td>2007</td>
</tr>
<tr>
<td>silapo</td>
<td>epoetin zeta</td>
<td>Stada</td>
<td>2007</td>
</tr>
<tr>
<td>omnitrope</td>
<td>somatropin</td>
<td>Sandoz</td>
<td>2006</td>
</tr>
</tbody>
</table>

MA = marketing authorization
Outstanding Issues and Evolution of the Process

Guidelines on biosimilars are evolving, with many issues to be resolved. Labeling and naming conventions are under review (see sidebar “What’s in a Name?”). To date, labeling and naming have been resolved on a case-by-case basis. Similar to generic drugs, if the labeling is not identical to the reference product, the biosimilar sponsor must decide if and how to deviate from the reference standard’s label, which may require submission of an application as a different product rather than as a biosimilar.

Another issue is how to analyze the submitted data. The 351(k) application must include a comparison of the proposed product to the reference product that is approved for marketing. Differences in formulations must be identified as these changes may have an effect on stability or the clinical efficacy. While perhaps not comparing apples to oranges, the comparison, because of the differences in inactive components and production, suggest a Macintosh to Macoun comparison.

The issue of interchangeability is unclear, with no FDA guidance for sponsors. The biosimilar is not deemed interchangeable with the reference product. The experience in the EU is not helpful on this issue, as no worldwide harmonization is in place. With Britain apparently leaving the EU and the impending move of the EMA to an EU country, the hoped-for worldwide harmonization of biosimilar applications, naming conventions, and interchangeability is not likely to occur in the next few years. A confounding factor for the United States is that some states have passed legislation prohibiting automatic substitution of biosimilar products for approved biologics (Table 4).

A future issue will be the management of second-generation products, or as they are called, “biobetters.” If biobetters are shown to have significantly improved clinical outcomes compared with the reference standard, would a superiority trial need to be conducted and would the trial be submitted as a 351(a) (biologic) or a 351(k) (biosimilar)?

A few groups proactively track and identify issues with biosimilars in the United States. The FDA has a sentinel initiative that tracks drug safety and efficacy. In 2015, the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) was created to specifically monitor the safety of biosimilars. The BBCIC is a diverse group of companies, research institutions, managed care organizations, and pharmacy benefit managers that focus on postapproval pharmacovigilance issues. Perhaps these groups will work together in the future for improved communication between the FDA and the companies and groups involved in biosimilar clinical trials.

Table 4. Legislation on Biologics and Biosimilar Substitution Varies by State. The Data are Current as of June 21, 2016.

<table>
<thead>
<tr>
<th>Category</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arizona</td>
<td></td>
<td></td>
<td>Massachusetts</td>
<td>Hawaii</td>
<td></td>
</tr>
<tr>
<td>California</td>
<td></td>
<td></td>
<td>Missouri</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colorado</td>
<td></td>
<td></td>
<td>New Jersey</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delaware</td>
<td></td>
<td></td>
<td>North Carolina</td>
<td>Arkansas</td>
<td></td>
</tr>
<tr>
<td>Florida</td>
<td></td>
<td></td>
<td>North Dakota</td>
<td>Connecticut</td>
<td></td>
</tr>
<tr>
<td>Georgia</td>
<td></td>
<td></td>
<td>Oregon</td>
<td>Maryland</td>
<td></td>
</tr>
<tr>
<td>Idaho</td>
<td></td>
<td></td>
<td>Tennessee</td>
<td>Mississippi</td>
<td></td>
</tr>
<tr>
<td>Illinois</td>
<td></td>
<td></td>
<td>Texas</td>
<td>Nebraska</td>
<td></td>
</tr>
<tr>
<td>Indiana</td>
<td></td>
<td></td>
<td>Utah</td>
<td>Nevada</td>
<td></td>
</tr>
<tr>
<td>Kentucky</td>
<td></td>
<td></td>
<td>Virginia</td>
<td>Vermont</td>
<td></td>
</tr>
<tr>
<td>Louisiana</td>
<td></td>
<td></td>
<td>Washington</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 = Enacted law, 2013 to 2016
2 = Passed legislature; not law
3 = Filed; failed/adjourned, 2013 to 2016
4 = Bill filed; pending or carryover, 2015 to 2016
5 = Other regulation; step therapy enacted law
Once a biosimilar is approved and marketed, additional issues may need regulatory guidance: What is the process to expand the indication of a biosimilar across other patient populations? In this scenario of expanded indications, will it remain appropriate to reference data from the reference product or the biosimilar, or will other studies be required? Will new clinical trials to determine pharmacodynamics and pharmacokinetics be required? What regulations should be created to guide pharmacovigilance tracking and reporting, particularly information concerning immunogenicity? How will sponsors decide if the application should be submitted as a biologic or a biosimilar? In the case of Teva’s filgrastim, the manufacturer elected to withdraw its previously submitted biosimilar 351(k) application, and instead submit a BLA (351(a)). Although tbo-filgrastim (toluidine blue O.2) has been on the market since November 2012, this product is not a biosimilar and is not interchangeable with Amgen’s Neupogen (filgrastim).15

ROLE OF THE MEDICAL WRITER
As with any FDA submission document, the role of the medical writer can vary with each biosimilar applicant and reference product sponsor company. The initial application contains nonclinical and clinical data, like a standard 351(a), and medical writers frequently prepare these documents. CMC (Chemistry, Manufacturing, and Control) sections of 351(a) applications are often written by medical writers and have a counterpart in a 351(k) application. Some additional questions and answers have been in draft form since May 2015 regarding the BPCIA 2009.16 As the topic matures and as more biosimilar applications are submitted to regulatory agencies, the role of the medical writer will be further refined.

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

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References

What’s In a Name?
“A rose by any other name would smell as sweet” (Romeo and Juliet, William Shakespeare) is frequently used to suggest that the names of things do not affect what they really are. Such thinking is generally wrong in terms of drug names.

The International Nonproprietary Name (INN) system, administered by the World Health Organization (WHO), has been used for approximately 50 years. The WHO Expert Committee assigns nonproprietary names to medicinal substances so that each can be recognized globally by a unique name. Although initially intended to facilitate prescribing, nonproprietary names have an essential role in tracking and tracing and attributing adverse events to the correct product, which is essential for monitoring the safety of marketed products. In the case of generics, the same INN is used for both the brand-name product and all generics of that product; in the case of biosimilars, however, WHO has proposed unique names for the reference product and each of its biosimilars.

The proposal set forth by WHO is that biosimilars should have a 2-part name; the first part would be the INN of the reference product and the second part would be a qualifier whose object is to make it clear that this is a biosimilar and also to identify it as a particular biosimilar. One approach for such a qualifier would be to use a 3-letter suffix to distinguish between biosimilars. Biologics are large complex molecules, often made larger and more complicated by molecular modifications, such as glycosylation, that can alter their bioactivity. Currently, the WHO INN policy for biosimilars has 2 approaches: one for glycosylated molecules and one for nonglycosylated molecules. Nonglycosylated biosimilars are considered to have highly similar posttranslational modifications and receive the same INN, but glycosylated biosimilars are considered to be comparable but distinct; they have the same INN name but are further qualified by a Greek letter suffix. No legal basis for new INN for biosimilars exits and naming was not addressed in BPCIA, so it is commonly understood that the law does not require biosimilars to have new INN.
Databases Dissected: What Medical Writers Really Use

By Arlene Walters; Julie L. Phelan, MD, MBA; and Sarah A. Prins, PhD

1 Freelance Writer, Chicago, IL, 2 President, Biomedisys Inc, Chicago, IL, 3 Prescott Medical Communications Group, Chicago, IL

INTRODUCTION
Medical writers use numerous databases (both free and subscription-based) and other information tools as they research, draft, and fact check their work. In order for medical writers to create high-quality work, the databases and information tools they use must be considered authoritative sources. To date, there has been no collective evaluation of databases and related information sources specific to the medical writing field. With this article, we would like to provide useful examples of reliable and reputable databases. Given that medical writers have diverse educational and professional backgrounds, it is likely that certain available resources are unknown by some within the profession.

METHODS
We discussed and reviewed sources we use to perform our work as medical writers and aimed to devise a list of databases and tools to incorporate in this article. Internet searches were employed to identify additional resources, and the following sources also were used: government and medical association websites, along with limited use of less medically relevant websites such as Wikipedia. The databases reviewed herein encompass a list of what we view as some of the most useful tools (Table 1).

RESULTS
Drug Marketing
CD Promo
Health care advertising agency personnel may sometimes need to look at promotional or educational materials (e.g., ads, sales aids, direct mailers) of competitive products to determine how a competitor may be handling their branding, overall creative strategy, and messaging so they can differentiate their brand. CD Promo, owned by dtw Research Inc, is a web-based visual library that contains images of US and international pharmaceutical promotional materials.1 (The product is called CD Promo because promotional images used to be delivered in CD format.) Related products include CD Promo SnapShot and CD Promo Message View.

An agency might use source materials from CD Promo as follows. An account executive could order all patient or professional promotional or educational materials of one or more competitive products. After receiving images, the creative and account services teams could then create an audit of their product versus a competitor’s. They might look at all branding elements and discover, for example, that their major competitor uses orange and yellow, so they might then recommend alternative colors.

While reading through the materials, they might learn that the product is positioned as a safe drug, so they might instead develop a strategy that is more focused on efficacy. In reviewing the competitor’s messages, they might build off these messages or find competitive angles to refute claims. In essence, the agency might create a formal or informal brand audit.

Why do this rather than simply looking at a product website? Websites do not always provide all of the competitive content, so it is more difficult to create well-rounded product positioning. Looking at printed pieces may provide a more complete picture of what the brand is doing, providing writers and their teams with deep competitive knowledge.

PRNewswire
Writers use PRNewswire2 (also known as “the wire”) to find breaking news about a product or industry and proactively gather competitive intelligence. Press releases are written by companies and then placed on PRNewswire because it is

All authors contributed equally to this article.
the definitive source for official company and organizational announcements.

Journal/Conference and BioPharma Profiles

With an abundance of journals and conferences to which manuscripts and abstracts may be submitted, identifying the right choices that will meet client or employer needs can be a challenge. Sylogent has developed databases that organize conference and journal information. These databases—Conference Authority and Journal Selector—are updated regularly, making them ideal resources for planning abstract, poster, and article submissions.

Conference Authority provides a general summary of key information (eg, URL and upcoming meeting information), abstract details, meeting scope, commercial activity, key words, and previous years’ meeting details. Where to submit abstracts is often dependent on the congress audience; the conference “Scope” section breaks down various details about the audience attending the conference. For example, details include the therapeutic areas emphasized at the conference, the number of attendees, attendee profiles (by field and/or employer status), and specific features (Figure 1A). A similar level of detail and organization can be found for journals using the Journal Selector database (Figure 1B). These Sylogent databases allow for quick conference/journal comparisons and can save a medical writer time that would otherwise be spent researching the web for this information. Though a subscription is required, these Sylogent databases are essential tools for medical writers who perform publication planning.

Adis publishes medical journals, books, and business solutions that are used by professionals worldwide within the medical field.4 For bio-pharma research and competitive intelligence tasks, its service AdisInsight is particularly useful; one AdisInsight search can reveal an enormous amount of information on drug research and development, such as key clinical trials, company deals, and drug safety.5 The drug information available goes well beyond the basic chemical properties (eg, therapeutic area, chemical name, highest phase indication, licensee, mechanism of action, adverse events, synonyms/brand names, and details of the last significant update)—although it is convenient that this information is available and can be easily exported. More interesting, however, is the software that AdisInsight users can operate to generate sophisticated graphical displays and an in-depth and easy-to-read drug development history. For example, users can easily find a detailed “life history” of any investigated drug. The life history is displayed in a table, listing the event date, update type, event details, and update date; such information can provide key insights into the drug development landscape of interest to any audience. Above all, the most distinctive benefit of Adis is that scientists write and approve the content, which no doubt contributes to the intuitive data output. Indeed, the sheer volume of expertly written and organized drug research and development information is a clear indication that this database can be a huge timesaver for anyone researching a drug for the first time. The information is updated more frequently than other large biopharma resources. Together, these attributes make Adis a reliable and practical database for medical writers.

Table 1. Database Tools Useful for Medical Writers

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<td>Research Reporting Guidelines</td>
<td>EQUATOR Network</td>
<td><a href="http://www.equator-network.org/">www.equator-network.org/</a></td>
</tr>
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</table>
Article Search Engines

Article search engines are a critical tool used by medical writers. For many, a common task is to quickly learn a new topic; therefore, researching trusted literature sources becomes a regular pursuit. PubMed and Embase are two trusted sources of biomedical literature; while they serve many similar functions, they differ in key aspects (Figure 2). For medical writers, understanding what these databases offer and how they differ can help save time when performing research for a new assignment.

PubMed is made available through the National Center for Biotechnology (NCBI), which brings educational resources in molecular biology, biochemistry, and genetics to the public. The NCBI is part of the US National Library of Medicine, which is a branch of the National Institutes of Health. PubMed is often the go-to literature database for medical writers as they begin to research a biomedical topic. An obvious highlight of PubMed is that it is free; with over 23 million records, it can be a comprehensive source of literature for writers without access to subscription databases (ie, freelances or those working at smaller communications agencies).

For those with access to subscription databases, Embase can be a useful option.* Embase contains over 30 million publication records; unlike PubMed, Embase sources include conference abstracts (~2 million) in addition to journal articles. PubMed and Embase search results are shaped by their respective thesauri that are used to index database records (medical subject headings [MeSH] in PubMed and Emtree in Embase). Emtree contains all MeSH terms, along with its own unique set of terms. This allows Emtree citations to be mapped to more broad and narrow search terms; more extensive indexing can give rise to higher numbers of—and perhaps more relevant—search results. In addition, Embase is particularly well-suited for researching drug information. For example, it is possible to build focused searches with subject headings that vary in coverage, such as “drug comparison,” “route of administration,” and “drug development.” In addition, though most Emtree and MeSH terms are continuously updated, the various terms that can correspond to individual drug entities

Figure 1. The categories of information Sylogent includes for conferences (A) and journals (B) are summarized using the Society for Neuroscience and The Journal of Neuroscience, respectively, as examples. The “Scope” sections are expanded to indicate the level of detail provided within categories.

* Individual subscriptions to Embase are currently advertised at $1,500 per month. Embase is also available to the public through many university libraries.
(eg, laboratory code, chemical name, and trade/generic drug names) are more often updated in Embase, along with back-posting of older records.9 Uniquely, however, PubMed records include a growing number of links to free full-text articles (PubMed Central). While Embase and PubMed stand alone as comprehensive search engines, if used together, their search results can be complementary.

Obtaining Retrieved Articles

Literature searches often retrieve publications for which only a title and perhaps an abstract are freely available. Articles can often be purchased (or “rented” for a limited period of viewing) directly from a journal’s website or through the Loansome Doc service in PubMed. Another option, however, is an impressive database of more than 12 million publication records that offers article rentals. For a monthly fee of $40, DeepDyve offers unlimited online reading; downloads of articles cost extra.13 With a free account, registered users have access to 5-minute previews of articles, which may be enough time for a medical writer to judge whether an article is truly needed—or to look up or verify a quick fact.

