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Volume 30 Number 2 / Summer 2015

JOURNAL

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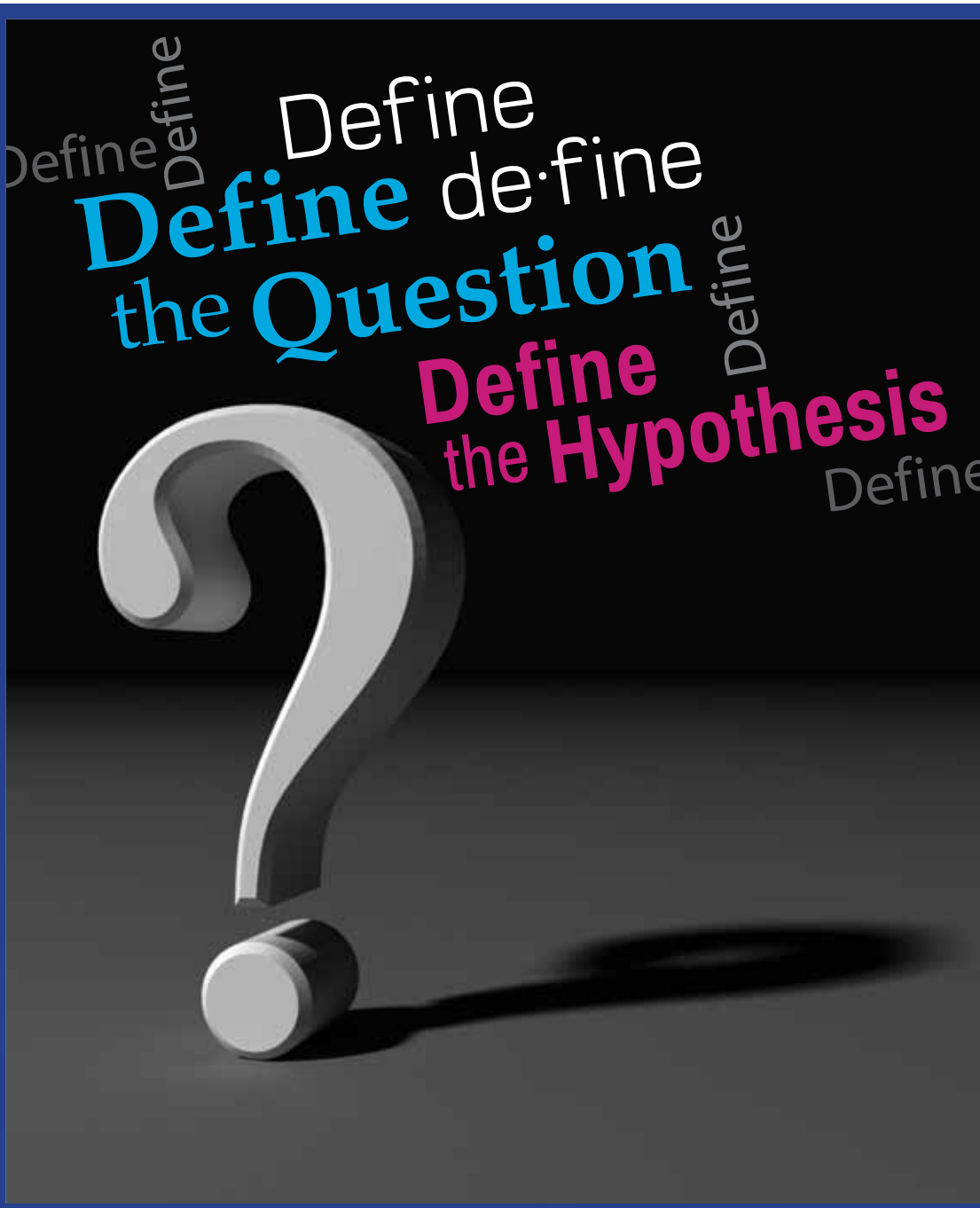

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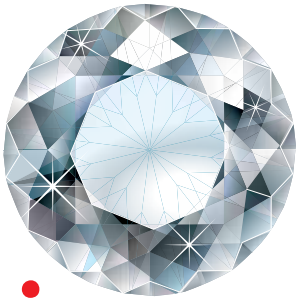

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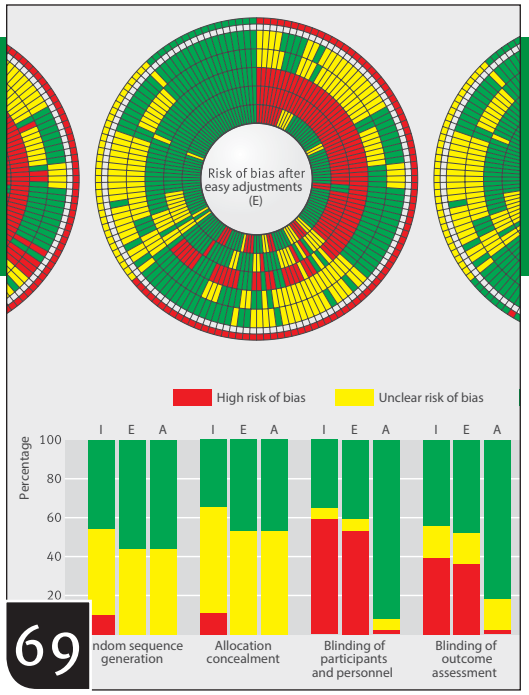

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL

V30 N2 / 2015

EDITORIAL OFFICE: JournalEditor@amwa.org. Abbreviated instructions for authors are available in this issue, with more detailed instructions available at: www.amwa.org/journal.

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SUBSCRIPTION: The *AMWA Journal* is published quarterly. Subscription is included with AMWA membership. Nonmember subscriptions cost is $75 per year.

CONTACT: American Medical Writers Association, 30 West Gude Drive, #525, Rockville, MD 20850-4347. Phone: (240) 238-0940; Fax: (301) 294-9006; Email: amwa@amwa.org.

The *AMWA Journal* is in the MLA International Bibliography and selectively indexed in the Cumulative Index to Nursing and Allied Health Literature (CINAHL) print index, the CINAHL database, and the Cumulative Index of Journals in Education (CIJE).

ISSN 1075-6361

PRACTICAL MATTERS

Applying the Communication Techniques of University Writing Center Tutors to the Medical Editor–Author Dialogue

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INTRODUCTION

Mark Twain had an adversarial relationship with editors, complaining for most of his career that editors, proofreaders, typesetters, and typists turned his writing into "a mass of senseless, d—d stupidity."[1] We can speculate he felt that way because, in his day, printers often accepted an editor's changes without consulting the author.[1] Although today's technology allows for more efficient communication between authors and editors than Twain saw in his time, there is a lingering perception (arguably erroneous) that the editor-author relationship is frequently antagonistic.[2,3] This perception could make some authors hesitant to engage with manuscript editors at all, or else inhibit authors' ability to develop productive author-editor relationships that are based on trust, collegiality, and shared purpose. Therefore, our challenge as medical editors is to use techniques that effectively balance the need for clarity of the text along with respect for authors' ideas. In other words, our communication approaches need to empower authors while accomplishing the common goal we share with them[3]: to produce an easy-to-read piece of writing that clearly and effectively communicates the author's message and intent.

Toward that end, we posit that some of the communication methods employed by university writing center tutors can be effective in supporting the dialogue between medical editor and author. To better show how tutor methods can be translated to editors, let us first briefly place writing centers into historical and methodological context. By definition, a writing center is a service, usually associated with higher education, with tutors who provide writing advice and assistance to enrolled students. Writing centers began to appear in earnest on college campuses in the 1960s.[4] Then most commonly known as writing labs, these academic facilities broadened over time from initially supporting students in first-year writing courses to now serving both undergraduate and graduate students in all courses of study, including disciplines such as medicine and other health sciences.[5,6]

Most writing centers operate with improving student learning as their primary mission; therefore, tutors are taught to stress the writer's ownership of the text and to focus on the writer's development by asking questions about the text in hand and about the writer's plans for revision.[5,7] Writing center administrators train tutors in communication methods such as active listening and receptive body language, and in providing specific types of oral and written comments that are conducive to successful tutoring sessions. Studies about the perceived success of tutoring sessions point to these specific communication techniques as useful in increasing the comfort level of the tutor and the student writer.[5,8,9] One study of over 4,000 tutoring sessions identified tutees' comfort as the top indicator of their satisfaction with these sessions.[8]

In this article, we briefly define some communication practices, used by writing center tutors, that we believe are applicable to medical editors' communication with authors. By categorizing these practices as informational or emotional support, we present examples of how these techniques can be applied by medical editors to facilitate positive, productive interactions with manuscript authors. Our discussion of these techniques is also informed by the results of a small online survey in which respondents—26 researchers at the University of Tennessee College of Veterinary Medicine, all editing clients of the first author—rated the value of specific communication techniques (detailed in Table 1).

A version of this article was presented as a poster at the American Medical Writers Association 72nd Annual Conference, Sacramento, CA, October 4–6, 2012.

Table 1: Importance of Editor Communication Techniques to Authors' Satisfaction with Author–Editor Interactions (N=26)

Editors' Communication Technique	Importance		
	Extremely	Somewhat	Not at All
Explaining why changes/suggestions are made.	92.3% (24)	7.7% (2)	0
Offering to answer questions about recommendations/changes.	92.3% (24)	7.7% (2)	0
Having empathy and responding enthusiastically.	88.5% (23)	11.5% (3)	0
Maintaining unconditional positive regard, wherein there is a sense of acceptance of the author and a willingness to help.	84.6% (22)	15.4 (4)	0
Listening actively and granting validity to concerns.	80.8% (21)	19.2% (5)	0
Creating an atmosphere of acceptance and trust.	73.1% (19)	26.9% (7)	0
Remembering the golden rule and avoiding use of sarcasm.	73.1% (19)	26.9% (7)	0
"Perception checking" by admitting confusion, guessing the basic message, and asking for affirmation.	73.1% (19)	26.9% (7)	0
Being patient by focusing on posture and tone of voice, and waiting for the author to finish a thought before commenting.	65.4% (17)	26.9% (7)	7.7% (2)
Paraphrasing to clarify understanding.	65.4% (17)	34.6% (9)	0
Leaning slightly forward, looking directly at the author, with friendly gestures of approval like smiling or nodding.	50.0% (13)	34.6 (9)	15.4% (4)
Summarizing to give the author a sense of progress.	46.2% (12)	50.0% (13)	3.8% (1)
Using third-person pronouns to stress reaction as a reader.[a]	41.7% (10)	41.7% (10)	16.6% (4)
Sitting beside the author, not across a desk from you.[b]	40.0% (10)	36.0% (9)	24.0% (6)

Techniques were based on previous studies about tutor and tutee satisfaction with tutoring sessions.[5,7,9,14,16,17,19]

[a] *n=24. Two people did not respond.*

[b] *n=25. One person did not respond.*

TECHNIQUE 1: INFORMATIONAL SUPPORT AND AUTHOR DEVELOPMENT

When tutors focus on an author's development by explaining why changes are being suggested and offering to answer questions about editing recommendations/comments, they are offering what is called informational support.[10–13] Medical editors can readily apply this tutoring approach in their work by taking the time to offer explanations for their recommendations. In some instances, the reason for making a change might be based on a style guide or grammatical principle. In substantive editing (sometimes called macroediting or comprehensive editing), the reason for the suggested change might be framed in terms of its positive impact on readers, such as improving comprehension or influencing perceptions, as illustrated by the examples in Table 2.

Examples such as these affirm the author's expertise with regard to the content by acknowledging possible reader confusion and providing suggestions for revision. Other ways to ensure the author retains ownership include reacting as a reader,[10,11] and, if an opportunity exists for in-person contact, placing the document physically closer to the author.[14] The idea that tutors should respect students' authority over their own texts is a commonplace of writing center theory;[15] demonstrating such respect in editing practice also leads to positive results. For example, among the many positive editor-author experiences noted by one study of 449 authors, one was when editors understood authors' authority over their own texts and represented reader needs and reader perspectives.[2]

Other ways that writing center tutors provide informational support and contribute to author development are by paraphrasing to clarify understanding[16,17] and by "perception checking"–ie, admitting confusion, guessing the basic message, and asking for affirmation.[17] With regard to ownership of the text, perception checking is particularly important for medical editors who are not content experts. At times, edits might inadvertently change the meaning of the text, but by paraphrasing to clarify understanding, editors are able to advocate for the reader while maintaining rapport with the author[18] and, importantly, demonstrate respect for the author's knowledge of the discipline even while raising questions.

At the first author's institution, a small group of editing clients (a mix of faculty, medical residents, postdoctoral asso-

ciates, and graduate students) were asked to complete an anonymous, online survey with 14 questions aimed at determining how specific editor techniques affect their satisfaction with author-editor interactions. The questions were developed to guide personal editing practices and were based on several previous studies about tutor and tutee satisfaction with tutoring sessions.[5,7,9,14,16,17,19] For the 26 respondents (51% response rate), the 2 communication techniques that were considered most important to authors' satisfaction with editing interactions were "explaining why changes/suggestions are made" and "offering to answer questions about recommendations/changes" (Table 1). Both are forms of informational support. In addition, 19 of 26 respondents (73%) thought perception checking was "extremely important" (Table 1). In another study that surveyed authors (predominantly technical writers) who had used the services of an editor, respondents reported that they were most likely to follow an editing suggestion when it was coupled with a "payoff statement"—a description of the way in which an edit would specifically benefit the reader and thus, the author.[2]

One editing situation that is particularly well-suited to the informational support technique is when authors seek assistance in responding to reviewers' comments.[12] Editors can provide support by editing for tone in responses and by offering another perspective if it seems the author may have misunderstood a reviewer's question. Editors can also be a source of knowledge when a manuscript peer reviewer makes an erroneous comment about style or the mechanics of language. For example, an editor will be able to supply an author with specific evidence from style manuals or author instructions to include in a rebuttal. Some examples of editor assistance in responding to peer reviewers are shown in Table 3.

TECHNIQUE 2: EMOTIONAL SUPPORT AND AUTHOR TRUST

Writing center tutors are trained to provide writers with emotional support and to garner author trust in a variety of ways, such as by promoting "unconditional positive regard"[12,13,20] in which the tutor does not approve or disapprove of the individual or his or her writing, but rather accepts the individual and is willing to help.[17] Other techniques are actively and reflectively listening and granting validity to writer concerns, even those regarding motivation (or lack thereof), and offering support via empathy and encouragement.[16] Reflecting a writer's concern back to him or her and normalizing the concern, if appropriate, allows the tutor to acknowledge the writer's experience without having to agree with it. Validating concerns in this way allows the writer be heard and indicates a desire of the tutor to understand the writer's perspective, thus helping build trust.