For medical writers who perform numerous literature searches, the costs of DeepDyve or Loansome Doc may be a small price to pay for increased article access. The reality is that open access publishing is still not the norm, despite the increase in the number of open access publishers and requirements of some research funders that provide for varying degrees of open access for articles that result from supported research. Despite such developments, however, many older publications are not available for free but can provide essential background information and historical perspectives. While the DeepDyve library is not specific to biomedical-related subject matters—and therefore its number of records may not seem impressive compared with the 20 million to 30 million contained in PubMed and Embase—DeepDyve may contain records that PubMed and Embase do not. Indeed, no single database (subscription or otherwise) offers everything. Overall, performing a thorough literature search may be most comprehensive when using multiple literature databases.

FDA Guidance Documents and Other Resources

The US Food and Drug Administration (FDA) website is host to a variety of useful databases and guidance documents.

In the Regulatory Process14 section of the portal resides the FDA’s main guidance documents, namely 21 CFR (Code of Federal Regulations). Title 21 is the portion of the Code of Federal Regulations that governs food and drugs within the US for the FDA, the Drug Enforcement Administration (DEA), and the Office of National Drug Control Policy (ONDCP). More specific to drug marketing and communications is the Office of Prescription Drug Promotion section, which provides guidance to promotional copywriters and other agency personnel.15

The Search Databases16 section of the FDA’s portal provides access to:

- Warning Letters submitted by the FDA to manufacturers,
- Information about FDA-approved brand name and generic prescription and over-the-counter human drugs and biological therapeutic products,
- National drug codes (unique product identifiers for drugs),
- and other useful documents.

Approved Drug Details and Clinical Trial Resources

Several US government-related resources exist for researching approved drugs and clinical trials. These resources include the Orange Book, ClinicalTrials.gov, and PubChem. The FDA publishes the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly called the Orange Book.
The Orange Book was first published in a print format in 1980. This resource lists drugs approved by FDA based on their effectiveness and safety in accordance with Section 505 of the Federal Food, Drug, and Cosmetic (FD&C) Act. It comprises 4 entities:
1. approved prescription drugs with therapeutic equivalents;
2. approved over-the-counter (OTC) drugs that cannot be marketed without new drug applications (NDAs) or abbreviated new drug applications (ANDAs) because they are not encompassed by present OTC monographs;
3. drugs approved per Section 505 of the FD&C Act through the Center for Biologics Evaluation and Research;
4. and drugs for other purposes such as military use, or drugs that have never been marketed or no longer are being marketed.

Since 1997, a search function for the Orange Book has been available on the FDA website; searches can be conducted by indicating active ingredient, proprietary name, applicant, application number, or patent number. The Orange Book is also available as a mobile application called the Orange Book Express on Android and iPhone operating platforms. The Orange Book can be used to research drug dosages, patent numbers, patent expiry, and patent exclusivity (and its expiry). These data can be used in reports discussing competitive landscape and in determining drug exclusivity in a particular market.

The NIH provides numerous resources on clinical trials and medical and scientific research. One useful web resource is ClinicalTrials.gov. ClinicalTrials.gov is commonly considered a “registry and results database” of human clinical studies conducted worldwide. On July 6, 2016, ClinicalTrials.gov had 219,533 studies in its registry involving all 50 states and 193 countries. Studies are usually listed in the registry upon their commencement, and study details are generally updated throughout the conduct of the study. ClinicalTrials.gov is useful for determining study phase, study type and design, primary and secondary outcomes, outcome measures, estimated enrollment, eligibility criteria, and inclusion and exclusion criteria. ClinicalTrials.gov can be used to determine how many clinical trials are recruiting patients or what dosing regimens have been studied in a clinical trial for a particular agent.

Additional databases provided by the NCBI are PubChem Substance, PubChem Compound, and PubChem BioAssay, which classifies the biological activity of chemical substances. These databases can be useful for medical writers who develop preclinical, phase I, and/or basic science materials. The PubChem Substance database comprises over 180 million records and includes information such as chemical structures, synonyms, descriptions, 3-dimensional protein structures, and biological screening data; the PubChem Compound records include over 63 million chemical structures, and the PubChem Bioassay records include over 1 million bioactivity data. PubChem data are deposited by various providers including chemical vendors, private and academic research institutions, and governmental organizations. The PubChem Substance database is an archive of all depositor-supplied data; its many records can be redundant because separate sources can provide different information regarding the same chemical structure. In contrast, PubChem Compound records are information hubs on each unique chemical structure recorded in PubChem Substance. The BioAssay database comprises biological activity test data of chemical substances. Where relevant, these PubChem databases are linked to one another and to PubMed scientific literature; when researching unfamiliar drugs and experimental protocols, this interconnectedness of chemical and bioassay information with scientific literature can greatly streamline the learning process.

### NIH Grants

The NIH Reporter database provides access to information about NIH grants awarded since 1992. The database can be searched by word or phrase; results can be filtered by name of principal investigator, institution, city, state, or other fields. The database is especially useful for exploring active areas of research, whether or not these areas have reached a clinical trial phase. Grant writers may find the database useful for identifying projects in a specific area of research that have been recently funded. Freelance writers may find it a useful tool for identifying potential clients who are either working nearby or who are working in therapeutic areas of interest.

### Clinical Practice Guidelines

Clinical practice guidelines can be great resources for writers interested in quickly learning about the expert consensus for various therapeutic areas. The National Guideline Clearinghouse provides searchable summaries of clinical practice guidelines that have met the standards for inclusion. For example, to be included in the database, guidelines have been developed on the basis of a systematic review of the evidence, and potential harms and alternative treatment options have to be considered.

The database can be searched by word or phrase or can be filtered by clinical specialty, National Library of Medicine medical subject headings, or name of organization that developed the guidelines. A guidelines synthesis feature compares guidelines on the same topic. For example, one synthesis page
comparatively provides the American Cancer Society and US Preventive Services Task Force guidelines regarding screening for breast cancer for women at average risk.

**Industry Analyses**

In the health care advertising agency environment, agencies are frequently called on to pitch new business to prospective pharmaceutical, biotech, and device companies. In order for team members to be knowledgeable, they need to gain expertise regarding therapeutic categories, the overall business and financial landscape relevant to a product, specific products and their potential competitors, etc. To gain this expertise, the team can use several methods, one of which is to order documents and/or obtain online access to DataMonitor Healthcare.27

DataMonitor is not a database but rather a company that provides in-depth research of the pharmaceutical and biotechnology industries. Their marketplace analyses help agencies understand developments across a range of diseases, companies, drugs, and strategic trends. DataMonitor analysts cull data from multiple sources (eg, federal government websites such as ClinicalTrials.gov, pharmaceutical companies’ websites, financial databases, medical associations). One can order an article (PDF) or obtain access to their online portal.27 While agency personnel could perform the research in-house using multiple databases, it can be a substantial timesaver to have DataMonitor analysts compile the information (important given that the pitch process is generally done at a very fast pace).

Here is an example of how DataMonitor could be used. An agency may be asked to pitch creative concepts to launch a new monoclonal antibody for Stage 3 breast cancer. The agency team will need to understand Stage 3 breast cancer, current and future breast cancer treatments, when the treatment can be used within the treatment protocol (ie, first line, second line), patient demographics, etc. The agency may use information from the DataMonitor report to create SWOT (strengths, weaknesses, opportunities, and threats) analyses, creative briefs, and strategic documents that they might use in their new business presentation and creative briefs that will drive creative ideas.

**Disease States**

Numerous authoritative associations for particular disease states exist within the US and internationally. An Internet search revealed a Wikipedia category, “Medical associations based in the US,” for which Wikipedia has 269 pages representing this category.28 A summary of some medical associations that medical writers frequently encounter is provided in Table 2. These organizations may have mission statements and may provide guidelines for their membership, which may comprise physicians, nurses, hospitals administrators, and other health care professionals depending on the mission of the organization. For example, the mission of the American Medical Association (AMA) is “to promote the art and science of medicine and the betterment of public health”; members of the AMA are physicians (US doctor of medicine [MD] degree, US doctor of osteopathic medicine [DO] degree, or an internationally equivalent degree), resident physicians, and medical students.29,30

Many associations publish journals and hold congresses/conferences to distribute important and relevant medical data releases from recent clinical trials and to update their members on changes in health care payers, governmental regulations and guidelines, etc. Therefore, many medical communications professionals work for these entities and help create and distribute medical communications to members of these associations.

**Research Reporting Guidelines**

The EQUATOR (Enhancing the Quality and Transparency of Health Research) Network (www.equator-network.org) seeks to promote the reliable reporting of research results in medical literature. The EQUATOR website provides a searchable database of more than 300 reporting guidelines, including the most prominent guidelines of CONSORT (Consolidated Standards of Reporting Trials), STROBE (Strengthening the Reporting of Observational Studies in Epidemiology), and PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses).31

The guidelines are clearly of interest to medical writers involved in preparing articles for publication in peer-reviewed journals. Other medical writers may also find the guidelines of value as tools that can help them develop skills in critically evaluating information reported in medical literature.

**DISCUSSION**

The purpose of this article was to create a helpful resource for medical writers, including medical communications and biopharmaceutical employee writers and freelance/consultant writers, so they can gain a better appreciation of database options and advance their navigation skills. We explored these key resources so medical writers have a wide array of research capabilities to fulfill the numerous tasks requested in various medical communications projects. After reading this article, medical writers will be aware of tools that will help them perform medical writing tasks.

We think this article can also serve as a tool for professionals interested in pursuing a medical writing career to evaluate whether their skillset matches the types of research projects...
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that these databases can be used to accomplish. Additionally, this article may help educate and better acquaint professionals who do not know what medical writers do on a daily basis as to the type of work medical writers perform.

It is worthwhile for medical writers to note that performing the most effective and thorough literature search may require multiple databases, particularly as systematic reviews—which require extensive literature searches—become increasingly popular and valued within the scientific community. Indeed, research has demonstrated that neither Embase or PubMed are individually sufficient resources to perform literature searches for systematic reviews.32

One limitation of this article is the potential for assessment bias due to authors’ personal work experience and database usage. Despite this limitation, efforts were made to provide an evenly balanced portrayal and discussion of all included databases. Furthermore, the authors include a diverse group of medical writers, allowing us to generate a comprehensive discussion of databases pertinent to countless medical writers.

Together, we have reviewed a broad and diverse portfolio of database resources by combining freelance, entrepreneurial, and medical communications expertise. We hope this article can serve as a valuable resource for AMWA members.

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

**Author contact:** arlene@arlenewalters.com

**References**


...continued on page 117...
A Case Study: Medical Writing as a Feminized Profession

By Hilary Graham, MA / Graduate Student in Technical Communications & Rhetoric, Texas Tech University, Lubbock, TX

ABSTRACT
Women are on an exodus from the science, technology, engineering and mathematics (STEM) workforce following their scientific education. While women are earning undergraduate degrees in biological sciences at a greater rate than men, they account for only 18% of full professors and 5% of executives at biotechnology companies; overall, men make up 70% of the scientific workforce. If women aren't making it to the top in scientific positions, where are they going? I argue that medical writing is one profession attracting women who leave the scientific workforce. Medical writing has become what is known as a feminized profession, which generally refers to an increase in the proportion of women practicing a particular occupation. Unfortunately, feminization can lead to a perceived de-skilling of the profession and an associated decline in compensation. While AMWA is currently predominantly women, it was founded in 1940 by Harold Swanberg, MD, and 5 of his male physician colleagues. This article is a case study that resulted from interviews with 3 practicing medical editors or medical writers. Common themes that emerged from the interviews included: the fluid entry into the field supported by a strong referral network, the flexibility the profession frequently provides, the increasing necessity to quantify the value of the work being performed, and the need to define what makes a good medical writer. While this small qualitative study cannot be generalized, it does provide a window into perceptions and practices. Further research is needed to shed light on the systematic inequities that occur when professions are feminized and gendered work is unequally compensated.

INTRODUCTION
Feminizing Professions—Where Women Go to Work
While women are earning undergraduate degrees in biological sciences at a greater rate than men, women account for only 36% of mid-ranking professors and 18% of full professors. The disparity is even greater in industry, with women accounting for 5% of executives and scientific advisory board members at biotechnology companies. Research clearly demonstrates that women are good for business, as biotechnology companies backed by venture capital are more likely to succeed when women are at the helm.

Why aren't more women making it to the top? Research demonstrates that factors include the inherent biases against women that are reflected during grant and manuscript reviewing, interviewing, and hiring processes. Unfortunately the problem is systemic with women as likely as men to be biased against women, even at the undergraduate level. Women are on an exodus after their scientific education. Since the late 1990s women have earned 57% of all bachelor's degrees, 46% of master's degrees, and 37% of doctoral degrees in scientific fields. But strikingly, men account for 70% of the scientific workforce. With women as the minority of “doers” in science, especially as their career progresses—where do they go?

A study by the American Association for the Advancement of Science (AAAS) demonstrated that men stop doing science for career reasons and women for personal reasons. The most recent volume of the book series Advances in Gender Research is specially focused on the role of gender in the academy, demonstrating the importance of this conversation. Many scholars are interested in retaining women in STEM careers, but which careers are absorbing women and why are they preferential?

I argue that medical writing is one such career that is attracting women who leave the scientific workforce. Medical writing has become what is known as a feminized profession—which generally refers to an increase in the proportion of women practicing a particular occupation. Currently more than 80% of AMWA members are women from diverse backgrounds, but this wasn’t always the case as AMWA’s founding physician members were all men. While most would consider the diversification of a profession positive, the feminization of a field often directly correlates with devaluation in prestige and pay.
Feminized Professions
A number of professions have been feminized since their male-dominated inceptions; specifically, nurses, teachers, librarians, veterinarians, pharmacists, and physician assistants are now predominantly women. Researchers have noted that specific health care professions have become feminized. Which leads to the question—what drives the feminization of a profession?

Science is a team sport, requiring a variety of skills and roles, with the literature demonstrating that women are more likely to collaborate. Medical writers are master collaborators by definition. They must interact with multiple team members from clinical scientists to data managers to statisticians to ensure that regulatory documents, manuscripts, or other materials they craft meet the standards of internal teams, regulatory agencies, or other audiences. Organizational development literature has examined the gendered division of labor and knowledge transmission but has not yet addressed the intricacies of the biomedical ecosystem.

In feminized professions, gendered work occurs, and men tend to excel despite their minority status. Gendered work implies that men retain higher status than women and that men have increased access to higher-status positions. Bottero further supports this claim, noting that when women enter a profession, this feminization leads to a perceived de-skilling of the profession. Adams continues this work noting that men have traditionally held higher-paying, higher status roles while women gravitate towards support roles.

American Medical Writers Association (AMWA): A Case Study
I have been a member of the American Medical Writers Association since 2009 and noticed the female majority membership from my first meeting, but AMWA didn’t start out with women in the majority. In 1940, Harold Swanberg, MD, and 5 of his physician colleagues formed the Mississippi Valley Medical Editors Association, which was renamed the American Medical Writers Association in 1948. During its infancy, AMWA was an association of physicians, a male-dominated profession during this era. Membership eligibility was broadened in 1951:

Active members’ shall comprise: (1) physicians and others who are actively connected with the editorial or business staffs of medical, dental or kindred periodicals; (2) medical librarians and health educators; (3) personnel of hospitals, foundations, educational institutions, publishing and technical companies and allied organizations, who are concerned with medical writing or publishing; (4) physicians who have had two or more articles published in a journal indexed by the Quarterly Cumulative Index Medicus.

The 1970s ushered in changes to the makeup of the organization with Jerry McKee becoming the first president who did not hold a doctorate (1976). In the following year, Virginia T. Eicholtz became the first woman president.

Since then, the majority of AMWA presidents have been women, and membership surveys have also indicated that women have been in the majority (Table 1). These data are quite interesting because as the profession has become increasingly feminized, the gap between men and women’s salaries has decreased. Does this parity of compensation translate to overall lower compensation for medical writers as a profession? It would be interesting to examine how the compensation of medical writers aligns with male-dominated professions that require similar levels of education and skill.

Although AMWA was founded by practicing physicians, the current membership (as reflected in participation in the AMWA

|---|---|---|---|---|---|---|---|
| Women | 72% | 75% | 82% | 83% | 83% | 84% | 85%
| Mean Salary Women | $36,135 | N/A | $64,556 | $71,775 | $79,609 | $87,315 | N/A
| Men | 28% | 25% | 18% | 17% | 17% | 16% | 15%
| Mean Salary Men | $46,865 | N/A | $78,733 | $84,259 | $93,677 | $103,627 | N/A
| Percent Salary Gender Difference | 30% | N/A | 22% | 17% | 18% | 12% | N/A
| Percent with Bachelor’s | 40% | 41% | 33% | 33% | 36% | 28% | 21%
| Percent with Master’s | 34% | 34% | 34% | 35% | 34% | 34% | 32%
| Percent with Doctorate | 21% | 23% | 31% | 30% | 30% | 38% | 40%

The percentages of men and women reflect participation in the salary survey, not necessarily the percentage of men and women in AMWA as a whole. Salary data are for full-time employees. N/A = data not available.

*Participation in the 2015 survey was not limited to AMWA members. Lapsed members and members of related organizations were also invited to participate.

*Men reported earning $4,000 more than women; the difference was not statistically significant (P > .05).
salary survey) consists primarily of communicators. In 1989, the majority of members held only bachelor’s degrees, with the minority of members holding terminal degrees. Over the past 20 years, the percentage of members holding doctoral degrees has increased substantially (Table 1). Given that a substantial share of members hold degrees in biology, medical technology, health sciences, nutrition, medicine, and pharmacy, I wonder if this uptick in education correlates with the exodus of women as the doers of science.

A number of studies have examined the drivers and implications of feminized professions. (See, for example, research in sales,28 pharmacy,29,30 and dentistry.31,32) I would like to extend this research by examining the reasons women choose careers in medical communication and the impact to the profession. Here, I report on a pilot study of female and male AMWA members, selected via convenience sample. I modeled a brief qualitative survey after the research of Adamson (2015) and Gidman and colleagues (2007).32,33

METHODS
This research draws on interviews with 3 people who are practicing medical editors or medical writers. I used a convenience sampling technique to recruit participants based on relationships developed via AMWA. The medical communicators all studied in doctoral and/or postdoctoral training in Houston, Texas, and all were working in Texas at the time of the interviews. Interviews were conducted over the phone. I compensated the participants for their time with modest gift cards. All names used here are pseudonyms; they provided informed consent regarding publication of this information in the AMWA Journal.

With the exception of some questions about where the participants received their training and when they graduated, the interviews were conducted in a conversational style. The interviews began with questions asking the interviewee to describe what attracted them to the profession and then moved on to inquire about training, including the distribution of men and women among their classmates and teachers. I also asked questions about the distribution of men and women among colleagues and in professional associations. Although the conversations took different courses, all interviewees discussed whether and how the predominance of women was affecting the field of medical writing. I asked the participants to talk about women and men medical communicators, in general, and then to talk about their own experiences, to the extent that they could make a distinction. For example, I asked why they thought medical writing was attracting so many women and went on to ask what had attracted them to the profession.

Following the recommendations of Bazeley,34 I used NVivo 10 qualitative analysis software from the beginning of the project to first transcribe the audio recordings and then later to track key themes and generate codes that emerged from the data.

My sample was derived from medical communicators at academic institutions who support manuscript and grant submissions. It is worth noting that this is not representative of the profession, as relatively few members of AMWA work at academic/medical schools, while substantial numbers work at pharmaceutical and biotechnology companies. Interviews with medical writers in different fields such as regulatory and continuing medical education might reveal different experiences, perceptions, and professional strategies. Table 2 details participant pseudonyms and demographics.

RESULTS
A Profession of Referrals
All three participants noted that they were referred into the profession. Upon entering graduate school and during training, each had planned to pursue employment as a tenure-track faculty member. Jane exited the tenure track path upon completion of doctoral training and Sam upon completion of postdoctoral training. Mary transitioned after not only successfully securing a position as an assistant professor, but also receiving a prestigious career development grant to support her research program.

Sam studied in a psychology doctoral program with clinical and biological specialties. He remembered that there were more women in the clinical track, whereas more men than women were in the biological track. (He was in the biological track.) He noted he always excelled at writing as compared with developing a research program through the generation of new theoretical models to test. As a result of his obvious

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ELS = Editor in the Life Sciences
strengths in writing and editing, he was referred by a friend to the manager of an editing team at a local research hospital. After an initial informational interview and a subsequent editing test, he was offered the job and has continuously worked in the group for more than 10 years; he recently became the group manager after the woman who hired him decided to leave the position.

Jane studied in a literature program with 8 women and 2 men in her cohort. She was open to other opportunities when confronted with a bad job market. She was referred into her first editing position—working for a faculty member at a local research university. He was very encouraging regarding her skills and the subsequent value she brought to his team of researchers, both in editing their work and in teaching them to be better writers. She now works as a medical editor.

Mary’s graduate school research group was 13 women and 1 man. As noted above, she successfully transitioned from a trainee to becoming an assistant professor. After spending 6 days a week working in the lab and the seventh day thinking of the work that had to be done, she was referred by a friend to the career of medical writing. She noted that the primary reason she left her tenure-track position was for personal reasons in hopes of achieving better work-life balance.

What Makes a Good Medical Writer?
Mary noted that she is a chameleon in her writing style and that she has an extended conversation with clients prior to working with them so that she can accurately employ their writing voice. For example, she will use therefore or thus based on author’s own natural language. According to Mary, adaptability and empathy are key traits of a good medical writer; she views these traits as undervalued. She also noted that writing as a professional requires patience and dedication, personality traits she feels women inherently possess. She also wondered if women were more talkative than men, which is not supported by recent research, but is nonetheless a culturally agreed upon phenomenon after the publication of Deborah Tannen’s seminal book about conversation styles of men and women.

Jane noted that she is a conduit of the authors’ intentions. She works with many authors for whom English is a second language. These authors do brilliant science but have difficulties expressing their findings in English. She notes that an open-mindedness to discover the author’s intentions is a critical personality quality of a good medical writer. Jane noted that she views each manuscript as a puzzle that she starts assembling from the figures and tables and fills in the gaps through queries to the author. She notes that forming a trusting relationship with the author through diplomatic suggestions is key to accurately reflecting the author’s thoughts and not introducing editorial errors.

Sam noted that a fondness and talent for language are critical to being a good medical writer. He also explained how effective communication with the author was key to success, as authors often had to be gently reminded of rules of grammar and of the appropriateness of the language for the intended audience.

Fluid Entry Into the Field
None of the interview participants set out to be medical writers, but because there were no stringent educational or credential requirements, such as the training and licensure required in law, medicine, or pharmacy, they were able to easily transition into the profession. This creates a situation in the profession in which biological age is not necessarily a good measure of professional experience. Because many people join the medical writing profession after engaging in other types of work, a “young” medical writing professional (in terms of experience) may, in fact, be middle-aged. I asked the participants if they thought this fluidity was a drawback to the credibility of the profession as the majority of medical writers’ professional peers and/or clients have matriculated through stringent educational or credentialing systems.

Sam noted that he thought the fluidity created an intellectually diverse workforce, which was a benefit to the profession. He thought the greatest difficulty medical writers face is a lack of understanding of the profession and that a credential, such as the Editor in Life Science (ELS), registers most effectively with physician-authors when he describes himself as “board certified.”

Jane does not believe that a degree in medical communication is necessary to become a medical communicator. The diversity of jobs in the profession and the nature of the work require tailored training for each position, and different educational backgrounds offer different strengths in working as a medical communicator. Adaptability and the ability to learn independently are important skills in this profession.

Mary thought that working as a tenure-track faculty member gave her credibility and that if she had stayed longer in academia, she would have additional credibility because she would have published more peer-reviewed articles and secured more grants. She noted having the ELS certification gave her editorial credibility, but what her clients really wanted was a strong portfolio that demonstrated that she could deliver work in their field. Mary felt her transition basically depended on a grammar refresher and that she would have required this remedial training regardless of the time of her transition.

Flexibility of the Work
Among respondents to an AMWA salary survey, one third were freelance, and of those 58% worked part time. In this case
report, all 3 respondents noted the predictable hours of a staff position and the flexibility available to freelance medical writers. Sam and Mary indicated that academic positions were more like lifestyles, whereas medical writing is a profession.

Bias
Sam noted he has never felt excluded in his office (composed of all women) or at AMWA meetings (majority women). He has not noticed bias against women coworkers or clients, but as this is his first and only position he cannot compare it with situations that are gender-balanced or male-dominated. However, even in feminized professions, gendered work occurs and men tend to excel despite their minority status. Mary shared a very striking example of when she was passed over for a faculty promotion by a man she considered to be less qualified. She described how frustrating and demoralizing this slight was and how it contributed to her departure from the tenure-track position.

Quantifying Worth
Mary said that when she was a graduate student she was so engrossed with science that she was pleased to earn a living wage. As she progressed into her postdoctoral fellowship and tenure-track faculty position, she learned that equally qualified men were making more, which she learned through the public salary database on The Texas Tribune website. Mary was further discouraged when she learned that a University of New Mexico study by economist Kate Krause found that women with children earn up to 14% less than women who do not have children. This wage gap often begins when a woman takes time away from paid work and compounds over time as salaries, even at new positions, are often based upon the wage at one’s previous position versus one’s inherent value at the present moment.

With grant funding becoming increasingly scarce, many departments that do not generate income for academic institutions are asked to quantify their value. This is especially difficult for central editing departments as the quality of the writing is just one factor in the success of a manuscript being accepted or a grant being funded and is not easily separated from the quality of the science being presented. Although it is not surprising that demonstrated value would be the basis for the continuation or cessation of a program, I do wonder if the fact that the majority of central editing departments are led by women and composed primarily of women somehow undermines the perceived worth of their services to the university.

CONCLUSIONS
As medical writing continues to mature as a profession, understanding the roots of the profession as well as its current status is crucial to the continued growth, recognition, and compensation of its members. Understanding how we are perceived both as a profession and as individuals is critical to influencing the value assigned to our work. Until the gender gap pertaining to career growth and compensation is eliminated we must proactively lobby for professional equality on an individual and organizational level, which starts with being equipped with facts about the status quo. While this small qualitative study cannot be widely generalized, it does provide a window into perceptions and practices. Further research is needed to shed light on the systematic inequities that occur when professions are feminized and gendered work is unequally compensated.

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Medical writers have amazing, sometimes bizarre, and just plain incredible stories about how they started their careers and overcame challenges along the way. These stories aren’t often captured or shared, so we embarked on a project to uncover and document these stories. We want to share some of the amazing stories we have collected so far—and inspire you to share a story of your own.

According to the 2015 AMWA Salary Survey, about 50% of respondents indicated that they hold biology, medical technology, health sciences, and nutrition degrees.1 That means a whopping half come from other disciplines. Even among those with a scientific background, the path from bench to medical writing is varied. Sharing our experiences is critical to understanding the “tremendous and growing” medical writing field, which has more than doubled its market size in the last decade. 2,3

Living Histories: Our Legacy as Medical Writers
Medical writing is credited with providing a time capsule for medical history.4 In June 2016, we started an online research project with the aim of documenting and sharing medical writer stories (or “life histories”) using open-ended, interview-like online survey methods adapted from history and social science research. We are asking medical writers of all backgrounds to contribute brief narratives about their experiences with getting started in medical writing and the challenges they have faced, written in their own words. These interview-like narratives create a rich tapestry of the unsung diverse and dynamic nature of the medical writing discipline, or, to borrow language again from the historical tradition, a “living history of everyone’s unique life experiences.”5

Collecting these stories facilitates open sharing of original experiences among the medical writing community, a discipline with its own rich history that is uniquely intertwined with and yet distinct from medicine.

Early Responses
In less than a month, 38 histories were collected from a range of medical writers. (Interim results are shown in Figures 1 and 2.) In the open-ended responses, 14 medical writers described how people and activities at AMWA had influenced their career paths.

Initial analysis of these histories has illustrated the breadth of experiences that lead to a medical writing career. Physicians told stories about leaping into medical writing to escape burnout, layoffs, business mergers, and political pressures. Many felt a calling to get back to their scientific roots—or, as one physician described it, back to “where I need to be.” One physician-turned-medical writer shared an unusual path to medical writing:

My entry to the field of medical writing or writing was entirely a result of a chain of some extraordinary events that involves a Bollywood star and an emerging world leader. ... [At an event promoted by the Bollywood star,] I met a local guy on social media… As I expressed my interest in writing, he signed me up on an online freelancing platform and assisted me throughout the journey. Post that, I went on to use my knowledge for various aspects of medical science. This is what I have been trying and I continue that even today as a medical writer, as a doctor, and as a part of this universe.

For one bench scientist, medical writing happened as a life-changing epiphany:
In my 30s, I quit this [bench] job to pursue something else. But what? ... [I thought] halfway through my week of applying for jobs... “No, I am only repeating...
looking for a job that I quit.” My inner voice said go hike in [mountain] foothills. On an August afternoon, the sun drenched the heat-soaked trails through a haze of smoky dryness that burned my lungs with each breath. As soon as I reached the mountain top, the sky shifted [and] went a mean cold gray, gusty with pine needles slapping my skin, and a fearful rainy chill blowing me closer to the cliff’s edge. I held on to a rough-skinned pine trunk for several moments, wrapping my legs around its trunk, drenched in the downpour. When the lightning jolted through the dark gray, the thunderous boom inside my head was one clear thought: “medical writing.”

Others discovered the path of medical writing early in their career as new graduates, graduate students, or medical residents. One resident said, “During training, I wrote and published more than any other resident.” Medical writing as a career, therefore, seemed a natural progression. For another new graduate, the first job opportunity was serendipitous:

A small fortune-cookie-like piece of paper showed up on the English Department job board: ad “medical writer needed.” While neither this stroke neurologist nor his editor knows how this ad came to be posted, I became this kind physician’s editor.

While we knew that medical writers came from fields other than science and medicine, the histories gathered thus far have revealed the diversity of skills that can be transformed into a successful medical writing career. A business specialist turned financial know-how into medical writing success by “…helping scientists to string their sentences together better, thereby increasing the chances that they would be awarded the money they sought.” Another medical writer combined a love of literature and composition with an unexpected opportunity for an inspiring and fortuitous story:

I feel like I should start this with, “once upon a time…” …with a BA in British Literature… I was living in a tent at a state park (not permanently—for just a few weeks until my apartment opened up). I had no job, I had no prospects for jobs, and my parents were terrified I’d want to move back home permanently… [I got a temp pharma job where] if the CRAs [clinical research associates] were willing to give me the writing that had previously been their responsibility, [the company] would hire me as a full-time, permanent employee.