Like students working with tutors, authors working with editors also benefit from feeling nurtured and respected. Writing center tutor techniques, when applied effectively to the medical editor-author dialogue, have great potential to increase the comfort level of both the editor and the author, as well as to make their relationship more productive. In their article "Coaching Faculty to Publish," Baldwin and Chandler recommend "validating and encouraging both the creator

Table 2: Examples of Medical Editors' Comments to Authors Focused on Informational Support and Author Development

Editor's Recommendation or Query	Editor's Explanation of Reader Impact
Consider reordering the results section so that first you present data on the primary outcome (diabetes incidence), then you present data on the secondary outcomes (cholesterol levels, mean blood pressure).	This reorganization will create consistency across different sections of the article (methods, results, discussion), while keeping readers focused on your study's primary research question.
Is your inclusion of non–daily smokers in the trial innovative for the field?	If yes, stating this could help convince readers of the importance of your work.
Suggest you clearly indicate the specific outcomes that were reported in the earlier publication from this trial.	Doing so will make it very clear to reviewers (and other readers) that you are reporting on a different set of outcomes in this manuscript (no concerns about duplicate publication).
Is there a reason you don't devote any text in the Results section to the protein function "regulation of macromolecule metabolic process"?	Because this regulation function was very common in your proteomics results (a prominent slice in your pie chart), readers might wonder why you aren't giving this finding much attention in the text body.

(author) and the creation (manuscript)" by acknowledging potential writing-associated frustrations and celebrating events like submission and acceptance of a piece of writing with an email, phone call, or note to the author.[12] They go further by discussing the editor's role in commending progress and encouraging perseverance.

The following list outlines some strategies for creating what Taylor calls a "helping relationship,"[17] in which the editor projects an air of acceptance of the author and an eagerness to help.

- Take the time to understand the author's meaning.
- Respond enthusiastically in a concerned way that shows "stronger concern for people than for things."[17]
- Provide a sense of acceptance of the author and convey a willingness to help. Do not give a message of approval or disapproval of the writing.[17]
- Golden Rule: "There's no room for sarcasm, superiority, aggression, or criticism."[19]
- Summarize to give the author a sense of progress.[17]
- Assist in responding to reviewers.[12]

Some of these techniques, especially avoiding judgmental criticism (different from critique), might be most effectively applied in face-to-face situations in which nonverbal communication is particularly important to the interaction. However, even within the constraints of written or electronic editing, helping relationships can be nurtured when editors take the time to go beyond simply fixing errors. Table 4 demonstrates some ways to show emotional support for the author in the form of written comments in the text; of course, these examples should be adapted as needed, depending on the writer with whom one is working.

In our survey, 88% of author respondents (23 of 26) indicated that working with an editor who conveys empathy and responds enthusiastically was "extremely important" to them. Similarly, student comfort level with tutors was reported by Thompson and colleagues as correlating significantly with tutee satisfaction with the session.[8] High satisfaction with their interactions with

Table 3: Examples of Medical Editors' Comments to Authors When Responding to Peer Reviewers' Comments

Editor Comment	Type of Informational Support
Does this reference indicate that 50% acquisition (regardless of the number of mice) is adequate for your animal study? I don't think the reviewer is questioning the validity of the 50% result; I think he/she is asking why more mice weren't used. Therefore, I'm not sure the reviewer's question has been adequately answered.	Offering another reader perspective
Rather than saying the reviewer misunderstood, can you say that you altered the sentence accordingly to eliminate the possibility of confusion?	Editing for tone
I don't see this comment addressed in the response. I think the reviewer wants to know who coded/identified the spheroids—a blinded coder or someone who knew the expected results?	Offering another reader perspective
I would probably go ahead and cite the study that supports your point. That way, you can show the editor exactly what study and stay objective without finger-pointing. The editor will put two and two together very quickly.	Editing for tone

Table 4: Examples of Medical Editors' Comments to Authors Focused on Emotional Support and Building Author Trust

Editor Comment	Type of Emotional Support
I left the abstract alone for now but would be happy to review and edit it after you've finalized the rest of the manuscript and decided on the target journal.	Conveys a willingness to help.
I really like the information you present in this figure. It efficiently communicates the core preliminary findings that justify the research you propose in this grant application. A few small improvements could maximize the figure's clarity: First, ...	Compliments the product. Summarizes to give the author a sense of progress.
The phrasing "support blood pressure" seems vague. Do you mean increase BP? Or maintain some target level of BP? Or something else entirely? I want to make sure your message is clear to all readers.	Makes the effort to understand the author's meaning.
I am glad to see some additional detail from the literature in this new draft. As a next step, I suggest you concisely summarize this new information into one tight paragraph that very clearly illustrates the need for your work (convince reviewers you aren't just doing another "me too" study). You're almost there!	Commends progress. Encourages perseverance.

medical editors may encourage authors to become repeat clients. Although writing is often a high-priority activity (as with faculty expected to publish peer-reviewed papers), writers who are also researchers, instructors, or practitioners often have low follow-through when it comes to completing writing projects because other responsibilities are more immediately demanding.[21,22] Additional factors that can impede the writing process are authors' anticipation of failure or embarrassment upon peer review[23] or difficulty self-motivating and staying focused.[22] Thus, authors who feel they have a highly supportive teammate in the writing process—manifested in an editor—may feel more encouraged to make progress. When authors are able to focus most on writing content and allow the medical editor to fine-tune the text, writer output might increase, as was found in one study that compared the publication rates of 26 faculty members before, with, and without the use of writing coaches.[12]

A limitation of our survey is the small sample of authors; therefore, the results should be interpreted with caution. Still, we believe that medical editors can effectively adapt the techniques of writing center tutors for use with authors. In light of evidence that supports a correlation between use of these techniques and writer satisfaction, editors who apply these techniques might be more successful in attracting, retaining, and influencing their clients.

Acknowledgments

The authors thank Sarina Manifold, LCSW, Veterinary Social Work, Veterinary Medical Center, University of Tennessee, for intellectual input on the practice of validation communication.

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

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Developing Better Discovery Skills

By Elizabeth Frick, PhD, ELS / President, The Text Doctor LLC, Boulder, CO

All of us have suffered the consequences of expensive, unasked questions in both our professional lives and our personal lives. As medical communicators, we must ask good questions to elicit information, but many of us lack adequate training in this skill. Add to that the natural reticence of some medical communicators, and it is no wonder that we walk away from interviews with subject matter experts or client meetings wishing we had remembered to ask X, Y, or Z. This article offers information as to why questions are so important, what types of questions are useful, how to strategize your questions, how to handle people answering the questions you ask them, and how to answer questions that others ask you.

WHY ARE QUESTIONS IMPORTANT?

We have all experienced the pain of unasked questions. When I was interested in replacing my windows with casement windows, I asked the salesman if I could clean the outside of the window from inside the house. The salesman assured me that I could. After the windows were installed, I found that a person with a 28-inch arm could clean each window from inside—but I have only a 24-inch arm. I failed to ask the right question: "Can a person with a 24-inch arm clean this particular width window?"

If you ask the right questions, it is more likely that you will get the information you need. A former secretary of the Department of Defense once famously spoke of the "unknown unknowns"; often, we don't know what we don't know, and asking questions in a logical, orderly way may uncover surprises that we need to explore. Good questions (and honest answers) will save you money and time.

If you are shy or question-phobic, reframe the concept of "asking questions" by calling it "discovery skills": everyone needs discovery skills.

WHAT TYPES OF QUESTIONS ARE USEFUL?

There are many different types of questions.

1. **Permission** questions demonstrate your positive intent in asking questions. They show respect and help you build trust.
   - Let me ask you…
   - Could you tell me more about the audience for this article….?
   - May I get some more information about….?
2. **Open-ended** questions stimulate thought and encourage continued conversation. They cannot be answered with one word or with a simple "yes or no" response.
   - What items are critical to ZZZ?
   - What are the risks?
   - How does this subassembly fit into the overall drug delivery?
   - What are some unique characteristics of this clinical trial? How does it differ from the XYZ trial?
3. **Closed** questions elicit "yes" or "no" answers or verifiable data. Once answered, this type of question may preclude further conversation without asking another question.
   - What format do you need?
   - Is there an internal style guide that I need to follow in addition to the *American Medical Association Manual of Style*?
   - What is the word limit? Page limit?
4. **Probing** questions help you explore more in a certain direction. You can elicit further detail by asking probing questions.
   - Why is that?
   - How would that look?
   - What if…?
   - Tell me more about…

5. **Encouraging** statements pose as questions and help speakers keep going without overt interruption. Silence is a great encourager!
   - Uh huh…
   - I see…
   - Oh, that's interesting.
6. **Restatement/paraphrase** questions show that you have been listening. They can keep the communication open, perhaps by showing that you are listening and want to clarify your perceptions. They are also a graceful way to check up on inconsistent information.
   - Let me play this back to you…
   - Here's what I have heard so far. Let me state it in my own words to make sure that I understand it correctly.
7. **Catchall** questions invite further information. As you listen to the answer, you might receive verification of information already offered. In addition, catchall questions might elicit another viewpoint.
   - Would you like to tell me anything I haven't asked you about?
   - What haven't we discussed that might be relevant?
   - What else is important for me to know?
8. **Checking** questions help you further clarify conflicting information, especially if answers have diverged from expectations.
   - Please explain that a little further…
   - Help me understand your intention…
   - Tell me more about…

STRATEGIZE

Once you have brainstormed your list of questions, it is important to plan your questioning strategy. I like to start with open-ended questions ("Please give us your vision of the course that you want us to build for you"), then move on to more specific questions ("How many interactions would you like in a given time period?" or "Do you have prior course materials that you could share with me?"). If you find that your specific questions are eliciting information that conflicts with earlier information, you might need to go back to more open-ended questions. ("Tell me again your vision for this project?")

Before you start offering questions, you must first establish a relationship with the interviewee or group that you are interviewing. You must convince them of the following:

- You care about their issues.
- You are honest.
- You want to understand their truth.
- You do not have an axe to grind.
- You meet your commitments.

If you find that your specific questions are eliciting information that conflicts with earlier information, you might need to go back to more open-ended questions.

You might help further the relationship by a diplomatic statement of purpose. ("We're all interested in understanding your truth") or by starting with a few social questions ("How was your trip?" "How is the hotel?" "Is this your first time visiting our company?") Questions not related to your area of discovery may help warm them up and show them how easy it is to answer your questions. It is probably best to avoid questions about politics, religion, or sports.

Then, you can start your discovery in a nonthreatening manner:

- Aim for dialogue, not interrogation.
- If you have 2 questions in one, separate them. The clarity of the questions will be improved, and you will prevent the interviewee from inadvertently giving one answer for both questions.
- Be mindful of different cultures; not every culture likes being questioned. You may need to consider avoiding eye contact; instead, try focusing on a person's lips.
- If your interviewee does not immediately answer your question, count silently to 10 to allow time for the person to formulate an answer. After 10 seconds, you might offer a paraphrased question or a different question.

Of course, probing and encouraging questions are always appropriate at any time. Catchall questions may be most helpful at the end of a question session.

LISTEN

- Listen. We can all learn to listen better.
- Use body language to show you are listening; lean toward your audience and focus on them when not writing.
- Take notes.
- If you can get permission, record the question-and-answer session.

RESPOND

- When asked a question, pause for a few seconds to think about your answer. It may be helpful to restate the question to help you think through your answer.
- If you are not sure how to answer a question, ask a clarifying question to give yourself time to collect your thoughts. ("Could you help me understand what you mean by X?")
- If you are in front of a group of people, restate the question to help those who may not have heard it. Be sure to restate the question exactly as it was asked.
- If, however, you need to rephrase the question in order to answer it, ask the questioner if your paraphrase or restatement is OK with him or her; this shows your respect for the questioner.
- If you still don't have an answer or don't want to provide it right away, turn the tables on the questioners and hear how they answer the question.

BECOME A BETTER QUESTIONER

- Be serious about improving your discovery skills. Asking the right questions is a crucial skill for any profession.
- Start today: Make a list of questions you recently neglected to ask and write down what your ignorance cost you. The next time some "failure" occurs in your work group or in your own life, ask yourself "What question didn't I ask that needed to be asked?" Keep your lists of questions and review them frequently!
- Hang out with a 2-year-old and listen carefully to his or her questions. What can you learn?
- Practice being a 2-year-old. When you are on a walk or driving your car, consciously form questions. ("Wonder why the snow is completely melted in that spot?" "Why is all the traffic in the left lane?")
- For fun online practice, go to **www.20q.net** to play "20 Questions" against artificial intelligence.

Always listen for good questioning behavior. I once consulted my physician about a black spot under my toenail. He asked, "What can you tell me about this spot?" What a great open-ended question to start with. I felt empowered in his discovery process. I have added that to my questions repertoire.

You can never have too many questions up your sleeve.

Author disclosure: *This article is based in part on a presentation the author made to the Society for Technical Communication in 2011. The author has no commercial associations that may pose a conflict of interest in relation to this article.*

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New European Clinical Trial Regulation: The Requirement for Lay Summaries and Its Impact on Medical Communicators

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INTRODUCTION

The European Clinical Trial Regulation (EU No. 536/2014)[1] published by the European Parliament in May 2014 introduced new requirements for authorization, conduct, reporting, and transparency of clinical trials with at least 1 site in a European Union (EU) member state. According to this regulation, sponsors will be obliged to provide results of clinical trials in a summary that is understandable to laypersons. This summary shall be publicly available in an EU-wide database that is yet to be established.

For globally acting sponsors, data disclosure policies need not only comply with requirements from the US Food and Drug Administration (FDA) but also with the EU regulations. This article gives an overview of the recent developments in regard to transparency of clinical trial data in the EU and the provision of lay summaries of clinical trial results. We highlight the implications and challenges associated with the new regulation for medical writers.