What Do We Have in Common?

These histories have revealed that the journey to become a medical writer can cover a wide landscape of experiences. Yet as medical writers we speak a common language (Figure 3). As one respondent stated:

How did a middle-aged mom with degrees in business administration and social work ever get a job as a medical communicator? Beats me… That being said, I’ve had a 20-year career in medical editing not because of any formal education or certification, but rather because I’m insatiably curious.
As a former daily newspaper editor, I brought to my present career in health care writing a belief that the best way to share information with consumers (lay readers) is to include patient voices. I am not talking about a one-off quote that you often see in a newspaper story or an online posting, or the superficial comments people say in pharmaceutical television commercials. I am talking about having a patient share a personal experience so that the reader is able to empathize and thus possibly have a memorable learning experience.

This storytelling technique, most recognized in fiction, can be effective in patient education brochures, pamphlets, web content, and other media where one wishes to share important information and is not constrained by the rules and boundaries of regulatory or technical writing. There is research published in health care literature revealing that using stories as part of an educational tool can help nursing students develop critical thinking and become more empathetic toward their patients as they understand differing cultural and ethnic backgrounds.1,2

In 2012, I based a health literacy capstone project for graduate school on my hypothesis that written stories could be just as powerful in getting consumers to remember health information as oral storytelling had been shown to be in educating nurses. I had been writing patient stories since 2005 for our hospital’s consumer publication and wondered if, in fact, readers might take preventive action after reading the personal accounts of others. For my project, I used a true patient account I had written in a 2009 publication about Jack Hausmann, an elderly man who woke up once in the middle of the night with a rapid heartbeat. He didn’t want to tell anyone, but when his wife, Betty, heard him—hours into the episode—she realized something was wrong and called 911. Fortunately, despite the delay, everything turned out fine—atrial fibrillation was diagnosed and he was put on medication. In the story, Jack and Betty discuss the importance of being alert to one another’s health problems and accompanying one another to physician visits to better understand any medical information they need to know. As part of my project, I had attendees at a 2013 health fair take a survey that included answering questions after reading the story and after reading a fact sheet. The results showed that participants scored higher on questions based on what Jack and Betty said than they scored on questions from a list of bulleted facts.

Although the results of one survey of 45 people is anecdotal and in need of more research, the study did suggest that people remembered more about what Jack and Betty said than they scored on questions from a list of bulleted facts.

I was truly fascinated by that result and thought about what I had learned years earlier as an English major studying authors and also how I learned to be a creative writer.

“….my neighbor had a lump on her breast for years. She didn’t want anyone to know. By the time she went to the doctor, she had advanced breast cancer. After she died, I swore to myself I would do everything I could to encourage women to have mammograms.”

—A woman in southern Delaware

“People are the prisms through which readers love to view the world.”

—Francis Flaherty, journalist/ NYU professor in journalism

This article is based on the author’s 2013 master’s capstone project at the University of the Sciences: Using storytelling and art elements in consumer print materials to improve health literacy.
Authors and English professors have written extensively on the techniques that make stories compelling. Accomplished journalist and author Tom Wolfe, for example, wrote that it is the emotion in a story that engages the reader. Emotion can be evoked when the reader feels as if he or she is inside the head of the people in the story. As New York Times editor Francis Flaherty wrote, “People are the prism through which readers love to view the world.”

Wolfe points to 4 basic techniques that create this emotional response, making the story a compelling one: a) stories are told in a sequence of scenes so that the reader moves forward with the characters; b) dialogue is used so the reader begins to hear the character speak; c) specific details are given about the characters, which stimulates images within the mind of the reader; d) a Henry James–style of telling a story through the voice of one or many characters is used. This style of writing entered nonfiction writing in the 1960s and became known as “New Journalism.” Wolfe stated that by ‘trial and error,’ journalists of that time, such as Norman Mailer, Gay Talese, and Truman Capote, had figured out a way to incorporate the gripping power and emotional involvement of the realist novel into their nonfiction writing.

Literature professors cite the importance of a story having a theme or meaning as an important element that can motivate a reader as he or she internalizes the message. Pulitzer Prize–winning author Jon Franklin says a story needs to have a character who finds meaning in life as he or she comes to grips with a problem or a challenge. For example, I believe that when one writes about a person with cancer, the meaning of the story may not be that the person is fighting the disease but that the person emotionally comes to terms with the fact that he or she has the disease. This again, allows the reader to internalize and relate to the character’s experience.

What Does This Mean for Medical Writers?

Like other professional writers and even poets, medical writers who write for lay or patient audiences often have the opportunity to educate, inspire, or motivate people. This is especially true today when we have found that lifestyle behaviors play such an important part in our health and longevity. At the top of this article, I gave an example of a conversation I had with an African-American woman in a low socioeconomic region of our country. I was working on a marketing project to increase participation in cancer screenings in an underserved minority population. Her story, told with tears in her eyes, touched me so deeply that I wanted to somehow capture her emotion to increase awareness of the importance of mammography in the early diagnosis of breast cancer. Interestingly enough, I don’t remember her name, I just remember how I felt when I heard her story.

How to Get the Most Out of a Patient Interview

Consent forms are filled out before you start any interview process. Make sure the patient knows how the story is going to be used.

I have been writing patient stories since 2005. The most important step in the process is the development of questions before the interview. Strong questions lead to your ability to write a compelling story.

- Develop a list of 3 or 4 open-ended questions that do not elicit “yes” or “no” answers.
- While of course you will ask what happened, you also need to ask how the patient felt and how his or her life has changed.
- Listen carefully, and go with the direction of the conversation, especially if it is going in a direction you did not expect.

The last step is to always have the patient review and approve the story you have written before it is published. Remember, it is the patient’s story.

RESOURCES


Since working on my capstone, I have noticed that many medical institutions are using patient stories. For example, check out websites of Mayo Clinic, www.mayoclinic.org/patient-stories, and Children’s Hospital of Philadelphia, www.chop.edu/giving/patient-stories#.V5VddfkrLak. You can be the judge of why they are using patient stories and what messages they are sending. Psychology researchers also are evaluating how and to what extent personal narratives influence health behaviors. (See McQueen et al for one example.) I think the only concern that I need to voice here is that storytelling clearly can be a tool to influence, as well as to educate. So, as continued on page 122
we discover our power as writers in this arena, we also need to think about how we are using that skill and why.

**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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Our backgrounds may be diverse, and there are many other examples, but we all have passion and insatiable curiosity in common.

We are actively seeking additional writers willing to share their stories at www.surveymonkey.com/r/WriterStories. Please contribute!

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The book opens with 2 very dramatic examples of microbial epidemics that are playing out in our world today, but almost immediately Mark D. Hardt takes us out of the hospital and into the world of sociology. In his book, The History of Infectious Disease in Pandemics in Urban Societies, Hardt examines infectious diseases from the perspective of demography and medical geography.

In a departure from typical infectious disease books, Hardt walks us through the 2,000-year struggle for supremacy between microbes and macrobes (primarily humans) from his perspective as a sociologist whose work focuses on urbanization, demography, and infectious diseases. Reminding us that the microbes have been on the Earth far longer than humans, Hardt explains the coexistence between the 2 combatants and notes that, despite the advantage of dwelling here longer, the microbes have only managed to best the macrobes for a mere few yet significant decades at a time throughout this struggle.

Hartd uses the Epidemiological Theory first posited by Oman to explain the dynamics between the two combatants. The theory breaks the struggle into distinct phases or transitions throughout history and explains the advantages and disadvantages facing each combatant. He details the roles that societal and environmental conditions play as he examines fertility, mortality rates, and population changes as measures for scoring progress or loss in the struggle.

As Hardt walks through the advances in science and medicine and changes in our societal conditions, he provides a well-referenced documentation of many historical events and practices that have shifted the outcome to each side along the way. He details changes in our society from the hunter-gatherer to the more sedentary urban dweller, explains the shift of the mortality advantage of the rural dweller to the city dweller, and reveals the reasons why the advantage has not always been straightforward or equally shared. He documents instances where microbes employ their 4 most frequently used advantages over us: human migration, trade, war, and conquest. This book will be of value to life science and medical writers as a well-documented reference for many historical advances and occurrences that have influenced public health outcomes throughout the years.

The cautionary tale that Hardt provides us is that “battles with microbes are not lost or won [although] humans are always ready to proclaim a war won. Victory over the microbes is unlikely to ever be celebrated.” Today as we take comfort in our success over smallpox, Hardt introduces us to the law of unintended consequences. It serves to remind us that although we have eradicated smallpox from the wild, we keep it intact in controlled laboratories, and last year we discovered there were vials containing the virus mistakenly left unattended in an old unguarded laboratory closet. Even our campaign to rid the world from polio is at least stalled, and measles infections have again resumed because one of our most successful tools in the war against microbes—vaccination—has become a victim of the complacency of success, political-religious suspicion, and historical amnesia. All of our tools and progress in this struggle between microbe and macrobe are subject to one disadvantage we possess that the microbes do not, human hubris. As the microbes continue to wait for their moment, humans tend to think they have the upper hand. Hardt leaves us with the thought, “this may not be a struggle for supremacy, but instead a dance of mutual survival.”

I had barely finished the book and submitted the review to the editor when the anticipated and yet dreaded news that the Zika virus, which has been spreading misery in a global march, had now arrived in South Florida and is being transmitted by our local Aedes aegypti mosquito populations. This newest tactic employed by the microbes in our ongoing struggle is aimed at a very specific human vulnerability. Although it can cause misery in any of us it infects, it almost seems sinister in that it targets the brain of the human fetus for its worst destruction. Peter Hotez, MD, PhD, dean of the National School of Tropical Medicine, Baylor College of Medicine in Houston, Texas, reminds us that the forces driving the spread of Zika as well as other vector-borne disease viruses are poverty, human migration, conflict, urbanization, deforestation, and climate change. As I listened to Hotez’s remarks I was struck by the parallels between this latest outbreak as described by Hotez and Hardt’s observations in this book. Little did I realize when I accepted the opportunity to review this book that I would find myself at ground-zero as Hardt’s observations begin to play out in the latest round of our microbial/macrobial conflict.

—Larry Lynam, MS, RM, SM

A microbiologist and a former biopharmaceuticals executive, Larry is a freelance medical and life sciences writer and workshop facilitator based in Coral Springs, Florida.
Health systems are increasingly focused on the power and importance of effective communication, and more are realizing the value of social media as an indispensable tool to build relationships by meeting their stakeholders where they already are—online or on mobile. In the age of Twitter, Instagram, Snapchat, and Facebook—not to mention YouTube, Pinterest, blogs, wikis, and more—hospitals and medical schools are using social media to inform, influence, and inspire, appealing to the heart, not just the mind. It’s all part of an effort to engage with key audiences outside of the exam room or the classroom, whether it’s with patients, students, scientists, donors, or others.

Fostering these relationships could quickly become incredibly complex for a system the size of UF Health, part of the University of Florida. The $3.1 billion academic health center has more than 22,000 faculty and staff and includes 6 health-related colleges; 9 major research centers and institutes; 2 affiliated private, not-for-profit hospital systems, with a total of 6 (soon to be 9) hospitals where UF physicians practice; and more than 100 outpatient practices spread over north central and northern Florida. For organizations this size, finding a common voice that helps forge a consistent brand identity while retaining the ability to customize content can pose a challenge.

Along with proper planning, the setting of standards, and a healthy dose of training and support, UF Health’s social media team preempts problems using a framework of commonly shared values to support unique voices that enhance the organization while protecting patient privacy, maximizing reach, maintaining and enhancing reputation, and listening and responding to the community.

The timing couldn’t be better for health systems to take the plunge. Consider the increasingly important role social media platforms are playing in how consumers make health decisions, from seeking preventive care to choosing a physician to selecting providers for lifelong care. A 2012 survey of 1,060 adults by PricewaterhouseCoopers Health Research Institute (PwC HRI) revealed that 40% would let information they collected on social media affect the way they handled a chronic condition or influence their approach to diet and exercise.1 In addition, 42% reported using social media to find reviews of health-related treatments and physicians, and 45% said social media content would affect their decision to seek a second opinion.

Studies have also shown that a strong social media presence can enhance the image of a health care organization. In one study, 57% of consumers said a social media presence would strongly influence their choice of a provider.2 In that same study, 81% of consumers saw a robust social media presence as indicative of the organization’s use of leading-edge technology.

And consumers are increasingly turning to social media for sharing and receiving information about their health experiences. In the PwC HRI survey, 25% reported posting about their health experiences, and 61% said they are likely to trust information posted by providers.

Academic health centers also are leveraging social media strategies to communicate across their other missions, drawing attention to research, attracting enrollees to clinical trials, recruiting medical students, and building new pathways to community engagement.

In today’s world, health organizations that aren’t on the social media bandwagon are missing out. At a glance, the number of followers of health-related social channels is booming, and content sharing is on the rise. A YouTube video posted by the Cleveland Clinic focusing on empathy in the health care arena has garnered more than 2.7 million views. The Centers for Disease Control and Prevention

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1Assistant Web Manager, UF Health Web Services, Gainesville, FL
2Chief Communications Officer, UF Health Communications, Gainesville, FL
has more than 602,000 followers on its Facebook page. The National Institutes of Health has also gotten into the game, with a dedicated web page listing dozens of social media properties (www.nih.gov/news-events/social-media-outreach).

And according to the 2012 Google/Compete Hospital Study, an analysis of the online habits of consumers indicated the number of people following YouTube to a hospital website increased 119% from 2011 to 2012, and these individuals were more likely to book an appointment, find a doctor or provider location, and/or contact a hospital.³

Social media enables health systems to become a part of people's lives even when they are well; through social media, health systems can offer helpful tips, provide emotional support, and share interesting information about the latest discoveries and clinical breakthroughs. Communication also extends beyond local geographic boundaries, raising awareness and reputation more broadly.

In this article, we briefly outline some of the tools we've adopted and share examples of the most effective social media channels we use to reach our varied audiences.

The Toolkit
UF Health's social media presence encompasses more than 150 official social media channels supporting the system's clinical, research, and educational missions (see https://social.ufhealth.org/accounts). Managers of official accounts work closely with the UF Health Communications team to develop communications plans that meet business and communications goals. Wherever possible, the social media team encourages content creators to feed into these channels rather than start up new ones to take advantage of established audiences so as to limit splitting of audiences into smaller and smaller niches.

Each of the accounts in turn links to a set of centralized social media accounts for all of UF Health. These centralized accounts focus on patient needs and perspectives; we use these accounts to convey empathy and wisdom. Empathic stories and content focus on our health care services and our commitment to quality patient care and service to our community; wisdom is demonstrated by highlighting our educational mission and research breakthroughs.

Social media formatting and messaging has become a key part of our communications processes. When drafting stories, UF Health communications staff members are required to include both Facebook and Twitter abstracts. Those abstracts are then passed on to our social media coordinator, who reviews the content, makes recommendations based on best practices that factor in audience engagement, and edits as necessary. This process has encouraged communicators to consider their piece holistically across all platforms and has helped them to best leverage the tone and style of each channel to support their message.