RECENT DEVELOPMENTS IN TRANSPARENCY IN THE UNITED STATES AND THE EUROPEAN UNION

At the time of launch of the NIH database ClinicalTrials.gov in 2000, it included only a subset of clinical studies conducted in the United States.[2] With the FDA Amendment Act of 2007, the requirements for registration on ClinicalTrials.gov were expanded, and it became obligatory for sponsors in the United States to post summary results of studies of approved products on the website by 2008.[3,4]

In contrast to the United States, the European Union did not have a legally binding obligation to publish trial results in existence at that time. In 2001, the EU directive 2001/20/EC was released. It aimed at harmonizing requirements and ensuring data quality for clinical trials across all EU member states.[5] The EU directive stipulated the creation of an EU-wide database, later called EUDRA CT, in which clinical trials conducted in the EU had to be registered. Then, in 2012, a European Commission guideline obliged sponsors to post summary results of all clinical trials conducted in at least 1 EU member state.[6] The results were to be posted in EUDRA CT; however, the functionality for posting did not become available before June 2014.[7]

In 2009, an assessment by the European Commission of the impact of the EU directive revealed that the operational requirements imposed had resulted in an increased administrative burden and higher expenses for sponsors and that, because of this, the number of clinical trials conducted in the EU had decreased.[8,9] To counteract this decline, the European Parliament issued regulation No. 536/2014,[1] which came into force on June 16, 2014. Unlike the former directive, the new regulation is directly applicable and overrules the respective national laws in all EU member states. Shortly after release of the Clinical Trial Regulation, the European Medicines Agency (EMA) adopted policy 0070, which became effective Jan 1, 2015, setting the scene for proactive publication of entire clinical trial reports and clinical submission documents by the EMA.[10]

In July 2013, member companies of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) recognized the need of greater transparency and proactively committed to publishing summary results of clinical trials for products approved in the United States or the EU and its member states.[11] This commitment to some extent preempted some of the requirements introduced by the European Clinical Trial Regulation. Since then, several pharmaceutical companies have started sharing their trial results with the trial participants on a voluntary basis.

CONTENT AND IMPLEMENTATION OF THE NEW REGULATION

Even though the European Clinical Trial Regulation was released in June 2014, it will become effective "not earlier than 28 May 2016," or once the new EU database has become available. The main content of the regulation is a harmonized clinical trials application procedure via a new EU database, which will document the procedure, assessment, and timelines for each clinical trial. Thereby, the regulation is thought to "create an environment that is favorable to conduction of clinical trials in the EU with the highest standards of safety for participants." In addition, the regulation introduces increased transparency concerning clinical trials.[1, 12]

SPECIFIC REQUIREMENT FOR LAY SUMMARIES OF CLINICAL TRIAL RESULTS

As part of the transparency efforts, Article 37 of the new European Clinical Trial Regulation states that sponsors are obliged to submit a technical summary of results of clinical trials. This technical summary will be very similar to the postings of clinical trial results on ClinicalTrials.gov and EUDRA CT. However, unlike in the United States, the posting "shall be accompanied by a summary written in a manner that is understandable to laypersons." The requirements for this lay summary are delineated briefly in Annex V of the regulation (Box 1) and were added only "at the last stage of negotiations," according to a recent position paper of the European Patients Forum.[13] Although discussions about returning summary results of clinical trials to patients and the public have been ongoing for some years in the United States and the EU,[14,15] this is the first time that a list of items that should be included in such a document has been given by a regulatory agency (Box 1).

Box 1. Content of the Summary of the Results of the Clinical Trial for Laypersons

The summary of the results of the clinical trial for laypersons shall contain information on the following elements:

1. Clinical trial identification (including title of the trial, protocol number, EU trial number and other identifiers);
2. Name and contact details of the sponsor;
3. General information about the clinical trial (including where and when the trial was conducted, the main objectives of the trial and an explanation of the reasons for conducting it);
4. Population of subjects (including information on the number of subjects included in the trial in the Member State concerned, in the Union and in third countries; age group breakdown and gender breakdown; inclusion and exclusion criteria);
5. Investigational medicinal products used;
6. Description of adverse reactions and their frequency;
7. Overall results of the clinical trial;
8. Comments on the outcome of the clinical trial;
9. Indication if follow up clinical trials are foreseen;
10. Indication where additional information could be found.

Source: Regulation EU No. 536/2014 on clinical trials on medicinal products for human use, Annex V[1]

IMPACT ON MEDICAL COMMUNICATORS

As the writing of lay summaries of clinical trial results requires expert understanding of clinical research and the specific skills associated with communicating to lay audiences, medical writers are ideally suited for this task.

Unfortunately, Annex V of the European Clinical Trial Regulation provides only scant guidance on the content of a lay summary. As most of the 10 items provided (Box 1) need interpretation and adaptation, there is a large potential for professional medical communicators to contribute. Sponsors, whether from academia or the pharmaceutical industry, will have to make reasonable assumptions about the implementation of the requirements.[16] Medical writers can support the implementation by developing lay summary templates and providing expertise for the writing in lay language. Although at first reading the requirements appear straightforward, on closer inspection many issues arise. Some of the requirements can be readily implemented (Nos. 2, 10), however all others need further specifications.[16] In Table 1 we list these issues and propose potential solutions.

Beside the issues that need interpretation, there are more general aspects that need to be considered in the writing of lay summaries of clinical trial results.

Annex V gives no guidance on format, length, and structure of the lay summary, therefore each sponsor will have to develop its own approach. In addition, the European Clinical Trial Regulation does not specify the language of the lay summary. While it might be reasonable to assume that the summary could be provided in English, it is obvious that this would exclude a large number of European citizens, because there are 23 other official languages in the EU. If the objective of increased transparency is taken seriously, lay summaries will have to be provided in all EU languages.

The European Clinical Trial Regulation provides no guidance on a target reading level, therefore medical writers need to determine the target reading level and need to devise strategies for achieving it. Current guidance in the United States

Table 1: Requirements for Lay Summaries, According to the European Regulation EU No. 536/2014: Identification of Potential Issues and Proposal for Implementation

Requirement[a]	Issue	Proposal for Implementation
1. Clinical trial identification (including title of the trial)	The trial title is usually written for a specialist audience in a technical language.	Devise an additional lay title that is shorter and simpler than the full trial title and provide it along with the full trial title.
3. Main objectives and rationale of the trial	Objectives and rationale are usually described in the trial protocol for a specialist audience in a technical language.	Provide a simplified description avoiding specialist terms, but also provide important medical terminology (like disease stages) to maintain specificity.
4. Inclusion and exclusion criteria	The clinical trial protocol usually contains many inclusion and exclusion criteria written for a specialist audience in a technical language.	Reduce the lists of inclusion and exclusion criteria from the trial protocol to the most important ones, like age, body mass index, and indication-specific criteria.
5. Investigational medicinal product	Depending on the product development stage, different drug identifiers are usually available, such as internal compound code, international non-proprietary name, or trade names. In addition, trade names often differ among countries or regions.	Provide the compound code for early trials and all available identifiers for later stages. If feasible, all available identifiers for comparator medication(s) should be given. Provide information if a placebo was used.
6. Description of adverse reactions and their frequency	By definition, the term *adverse reactions* refers to the concept of drug-related adverse events. Especially in early drug development programs, this concept might not be appropriate, and it would be reasonable to report all adverse events. In addition, there are several levels of granularity in frequencies of adverse events and in reporting of adverse events (eg, MedDRA preferred terms and system organ class).	To keep consistency with other sources, provide adverse events using MedDRA preferred terms as default and system organ class level only if useful. The medical terms may need an additional explanation in lay terms. Provide frequencies of all adverse events, deaths (if any), adverse events leading to trial discontinuation. Provide clinical laboratory data only if considered useful for the reader.
7. Overall results of the trial	Because clinical trials usually have several different end-points (primary, secondary, further), it is not clear if this section should contain all efficacy and safety data, and to what extent numerical data should be presented. Quality of Life data might be of special interest for patients, but these are often not included as primary/secondary endpoints.	Focus on the primary and the key secondary endpoints. Provide numerical results to make the data comparable to other resources (clinical trial reports, publications, trial results databases). Include Quality of Life data, if relevant results were obtained in the trial.
8. Comments on the outcome of the trial	This item might refer to the trial objective or the primary endpoint, but it is not clear on what the sponsor is supposed to comment. Because reporting of the trial results is already mentioned above, this might require qualitative statements. However, qualitative summary statements are easily perceived as promotional.	Provide a high-level factual statement on whether the trial fulfilled its objective.
9. Follow-up trials	Whereas the terms *trial* and *study* are precisely defined in the regulation, a definition of what should be considered a follow-up trial is missing. All planned trials investigating the same product might be mentioned. Likewise, already recruiting trials only, or any planned future trials could be reported as well. However, this might be perceived as advertising future studies conducted by the same sponsor.	Only true extension trials related to the trial in question should be reported.

[a]*Items 2 and 10 can be readily implemented and are therefore not included in this table. MedDRA=Medical Dictionary for Regulatory Activities*

and in the United Kingdom recommend that information for patients is written at a reading level of 6th to 8th grade.[17–19] Once a reading level target is agreed upon, medical writers of lay summaries will need to develop criteria to assess whether their texts fulfill the requirements associated with this target. This may involve the development of thesauruses for clinical research terms and their lay language translations, and the use of software tools to measure readability.

The development of lay summaries provides an opportunity to involve patients and patient organizations, if not for the routine process then for the development of an appropriate template. In a recent position paper, the European Patients Forum suggests ensuring the "layness" of result summaries by including patients or patient representatives in the review in a yet to be defined process.[13] Implementing this proposal, however, would have logistical challenges as it will be difficult to find appropriate patient representatives for all diseases studied in clinical trials.

One of the major issues for sponsors of clinical trials is how to maintain consistency between the many different communication channels for sharing clinical trial data with various audiences. To achieve full transparency, the data mentioned in lay summaries need to be linked to the more technical summaries provided on ClinicalTrials.gov and in the EU database. Describing results in a manner understandable to laypersons will need to account for the level of numerical literacy in the general population. This means that details of the statistical analyses will likely have to be omitted, as, eg, odds ratios, P values and confidence intervals will not be informative for a lay audience with a reading level of 6th to 8th grade. As a result, it might be difficult for a lay reader to relate the content of a lay summary to the detailed data provided in the corresponding technical summaries. Sponsors will have to find a balance between the possible low numerical literacy of lay readers and consistency throughout different public sources.

CONCLUSION

The discussions about returning results of clinical studies to participants and the provision of summary results to lay audiences have been ongoing for several years. With the new European Regulation lay summaries of clinical trials will become mandatory in the EU. Because expectations on returning clinical trial data to patients are also increasing in the United States,[20,21] it is highly likely that such summaries will become a standard in clinical research that is conducted on a global level. Although the summaries are yet another requirement for the pharmaceutical sponsors, they have the potential to play a role in improving health literacy among the general public. Very likely, though, because of the lack of detailed guidance on their content, lay summaries will be of varying quality and content depending on the sponsors' interpretation of the regulation.

Declaration: *The views expressed in this article are those of the authors and do not necessarily reflect those of Boehringer Ingelheim Pharma.*

Author disclosure: *The authors declare no conflict of interest.*

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Patient Decision Support in Renal Care: A Clinical Perspective

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Shared decision making acknowledges the interface between and mutual importance of empirical evidence and patients' values and preferences. While research has clearly demonstrated the effectiveness of using patient decision support tools, uptake in the clinical arena has been slow. Moreover, the opportunity for medical writers to assist in the development of high quality decision support tools has been inadequately leveraged.[1] Using a clinical exemplar, we show the evolution of a program of research grounded in the clinical reality of patients living with end-stage kidney disease. Embedded within the exemplar are practical descriptions of opportunities of how medical writers can engage in these initiatives to enhance clinical applications and key deliverables.

Consider the following scenario. Joan's kidneys are not working well. She knows that when her kidney function drops to 10% of usual function she will likely need dialysis, most probably before a kidney transplant becomes available. This will be a big change in Joan's life. She is worried about her family, about what will happen to her work and her lifestyle, and about how she will feel. She knows she needs to make some decisions and isn't sure what kind of dialysis is best for her.

It is important for Joan to decide which treatment option is best for her early because preparation is required for each of the possible options, regardless of which choice she makes. If her kidney disease progresses more quickly than expected, it could mean that Joan may be faced with making an urgent choice, in a state of illness that is more acute and while experiencing heightened anxiety. If she delays making a decision, it could mean starting a type of dialysis that would not be her first choice and would not fit well with her values and lifestyle. Like most patients in this situation, Joan is feeling uncertain, worried, and frightened.

By thinking about her options ahead of time, Joan can put the pieces together and take steps that will improve her health, quality of life, and independence. Early preparation can lower risks associated with urgent hospitalization or an unplanned start to dialysis. Meta-analytic reviews of the literature about the impact of patient decision support confirm that patients who have their decisional conflict assessed by health care professionals who have been trained in decisional coaching are able to reduce their conflict and are more likely to adhere to, and be satisfied with, their choices.[2] Embedding tools that support shared decision making such as patient decision aids (PtDAs) and patient decision coaching into care pathways has the potential to promote open and early communication between patients and health care providers, facilitate compassionate and relevant treatment decisions, and promote high quality health care. However, it is important to build awareness and understanding about shared decision-making approaches in clinical care. In this article, therefore, we discuss ways medical writers can work with clinicians to help people like Joan to be better prepared for making choices about their care and preferences for treatment.

What Is Shared Decision Making?

Shared decision making leverages two complementary sets of expertise. First, patients know their bodies, their health, and what's important to them. Second, the health care team knows about the latest treatments and options that could

This article is a follow-up article to "The Growing Need for Shared Decision-Making Tools and How Medical Writers are Equipped to Meet It," which appeared in the Winter 2014 issue of the AMWA Journal *(Volume 29, Issue 4).*

benefit patients. In shared decision making, patients and practitioners (who may include physicians, nurses, and social workers) decide together on a best option. Patients bring information about what is most important and practical for them. Practitioners provide information about the likely reasonable options, benefits, and risks. The goal is for the patient to make a decision that is based on the most up to date scientific evidence and that is in harmony with his or her values. For some decisions, it is quite easy for patients and practitioners to reach a decision. For instance, it is usually fairly straightforward to make a decision about taking iron replacement medication when on dialysis because the evidence clearly shows that the benefits far outweigh side effects or long-term complications. However, for many kidney care decisions—such as whether to choose a home dialysis or in-center dialysis option—there is no clear right or wrong choice.

A complementary set of special expertise exists within the professional medical writers' toolbox. Given that language shapes reality and understanding, medical writers—with their skills in translating complex information such as probability ratios, use of patient-centered language, and selection of most-relevant message mediums—could round out decision support teams.[1]

Why Are Many Kidney Care Decisions Difficult?

Several options are available for treating or managing end-stage kidney disease. People whose kidneys are at end stage may have as many as 5 options: 1) kidney transplant, from a living or deceased donor; 2) no dialysis, with care to manage symptoms until natural death occurs; 3) peritoneal dialysis at home; 4) hemodialysis at home, or 5) hemodialysis in a facility. Often one decision leads to the need to consider more decisions. For instance, most patients want a kidney transplant, and transplant is the treatment of choice because it prolongs survival, improves quality of life, and is less costly than dialysis. When considering a kidney transplant, patients must decide whether they would like to be on the waiting list for a deceased donor or accept a living kidney donation from a loved one or anonymous donor if available. Some people may prefer to not ask relatives to donate a kidney. Others, however, may think it is more important to receive a kidney from a known relative. Therefore, personal views about the importance of the various features of the options may lead people to make different decisions.

None of these decisions is wrong; each is the right decision for the person at that time and in that situation, but patients facing these tough decisions may feel uncertain about which option to choose or what next steps to take.[3]

This uncertainty is called decisional *conflict.*[4,5] Such conflict can be caused by not having enough facts or knowledge; being unsure about what to expect; feeling unclear about what is most important to avoid or achieve from the possible consequences of the different options; not having enough advice or resources to make the decision; and/or feeling pressured by others to make a decision.[4] Moreover, it is often difficult to make decisions about newer treatments because there may be limited or inconclusive scientific evidence about their effects. In these and other kidney care decisions, therefore, decision tools can help prepare patients for discussions with their health care teams. Medical writers could help decision tool creators ensure clarity in language as well as show the linkages between factual detail and complex relationships, such as visualizing outcome probabilities and showcasing complex information in approachable formats.

Are There Tools to Help Make Decision Making Easier?

Decision support tools can help patients and their care team figure out individual decision-making needs and can be used to plan next steps. Decision support tools complement discussions between patients and their practitioners. They do not replace these discussions. Medical writers, with their skills in translating complex information and probabilities into accessible formats, could contribute substancially to the design and testing of decision support tools. A few examples of decision support tools follow.

Option grids and patient decision aids are 2 types of decision support tools. Option grids compare usual treatment or screening options.[6] These grids are set up with patients' frequently asked questions in rows, various treatments options listed in columns, and the answers for each option written under the appropriate column heading. Health care professionals can use the grid during discussions with patients about treatment planning.

Patient decision aids are another type of decision support tool. The decision aids are different from usual patient education materials. In decision aids, the options and facts are tailored to a patient's own stage of disease. The advantages and disadvantages of each option are presented, and patients consider which outcomes are most important to them. Some decision aids also present information about the likelihood of experiencing complications, side effects, or other consequences related to the different options.[7] Some decision aids focus on a single health decision, whereas others are more general about decisions related to a health condition.

One way the skills of medical writers could be specifically useful is in the design and testing of decision support tools. Medical writers, with their aptitude for organizing scientific data and text into accessible language and skills in formatting and presentation of information, can enhance decision support tool conception and development.[8]

A Clinical Example

In 2012, the Ottawa Hospital and the Ontario Renal Network undertook a collaborative initiative to develop, implement, and evaluate decision support tools and protocols in nephrology and ambulatory care settings. A pilot study—Shared End-Stage Renal Patients Decision Making (SHERPA-DM)—was undertaken at the pre–renal insufficiency (PRI) clinics at the Ottawa and Renfrew Victoria hospitals. With extensive patient and family engagement, the initiative was designed to address decisional conflict of patients with end-stage renal disease (ESRD) through the implementation of 3 key resources:

i. *Renal Treatment Options Grid*. "Comparing treatment options for when your kidneys are not working," a tool that describes potential treatment options and provides answers to patient-identified frequently asked questions. (Figure 1);
ii. *Patient Decision Aid*. "When you need to think about dialysis options, should you receive your dialysis at home or in a facility?" a tool that guides patients through the decision-making process by providing information to support treatment selections that align with patient priorities. (Figure 2*);*
iii. *Decision Coach Training*. Skill-building workshops to train providers on how to effectively coach and support patients through decisional conflict.

The first step was to educate nephrology health care practitioners on decision coaching strategies for health care providers. Five workgroup sessions were held to teach health care practitioners about decisional coaching, how to coach patients, and the benefits of decision coaching. These interactive sessions included literature review, identification of barriers, and problem solving to the local context and involved simulation exercises to allow practice usingthe tools.

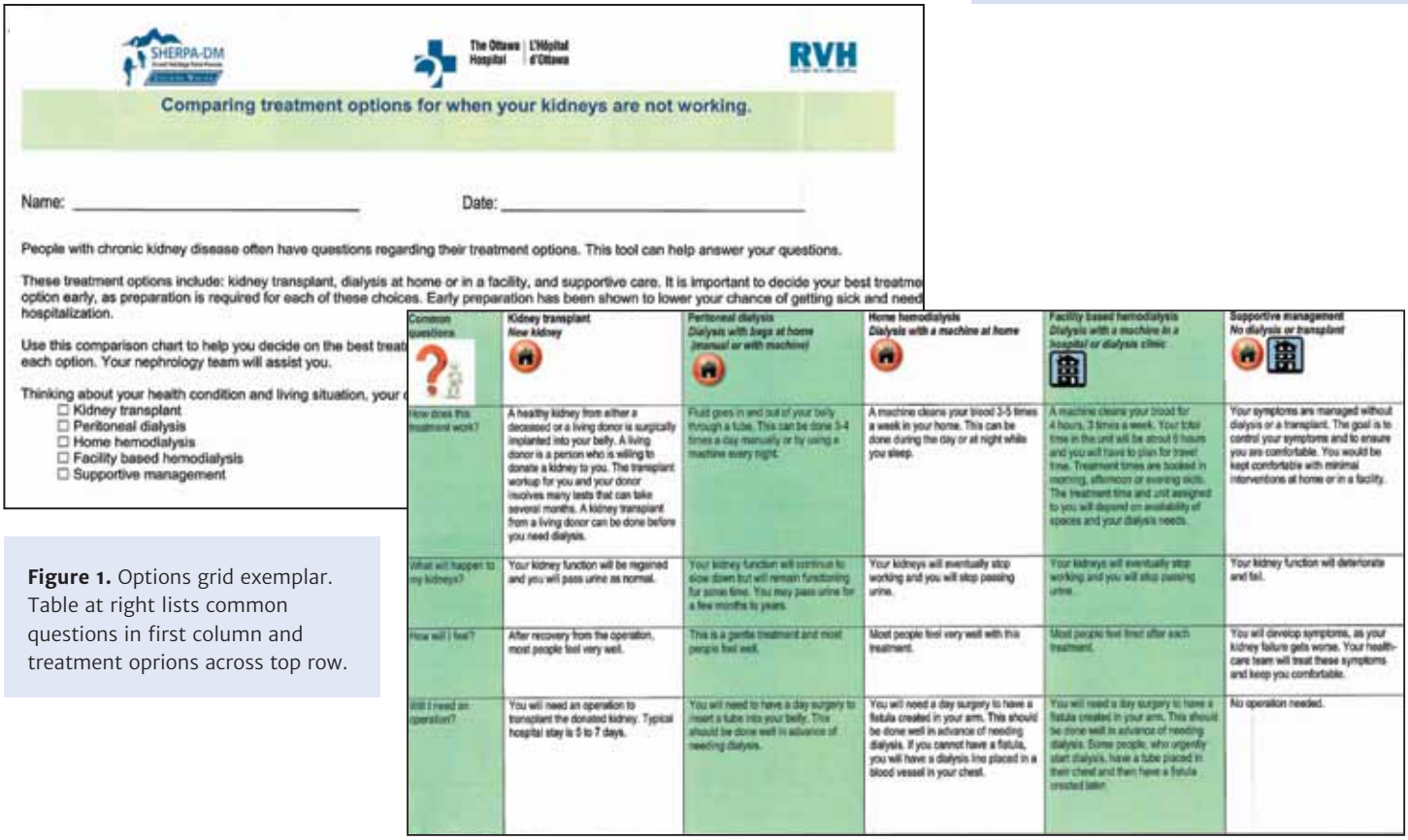
After the provider education sessions, the tools were implemented in the clinical practice area. All new patients at the PRI clinics attended a decision-coaching visit with a nurse and social worker who used the tools to facilitate the session. The decision support tools were evaluated by patients and providers for acceptability, usability, and feasibility of integrating into existing care pathways.

More than 95% of patients polled indicated that they would recommend the options grid to a fellow patient, and 100% (n=17) of the same patients would completely endorse the patient decision aid to other patients or health care providers. Both patients and providers reported feeling better prepared to identify a treatment option after reviewing the options grid and unanimously agreed that the tool provided clear and relevant descriptions of potential treatment options. All patient respondents (n=17, 100%) reported that the SHERPA-DM patient decision aid was relevant for people making choices for place of dialysis care, made them feel that they could use the decision aid when facing this decision, and was helpful for people who are facing decisions about home-based versus facility-based dialysis treatment. Health care providers indicated that the SHERPA decision aid increased the likelihood that patients' decisions are based on what is most important to them; endorsed the continued use of the tool in the clinical practice setting; and 90% (n=21) found that the tool helped patients participate actively in the decision-making process. The contribution of a medical writer trained in writing and conducting usability tests and surveys, interviews, and focus groups was a missed opportunity in this step. Additionally, having medical writers assist with the evaluation could have removed an element of bias because the medical writer could be viewed as a neutral party.

What Is Next in This Clinical Setting?

Use of decision coaching facilitated by the decision support tools developed during the pilot have become the standard of practice in the pilot site settings. Currently the authors are also leading a rollout of the decision support tools and decision coaching approaches in the Ottawa Hospital Hemodialysis New Start Program. This program introduces new patients who are beginning hemodialysis to treatment in an environment designed to provide intensive education with a focus on a self-management approach. We are also working with another regional nephrology program to implement the patient decision support program.

Because of the promising outcomes of the pilot program, the Ontario Renal Network sought to disseminate the options grid and decision aid tools across Ontario's chronic kidney disease programs. There is general recognition that while the instruments developed by the study team addressed a unanimous desire for an increased presence of information and decision-based tools to better support patients, implementing these tools in the absence of provider skills-building is not an effective approach. While the initial pilot exercise included decision support coaching, the curriculum developed was



Comparing treatment options for when your kidneys are not working.

Name: _____ Date: _____

People with chronic kidney disease often have questions regarding their treatment options. This tool can help answer your questions.

These treatment options include: kidney transplant, dialysis at home or in a facility, and supportive care. It is important to decide your best treatme option early, as preparation is required for each of these choices. Early preparation has been shown to lower your chance of getting sick and need hospitalization.

Use this comparison chart to help you decide on the best treat each option. Your nephrology team will assist you.

Thinking about your health condition and living situation, your
- ☐ Kidney transplant
- ☐ Peritoneal dialysis
- ☐ Home hemodialysis
- ☐ Facility based hemodialysis
- ☐ Supportive management

Common questions	Kidney transplant *New kidney*	Peritoneal dialysis *Dialysis with bags at home (manual or with machine)*	Home hemodialysis *Dialysis with a machine at home*	Facility based hemodialysis *Dialysis with a machine in a hospital or dialysis clinic*	Supportive management *No dialysis or transplant*
How does this treatment work?	A healthy kidney from either a deceased or a living donor is surgically implanted into your belly. A living donor is a person who is willing to donate a kidney to you. The transplant workup for you and your donor involves many tests that can take several months. A kidney transplant from a living donor can be done before you need dialysis.	Fluid goes in and out of your belly through a tube. This can be done 3-4 times a day manually or by using a machine every night.	A machine cleans your blood 3-5 times a week in your home. This can be done during the day or at night while you sleep.	A machine cleans your blood for 4 hours, 3 times a week. Your total time in the unit will be about 6 hours and you will have to plan for travel time. Treatment times are booked in morning, afternoon or evening slots. The treatment time and unit assigned to you will depend on availability of spaces and your dialysis needs.	Your symptoms are managed without dialysis or a transplant. The goal is to control your symptoms and to ensure you are comfortable. You would be kept comfortable with minimal interventions at home or in a facility.
What will happen to my kidneys?	Your kidney function will be regained and you will pass urine as normal.	Your kidney function will continue to slow down but will remain functioning for some time. You may pass urine for a few months to years.	Your kidneys will eventually stop working and you will stop passing urine.	Your kidneys will eventually stop working and you will stop passing urine.	Your kidney function will deteriorate and fail.
How will I feel?	After recovery from the operation, most people feel very well.	This is a gentle treatment and most people feel well.	Most people feel very well with this treatment.	Most people feel tired after each treatment.	You will develop symptoms, as your kidney failure gets worse. Your health-care team will treat these symptoms and keep you comfortable.
Will I need an operation?	You will need an operation to transplant the donated kidney. Typical hospital stay is 5 to 7 days.	You will need to have a day surgery to insert a tube into your belly. This should be done well in advance of needing dialysis.	You will need a day surgery to have a fistula created in your arm. This should be done well in advance of needing dialysis. If you cannot have a fistula, you will have a dialysis line placed in a blood vessel in your chest.	You will need a day surgery to have a fistula created in your arm. This should be done well in advance of needing dialysis. Some people, who urgently start dialysis, have a tube placed in their chest and then have a fistula created later.	No operation needed.

Figure 1. Options grid exemplar. Table at right lists common questions in first column and treatment oprions across top row.

delivered in person, which raises concerns regarding the feasibility of scaling up and disseminating this material across the province, given the geographic spread of Ontario's chronic kidney disease programs and providers. With the support of the Canadian Foundation for Healthcare Improvement, the Ottawa Hospital and the Ontario Renal Network have embarked on a project to work with patients and families to develop a readily distributable training video for health care providers on decision coaching and how to best address the common questions, fears, and anxieties of patients and family members experiencing decisional conflict.

Video teaching aids have long been used to scale up education outreach and strengthen spread of innovations.[9] There is good evidence that video vignettes and simulations are effective teaching tools in clinical practice. Specifically related to shared decision making and use of a patient decision aid participants in a randomized control trial rated a scenario-based video as the most effective learning aid in an interactive skills building workshop for decision coaching related to place of care at the end of life.[10] The study team has worked with a professional videography company to produce a video to assist providers in developing their decision coaching skills. The video was coauthored by a patient and health care provider and features 2 vignettes contrasting a patient decision coaching clinical approach against a traditional patient teaching approach. Interspersed within the video are commentaries and reflections by both a patient and health care providers who have used both approaches. Implementation in another regional nephrology program and evaluation is underway. An important part of the implementation plan will be to create a synergy between the use of standardized tools with the need to contextualize decision support practices to the local clinical realities. Again, medical writers could inform such initiatives through their expertise in script writing and in tailoring information to select audiences.