Facebook (facebook.com/UFHealth)
Facebook continues to be UF Health's primary channel for social media communication. Posts focus on a mix of research and news stories and highlight various service lines, such as cancer, cardiovascular care, or neuromedicine. Apart from paid advertising posts that are part of an ongoing integrated marketing campaign, UF Health's Facebook strategy relies solely on free posts—known as organic reach. The social media team continuously performs A/B testing on these messages—by testing differing language and times for publishing. UF Health has seen a triple-digit increase in engagement over the past year with its posts, with a number of organic posts surpassing the reach for paid campaign posts during the same period.

A key takeaway is to let your social media team prioritize its publishing schedule based on audience trends; whereas news releases are scheduled during the day to tie to a media cycle, social media audiences might not be active until after the working day or late evening. Untethering our social publishing from an integrated, all-at-once publishing strategy has led to much higher levels of engagement and sharing.

In addition to the Facebook page, the social media team monitors local community group Facebook pages for positive and negative feedback and directs people to patient advocates when the need arises.

Pinterest (pinterest.com/UFHealth)
UF Health's recently launched Pinterest channel is used for promoting lifestyle and healthy preventive behaviors, as well as sharing words of affirmation and healing. While our strategy is still being developed, we see Pinterest as being an important part of our efforts to discuss health care with female audiences, in particular, female heads of household. An Ahalogy online poll of 1,015 respondents reports that 85% of Pinterest users are female,⁴ and the US Department of Labor reports that women make about 80% of health care decisions for their families.⁵

Twitter (twitter.com/UFHealth)
In addition to using Twitter to share the same mix of stories from Facebook, UF Health monitors Twitter to see how keywords are being used in specific geographical locations to gauge customer and community sentiment regarding the organization. This information is used to shape communications for upcoming marketing campaigns and is also provided to senior leadership so they can identify trends in customer satisfaction and make changes to improve patient satisfaction.
**UF Health Blog (ufhealth.org/blog)**

UF Health launched a new consumer-oriented health blog in early 2016. This blog allows us to refocus stories that are trending on social media toward UF Health. Instead of linking to an external news resource, we discuss the story from the viewpoint of related UF Health experts and service lines. In addition, we share general health tips and guidelines that allow our resident experts to be more visible to the community and to enhance the organization’s reputation.

**What’s Next?**

*Instagram.* Launching this fall, UF Health’s Instagram channel will serve as a behind-the-scenes look into all of the units that make up UF Health. Departments will act as Instagram ambassadors and do a takeover of the account to communicate the UF Health experience from their eyes. The program will allow departments that might not have a long-term social media plan to instead participate through a short-term commitment and to become familiar with the resources needed for possible expansion later to an ongoing account in another channel.

*Live-Streaming Video.* Fidji Simo, the director of the team that manages Facebook Live, reports that 500 million people watch 100 million hours on its platform every day and that people spend 3 times as much time watching videos when they are actually live than prerecorded.6

UF Health also has begun to explore opportunities for live streaming. Given issues of patient privacy, live streaming has been restricted so far to traditional press and public events, but initial results have proved encouraging and have shown a marked increase in the level of engagement compared with packaged videos. Our next step is to explore doing live question-and-answer sessions, building on the participatory forums that Twitter and Reddit’s Ask-Me-Anything platform provide.

**Clinical Trials.** Recruitment for clinical trials via social media continues to be a unique challenge for health care organizations, particularly around issues of privacy and patient trust. Initial pilot studies indicate that different patient populations respond differently to various methods of clinical trial recruit-
dent online. The UF Health social media team is working closely with its Institutional Review Board and the UF Clinical and Translational Science Institute to explore opportunities and challenges in this area, to develop a best practices document, and to make recommendations for the organization.

A Cautionary Note
Despite the obvious opportunities, social media in the health care arena raises many questions: privacy, ethics, professionalism, and content monitoring and governance all pose serious issues that require a health care organization to proceed more cautiously than other business sectors might.

Health systems seeking to build or expand on a social media strategy must be mindful of these considerations and should establish guidelines and best practices for use. Handled poorly, social media activity can hurt an organization's image more than help it and has the potential to breach patient privacy. Organizations looking to expand their social networking efforts should ensure they have established clearly defined goals for the use of social media, then match the medium to the desired message.

As part of the process of creating an official UF Health social media account, communications coordinators are required to provide a detailed content strategy that outlines their audiences, tone, and publication schedule (http://web-services.ufhealth.org/help-support/social-media-account-request-form). A social media communications committee reviews the strategy, assesses whether existing channels might be used instead, and then works with that group to refine their processes and practices prior to creating an account. This process enables us to carefully expand our social media presence by nurturing our existing channels with additional content streams and ensuring that new accounts have a solid, self-sustaining base prior to launch.

The UF Health social media team provides ongoing community support for social media managers within the system. Within Bridge, UF Health's intranet, a social media managers group shares information about upcoming campaigns and discusses best practices. This group also meets bimonthly for brown bag lunches to discuss new trends and platforms and to present data on successful campaigns and information about lessons learned.

Twice a year, the team holds "microconferences" to discuss developing a social media voice and to discuss tracking and analytics for social media efforts. The team also encourages managers to attend monthly social media managers meetings hosted by the University of Florida's social media team for insights from other colleagues outside of the academic health center.

At UF Health, social media policies prohibit the posting of confidential and/or protected health information (PHI), including patient photos without written consent. Social media coordinators are trained on proper responses to self-disclosures of PHI and to communicate with the social media team when issues arise, so the team can respond accordingly if content needs to be removed. Employees are required to follow guidelines on personal social media accounts and blogs, which require they identify that their posts reflect their views as an individual and not of the organization as a whole. A list of all our social media guidelines and policies can be found at web-services.ufhealth.org/help-support/policies/.

Summary
Social media's role as a real-time communication channel will continue to present new opportunities and new challenges for health care organizations. Developing a sensible strategy can help build reputation; increase transparency to the public; educate, inform, and enlighten; and, ultimately, empower health care consumers and other audiences seeking information to guide their decision-making.

Authors' disclosure: The authors have no conflicts of interest to report.  
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Authors' disclosure: The authors have no conflicts of interest to report.  
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A Social Media Sampling
UF Health's focus on empathy and wisdom on social media celebrates the achievements of our patients, their caregivers, and the community. A sample of some of our posts over the past few months can be viewed on Storify: https://storify.com/UFHealth/uf-health-social-empathy-and-wisdom


SOCIAL MEDIA
We have been involved in a multiyear research project aimed at identifying best practices in writing and editing needs assessments (NAs) for continuing education in the health professions, including continuing medical education (CME). NAs for CME programs, for example, typically analyze health care providers’ deficiencies in knowledge, confidence, competence, or performance in a given therapeutic area. These deficiencies, or gaps, are important because they are used to guide the development of educational interventions, with the ultimate goal of improving patient care. NAs can vary in length from 1 page to more than 10 pages depending on the number of gaps, the quantity of supporting evidence, and the resources available. Since the ultimate goal of our project is to improve the quality of CME needs assessment, this update will follow the standards for quality improvement reporting excellence (SQUIRE) guidelines.

WHY WE STARTED

This project began in 2010 when Sandra Binford, MAEd, and I (DH) carried out a small pilot project to analyze a handful of NAs written by various authors and collected from several sources, including clients and an AMWA roundtable. At the time, Sandra and I were both active members of the Alliance for Continuing Education in the Health Professions (Alliance) as well as AMWA. Out of respect for confidentiality agreements with our clients, we did not investigate or exchange proprietary information. Nonetheless, we noticed a great deal of variation among NAs, especially in the sources of evidence used by the writers, how writers presented this evidence, and how they cited it in reference lists. Writers varied in their decisions regarding whether to interview experts or to include charts and graphs, and which reference style to use—American Medical Association, American Psychological Association, or a hybrid reference style. We found all of this variability interesting because effective continuing education begins (Figure 1) with a high-quality NA.

Other quality improvement (QI) initiatives, both inside and outside the health care industry, have involved efforts to understand sources of variation in key work processes and to reduce unwarranted variation as much as possible. Pioneers of quality improvement in health care studied what appeared to be haphazard tonsillectomy rates first in England and Wales, and then in Vermont. W. Edwards Deming, considered by many to be the father of quality improvement in American manufacturing, became famous for using statistical process controls to reduce shoddy workmanship along Japanese assembly lines after World War II.

WHAT WE DID

In 2014, fellow AMWA member Ruwaida Vakil, MS, and I (DH) carried out our first survey regarding practices related to writing NAs. We used SurveyMonkey and limited the instrument to 10 questions. We asked respondents to tell us how long they had been writing NAs, what sources of evidence they used to assess practice gaps, and how they presented the evidence.

Best Practices for Writing and Editing CME Needs Assessments: 2014 and 2015 Results From Surveys of Practitioners

By Don Harting, MA, ELS, CHCP, and Nathalie Turner, MS, ELS

CME Specialist, MCM Education, Newtown, PA, and President, Harting Communications LLC, Downingtown, PA
Senior Grant Developer, Medscape Education, Seattle, WA

Figure 1. Continuing education cycle.
AMWA and the Alliance both helped us promote the survey by providing a link to their members via email and social media. The survey opened September 3, 2014, and closed September 19, 2014. Raw survey results were promised to everyone who completed the questionnaire. We received 109 responses; 6 were from people who had never written an NA. The adjusted sample size was 103. A few questions allowed respondents to briefly elaborate on their answers. We supplemented these quantitative data with qualitative data from a virtual focus group via Google Hangouts and a live focus group over dinner at a restaurant in Newtown, Pennsylvania.

In 2015, both authors (DH and NT) carried out the second survey. We again used the free version of SurveyMonkey and limited the instrument to 10 questions: 5 from the initial survey to track trends and 5 new ones to attract repeat participants and incorporate additional ideas. AMWA helped us promote this survey to members, but the Alliance did not. However, we did receive promotional support from the Mid-Atlantic Alliance for CME (MAACME), which encouraged members to participate. The survey opened September 13, 2015, and closed October 12, 2015. Raw results were again promised to participants. We received 67 responses, from which we subtracted 5, from people who had never written an NA, leaving an adjusted sample size of 62. We supplemented these survey data with telephone interviews conducted by 3 volunteers. A third survey is planned for September 2016.

WHAT WE FOUND

Year 1 results were presented in a poster at AMWAs 2015 national meeting in Texas. In brief, the results from Year 1 indicated that the majority of respondents had been writing NAs for 5 years or more, followed a template provided by the client or their employer, included at least 1 chart or table, and considered a review of the medical literature to be the most essential type of evidence for inclusion.

In Year 2, approximately two thirds of respondents (68%) had written their first NA more than 5 years previously. About half (47%) told us that in the previous 6 months they had written NAs as a staff employee. Approximately one third (34%) told us they were freelances during that period. A medical literature review was again the most common response (69%) to the question asking respondents for the type of data their clients or employers considered essential to include in a first-rate NA (Figure 2).

In 2014, respondents told us they used charts or tables to show alignment of gaps, objectives, and outcomes. In 2015, respondents indicated that the most frequent column headings for these charts were (in descending order) “Learning Objective,” “Practice Gap,” and “Desired Outcome,” though many variations on these terms were used. Professional experience told us that including perspectives from patients in NAs is becoming more common, so we included a new question on this topic as a way to set a baseline for future measurement. Figure 3 shows responses to this question.

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whether they agreed with the statement “PI-CME methodologies are changing the way I write my NAs,” only 21% agreed.

When writing NAs to justify education for physicians and nurses, medical writers often inquire about barriers to effective practice. We asked a similar question. When respondents ranked a list of barriers in terms of their importance to professional practice, “clinical practice guidelines out of date or do not exist” received the top score of 7.1 on a scale of 1 (low) to 10 (high). “Not enough lead time to do adequate research” came in a close second with a score of 7.0. “Few published data on topic” came in third at 6.3 (Figure 4).

**WHAT IT MEANS**

We have distilled key information from both surveys into a set of 3 “recipes” for quality needs assessments (Box 2). These recipes differ according to the ingredients they contain, as well as the time and money needed to produce them. In addition, we would like to note that the lack of up-to-date practice guidelines underscores the importance of CME, and, by extension, the work of all medical writers who develop programs aimed at helping clinicians stay abreast of changes in their specialties. Despite PI-CME’s origin as a pilot project of the American Medical Association’s Division of Continuing Professional Development, its relevance with respect to how NAs are written may be waning in favor of QI-CME, with its closer links to manufacturing. This, along with the rise of managed care in the 1970s and the current federal mandate in favor of electronic health records, could be interpreted as one more sign of physicians’ lost professional autonomy.10 The patient’s perspective has gained prominence in CME, but whether this prominence grows or shrinks remains to be seen. Clearly, if we wish to use best practices when designing a chart to show alignment between key program components, our charts must have the column headings described above. Finally, survey respondents have told us 2 years in a row that the medical literature review remains the single most important type of evidence. Unless some other type jumps to the top of the list in our next annual survey, it seems clear that training programs aimed at equipping future NA writers with basic skills should include instruction on how to carry out a first-rate review of the medical literature. Since needs assessments are also an important part of publication planning, this skill could be beneficial to other types of medical writers as well.

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

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**Box 1. PI-CME and QI-CME**

Accepted by the American Medical Association (AMA) in 2004 as an approved learning format, PI-CME activities are defined by the AMA as “a process by which evidence-based performance measures and quality improvement (QI) interventions are used to help physicians identify patient care areas for improvement and change their performance.”

PI-CME consists of 3 stages: 1) comparing one’s current practice against recognized, evidence-based standards and assessing one’s current performance to identify performance gaps and discover opportunities for improvement; 2) developing and implementing a practice-improvement plan; and 3) reassessing one’s practice to evaluate the effects of the improvement plan.

QI-CME is defined as “a systematic, formal approach to the analysis of practice performance and efforts to improve performance.” QI-CME is designed to reveal clinicians’ practice gaps as determined by quality measures and offer a solution, through education intervention, to meet their individual educational needs.

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**Figure 4.** Respondents’ mean ratings of relative importance of barriers to professional practice. N=60.
References


Box 2. Recipes for Quality Needs Assessments

Here is a list of ingredients to include in needs assessments produced to support requests for commercial funding of continuing medical education. The “better” and “deluxe” recipes assume more resources are available for production. The list was developed based on 2 years of survey data.

STANDARD Needs Assessment*
1. Medical literature review
2. Practitioner survey
3. Reference to clinical practice guidelines
4. Key opinion leader interview(s)
5. Alignment chart with columns labeled
   • “Learning Objective”
   • “Practice Gap”
   • “Desired Outcome”

BETTER Needs Assessment
6. Perspective from a patient or patient advocacy group regarding patient-level gaps
7. Text or chart showing outcomes data*
8. Evaluation reports from participants in previous activities**

DELUXE Needs Assessment
9. Reference(s) to national health care quality standards ***
10. Evidence of change measured against a validated quality benchmark***

* Recipes are cumulative.
** Some practitioners consider these to be part of a standard NA.
*** Published by National Quality Forum, Agency for Healthcare Research and Quality, Patient-Centered Outcomes Research Institute, or similar agency.

References


Biosimilars continued from page 103

In my previous President’s column, I described the results of the survey of medical communicators that was conducted as part of AMWA’s Strategic Planning Initiative. One result was that many respondents cited “advanced medical writing skills” as an area in which they wanted more education.

In response to this finding, AMWA’s Education Department created an Advanced Writing Skills Advisory Group to find out what sort of advanced skills AMWA’s mid-career and advanced-level members are interested in learning. This group, chaired by Cindy Hamilton, an AMWA past president and long-time educator, was charged with identifying evidence-based educational topics for medical communicators in the middle or advanced stages of their career (defined as 6 or more years of experience).

Rather than conducting a gap analysis of AMWA’s existing educational materials (which has been done several times before), the group developed a research plan to collect information from stakeholders about advanced topics that might be of particular interest. The first step of this plan involved interviewing 23 hiring managers who supervise medical writers in 4 types of settings: pharmaceutical, medical device, and biotechnology (collectively labeled pharma) companies that prepare regulatory documents; contract research organizations that prepare regulatory documents; pharma companies that prepare nonregulatory documents (eg, manuscripts, abstracts, posters); and medical communication companies that prepare nonregulatory documents.

In 15-minute structured telephone interviews, hiring managers were asked to discuss the knowledge, skills, and abilities (KSAs) involved in their medical writers’ work, in terms of both the KSAs their medical writers use most often and those in which they need further education. The KSAs were based on the 5-domain model that AMWA’s Certification Commission developed when it was gathering information to inform the design of the MWC certification exam. The 5 domains are Gathering (determining a document’s purpose, target audience, and output type); Evaluating (critically reviewing, fact checking, and identifying inconsistencies in gathered information); Organizing (eg, outlining, using templates, identifying references); Interpreting (which includes understanding the content of the document and deriving key messages, implications, and clinical relevance); and Presenting (writing the document to adhere to standardized formats, guidelines, and ethical standards).

The hiring managers’ responses indicated that all 5 domains are frequently used by the medical communicators they supervise: On a 5-point scale indicating frequency of use (1 representing no use and 5 representing daily use), average scores for all 5 domains ranged from 4.3 to 4.8. Responses were also similar across domains regarding the need for education. On a 5-point scale (1 indicating no need and 5 indicating very strong need), average responses ranged from 2.6 to 2.9 for the 5 domains, indicating a moderate need for education in each domain. Responses did not differ substantially among hiring managers from different work settings or between producers of regulatory and nonregulatory documents.

After rating the need for education in each domain, respondents were asked to consider their highest-rated domain and to identify specific topics in that domain that they believed merited the development of new educational programs. Several specific areas were mentioned by multiple respondents:

- Critical thinking—the ability to interpret information rather than merely repeating it and to build logical, fact-based arguments
- Soft skills—teamwork, negotiation (for example, of timelines and content), conflict resolution, working with higher-ranking members of the organization, and time tracking/management
The Education Committee has asked the AMWA staff to begin searching for subject matter experts who could help AMWA to develop new educational materials in the advanced topics that were found to be of greatest interest, specifically critical thinking, guidelines, soft skills, visual presentation, and pharmacokinetics.

It should be noted that the Advanced Writing Skills Advisory Group’s mandate was to focus solely on subject matter. Methods of delivery (e.g., workshops, open sessions, webinars, online interactive learning) will be considered later, after subject matter experts are identified, so that the best delivery method can be chosen for each topic as educational materials are developed.

I would like to thank Cindy Hamilton, Susan Aiello, Melissa Bogen, and Kathy Spiegel, as well as Administrator of Education Kristina Wasson-Blader and staff liaison Lauren Ero, for the hard work they have done on this important project, which will help AMWA to be of value to its members in every stage of their careers.

2016 Swanberg Award: Flo Witte, PhD, ELS

By Bart J. Harvey, MD, PhD / Chair, 2016 Swanberg Awards Committee

The Harold Swanberg Distinguished Service Award is presented each year to “an active member who has made distinguished contributions to medical communication or rendered unusual and distinguished services to the medical profession.” The 2016 award will be presented at the annual conference in Denver, Colorado, to Flo Witte, PhD, ELS.

Like many of her AMWA friends, Flo came to the field of medical editing via a circuitous route. She began her university experience as a premed student at the University of Southern Mississippi but quickly realized that her strengths were in the humanities, not the sciences. As a result, she switched her major to music, with a double emphasis in piano and voice. However, after several surgical procedures for chronic tendinitis in her hands, Flo had to give up the piano and change her major, although she did continue to study voice at USM for several years. For a new major, Flo chose English and went on to earn not only a BA, but also an MA in English and secondary education, with a focus on Southern literature.

While working on her MA in English, Flo was required to take a foreign language. Although she had taken two years of French in high school, she didn’t especially like it, so she instead chose German because of her family background. She fell in love not only with the German language but with languages in general. While earning an MS in German, she also took several semesters of courses in Spanish, Italian, Latin, Old Norse, and Egyptian hieroglyphics!

In 1978, after completing her MS in German at USM, she applied for and was awarded a Fulbright Scholarship. That award allowed her to spend a year in Germany studying German language and literature at the University of Bonn while living in Cologne and being a frequent passenger on the streetcar line connecting the 2 cities. During weekends and on university holidays (Flo enjoyed the fact that there were many more holidays in Germany than in the United States!), she traveled as much as she could and worked on perfecting her accent and learning as much of the language as possible.

Upon returning to the United States after her Fulbright year, Flo applied to 3 universities for fellowship money so that she could pursue her goal of pursuing a PhD in German. The University of Kentucky offered her the largest stipend, so she moved to Kentucky in 1980. Unfortunately, recognizing that there were not enough jobs to go around for all of the German PhDs in the United States, she instead completed an MA in international marketing in 1983 through the Patterson School at the University of Kentucky.

Flo has always been a teacher; she believes that teaching is her gift. From 1974 through 1977, she taught English and German at Watkins High School in Laurel, Mississippi. Between
1980 and 1990 she taught classes in German and English at the University of Kentucky as a part-time instructor—the operative word being “part-time.” She was always given the assignments that no one else wanted, teaching night courses in German I and II and early morning courses in German for Reading Knowledge for graduate students who had to fulfill a language requirement. She taught a full-time course load but was paid a part-time salary. As a result, she had to do other things to support her “teaching habit,” including selling vacuum cleaners and life insurance and working part-time in a paint store as a data entry clerk.

In 1990 Flo heard that the Department of Surgery at the University of Kentucky had an opening for a medical editor. At that point she had no idea what a medical editor did, but she knew that she had skills in writing, so she applied and was hired. A coworker told her about AMWA, so Flo became an AMWA member as quickly as she could and attended her first national conference in 1991.

After she learned about medical writing and editing, she realized that everything she had done up to that time came together and was applicable to her new career—her music background gave her an eye for detail, her studies in English and German taught her about the grammar and structure of the language, her studies in German made her more sympathetic to writers whose first language wasn’t English, and her business degree has helped her in organizing and managing her freelance business. However, she felt that something was still lacking in her educational experience, so she applied to and was accepted into the PhD program in health communication at the University of Kentucky and after 11 long years of taking 1 or 2 courses per semester and writing her dissertation while working full-time, in 2007 she finally earned the title of Dr Witte. Flo believes that the advanced degree has gained her additional respect from clients and has opened some doors to opportunities that she would otherwise not have enjoyed.

As an AMWA member, Flo has made many varied contributions. She has served as chapter delegate, conference organizer, and president for the Ohio Valley Chapter. At the national level she has been a multi-time administrator—of education, awards, and publications; the annual conference workshop coordinator (2001–2002); and AMWA’s president (2003–2004). In recognition of her contributions, Flo was awarded an AMWA Fellowship. With friend and colleague Nancy Taylor, Flo co-edited AMWA’s *Essays for Biomedical Communicators*, Volume 2, in 1999 and then the 2nd edition of Volume 1 in 2001. She also created 2 of AMWA’s self-study modules: “Basic Grammar and Usage for Biomedical Communicators” and “Sentence Structure and Patterns.” In addition, she provided valuable assistance in the development of other self-study modules developed by AMWA.

Flo also led networking breakfasts and roundtables and served on the panel that was considering the creation of a certification program. Although her many AMWA contributions are widely acknowledged and appreciated, arguably it has been in teaching that Flo has made her greatest contribution to AMWA. Flo taught her first workshop in 1993 at the annual conference in Atlanta and taught at 20 consecutive conferences before recently missing a year. At many annual conferences she taught not only 2 workshops but sometimes 3 and, occasionally, 4—and Flo did them all with aplomb. Not only has Flo been the teacher of a great many workshops, but she has also been the creator of at least 4 of them. First, she co-created an advanced grammar workshop with Nancy Taylor, and when they found that the advanced students didn’t know basic grammar, she and Nancy created a basic grammar workshop. That workshop eventually was broken into 2 parts: Basic Grammar I and Basic Grammar II & Usage. Next, Flo created another advanced grammar course, this one called Rhetorical Grammar, which has remained a popular choice. Then in 2009, Flo and Nancy created Diagramming for Clarity and Style. In addition to creating these courses, Flo has taught other workshops to great acclaim for years: Proofreading, Sentence Structure & Patterns, Punctuation for Clarity & Style, Writing Abstracts, Essentials of Copyediting, Microediting, Effective Paragraphing, and once, in the early years, something called Techniques and Sequence in the Editorial Process. Flo was one of AMWA’s first workshop leaders to teach onsite workshops for companies and educational programs as varied as Amgen, Eli Lilly, 3M, Edwards Lifesciences, University of Wisconsin, Roche, and Regeneron. And the numbers are mind-boggling: Flo has taught 55 workshops at annual conferences, 69 workshops at various chapter conferences, and 59 workshops onsite—a total of more than 180 workshops! In recognition of her teaching contributions and excellence, Flo was the 1999 recipient of AMWA’s Golden Apple Award.

Flo has also been a valuable contributor to the *AMWA Journal*. In addition to serving as a reviewer, peer reviewer, and proofreader, she has also written several articles that have been published in the journal:

- Seminal Moments in AMWA History: 70 Years of Medical Communication Excellence. 2010;25(4):167. (with Ross and Thompson)
- In Memoriam tributes to Edie Schwager and Guy Whitehead.
Wanted Editor-in-Chief

AMWA is seeking an Editor-in-Chief to provide vision and strategy for the AMWA Journal. The Editor-in-Chief creates content plans, solicits manuscripts, and oversees all contributors and volunteers for AMWA’s quarterly, peer-reviewed journal.

For more information please contact rachel@amwa.org.

But Flo’s contributions and accomplishments have not been limited to AMWA. As noted above, she served as director of the Publications Office of the Department of Surgery at the University of Kentucky and as director of the Scientific Editing Department at St. Jude Children’s Research Hospital in Memphis. In 2004, she established her freelance business, Bluegrass Editorial Services Team, LLC. She was an active member of the Council of Science Editors, for which she also taught workshops, and she is a board-certified editor in the life sciences (ELS). For several years Flo served as a reviewer for Health Communication. She has also written the following publications in the medical literature:


Flo Witte’s numerous and diverse contributions to medical communication and to the medical profession make her a very impressive and deserving recipient of this year’s Harold Swanberg Award.
Join us in the Mile-High City for the 2016 AMWA conference. Our motto for this year promises "trends and opportunities for medical communicators," so let’s break that down.

**Trends**

**Jargon, Social Media, and Career.** For starters, the presenters at our general sessions will offer a range of perspectives on medical communications. We open the conference with the Alvarez Award Address (2:00 PM, October 6) by Roxanne Khamsi, chief news editor of *Nature Medicine*. Ms Khamsi will discuss new findings on the use of jargon in the medical literature. For the McGovern Award Address (8:30 AM, October 8), Dr Kevin Pho, physician and social media thought leader, will discuss how social media changes the patient-provider relationship. Finally, at the Sablack Luncheon (12:30 PM, October 8), AMWA’s own Flo Witte, PhD, ELS, will accept the Swanberg Award and discuss the trends and opportunities she’s experienced over her career as a medical writer and editor.

**Dossiers, China, and More Career.** Roundtables are not new to AMWA. But this year, they are included in the conference fee. We’re hosting one giant session of 50 roundtables (12:15 PM, October 7) over lunch—and you have to eat lunch. Stay abreast of various trends and topics including *Email Tones in Science and Medical Communication, HTAs & AMCP Dossiers: Find Out What They Are...*, *Using Document Design to Get Your Message Across, Structural Racism and the Unfulfilled Promises of Personalized Medicine,* and *Comparisons of Medical Writing in the United States and China,* to name a few. Register today to join the conversations.

**Interviewing, eCTD, and Freelance and Industry Career.** Also included in the price of admission are 50 open educational sessions. Sixty-minute, 90-minute, and 2-hour sessions (4:00 PM, October 6, all day October 7, all morning October 8) will cover myriad topics including *In-Depth Interview Techniques and Best Practices, Create eCTD Compliant Regulatory Documents and Protect Your Professional Reputation, Writing Health Content That Moves People, How to Conduct an Effective Comment Resolution Meeting,* and *Build Your Freelance Business with a Strong Online Presence.* Company representatives will also be sharing hiring and medical writing management practices. Here’s the best news: you don’t have to preregister to attend.

**Scholars Among Us.** Those who study how medical communicators work elevate the field for all of us. Lucky for AMWA, 9 groups of investigators are sharing their findings or lessons learned in poster form. Stop by the Resource Hall (8:00 AM, October 7) and visit with the emerging thought leaders within our ranks. (See online version of journal at www.amwa.org/journal for poster abstracts).

**Preconference Intensives.** For the first time, AMWA is offering a full-day Writing Clinic (9:00 AM, October 5) for scientists transitioning from bench to laptop and for editors who don’t consider themselves writers. If you have never taken a writing class, you are not alone. This clinic compresses a full semester of writing exercises into a fun and no-pressure environment. Another opportunity on Wednesday is One-on-One Mentoring: Taxonomic Analysis and Revision of Medical Writing, with individual meetings and emailed revisions of writing samples.

**Opportunities**

**Testing, Testing.** What better way to prove your prowess as a medical writer than by proving your prowess as a medical writer? At the AMWA conference each year, you have an opportunity to take AMWA’s very own Medical Writer Certification (MWC) exam. If you’re an editor, you can prove your prowess as an editor by taking the certification exam from the Board of Editors in the Life Sciences (BELS) at the AMWA conference too. If you’re both a writer and an editor, though,
Keep pace with the field. Develop your skills. Build your network.

Look out, Denver: AMWA’s coming.

Many thanks to the Annual Conference Committee members for bringing you this year’s program:

Yeshi Mikyas, PhD, ELS, CMPP
2016 Conference Administrator
MedImmune, Gaithersburg, MD

Hope Lafferty, AM, ELS
Conference Administrator-Elect
Hope Lafferty Communications, Nashville, TN

Tara Ann Cartwright, PhD
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Julie Gelderloos, PhD
Gelderloos Medical Writing, LLC, Boulder, CO

Susan Daniels, PhD
Houston Methodist Hospital, Houston, TX

Sharmila Natarajan, PhD
MedImmune, Gaithersburg, MD

Becky Phillips
Education Manager, AMWA, Rockville, MD

you will have to choose. Both exams are offered around the same time (October 6 in the morning). Consider this a good thing. The overachievers in our group might opt to take these rigorous exams back-to-back, and I don’t think AMWA carries enough insurance to cover the fallout. Deadlines for applying to take the test are well before the conference, however, so if you have missed this year’s deadlines (August 31 for MWC, September 14 for BELS), keep an eye out for future opportunities.