Conclusion

Shared decision making exists at the intersection of patient and provider expertise. Solid and cogent evidence supports the usefulness of PtDAs in clinical practice. Medical writers are often called upon to clearly communicate complex topics and specialized information to lay audiences. Promoting early involvement of medical writers could strengthen efforts to build sustainable, meaningful decision support tools and strengthen connections with decision aid creators. Timely access to PtDAs and decision coaching may help patients like Joan, living with a life-limiting illness, to better match their kidney care with their informed preferences. Multipronged approaches are needed to facilitate spread. By customizing implementation processes to the local realities and providing

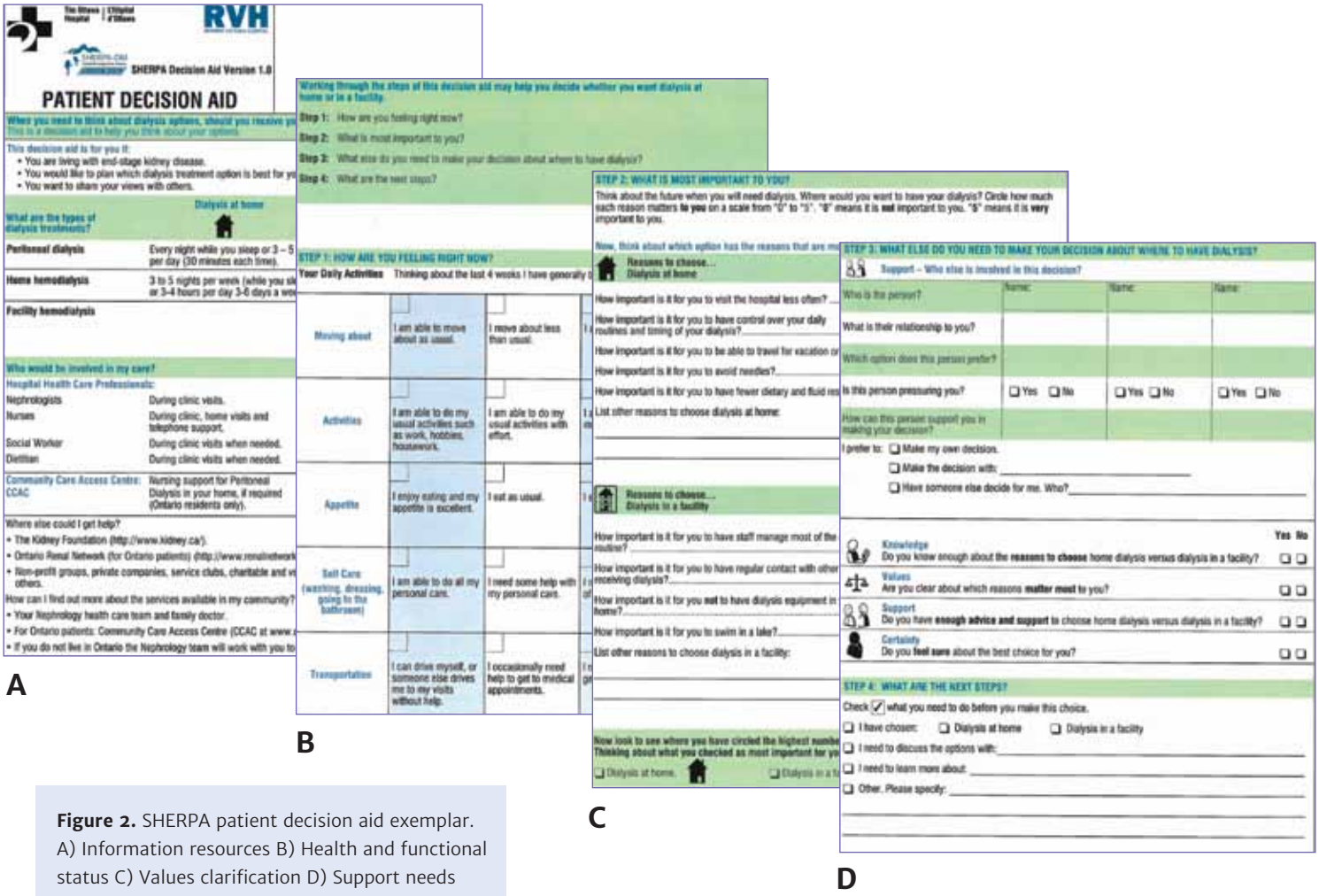


Figure 2. SHERPA patient decision aid exemplar. A) Information resources B) Health and functional status C) Values clarification D) Support needs next step

standardized teaching strategies with careful monitoring of outcomes and progress, population-based coverage is possible. The final outcome will be relief of unresolved decisional conflict related to renal care and improvement in quality of life for patients living with chronic kidney disease. Exploring ways to engage professional medical writers to help support decision support tool development presents a unique opportunity to enhance messaging and dissemination.

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

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THE RESEARCH INTERVIEW

Q&A with the Authors of "Avoidable Waste of Research Related to Inadequate Methods in Clinical Trials"

In a recent issue of the *BMJ*, **Yordanov et al.** report on their study of hundreds of randomized clinical trials.[1] They were interested in the concept of "wasted research related to inadequate methods" and looked at trials included in reviews recently published in the Cochrane Database of Systematic Reviews. For trials at "high risk of bias" in at least 1 domain, they assessed whether simple and inexpensive methodological adjustments at the planning stage could have decreased the risk of bias. The domains included sequence generation for randomization of participants, allocation concealment (so that researchers cannot influence how participants are assigned), blinding of participants and personnel, blinding of outcome assessment, and incomplete outcome data.

Victoria White, MA, ELS, editor of the *AMWA Journal*, conducted an email interview with the study's first 2 authors, **Youri Yordanov**, a physician and doctoral student at INSERM in Paris, and **Agnes Dechartres, MD, PhD**, a researcher at INSERM.

Q: It would appear that your research is of interest to medical writers in various ways. It highlights the idea that too much research yields findings that are not very interpretable. It also suggests various stages in which research waste could have been prevented, partly through better reporting of methods. Before we get into the design of your study and its important findings, can you define some key terms and concepts for us so that we will understand how they are being used in this study? In particular, what are research waste, risk of bias, and inexpensive methodological adjustments?

A: Research waste related to inadequate methods refers to trials with methodological problems resulting in high risk of bias (eg, inadequate randomization method resulting in high risk of selection bias) that could have been avoided by better planning of the trial.

Risk of bias refers to the tool developed by the Cochrane Collaboration for assessing risk of bias.[2] This tool includes elements associated with treatment effect estimates such as randomization method, allocation concealment, blinding, exclusion of patients from analysis.

By inexpensive methodological adjustments, we are referring to methodological adjustments that could have been easily performed from the planning stage of the trial and that represented less than 5% of the total cost of the trial as assessed by experts in the field.

Q: With our medical writer audience in mind, what do you see as your key findings?

A: In our study, we aimed to evaluate if part of the waste of research related to inadequate methods in clinical trials included in recent Cochrane reviews could have been avoided by simple and inexpensive methodological adjustments at the planning stage of the trial. We found that such adjustments could decrease the number of elements at high risk of bias in nearly half of trials and could transform all elements at high risk to low risk in 12% of the 142 trials in our sample (95% CI, 7% to 18%) (Figure 1). In a simulation study correcting for incomplete reporting, this avoidable waste represented 42% (95% CI 36 to 49%).

Q: How did you go about evaluating the trials for risk of bias?

A: We evaluated the risk of bias using the Cochrane risk of bias tool, a tool including elements associated with treatment effect estimates.[2] In this study, we initially relied on the risk of bias assessment conducted by the review authors and then reassessed risk of bias for a sample of trials.

Q: Can you briefly describe the simulation study you did to re-estimate the avoidable waste if all trials were adequately reported?

A: Many trials in our sample did not adequately report all elements so that the risk of bias could not be assessed. Therefore, we could not fully assess the avoidable waste due to inadequate methods. For example, in our sample, allocation concealment was not reported in 54% of trials, so risk of bias for this element and for those trials was unclear. So, the second

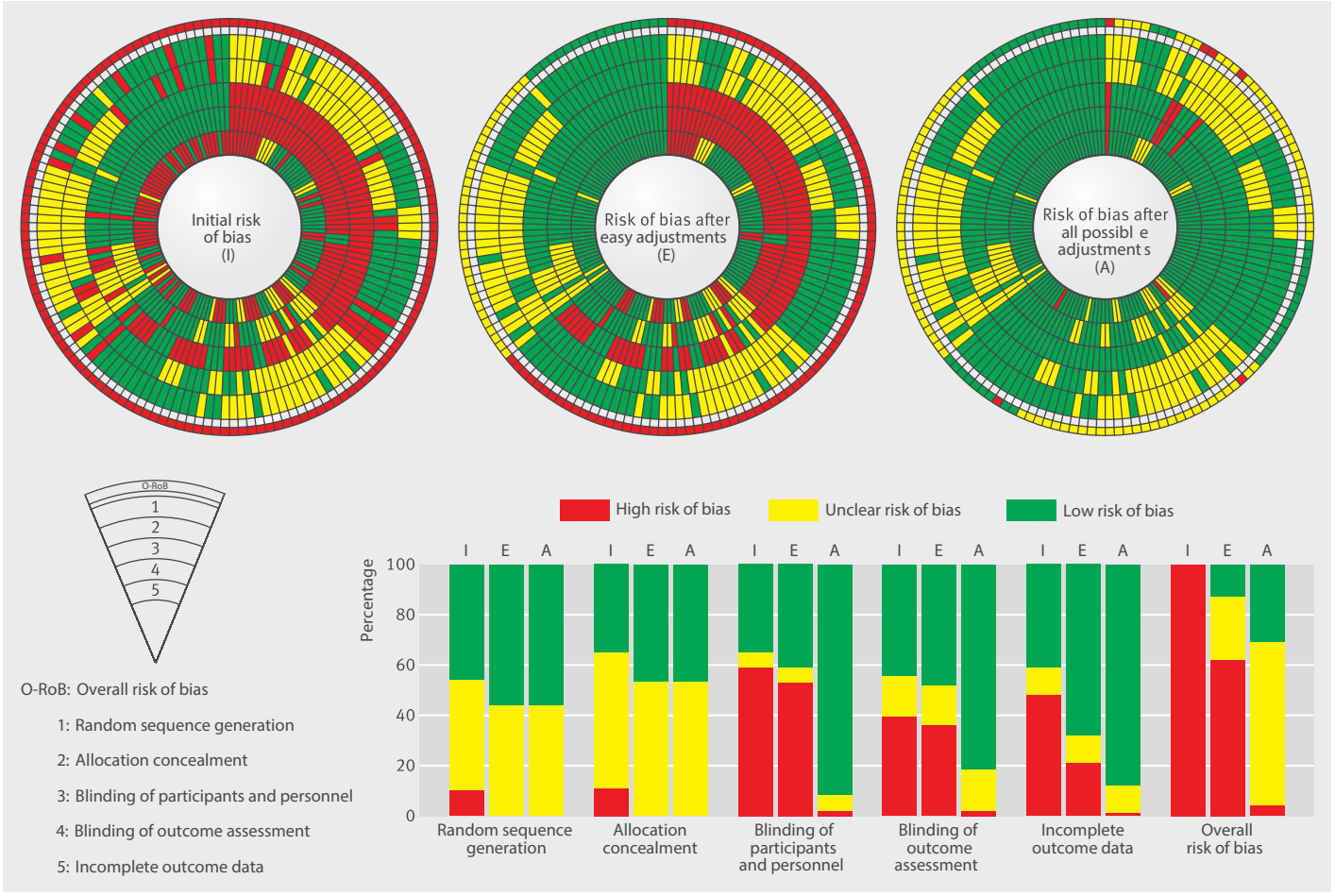

Figure 1. Risk of bias in various aspects of clinical trials as reported in the study by Yordanov et al. The researchers examined 200 clinical trials that had been determined to have at least 1 aspect "at high risk of bias" according to authors of Cochrane reviews. Yordanov et al. reassessed the risk of bias and confirmed that 142 were at risk of bias. In this figure, the spokes represent the trials; each "brick" represents a domain at low, high, or unclear risk of bias. The yellow bricks—unclear risk of bias—represent an area in which better communication of methods could assist with the interpretation of clinical trial results. *Reprinted with permission.*[1]

part of our study was a simulation of what would be the avoidable waste due to inadequate methods if all methodological elements were adequately reported. To do so, we considered all elements that were not adequately reported as missing data and used multiple imputation [a statistical technique] to attribute a high or low risk assessment to these domains. Then, we re-estimated the avoidable waste by assessing whether simple and inexpensive adjustments could transform elements at high risk into low risk. After this imputation, we estimated that the avoidable waste related to inadequate methods could represent 42% (95% CI 36% to 49%). This means that if all trials were adequately reported, simple and inexpensive adjustments could transform all elements at high risk to low risk in 42% of trials that initially had one element at high risk of bias.

Q: You mentioned that in 54% of the trials in your sample, allocation concealment was not reported. Just so that we are clear, you are not saying that 54% of trials don't report this.

Your sample didn't consist of trials in general, but rather it consisted of 200 trials for which Cochrane review authors had already determined that 1 domain was at high risk of bias. Is that correct?

A: Yes, from the random sample of trials confirmed to have at least one trial at high risk of bias, information on allocation concealment was not reported in 54% of the trials.

Q: In the article, you and your coauthors mention that it would be beneficial to have "more active implementation" of the CONSORT guidelines, which describe how to report various aspects of randomized controlled trials. Do you have suggestions for how to more actively implement the guidelines?

A: There is evidence that the quality of reporting in trials remains insufficient. In our study, we found that 74% of the trials in the sample had at least 1 methodological element at unclear risk of bias because of incomplete reporting. However,

there is a massive diffusion of reporting guidelines such as the CONSORT Statement and endorsement by journals. Turner et al. estimated that over 600 journals have endorsed the CONSORT Statement.[3] Many editors endorse the CONSORT Statement, but they only mention the existence of reporting guidelines in the instructions to authors. Some editors have implemented more active policies, such as asking authors to submit a checklist at the submission or acceptance stage or asking peer reviewers to evaluate the quality of reporting using the guidelines. A study showed that active implementation of CONSORT abstract guidelines was associated with an improvement in the reporting of abstracts.[4]

Q: What are the limitations of your research? And where might you go next with this topic?

A: Our study has several limitations. Our sample of trials is from Cochrane reviews, which may have excluded trials not meeting certain methodological criteria. Also, we relied on review authors' risk of bias assessment and reassessed risk of bias for a random sample of 200 trials at high risk of bias. We may thus have underestimated the number of trials at high risk of bias. Even if we attempted to provide a classification of all methodological problems in as much detail as possible, feasibility and costs of adjustments may vary across trials for the same methodological problem.

In our study, we focused on the waste related to inadequate methods. As outlined by Chalmers, waste of research occurs at all stages of clinical research, from the choice of questions that are not relevant to under-reporting of trial results.[5] So, there is a lot to do to decrease the waste at each stage.

SUMMARY

1. Many clinical trials reported in the medical literature are not adequately designed, potentially biasing the outcomes.
2. Simple, inexpensive changes in trial design may be able to influence the value of trial results.
3. Even trials that are properly designed may not be adequately reported; clear reporting can increase the probability that the results of properly designed trials can be interpreted correctly.
4. Adhering to the reporting guidelines in the CONSORT Statement could reduce research waste.

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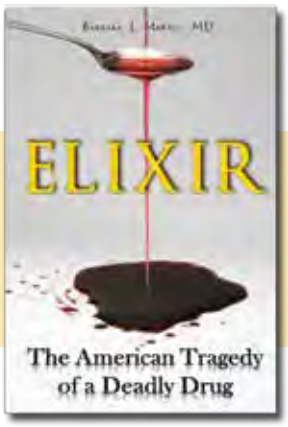
Elixir: The American Tragedy of a Deadly Drug

Barbara J. Martin, MD

Lancaster, PA, Barkerry Press 2014; Paperback, 334 pages, $17.95



In today's hyper-connected world, hardly a week passes without a nearly instantaneous recall of defective products including medications. News is trumpeted via tweets, 24-hour cable news, website postings, or a text from mom. As a result, and spurred by legislation, we now remove dangerous, deadly products from circulation quite rapidly.

Not so in 1937. Radio stations served up primarily local news. Rural newspapers did not extensively cover national events. Long-distance phone calls were expensive and the post office slow. For high-speed communication, you went to the nearest Western Union office to send a telegram.

This is precisely what a group of Tulsa, Oklahoma, physicians did on Saturday, October 9, 1937. They urgently wired the editor of a respected medical journal to report at least six deaths among their patients after prescribing Elixir of Sulfanilamide. Thus begins the story Barbara J. Martin, MD, documents in her extensively researched book, *Elixir: The American Tragedy of a Deadly Drug*.

The book is an important recounting of significant events that changed the pharmaceutical industry and still have relevance. As Martin describes with precise detail, in the 1930s, distribution and sales of drugs went largely unregulated. Sulfanilamide was one of the first widely available antibiotics. In pill form, physicians prescribed sulfanilamide to treat a range of bacterial infections, including venereal disease. Nearly anyone could obtain such drugs over-the-counter.

Oddly, the practice of swallowing medicine in tablet form was disliked by many. To boost sales, the S. E. Massengill Company created a more palatable liquid formulation. The company's chemist, Harold Watkins, devised a formula to dissolve sulfanilamide powder in a clear, odorless, sweet glycol compound known as *diethylene glycol*. Watkins was either unaware of, or disregarded, warnings that diethylene glycol was not safe for human consumption. Dr Martin recounts the chemist's rather checkered past.

The S. E. Massengill Company introduced "Elixir Sulfanilamide" to the marketplace in early September 1937. Direct shipments went to hospitals, retail pharmacies, and doctor's offices, spurred on by the company's sales force.

Within a month, Tulsa became ground zero for what mushroomed into a growing episode of such poisonings. The Tulsa physicians noted a consistent progression of symptoms: anuria, acute nephritis, and liver degeneration. Patients suffered severe abdominal pain, nausea, and vomiting, eventually succumbing to a stupor. Because sulfanilamide in pill form had proven safe and efficacious, diethylene glycol became the prime suspect for the mortalities appearing across the nation.

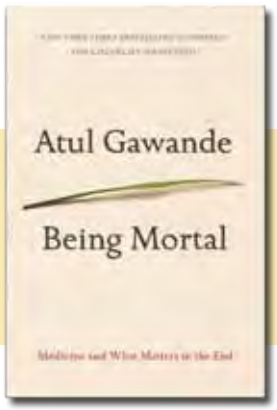
Food and Drug Administration (FDA) inspectors visited S.E. Massengill's headquarters to investigate Watkins' recipe and initiate a recall. With the death toll mounting, FDA officials doggedly sought to remove the deadly drug from the market despite stonewalling and subterfuge by doctors and pharmacists. Unfortunately, at least 100 deaths were attributed to Elixir Sulfanilamide in the intervening weeks.

The resulting publicity aroused public ire. Eventually, despite heavy lobbying by industry, President Franklin Roosevelt signed the 1938 Federal Food, Drug, and Cosmetic Act that required drug manufacturers to prove the safety of products before marketing them to the public.

It is not surprising that Dr Martin researched this subject for a decade, given the many obscure details she reports. Although often fascinating, the catalog of individuals who succumbed to the deadly drug can at times seem a tad repetitious. This is a minor quibble, however. Dr Martin's comprehensive account of an American drug calamity is a significant contribution to the medical community and general public.

—William Van Nostran

William is a medical communications specialist at the Rebecca D. Considine Research Institute, Akron Children's Hospital, in Akron, Ohio.



Being Mortal: Medicine and What Matters in the End

Atul Gawande, MD, MPH

New York, NY, Henry Holt and Company, 2014; Hardcover, digital formats, 304 pages

Dark humor prevails during medical internship, and a repeated example during my postgraduate training was the death-or-mumba joke. In this cynical joke, people appear to be given a choice between death and an unknown option, mumba, which ostensibly averts death at the cost of horrific agony. The choice, however, proves to be an illusion. The joke is retold as an analogy to the series of invasive, often painful procedures that hospital staff impose on terminally ill patients to delay the inevitable. But the medical mumba is nearly always performed at the cost of a patient's comfort and dignity. And regardless, the inevitable comes, well, inevitably.

In his thoughtful and heartrending book, *Being Mortal*, Harvard surgeon Atul Gawande admits,

> The waning days of our lives are given over to treatments that addle our brains and sap our bodies for a sliver's chance of benefit…Lacking a coherent view of how people might live successfully all the way to their very end, we have allowed our fates to be controlled by the imperatives of medicine, technology, and strangers.

Gawande argues that there are better ways to deal with the frailty of aging and imminent death, although he finds they are often incompletely implemented. Through recurrent threads of anecdotes—professional and personal—and a complementary survey of the literature on aging and dying, *Being Mortal* is Gawande's chronicle of "the modern experience of mortality" and how that experience is undergoing important cultural and medical revolutions in the midst of 21st-century health care.

Gawande organizes his examination of American death and dying into 8 chapters—the titles of which play like a riff on Kübler-Ross's 4 stages of grief (curiously not mentioned in *Being Mortal*). First, in "The Independent Self," there is the veneration of autonomy, which, of course, cannot last. When the body breaks down ("Things Fall Apart"), a gradual reliance on others ("Dependence") is ultimately met with placement in dismal nursing homes—which, Gawande reveals, were developed to relieve hospitals of elderly long-term inpatients and not to provide anything resembling a *home* for the aged. In "Assistance," "A Better Life," and "Letting Go," Gawande explores the development and benefits of a more home-like assisted living (in its originally intended form), along with hospice and palliative care. He describes how palliative care has been found, ironically, to extend the lives of terminally ill patients over "the seemingly unstoppable momentum of medical treatment"—or mumba, as it were.

Chapter 7, "Hard Conversations," is the revelatory chapter of *Being Mortal*. Here, Gawande juxtaposes his physician father's lengthy battle with a spinal-cord tumor and Gawande's parallel care for a woman with metastatic cancer. By using these case studies, Gawande highlights a momentous conflict when death looms: whether to pin your hopes on risky interventions or to seek palliative care. As Gawande learns, these end-of-life options aren't necessarily mutually exclusive.

Chapter 7 also features a troubling discovery. Gawande finds that physicians, including himself, are ready to offer any number of last-ditch treatments to their terminally ill patients; however, physicians are ill-equipped to have the tough, time-consuming conversations with patients about their values and priorities when death is probable. "We've created a multitrillion-dollar edifice for dispensing the medical equivalent of lottery tickets," Gawande explains, "and have only the rudiments of a system to prepare patients for the near certainty that those tickets will not win. Hope is not a plan, but hope is our plan."

In the final chapter, Gawande explores the concept of courage. Confronting mortality is certainly brave, he finds, but acting on the truth of one's discovered fears and hopes in the face of an impending death is braver still.

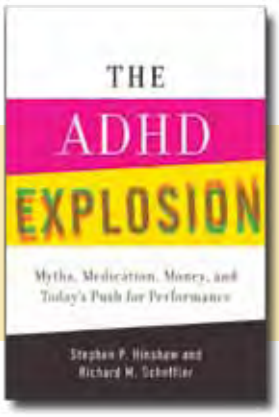
Despite its uncomfortable subject, *Being Mortal* is an absorbing and important—even vital—read. It is recommended for those who face the inevitable—meaning,

continued on page 75

The ADHD Explosion: Myths, Medication, Money, and Today's Push for Performance

Stephen P. Hinshaw, PhD, and Richard M. Scheffler, PhD

New York, NY, Oxford University Press, 2014; Hardcover, digital formats, 288 pages



In this highly informative book, *The ADHD Explosion: Myths, Medication, Money, and Today's Push for Performance*, psychologist Stephen Hinshaw, PhD, and health economist Richard Scheffler, PhD, both of University of California, Berkeley, address the societal impact, health care costs, and long-term outcomes for those affected by ADHD. The authors also provide guidelines for research, practice, and public policy concerning ADHD. More importantly, they encourage information exchange between scientists and clinicians.

Over the past 2 decades, the United States has observed a sharp increase in ADHD (attention deficit/hyperactivity disorder) diagnoses. The rates of ADHD diagnosis continue to grow beyond the United States, revealing an emerging global crisis. Surprisingly, whether this rapid expansion is due to a focus on diagnostic testing, intensified scientific research, policy decisions, response to advocacy, or marketing of treatments, remains unclear.

Individuals with ADHD often exhibit deficits in social relationships and family interactions. Patients with ADHD also are prone to impulsive high-risk behavior, delayed independence, academic and workplace underperformance, poor physical health, and problems with the law. Unfortunately, the consequences of ADHD symptoms often are devastating, long term, and rob an individual of major life chances. Effective treatment for ADHD includes a combination of medication and behavioral intervention. The pairing requires coordination between physicians, care providers, and teachers to provide optimal benefits.

This unique book is useful for parents, educators, mental health professionals, students, and adults. Most chapters begin with a case study of an individual or family suffering with the disorder. These stories depict the poignant issues faced daily by those with ADHD. Although this book addresses the major social and cultural issues surrounding ADHD, the authors do not provide a direct explanation for the skyrocketing numbers of ADHD patients. Instead, the book presents a historical perspective of ADHD in an attempt to improve medical treatments and public policies.

The introductory chapter presents the history of ADHD and the tremendous financial and emotional costs associated with this medical condition. Subsequent chapters scrutinize the science of ADHD, standards for accurate diagnosis, responsive treatments, and state educational policies. Concluding chapters address negative media depictions of ADHD, the global perspective in treatment strategies, and the stigmatizing views surrounding the condition.

As a nation, we must alter our fundamental attitudes regarding ADHD as well as improve standards for diagnosing and treating individuals who have ADHD. Together, we can help these individuals improve their quality of life and the quality of life of their care providers. Individuals with ADHD have the potential to lead productive and successful lives, when appropriately supported by a compassionate, educated, and humane society.

—Tara Ann Cartwright, PhD

Tara is a medical writer and editor in Research Triangle Park, North Carolina.

Dr. Mütter's Marvels: A True Tale of Intrigue and Innovation at the Dawn of Modern Medicine

Cristin O'Keefe Aptowitz

New York, Penguin Group, 2004; Hardcover, digital formats, 371 pages

Inspired by a childhood trip to the Mütter Museum of the College of Physicians of Philadelphia, Cristin O'Keefe Aptowitz created a biography of Dr Thomas Dent Mütter (1811–1859) with the nontraditional touch of a poet-storyteller. *Dr. Mütter's Marvels: A True Tale of Intrigue and Innovation at the Dawn of Modern Medicine* spans the close of the 18th and beginning of the 19th centuries. Although the title implies a focus on medical specimens and the man who gathered them, the book describes broadly the medical practices of the era. Readers expecting a thorough exploration of the marvels collection will be disappointed; the "oddities" are connecting devices in the deeper story of Mütter's inspiration, teaching and surgical techniques, and legacy.

Content is presented in a fluctuating timeline: Mütter's medical career, in three stages, is interspersed with connected childhood events. This technique adds interest but can be unclear, especially after frequent jumps. Mütter is described as a gregarious personality and outspoken advocate for plain language, compassion, and anesthesia who earned his reputation through work, not pedigree, and was mocked first for his appearance and later for advancing medical concepts beyond the traditional scope. His specialization in plastic surgery and development of a complex technique still used today are highlights. Any reader will appreciate his compassion toward the frailest and most-deformed patients and his charismatic teaching methods. Implications that Mütter changed perceptions almost singlehandedly and the suggestion of colleague animosity seem more relevant to the storyline than to reality.

Within the context of Mütter's life, Aptowitz adeptly explores the establishment of medical colleges, early teaching lectures, and dire straits of patients (and physicians' attitudes toward them). She is exemplary at showing, not telling, the reader about common medical risks, such as the spread of infection without aseptic technique. The story only seems less than effortless when women's issues are brought to the fore. Data are indexed and described in end notes. Placement minimizes story disruption but challenges readers interested in medical details to identify quoted conversation sources. Illustrations and chapter-introducing lecture quotations are well-placed extras.

Dr. Mütter's Marvels as biography in the form of storytelling weaves complex facts into a truly enjoyable read—a fun introduction to an interesting surgeon and teacher, and a window into important medical history. Readers will wish to explore more about this man and his marvels that played a particularly interesting role in the transition of medicine from a study of "humours" to, eventually, data-driven patient care.

—Nicole M. Van Hoey, PharmD

Nicole is a freelance writer/editor in Arlington, Virginia.

Being Mortal *review continued from page 73*

everyone. For those whose loved ones face progressive limitations or an impending death, the book holds special urgency. Gawande's professional and personal examination should guide and inspire clinicians and patients alike, as well as medical writers. Medical writers, in particular, may appreciate the increasingly popular blind-endnote style of *Being Mortal*.

There are ways to live at the end of life that sidestep mumba. *Being Mortal* is Gawande's timely, lucid, and compassionate appeal—to physicians, especially—that we must and can manage frailty and dying more honestly and humanely.

—Barbara J. Martin, MD

Barbara is a freelance writer in Lancaster, Pennsylvania, and author of Elixir: The American Tragedy of a Deadly Drug.

Definitions: How to Say What You Mean

By Laurie Endicott Thomas, MA, ELS

You can use words to convey meaning only if your audience understands what you intend those words to mean. You can baffle your readers by using words that mean nothing to them. You can also mislead them by using words that seem to mean something other than what you meant to say. One way to avoid those problems is to use common words whose meaning would be obvious to anyone. For example, you would write "itching" instead of "pruritus" in a piece for a lay audience.

Of course, we medical communicators must often discuss concepts that are unfamiliar to most people. Thus, we must often use words that are new to some members of our intended audience. Sometimes we must even use familiar words that take on an unusual meaning in a particular context. In those circumstances, a good writer would give those words a proper introduction by defining them at first mention. Lazy writers often fail to give these definitions. Bad writers give bad definitions.