**Friends and Followers.** A new staple for AMWA is Speed Networking. By popular demand, we’re offering 2 sessions this year (4:00 PM, October 6; 11:00 AM, October 7). You don’t have to sign up in advance, but make sure you show up early. These sessions are always packed and space is limited.

**High Tea with Exhibitors.** Maybe it’s the altitude, maybe I’m lowbrow, but who cares about coffee when you can have high tea? In Denver no less! Stroll around the Resource Hall and visit with the exhibitors (3:00 PM, October 7). Refreshing.

**AMWA Workshops.** Credit workshops are the foundation of the AMWA educational program, but this year the workshops are also an opportunity in themselves. We’ve scheduled all the credit workshops so they don’t compete with any open educational session. So you no longer have to choose between working on your certificate and learning something cool about the field.

**But Wait, There’s More**
So much more. Whether a trend, an opportunity, or something just as delightful, the 2016 AMWA conference is designed for medical communicators at every stage of their careers and across industries.
As happens so often with statistics, fairly simple concepts are made difficult by the language that is used to describe them. This is also the case with the topic of this Stats Refresher: linear regression. (While linear regression is straightforward, it has so many features that I will need to split the description into 2 parts; the second part will be in the December issue of the *AMWA Journal*.)

The word *linear* all but gives it away; the word *regression* causes the confusion. (I will try to clarify it later.) Linear regression is used when we are looking for a way to describe the relationship between 2 variables. One variable is the “independent variable”—also referred to sometimes as the “predictor variable” or “explanatory variable”—that we believe determines the value of the other variable, which is therefore called the “dependent variable” or “response” or “outcome variable.” It is very important that we are clear on which one is the “cause” = “independent variable” and which is the “effect” = “dependent variable”; the relationship is unidirectional.

Let’s do a little experiment. All we need is a microwave oven, 15 identical glasses of ice-cold water (32 degrees Fahrenheit), and a thermometer to measure temperature. We set the microwave on 100 watts. The idea is that we put one of the water glasses into the microwave, let it heat for a few seconds, and measure the temperature as soon as the microwave stops. We note our results in a table (Table 1) and create a graph (Figure 1).

Looking at the data, we get the idea that the data points seem to wobble around a straight line. We could take a ruler and try to draw a line that fits the data points (Figure 2). This line would try to be close to all points. It would be a compromise to best represent all data points. One could also say that the data points are made to “regress” to the line that represents them best (quite a wobbly way of trying to account for the word “regression”).

Relying on our eyes and a ruler, we realize that there are several potential “best fits.” If we want to know it precisely, we need to do a better job of drawing the line that best fits all the data points. (I will try to illustrate this better later.)

**Table 1.** Results of the experiment. A glass of ice-cold water is put into a microwave. The microwave is set to 100 watts and is set to deliver power for 1 to 30 seconds.

<table>
<thead>
<tr>
<th>Time in microwave, in seconds</th>
<th>Temperature of water, in degrees Fahrenheit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>41</td>
</tr>
<tr>
<td>3</td>
<td>52</td>
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<tr>
<td>5</td>
<td>54</td>
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<td>61</td>
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<td>100</td>
</tr>
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<td>29</td>
<td>104</td>
</tr>
<tr>
<td>30</td>
<td>118</td>
</tr>
</tbody>
</table>
we need to go beyond visual inspection. There are simple mathematical methods to determine the line that actually is the best fit for our data.

Nevertheless, we have made an important conceptual step. By drawing a straight line, we have identified the relationship between our variables (time in microwave, temperature of water) as linear. In other words: we have developed a model about the relationship between the 2 variables. Our model assumes that the relationship between the 2 variables is linear. This means that for any value of X (time in microwave, independent variable) there is exactly 1 corresponding value of Y (water temperature, dependent variable).

In a linear relationship, the value of X (time in microwave) predicts or determines the value of Y (temperature of water). As the line goes from lower left to upper right corner, we also see that the higher the value of X, the longer the time in the microwave, the higher the temperature.

Lines like the one we have drawn have a simple mathematical description:

\[ Y = a + (b \cdot X) \] (Y equals a plus b times X)

In this formula, a represents the “intercept”; this is the value of Y when X = 0. Furthermore b represents the “slope”—the steepness of the line. A line without a slope, ie, when b = 0, is a horizontal line.

When we use one of the readily available software packages such as Excel or GraphPad Prism, we can have the program calculate the regression line (Figure 3) and provide us with the formula for our regression.

\[ Y = 41.837 + (2.1788 \cdot X) \]

Water temperature (Y) = 41.837 (intercept) + (2.1788 [slope] • time in microwave [X])

Now what can we do with this knowledge? Having a formula provides us with a range of possibilities. For example, we can now calculate the water temperature for a time that we have not measured. In our experiment we did not measure the water temperature after 15 seconds in the microwave. Now with the formula we can simply calculate it by entering 15 in the appropriate place in the equation.

\[ \text{Water temperature (after 15 seconds)} = 41.837 + (2.1788 \cdot 15) = 74.519 \]

Having the regression formula also allows us to test for significance, ie, do hypothesis testing. Although simple, this is beyond this short paper.

For a comprehensive description of a linear regression we would also need to show 2 additional characteristics. In the graph showing the linear regression we would have to include the 95% confidence intervals for the regression line and we should give the reader some idea on the ‘goodness of fit’ of our regression line and the data points.

As we saw when we tried to visually fit the straight line to the data points, there are many potential fits. The line fitted to the data is an estimate of the relation between the variables. Because our data are neither perfect, nor complete, we should consider the uncertainty of the estimated line. By showing the 95% confidence interval for the regression line, we can say that this interval includes the true regression line with 95% probability (Figure 4).

Many software programs provide not only the formula for the regression line but they also provide an indicator for the goodness of fit of the regression line with the data, the so called \( R^2 \) value or coefficient of determination. The \( R^2 \) value is always
between 0 and 1. A value of 0 indicates that there is no fit of the data and the regression line and 1 indicates a perfect fit where all data points are on the line. In our example the $R^2$ was 0.948. This means that our regression model explains 94.8% of the variance of the data points around the regression line. This is an extremely good fit. The remaining 5.2% of the variance are caused by other factors such as measurement errors, machine variation, etc.

This was only a short glimpse into the many useful features of linear regression. The technique is so powerful and convincing in its apparent simplicity that it lends itself to misinterpretation and abuse (for an excellent description of the pitfalls see the chapters in T. Lang’s and M. Secic’s book). Therefore medical writers need to be very careful when they describe linear regressions. In particular, they should be clear on what is thought to be the cause and what is seen as the effect. There must be a plausible medical or biological rationale for the 2 variables investigated to be in a “cause and effect” relationship. If there is no plausible rationale, results of linear regression analysis become meaningless and arbitrary because items are being put in a relationship that truly have nothing to do with each other. Also simple linear regression considers only 2 variables. There could, however, be additional factors influencing the relationship of the 2 variables that we are not aware of. Mathematics will always provide us with a regression line; whether it truly represents reality needs to be judged based on expertise and knowledge.

For those who have become interested in linear regression, reading any one or all of the resources is highly recommended.

**Assumptions for Linear Regression**

a) **The linear model is correct.**

Clearly not all relationships are linear; in many instances the relationship between 2 variables is much more appropriately depicted by a curved line, in which case linear regression is inappropriate.

b) **The scatter of the data around the line is normally distributed.**

Linear regression assumes that the scatter around the line is normally distributed. This can be easily tested by plotting all the distances from the line and visually inspecting them. It should look like a bell-shaped curve. There are also mathematical ways to test this.

c) **The variability of the data points around the line is the same in the entire range.**

This means that the standard deviation around the best-fit line is the same along the entire curve.

d) **Data points must be independent.**

It must be due to chance whether a particular data point is above or below the line. The location of one data point must not influence the location of another data point.

**RESOURCES**


What are some strategies you use to maintain work/life balance and avoid burnout?

This is a tough question for me because I’m a recovering workaholic. Yes, step 1 is admitting you have a problem. When I started my freelance business many years ago, I worked 3 years straight before I realized I hadn’t taken a vacation or a day off. Actually, it was my wife who pointed it out. But in my defense, we didn’t miss any mortgage payments, either, which was especially impressive during those early years.

I’ve always struggled with work/life balance—it’s a work in progress. But before you judge me too harshly, I think that I have had a much better work/life balance than many men I know who don’t work for themselves. I started my freelance business when my older daughter was 4 years old and my younger daughter was 11 months. I set up a playpen (remember those?) right in the doorway of my home office because it was barely large enough for me, my desk, and my computer. My breaks were my youngest daughter’s feedings. I delayed teleconferences when either girl was inconsolable or in dire need of a book being read. Deadlines deferred to diaper changes, billing to Barbie Dolls.

As my girls grew older and were in school, I am proud to say I didn’t miss a thing they had going on during or after school. I simply told clients I had a meeting and scheduled around it. By their late teens, if you’d asked them what it was like having their dad around all the time they would have responded, “He was always working.” That’s what it seemed like to them at the time. But now that they’re working adults and one has a daughter of her own, they both realize how good I had it. Alas, neither of them works for herself—yet.

My wife has been a great force behind what little work/life balance I do have. The evil eyes through the glass door of my office at 6:30 PM. The plane tickets tossed on my desk with the directive to “put this on [my] calendar.” She’s had a lot of patience with me over the years.

But when I do go on vacation, I go on vacation. No work calls. No email. No talking about work. No thinking about work. Complete decompression. The day my clients think is my first day of vacation is always 1 to 2 business days before my actual first day of vacation, because craziness comes out of the woodwork the moment clients realize you’re leaving “tomorrow.” And I always give myself a day at home after a vacation to reconnect with reality. So if I get home from vacation on Sunday, I tell clients my first day back in the office is Tuesday.

To sum it all up, my strategies are mostly lame but I do have some semblance of work/life balance. I recommend:

• Keep your children in sight because they sure don’t want you to work.
• Make time during the day for family because most people can’t, and clients have no idea what you’re doing when you tell them you “have a meeting.”
• Encourage your partner or friends to make plans and include you and make it impossible for you to back out.
• DO NOT WORK ON VACATION—not even a little, not even once.
• Give yourself a “bridge day” before vacation to start decompressing and another “bridge day” after vacation to mentally come back.

—Brian Bass

After working so many hours during the first 3 years of starting my own business, and ending up with mononucleosis, I made a few self-preserving decisions, to which I have adhered about 90%.

1. I vowed to take 4 to 6 weeks’ vacation every year. Not necessarily consecutive weeks, but a few times I went to Europe for 5 weeks and once to India for 2 months. Other times, I took time off in 2-week increments or a series of long weekends.
2. I went to a health spa for at least 2 weeks each year. There are many throughout the United States and I’ve
been to several. At present my favorite is The Oaks at Ojai in California because I can drive there and it is less expensive than some of the others, such as Canyon Ranch or Rancho LaPuerta. Health-spa vacations are the absolute best, IMO—better than bicycling in Ireland, going to Europe, or going to Hawaii! Over the last several years, I have attended yoga retreats rather than health spas, which are almost as good and less expensive; also, it’s easy to sign up for 3-day weekends of restorative or other yoga practice and return home refreshed.

3. After about a decade, I expanded my career activities so that the “other side” of my brain would be activated more, not so much focus on research, writing, critique, editing, etc. Examples: I became a therapeutic body worker, certified in shiatsu as well as in acupressure, and treated clients 1 day a week for about 10 years. While in India, I spent a month in an ashram, doing a 300-hour intensive yoga teacher-training program to become certified as a yoga instructor. Today I give classes only as a substitute or for private clients. Finally, I had studied Tarot cards for decades as a hobby but became a professional reader about 3 years ago—not so much for the extra income but because it is relaxing, connects me with people, and is fun. I give readings for weekend fundraising events, parties, and exhibition shows, and for private clients. None of this interferes with medical writing because it is all quite intermittent and I can schedule it around my business.

In my opinion, these actions are precisely why I have been able stay so long in this high-learning-curve industry, writing journal articles, patient education, sales training, CSRs and other regulatory documents, editorial review of complex books and papers, etc. The contrast between my career in medical communications and these other activities is dramatic! I strongly recommend any or all of the above, or immersing oneself in playing a musical instrument or creating art if that’s your thing. Just as long as it is something completely “other.”

—Cathryn D. Evans

Well, as many of you know I didn’t always do such a good job with that and several years ago I did burn out. I was lucky enough to be able to take a 3-month sabbatical that helped immensely, as did a good therapist with experience working with clients who had work/life balance issues. That was 4 years ago and I’m happy to say that I’m much better. Here are some things I learned:

- **Take careful control of your work schedule.** Know how many days it will take you to complete an assignment and build in a day or two for the unexpected. Keep a spreadsheet. If you don’t see any open days, then you don’t have the bandwidth for more projects.
- **Combine work/personal calendars.** I block off 90 minutes a day for the gym. Every day.
- **Work in blocks of time.** I also block off entire afternoons or entire mornings for work rather than having my concentration split with phone calls scattered throughout the day.
- **Work a regular schedule.** I am at my desk by 6:30 AM and typically leave my desk around 5. I no longer work after dinner (which I did for many years). I maintain a very structured day: Work, breakfast, work, gym, lunch, work, nap, work, end of day.
- **Have a dedicated place for work.** If you are a professional, you need an office, preferably with a door you can close. Don’t have the room? Put a screen around your desk when the day ends so you don’t have to see the “office.”
- **Limit weekend work.** I used to work nearly every weekend. I now work very few weekends and if I do go to my computer, it’s mainly to catch up on emails and organize the coming week, rather than writing.
- **Develop outside friendships and hobbies.** If you don’t have any reason to stop working, you won’t. So join a book club, start a group on meetup.com, or get a dog. Make sure your life outside work is just as engaging as your work life.
- **Take vacations.** I plan at least 2 big vacations a year of 1 or 2 weeks and several long weekends. I make sure all my projects are due before my vacations start and that clients are clear about the fact that I won’t be starting anything new until I return.
- **Set realistic financial goals and track your progress.** If your goal is to earn $5,000 a month, then once you’ve booked that amount of work, your month is full and the extra time is yours to do with what you want.

—Debra Gordon
What tools and techniques do you use to manage your time (including meeting deadlines and avoiding distractions)?

I keep myself on track and avoid wasting time with an old-fashioned hand-written timesheet and by limiting email and social media. I track all of my time (client and administrative) on a notepad by my desk. At the end of each day, I transfer the information to a weekly timesheet and to the relevant client files. You can also use a computer program to do this. Tracking your time helps you focus on getting your work done. If you were in the office for 8 hours but only have 6 hours on your timesheet, for example, you’ll realize that you spent the other 2 hours playing a computer game or talking on the phone to friends or family.

To avoid distractions, I keep my email turned off for most of the day and limit social media to once or twice a day. About every hour, I open my email to answer client and other high-priority emails. I answer the other emails about twice a day. I usually check my social media in late afternoon, after I’ve gotten my priority work for the day done.

—Lori De Milto

When it comes to meeting deadlines and managing distractions, I find it’s best to have an on/off switch instead of a rheostat. Clients are counting on me to deliver and one of the 3 cardinal sins of freelancing is to miss a deadline (the other 2 are missing the target and missing the budget).

Each night before I leave my office I make a list of the projects that absolutely, positively, must be done tomorrow (the mission). Then I add to that list the things that are important to do tomorrow (not mission-critical), then I list the things I’d like to do tomorrow (not even part of the mission). Then, when I come in the next morning, I turn the switch on and nothing gets in my way of completing the mission-critical tasks. Everything else can fall by the wayside if it has to.

When I’m tackling mission-critical tasks I’ll close Outlook to eliminate email distractions, and a few times I’ve even unplugged my office phone and turned off my cell phone. I won’t hesitate to reschedule a personal appointment if it gets in the way. Unfortunately for me (see my response to work/life balance), lunch is expendable if it jeopardizes a deadline. Frankly, lunch is expendable even if it just means breaking my train of thought when I’m on a roll. I never use my computer to “search the net” for anything that isn’t work related, so that eliminates a distraction that I know some people have.

—Brian Bass

Although I do not charge by the hour, my invoicing software has a built-in timer. This helps me to not only log the time I spend on a project but also to estimate wasted time. I turn the timer on when I work in the project; if I take a break to check my email or social media, I make sure to pause the timer. Each week I take a look at the actual logged worked hours so that I know how much time I have wasted. I minimize my distractions by running my email software in the background so that it is not on the screen. I usually mute the ringer on my phone so that it does not disturb my train of thought when I am working. My phone service notifies me by email when I get a voicemail so that I do not miss important calls. I use my evenings to check social media. In the more than 9 years that I have been freelancing fulltime, I have not yet missed a client deadline. In fact I usually am done earlier than estimated. Part of that is because I make sure I overestimate the time it will take me to complete the project. I always make sure I allow a day or 2 for any unexpected issues. That way I know that I will meet the deadline. I also make sure I am not working on too many projects at once and always have my calendar out when I am scheduling new projects.

—Ruwaida Vakil

Do you have a question for the Freelance Forum?
Send it to JournalEditor@amwa.org
Dear Oh Dear Reader: “YOU match it up!”
A Tribute to Guy Whitehead’s Heady Guidance

By Mary E. Knatterud, PhD / Editor, Scholarly Manuscripts, Departments of Surgery, Otolaryngology, and Urology, University of Minnesota Medical School, Minneapolis, MN

Those 4 words—“YOU match it up!”—were sardonically yet gently sighed by dear Guy Whitehead, PhD, during both of his locally offered Sentence Structure and Patterns workshops that I sat in on, back in the late ‘80s and early ‘90s, here in our southeastern corner of Minnesota. To this day, when I am editing, those 4 words bubble up in my mind whenever I gleefully delete the reader-unfriendly word respectively, the trigger behind his somewhat weary directive.

And those 4 words once again burst into my consciousness as I read, in a recent issue of the AMWA Journal, of his death earlier this year (on January 14, 2016). I hadn’t heard. Curled up in my screened porch catching up on back issues, I came upon the sad news and almost leaped out of my chair:

I felt a Cleaving in my Mind –
As if my Brain had split –
I tried to match it – Seam by Seam –
But could not make them fit.

I don’t know how many other Emily Dickinson verses feature the verb match, but that one melds with Guy Whitehead’s “YOU match it up!”

Every mindful of the typically overwhelmed reader, Guy knew that the careless deployment of respectively made comprehension more labor-intensive and time-consuming, if not downright impossible. I can still see him, standing with dignity (tinged with exasperation) over his trusty overheads, as he walked us workshop participants through a sentence whose parts the author had failed to clearly match up, and as he then empathetically invoked the in-trouble reader by muttering “YOU match it up!” Left unsaid, of course, was “and good luck to your mental health as you valiantly try to do so.”

I thought of Guy this spring when I came across the following 2 infelicitous examples of respectively in 2 separate, otherwise well-written articles in the normally well-edited New England Journal of Medicine:

Upticks in the incidence of local and regional disease in the late 1970s and early 1980s and again in the late 1990s may reflect the increasing use of sigmoidoscopy and colonoscopy, respectively. (April 28, 2016, p. 1607)

The groups of concern in the lawsuit—Asians and native Hawaiians or other Pacific Islanders, including those of mixed ancestry—account for 56% and 26% of Hawaii’s population, respectively. (May 26, 2016, p. 2004)

In both of the foregoing sentences, the author (or editor) should have done the matching up, so that the reader wouldn’t have to backtrack to figure out what is supposed to go with what.

Guy was a fellow author’s editor, a fellow member of the North Central chapter, a fellow AMWA Fellow, and a fellow PhD in English—and one of my all-time favorite colleagues in our shared subfield of scholarly medical editing. From the day I first met him nearly 3 decades ago, he was an inspiring mentor and a kind friend; already retired by then, he was my dad’s age, and just as tireless and intelligent. I later found out that he was also the father-in-law of one of my most beloved professors of English at the University of Minnesota, Julie Ann Carson, PhD, who deftly supervised one of my Plan B master’s theses (on the then-new topic of linguistic sexism).

Guy was based in Rochester, Minnesota, about a 90-minute drive (in non-icy weather) from my workplace in the Twin Cities, but I often saw him at our regional chapter meetings as well as at umpteen national conferences. In one city somewhere one fall, as I looked over my Punctuation for Clarity and Style workshop notes in a largely deserted area of our hotel, he suddenly emerged from a dim hallway. My startled glance quickly gave way to a smile and a hug. He looked tired (I am sure I did too) but remarked that he no longer had an employer paying his expenses. A few years later, he honored me with an invitation to join him at his “Mayo Clinic table” as he received his amply merited Swanberg Award (in 2004 in St. Louis).

I never earned official AMWA credit for either of his workshops that I took, since they were each presented gratis by him here in Minnesota, but I took away so much from them—including that memorable mantra of his against respectively. He was firmly against any syntactic snarl that disrespectfully derailed readers or that discourteously squandered their time or good will. Thanks to his overt blessing and his handwritten notes, I, too, taught his Sentence Structure and Patterns workshop (from the fall of 2001 through the fall of 2005, ie, from Norfolk through Pittsburgh). I owe him so much.

May he rest in matchless peace, where everything is sagely edited and seamlessly matched up.

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Back to the Future: Reinventing Medical Writing at Merck & Co.

Joan Affleck, MA, MBA, ELS, Executive Director, Head of Medical Writing
Mary McKenna, MS, Director, Medical Writing Business Operations & Service Development, Merck & Co Inc, Rahway, NJ

The opportunity to establish a strong, central medical writing function comprised of professional Medical Writers and Operations staff comes rarely, especially inside the walls of one of the premier biopharmaceutical companies. The medical writing function at Merck & Co. experienced the impact of many recent trends in the industry, from outsourcing all medical writing tasks to distribution of those tasks across therapeutic areas and the in-house clinical staff. Based on those experiences, the company elected to develop a new medical writing team to provide complete end-to-end support for its clinical development pipeline. We describe the challenges faced by the new department and its key customers in accomplishing this change without negative impact on the business of delivering hundreds of protocols and clinical study reports, thousands of patient narratives, and multiple regulatory filings during its first year. Careful strategic planning; dedicated, highly experienced leadership; extensive stakeholder engagement; and corporate support have been essential to the successful launch.

Programmed Narratives: Working Smarter Not Harder

Gia Barss, DVM; Associate Medical Writer, Veristat LLC, Southborough, MA

In this presentation I will describe step by step how our company has implemented an interdepartmental process that allows large numbers of narratives to be created more efficiently and with fewer data errors through the use of programming. We have used this process on narrative projects ranging from 25–1200 narratives. We program the ‘headers’ of the narratives that include the same information for each subject (demographics, medical history, concomitant medication, etc). This information is often painstaking to pull out of listings manually. Through interdepartmental cooperation, we have been able to take on larger projects and complete them on time.

Spotting the Wolf in Sheep’s Clothing: Predatory Open Access Publications

Chandler Wilson Carroll, BA, Baylor Scott and White Health, Temple, TX

As the number of predatory Open Access publications increases, it is important that researchers be able to recognize their practices. And while the literature defining predatory Open Access publications is thorough, few publications give researchers advice on how to recognize them in practice. This presentation provides a varied list of tools to help researchers identify and avoid predatory Open Access publications. Additionally, I discuss Beall’s list of Potential, Possible, or Probable Predatory Scholarly Open-Access Publishers, the Directory of Open Access Journals, and the Eigenfactor Index of Open Access Fees and identify many prominent, stealthy tricks used by predatory Open Access journals, including email and conference invitations. Common sense wisdom on the part of new researchers and their mentors is also detailed. As medical communicators, we must be able to easily recognize these predatory Open Access publications so that we can navigate the research community around them.
Readability of Informed Consent Forms: Requirements and Tools for Success

Jeffrey Cohn, PhD, Kent D. Steinriede, MS, David Meats, BS, inVentiv Health, Ann Arbor, MI

The readability of Informed Consent Forms (ICF) is vital to protecting the rights and safety of clinical trial subjects. Federal regulations (21 CFR 50.20) and the International Conference on Harmonisation Good Clinical Practice (4.8.6), require study information to be understandable to subjects.

It is critical that ICFs be written at the appropriate level. The Flesch-Kincaid Grade Level and Flesch Reading Ease tests assess readability, based on word and sentence length. The Dale-Chall formula incorporates complex word frequency and a built-in vocabulary. For writers in need of additional guidance, training materials are available online. The Program for Readability in Science and Medicine (PRISM) has developed a comprehensive toolkit for implementing standard language and document structure. The National Institutes of Health (NIH) and The Centers for Medicare & Medicaid Services (CMS) have also developed health literacy toolkits focusing on clarity, format, organization, and tone.

For writers developing content for the layperson (~8th grade reading level, as required for ICFs), guidance provided by PRISM, NIH, or CMS, with a first pass review using the Flesch Reading Ease test, may be most appropriate. Development of a validated readability statistics tool is warranted.

Best Practices for Posting Clinical Trial Results to ClinicalTrials.gov: How Medical Writers Can Prepare by Utilizing the Clinical Study Report (CSR)

Jennifer R. Houser, MS, RAC, CCRP, Seattle Genetics Inc, Bothell, WA

This poster presentation will focus on the different regulatory requirements (FDAAA 801, FDAMA 113, Clinical Trials Directive 2001/20/EC) for disclosing clinical trial data on ClinicalTrials.gov, as well as certain other obligations (Declaration of Helsinki, ICMJE policy). The poster will also present a summary of the data required on ClinicalTrials.gov and a mapping schema showing where similar information is typically provided in a full CSR. Best practices for planning will take into account timeline considerations, collaboration with cross-functional team members, and strategies for when there is only a synoptic or abbreviated CSR available that may not address all the data required by ClinicalTrials.gov. The conclusions will highlight how medical writers may use disclosing results on the public registry as an opportunity to showcase their expertise and career flexibility.

Collaborative Writing Toolkit: Results of a Survey of American Medical and Technical Writers in Health Care

Angela Johnson, MSE, PMP, RAC, GE Healthcare, Waukesha, WI

Collaborative documentation is increasingly becoming the norm, but there are many different ways teams collaborate. Writers play very different roles depending on their team’s collaboration style, which impacts how they conceptualize, draft, and revise collaborative documents. This poster presents the results of an original research survey conducted by the presenter that examines the practices, preferences, and technologies used by 100 medical and technical writers in the health and biomedical fields. The responses to this 60-item survey provide insights into the diversity of writers and their teams in using conventional and online collaboration tools, such as Google Docs. The study provides insights about what sets apart ‘power users’ in MS Word and which cross-cultural communication skills are most needed to succeed in teams with certain work habits. Learn about how teams collaborate on documents, and gain insight into the working style that you and your team prefer. This presentation will arm you with the knowledge and intuition to make strategic decisions when collaborating with new and existing teams, thus boosting your productivity and expanding your career opportunities.

Ensuring the Accuracy of Cited Claims in the Medical Literature: An Important Role for Medical Writers

Scott Mogull, PhD, Texas State University, San Marcos, TX

Accurately summarizing previous research findings is essential for constructing a sound scientific argument and educating readers in medical research articles. In a systematic review, I evaluated the data and methods of studies on the accuracy of cited claims, or quotations, in medicine. Across medical fields, the mean rate of quotation errors is 14.7% (10.7 to 18.6) at a 95% confidence interval. These content (factual) errors are predominantly, 67.4% (58.7 to 76.1 at a 95% confidence interval), “major” errors or cited claims in which the referenced source either fails to substantiate, is unrelated to, or contradicts the
In the studies reporting quotation source errors, the mean error ratio of improper secondary (indirect) citations to references selected was 17.5 (6.6 to 28.4) at a 95% confidence interval. The quantitative outcome of this investigation is a more accurate estimate of the quotation error rate in original medical research articles than previously reported. After adjusting for methodological differences between studies, the mean rate of quotation errors to quotations analyzed is 14.7% (10.7 to 18.6, 95% confidence interval), which is approximately 5% to 10% lower than previous estimates. The role of medical writers in addressing this issue is examined.

**Evaluation of a Workshop-Based Approach to Writing a Theme Issue of an Academic Journal**

Gina Uhlenbrauck, BA, ELS1; Jonathan McCall, MS1; Karen Staman, MS2; Liz Wing, MA3; Darcy M. Louzao, PhD3; Marijo Mencini3; Tammy Reece, MS, PMP, CCRA1

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Over a 1-year period, a team of 4 medical writers assisted groups of multidisciplinary authors (eg, clinicians, bioethicists, regulatory experts, patient advocates) in a project designed to produce 12 academic manuscripts for a theme issue of the peer-reviewed journal *Clinical Trials* on ethical and regulatory issues in pragmatic clinical trials. Distinct from other projects in which authors are assigned topics to write independently, each group worked collaboratively over recurring web conferences and teleconferences and during an intensive 2-day in-person working meeting, where authors refined their ideas and presented draft summaries to other working groups for evaluation and feedback. Depending on the needs of each group, the medical writers facilitated discussions; helped outline, draft, and edit manuscripts; provided reference materials; and generally served in a supporting role throughout the project. There was also operational support (ie, project managers) and leadership from the issue’s guest editors. Surveys were administered after the in-person meeting and again after article publication to obtain feedback on the writing process. We will present a summary of what worked well and what could be improved if this writing model were to be used again, on the basis of the survey responses and medical writer experiences throughout the project.

**Life Changing Decisions: What Patients Need to Know**

Kathi Whitman, MA, Intermountain Healthcare, Sandy, UT

Typical decision-making tools for patients choosing dialysis treatment focus on details about different treatment methods and associated risks and benefits. The Agency for Healthcare Research and Quality (AHRQ) defines shared decision making (SDM) as also needing to consider patient’s characteristics and values. A search of published tools for this patient population failed to yield something that adequately facilitated the desired patient-provider conversation about these concerns with dialysis decisions.

- Working with kidney disease experts, the author:
  1. Reviewed existing literature on health literacy for dialysis patients
  2. Surveyed patients and providers about information needs, treatment fears, and barriers to SDM
  3. Transitioned existing patient education into a pilot decision aid

The resulting decision aid addresses patient concerns about cost, physical appearance, accountability for treatment, aversion to needles, caregiver availability, and diet. We recommend that this tool be used:

1. During follow-up appointments with later-stage kidney disease patients to initiate conversations about potential dialysis decisions
2. As part of a three-step, SDM program (patient education, self-evaluation of characteristics and values, and collaboration with providers)
3. To increase patient decision satisfaction, preference for home-based (and lower cost) options, early decisions about access, and adherence
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