Types of Definitions

To give good definitions, you need to understand that there is more than one kind of definition. Each kind of definition serves a particular purpose.

- **Lexical definition**—the kind of definition you find in a dictionary. It explains what people generally mean when they use that word.
- **Reportive definition**—an explanation of the meaning that the word carries for a particular group of language users, if that meaning differs from the definition given in a standard dictionary.

Lexical definitions are the most common kind of definition that writers and copyeditors encounter. Whenever you use a technical term that would be unfamiliar to your readers, consider giving them the dictionary definition of that word, to save them the trouble of looking the word up. If the dictionary definition of a word differs from how that word is commonly used, you may need to give the reportive definition and explain how it differs from the lexical definition. For example, a word may mean something different to medical doctors than it means to members of the general public.

When you are editing someone else's work, look to see whether the lexical definitions that the author gave match the dictionary definitions. If they don't match, query the author. Sometimes there are good reasons for a mismatch, such as in cases of stipulative definition.

- **Stipulative definition**—a definition that gives a term a specific meaning in the context of a particular discussion or argument.

Some stipulative definitions are arbitrary, such as when a scientist must coin a new word for a new concept (eg, when Murray Gell-Mann coined the word *quark* to refer to a new type of subatomic particle). Often writers give an arbitrary definition to a familiar word. When taken to a ridiculous extreme, this practice results in Humpty-Dumpty words, which are words whose stipulative definition seems to be deliberately misleading. ("'When I use a word,' Humpty Dumpty said, in rather a scornful tone, 'it means just what I choose it to mean—neither more nor less.'"[1]) Other stipulative definitions are restrictive, such as when medical writers specify that an elderly person is someone who is at least 65 years old.

Many legal definitions are a form of restrictive stipulative definition called a precising definition:

- **Precising definition**—a definition that extends a lexical definition by adding criteria that narrow down the members of the set being described.

Good writers and good editors think carefully about the definitions being presented in a piece of writing.

A precising definition clarifies precisely what a term denotes. We often see precising definitions in medicine, such as when drug labels specify that the dosage recommendations for children should be followed for those 12 years of age or younger.

When you start thinking about definitions, you inevitably have to deal with a branch of logic and mathematics called set theory. Many definitions, including precising definitions, clarify whether someone or something should be included in the set described by the term in question. There are several ways in which definitions relate to sets.

- **Intensive definition**—a definition that specifies the rules for including members (and excluding nonmembers) of a given set.
- **Extensive definition**—a definition that defines a set by listing all of the set's members.

Consider the term *starting lineup*. A lexical definition of *starting lineup* is "the set of players who will actively participate in a game when the game begins." The intensive definition of *starting lineup* would be a set of criteria, such as whether a person is present at the time and place where the game will be played and whether the person is eligible to participate (eg, not listed in injured reserve). The extensive definition of a particular starting lineup is the list of all of the players who make up that starting lineup.

Medical communicators must often deal with theoretical and operational definitions:

- **Theoretical definition**—a description of an abstract concept (eg, intelligence).
- **Operational definition**—a definition based on 1 or more tests of some observable trait (eg, an intelligence quotient [IQ] 120 or higher).

Theoretical definitions pose some serious philosophical problems. For example, intelligence has something to do with the ability to solve problems. But does it make sense to say that learning to solve a particular kind of problem makes one more intelligent? Operational definitions also pose some serious philosophical problems. What does a person's score on an IQ test really mean? Is someone who scored 121 on a given test on a particular day really "superior" to someone who scored 119?

Theoretical definitions are similar to Socratic definitions, which are named after the Greek philosopher Socrates:

- **Socratic definition**—an answer to a question in the form "What is F-ness?" (eg, What is piety? What is justice? What is virtue?).

It can be surprisingly hard to come up with a good theoretical or Socratic definition. For example, what is health? What is mental health? Those are important questions, even if they are not always answerable.

Sometimes, definitions are used for poetic or rhetorical purposes:

- **Metaphorical definition**—a definition used for artistic effect rather than for conveying literal meaning (eg, happiness is a warm puppy).
- **Loaded definition**—a definition that expresses a value judgment rather than a description of conventional meaning (eg, an embryo is a preborn child).

Good and Bad Definitions

Good writers and good editors think carefully about the definitions being presented in a piece of writing. Do the lexical definitions reflect the definitions in a standard dictionary? Do the reportive definitions reflect actual usage? Are the stipulative definitions psychologically acceptable?

Definitions should not be circular. In other words, you should not repeat the word in its own definition (eg, a *dog* is an animal whose parents are *dogs*). Nor should a set of definitions be circular (eg, a *cause* is something that produces an *effect*, but an *effect* is something that results from a *cause*).

Definitions should be neither too broad nor too narrow. An overly broad definition would apply to too many things. An overly narrow definition would exclude too many things.

Medical communicators should also avoid metaphorical definitions (eg, happiness is a warm puppy), especially in works intended for an international audience. A metaphorical definition is a form of poetic discourse, not a means of technical communication. Medical communicators should also avoid using loaded definitions, especially if the purpose of the piece is to convey scientific information rather than to express a political opinion.

Laurie Endicott Thomas is the author of Not Trivial: How Studying the Traditional Liberal Arts Can Set You Free *as well as the upcoming book* No More Measles!

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Hypothesis Testing in Clinical Trials

By Thomas M. Schindler, PhD / Head Medical Writing Europe, Boehringer Ingelheim Pharma GmbH & Co KG, Biberach, Germany

A clinical trial is really an experiment, a test of whether a treatment, drug, device, or method works, that is, produces the results that we hope for. By conducting a clinical trial, we venture into the unknown, and the result of our study can either be positive (the drug works) or negative (the drug does not work) or, at worst, inconclusive (we are as clever as before). Nevertheless, we do not enter the territory of the unknown unprepared. When we plan and conduct a clinical trial, we want to test a preconceived idea about the effect of our intervention. Our hypothesis, our idea of how the intervention will change something important in the patients treated, is based on the mechanism of action of our drug or on the results of previous trials or trials with similar substances done by somebody else.

On the basis of what we reasonably assume, we formulate a hypothesis and test it in our study. In most instances, we are interested in differences between 2 groups: participants who received a new treatment and participants who did not. When we observe differences, we want to be able to evaluate whether it is reasonable to conclude that the differences were caused by our intervention or whether they are likely to have resulted from chance. *Hypothesis testing* is a widely used method in clinical research to design studies so that we can gather the appropriate evidence.

To illustrate this method, it is best to go through a simplified example of a study. For demonstration purposes, I concentrate on the principles and leave out details regarding the statistical tests that might be done in a real trial. Suppose we had discovered a new substance, a potential treatment for diabetes. In patients with diabetes, the concentration of sugar in the blood is higher than in healthy people. The amount of sugar in the blood can be determined either by measuring the concentration of glucose or by measuring the concentration of glycated hemoglobin (abbreviated as HbA1c), which is formed when hemoglobin, a protein within red blood cells, joins with glucose in the blood.

Because a person's glucose concentration varies with time of day and the intake of food, it is better to analyze the more stable and more long-lived HbA1c. Its concentration is expressed as a percentage of glycated hemoglobin from all hemoglobin. The value in healthy adults is 4% to 5.9%; in patients with diabetes, it is above 6.5%. We know from previous experiments that our substance lowers blood sugar levels and hence HbA1c levels. We therefore believe that patients with diabetes who are treated with our compound will have lower concentrations of HbA1c in their blood after, let's say, 24 weeks of treatment. To test whether our compound has the desired effect, we compare patients who have taken our compound with patients who have taken a lookalike/taste-alike placebo pill without any active substance. To avoid biasing the results, we randomize research participants into the treatment or placebo group. Participants, physicians, caregivers, and personnel measuring HbA1c levels do not know who is in which group (randomized, double-blind design).

Formulating 2 Hypotheses

We then formulate a hypothesis that can be "translated" into variables that can be measured. If the hypothesis is not clear and precise, it could lead to inconclusive results. Despite the belief in our compound, we need to be aware that our hypothesis could be wrong.

In hypothesis testing, we formulate not 1 but 2 hypotheses: the *null hypothesis* and the *alternative hypothesis*. We start with the null hypothesis. This is the hypothesis that fully contradicts our intuition or conviction. It embodies the outcome that our drug has no effect. In our example, the null hypothesis (also called H_0) could look like this:

"After 24 weeks of treatment, the mean concentration of HbA1c in patients who received our compound is the same as the mean concentration of HbA1c in patients who have received a placebo."

In the alternative hypothesis (also called H_1), we clearly and precisely formulate what we believe is the effect of our compound. The alternative hypothesis could look like this:

"After 24 weeks of treatment, the mean concentration of HbA1c in patients who received our compound is different from the mean concentration of HbA1c in patients who have received placebo."

By just stating that we believe the mean values will be different, we take a conservative approach. Thus, we retain an openness for 2 potential outcomes, ie, that the mean HbA1c concentration in the group of patients who took our compound could be either lower or higher than in the group that took placebo. We set a criterion level for decision. That is, we set a *P* value threshold for whether to accept or reject the null hypothesis. As a threshold for this example, we will use .05; if the *P* value we obtain is below this value, we reject the null hypothesis (although still recognizing that there is a possibility that the null hypothesis is true).

We now conduct our study and measure HbA1c levels after 24 weeks of treatment. We calculate the mean values for both groups. As said above, we hoped for a difference. Let's assume we determined that the mean concentration in patients treated with our compound is 1 percentage point lower than in the patients taking placebo. We have determined a difference, but how sure can we be that this reflects a real effect?

To find this out, we check whether the difference we see could have been observed if the null hypothesis were true. More precisely, we determine the probability with which we could have seen the difference that we have found in our study if the null hypothesis were true. Because we determine a probability, we obtain a *P* value. *P* values are in the range between 0 (unlikely) and 1 (certain). The smaller the *P* value, the more unsustainable is the null hypothesis. When the null hypothesis is untenable, we can reject it and adopt the alternative hypothesis.

Determining the *P* Value

We obtain the *P* value by first calculating a *test statistic* according to the following formula:*

Test statistic = (observed value – hypothesized value) / standard error of observed value.

The resulting value for the test statistic can then be compared with a standard normalized table that gives us the *P* value for this value of the test statistic. (The explanation of how to arrive at the standard normalized table is simple but beyond the scope of this paper. For more detail, please consult 1 of the books mentioned in the references.) For our example, we assume that our data has an almost normal, bell-shaped curve distribution, the so-called *t* distribution. (The distribution of data affects which statistical tests should be used.)

In our example, the alternative hypothesis had simply stated that there is a difference between the groups. Thus the mean value for the treated group could be either higher or lower than for the group that received placebo. By stating the alternative hypothesis in this way, we have been looking in both directions; therefore, we need to consult a standard normalized table for 2-sided or 2-tailed *P* values.

Our observed value is 1% (ie, a 1 percentage point difference), the hypothesized value according to our null hypothesis is 0% (ie, no difference), so the value in the numerator is therefore 1, and let's assume the standard error is 0.413%. Thus our calculation (1 ÷ .413) yields a test statistic of 2.42. Consulting the appropriate table for a 2-sided test, we obtain a *P* value of .0155. This means that under the condition that the null hypothesis were true, a value of 2.42 would have come about with a probability of only .0155 (1.55%). The *P* value we have obtained is below the threshold of .05, therefore we can reject the null hypothesis and adopt the alternative hypothesis. That is, we can state that our study has shown a difference between treatment groups. However, there is always a risk that the observed study result is a false positive, that is, that we are wrongly concluding there is a real difference or effect when, in fact, there is not. (This is known as a type I error.)

Interpretation of *P* Values

As in our example, in the life sciences and medicine, *P* values resulting from hypothesis testing are used to arrive at a decision about whether to reject or accept the null hypothesis. The continuous range of probabilities between 0 and 1 is dichotomized to arrive at a "yes or no" decision. In other words, we want to arrive at a "black or white" decision based on a range of grey values. The dichotomy is achieved by introducing a threshold. If a *P* value is below the threshold, we decide that we can reject the null hypothesis. Conversely if the *P* value is above the threshold, we cannot reject the null hypothesis. This does not mean that we have to believe that the null hypothesis is true. We need to state that there is not enough evidence to reject it (ie, chance or random variation is a reasonable explanation for the observed results, so we do not need to consider alternative explanations).

We must realize that by hinging our decision on a threshold, we are dealing with 2 risks. We can obtain a *P* value below the threshold and reject the null hypothesis when, in fact, the null hypothesis is true; this is called a type 1 error (false positive finding). Alternatively, we can obtain a *P* value that is above the threshold and therefore retain the null hypothesis

**Explaining this calculation is beyond the scope of this article. Conceptually, think of this formula as a way to take into account the sample size and how variable the data points are.*

when, in fact, the null hypothesis is not true; this is called a type 2 error and can be thought of as a false negative finding.

Conventional thresholds for decision making used in the medical literature are .05 (or 5%) and .01 (or 1%). With these thresholds, a *P* value below the threshold, for example, .05, is demonstrating a statistically significant effect, and a *P* value above .05 indicates a nonsignificant effect. Hypothesis tests are also often called *significance tests*, and the thresholds are also called *significance levels* or *alpha levels*. The word *significance* is burdened with misconceptions because statistical significance may not be indicating clinical significance.

It is important to remember that a *P* value in hypothesis testing does not tell us anything about the magnitude of the effect. In our example, we determined a difference of 1 percentage point in mean HbA1c concentration. As shown above, this difference is unlikely to have occurred if our compound had no effect, as stated in our null hypothesis. What we do not know is how reliable or certain the effect size is. We have performed just 1 experiment, that is, conducted 1 study. If we were to perform several studies, we would be likely to determine values that are different from the one in our current study. We might, for example, find differences ranging from 0.8% to 1.4%. To evaluate the uncertainty in the magnitude of our variable of interest, we need to calculate confidence intervals—a topic we plan to cover in a future article.

Summary

Hypothesis testing is a common method applied in clinical research. It is a method to decide between a null hypothesis (no effect) and an alternative hypothesis (an effect exists). We determine the likelihood of obtaining this value if the null hypothesis were true. Through hypothesis testing, we obtain a *P* value. The *P* value is then compared with a predetermined criterion of acceptance (eg, the threshold of .05) and informs us about whether we can reject the null hypothesis or not (ie, conclude that chance or random variation is a reasonable explanation for the observed results). If the calculated *P* value is below the threshold, we can reject the null hypothesis (ie, chance or random variation is a sufficiently improbable explanation for the observed results) and accept the alternative hypothesis. *P* values do not tell us anything about the magnitude of the effect. *P* values also do not give us any indication about whether the effect that we have observed is clinically meaningful.

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Brian Bass


Melissa L. Bogen


Lori De Milto


Debra Gordon


Donna L. Miceli


Phyllis Minick


Elizabeth L. Smith


Ruwaida Vakil

Q Do you always use a written contract when you are working with clients? Is an email message sufficient? Do you have a lawyer review your contract?

A I do not always have an official written contract, but I do always try to make sure that I have a detailed agreement, in writing, before I start a project. Over my years of freelancing, many of my clients have had their own standard contracts. In some cases, they are primarily nondisclosure agreements; in others, they are more detailed. I have never developed a standard contract of my own, but in cases where a client doesn't ask me to sign a contract, I write a detailed description of the project, including the price and exactly what they are getting for that price. I usually send this as a separate attachment to an email requesting that the client review it and confirm that it accurately meets their expectations. I save both online and hard copies of this and all communications related to the project. On rare occasions, I have agreed to do a quick-turnaround project, without a formal written agreement, for a client with whom I have had a long-term, mutually trusting relationship. I do not have a lawyer review my contracts, but I do review them carefully myself and don't hesitate to question a stipulation I disagree with, and occasionally, before signing, I add a stipulation of my own. Fortunately, I have never had to challenge a client for breach of contract.

—Donna L. Miceli

It really depends on your relationship with the client. During the project discussion phase (usually by telephone; sometimes in person) prior to start-up, I make sure that the client and I are on the same page regarding expectations, deadlines, reviews, and payment.

For an established long-term client, I normally do a letter of agreement by email, outlining the parameters of the project as discussed. I include a timeline for reviews and deadlines for various aspects of the project, always with the caveat that delays during the review process (especially if multiple persons or departments must sign off on the project) may delay the later deadlines. I also spell out the invoicing process to be used. (I use the milestones of start-up, submission of outline, submission of first draft, and submission of final draft). Because I work on a project fee basis rather than hourly for most clients, I also include a statement that if the project parameters are expanded or changes in direction occur, we will renegotiate the fee upward to cover the additional time involved.

For a new client (someone I have not worked with in the past), I usually ask them to send me their written contract and make any necessary changes to it to conform to the above project parameters. I had a lawyer review our initial contracts in the past, but having been in business for many years, I only contact him if I have a major question on the terminology in the client's contract. Communication with the client—both a known client and a new one—up front are vital to the success of the project.

—Elizabeth L. Smith

Most assignments in which I'm engaged include a contract, but the written contract isn't mine. I prepare a detailed project estimate based on the understood scope of the assignment, and I send that to the client for consideration and approval. That document may also include an invoicing schedule, enabling larger projects to be billed after major milestones so that I can maintain cash flow. In the cover note, I ask the client to respond with any questions and to confirm whether I have approval to proceed. When I receive an email confirming approval of my estimate and/or direction to get started, I'm fine with that serving as my contract.

Often, my clients have their own contract requirements. Most call it a statement of work; others call it a writing contract. This document typically has boilerplate language about me being an independent contractor, out-

lines the time frame for delivery, reiterates information from other documents I've signed (eg, a nondisclosure agreement), indicates to whom ownership of the materials belongs (copyright), provides for a right of cancellation of the contract, and includes other miscellaneous tidbits such as a confidentiality clause and a provision that no changes can be made to the contract except in writing and by mutual agreement. What I like best is that my estimates are so detailed that my clients usually copy and paste my language describing the deliverable, costs, and payment schedule from my estimate into their statement of work or writer's contract. I still review that language carefully to make sure nothing has been changed—like the addition of another round of revisions. It's sneaky, but it happens!

I sign, scan, and return the partially executed contract and ask that the contract be returned to me when it is fully executed (ie, after my client's representative has also signed the document). I keep that on file along with my estimate and ultimately with my invoice when the project is complete. I save all these materials in a job folder, which I retain along with my corporate tax returns for the requisite 7 years.

—Brian Bass

Q Besides AMWA, what other organizations do you recommend a new freelance medical writer explore?

A

As a sage AMWA member once told me, if you want to get work in an industry, go to that industry's meetings and introduce yourself to people. With that in mind, the list below is by no means exhaustive, but nevertheless it is a pretty good compilation of organizations to consider joining or attending their meetings. At the very least, it's worthwhile to review their websites for member benefits, job boards, member directories, and meeting schedules.

Organizations Other Than AMWA to Consider Joining

Accrediting Council for Continuing Medical Education, **www.accme.org**
American Association for the Advancement of Science, **www.aaas.org**
American Chemical Society, **www.acs.org**
American College of Clinical Pharmacy, **www.accp.com**
American Medical Association, **www.ama-assn.org/ama**
American Medical Women's Association, **www.amwa-doc.org**
American Pharmacists Association, **www.pharmacist.com**
American Public Health Association, **http://apha.org**
American Society for Microbiology, **www.asm.org**
American Society of Clinical Pathologists, **http://ascp.org**
American Society of Journalists and Authors, **http://asja.org**
Association of Clinical Research Professionals, **www.acrpnet.org**
Association of Health Care Journalists, **http://healthjournalism.org**
Board of Editors in the Life Sciences, **http://bels.org**
Council of Science Editors, **www.councilscienceeditors.org**
Drug Information Association, **www.diahome.org**
Editorial Freelancers Association, **www.the-efa.org**
European Medical Writers Association (our sister organization), **www.emwa.org**
Federation of American Societies for Experimental Biology, **www.faseb.org**
Health and Science Communications Association, **http://hesca.net**
International Society for Medical Publication Professionals, **www.ismpp.org**
National Association of Science Writers, **www.nasw.org**
Public Relations Society of America, **www.prsa.org**
Regulatory Affairs Professional Society, **www.raps.org**
Society for Neuroscience, **www.sfn.org**
Society for Scholarly Publishing, **www.sspnet.org**
Society for Technical Communication, **http://stc.org**
Association for Women in Communications, **www.womcom.org**

Potentially Valuable Organizations to Join

Two organizations stand out as worthy of special mention: the Association of Health Care Journalists and the Drug Information Association (DIA).

The first, the **Association of Health Care Journalists** (**http://healthjournalism.org**), has a superb benefit for freelance medical journalists: free access to journals and databases, including Elsevier's ClinicalKey and

ScienceDirect, UpToDate.com, the Cochrane Library, *Health Affairs*, the *American Journal of Public Health*, and the *Journal of the American Medical Association*. The Association of Health Care Journalists has chapters in Atlanta, Chicago, Cleveland, London, New York City, Philadelphia, the San Francisco Bay area, and Washington, DC. With the yearly membership fee of $60, it's a bargain if you meet the membership requirements.

The **DIA*** (**www.diahome.org**) stands out as an organization that can provide opportunities for education and networking with industry experts worldwide in a multitude of fields related to drug and medical device development. The DIA is a multidisciplinary scientific organization of more than 23,000 members, from more than 80 countries, who work in every facet of the discovery, development, and lifecycle management of pharmaceuticals, medical devices, and related products—just about anything associated with bringing new products to market.

Special Interest Area Communities (SIACs) are subgroups within the DIA that provide a discipline-specific global community. Among the 25 communities is 1 for medical writing.

The DIA holds 2 major meetings: in Europe in March and in the United States at the end of June. While the European meeting is smaller and Eurocentric (with about 3,000 attendees), the US meeting tends to be larger and global in focus. In addition, each year, the DIA conducts more than 50 conferences or meetings around the world designed to provide updates on the latest innovations and information that affect all disciplines of drug and medical device development.

Medical writers with an interest in how drugs and devices are developed would do well to consider joining the DIA because the DIA's professional development opportunities, meetings, and worldwide access to industry leaders allow such writers to expand their repertoires, network, and enrich their careers. One unique advantage of the DIA is that US Food and Drug Administration and European Medicines Agency regulators attend and present at DIA meetings, allowing for invaluable interaction and networking opportunities. Also, hundreds of vendors have booths at the meetings, enabling attendees to talk to many service providers and pharmaceutical industry leaders.

—Melissa L. Bogen

** The information on the DIA is adapted from a longer article by Melissa L. Bogen, "What Is the Drug Information Association?"* AMWA J. *2011;26(3):130-131.*

As much as medical writing and editing are specialties for which AMWA is the perfect launch pad, we should never overlook our local community organizations. I never thought of this option until I left my full-time position in a medical research organization and decided I now had time for some volunteer work. Only after taking part in Kiwanis, the community Merchants Association, local planning organization (reviewers of property and land use permits) and parks group did I realize how much those contacts would benefit my freelance business base. For example, at a senior residence, which I approached with a grant proposal for a beach project, a resident doctor hired me to edit the book he authored. That was a 1-year, very-well-paid commitment. A member of Kiwanis and office manager connected me with his dermatologist employer who was publishing medical journal articles in need of collaboration. The Merchants Association displayed a pamphlet I had produced as a community public relations piece, and that display attracted several new clients for my services. I had viewed these organizations as unlikely sources for work, but they proved to be a gold mine of profit and business.

—Phyllis Minick

Q I have business cards, a brochure, and a website. Now how do I attract clients? I do not like cold calling.

A Direct marketing and networking have been the best ways of landing clients for me. Through direct marketing, you can choose your clients, rather than simply working with the clients that happen to find you. Building your prospect list takes time and effort, but it's worth it. Use professional association member directories, lists of leading companies, and online directories (eg, clinical research organizations, continuing medical education providers, and medical associations) to develop a list of prospects you'd like to work with. Search LinkedIn to find the person (people) most likely to hire freelances; this is usually a vice president or director of medical writing, marketing, or communications.

You can usually figure out the email addresses for your prospects by visiting the organization's news or media web page and noticing the email address format. You can also get mailing addresses from the website.

For direct email, send a short personalized message (no more than 4 sentences) focused on the benefits you provide to clients and showing that you know something about the organization. Include a link to your website. A direct mail postcard or flyer takes more creativity, time, and money—but it captures attention in a way that email won't.

A strong network also helps you land clients, but this takes time. Volunteering for AMWA is a great way to develop relationships where people trust you and know that you're competent—and will be willing to refer work to you. In all networking (online and in person), focus more on helping others (eg, sharing information and resources and connecting people) than on asking for help.

—Lori De Milto

I'm sorry you don't like cold calling, but simply putting business cards, a brochure, and a website out there won't get you clients. Clients get you clients. Referrals. People talking about you and then going to your website and reading your brochure. There is simply no easy way to develop a successful freelance business without cold calling. Luckily, today you can "cold email." You need to make a list of companies that could use your services, identify the right person within the organization, link to them, email them, and send them a handwritten card. And you need to do that for 10 potential clients a day until you start landing them.

You also should let every person you know and have ever worked for know what you're doing. Marketing is a numbers game; the more you put yourself out there, the more work you will land.

—Debra Gordon

No one likes cold calling—particularly the victims—so take that off your list and put it out of your mind immediately.

Business cards, brochures, and even websites are full of potential energy. They're going nowhere and doing nothing for you on their own. To make them work, you've got to release their energy. You do that by being proactive in your marketing effort.

For example, potential clients aren't going to walk up to you on the street and ask for your business card or brochure. The chances of them stumbling onto your website is slim, too, if they don't have a reason to look for it. This is where marketing comes in.

Business cards, brochures, and websites aren't marketing. They're marketing tools. An axe doesn't work until you pick it up and swing it. And it doesn't work well unless you swing it at what you want to hit. And each time you swing that axe, you get better and stronger at using it. Marketing works the same way.

Marketing has to be carefully planned and consistently implemented to get your messages into the minds of potential customers. You have to first identify the types of materials you want to write and who would buy those types of writing. Then you should develop a list of those companies and the people within those companies. Now you can go to conferences where they meet and introduce yourself. You can hand them your business card and follow up by mailing them your brochure. Your business card and brochure should both be driving them to your website.

None of this will get you an assignment (at least it's not likely). But with luck it will get you a meeting to discuss your capabilities and expertise and the potential client's needs. That's where the magic happens and where your marketing efforts pay off.

—Brian Bass

Having a business card, a brochure, and a website are a great start to marketing. However, just developing those key pieces does not mean you are done with your marketing. You must attract clients to your cards, brochure, and website. There are several ways to attract clients that do not involve traditional cold calling. I have marketed my services via volunteering to be a public speaker—both in person and online through webinars. I have also marketed myself through LinkedIn, which can be a valuable way of scouting new clients if you use it well. You start off with a good complete profile that highlights your strengths. Your profile should include a professional headshot, samples of your work, and some good recommendations. You should also try to connect with other people in your industry and contribute regularly to discussions in key industry groups. Your website should also be optimized so that it has the key words that show up in Web searches (search engine optimization or SEO). Having a listing in the AMWA freelance directory is also a great way to advertise yourself. On LinkedIn, you can directly reach out to potential clients too, but you need to research companies well so that you have a targeted approach. Creating targeted mailing lists to send your brochure out will also ensure that you reach out to the kind of clients that you would like to work with.

—Ruwaida Vakil

SOCIAL MEDIA

Live-Tweeting: Report Conference News in Real Time

By Brande Nicole Martin, MA / Director, Digital and Editorial Content, American Medical Association, Chicago, IL

Give me an iPad or smartphone and a conference hashtag (eg, #AMWA15), and I am ready to live-tweet. What is live-tweeting? It is using Twitter to report from an event or conference in real time.

As a health communicator, you attend conferences regularly and may have started to use social media platforms, such as Twitter, to share the most engaging quotes, images, and videos from conferences. If you are new to Twitter or uncertain if you should use the platform, the idea of covering the important conference topics in 140 characters or less may seem impossible.

On the contrary, live-tweeting provides a great resource for the conference attendees and organizers, presenters, and especially those not attending the event who are following the hashtag posts. Taking pictures of the venue, host city, groups of participants, social events, slides of the presentation, and the speakers brings the Twitter follower closer into the actual experience of attending the conference.

Live-tweeting brings the conference to life for the virtual attendees. I have experienced both perspectives as someone live-tweeting and as a Twitter follower unable to be at the event but actively reading the insights and highlights tweeted from the various sessions.

Benefits of Live-Tweeting

In an email interview, Katharine O'Moore-Klopf, ELS, an AMWA member and managing editor of the *Journal of Urgent Care Medicine*, identified some of the benefits of live-tweeting, based on her experiences with covering conferences:

- It reinforces the knowledge that attendees are picking up [at the meeting].
- It engages meeting attendees, reinforcing their loyalty to the organization.
- It provides publicity about the conference in a form that readers will enjoy because it pulls them into the atmosphere of the conference and tells a good story.

In an email interview, AMWA member Robin Whitsell, BA, BPh, president of Whitsell Innovations Inc, wrote: "You can find and meet like-minded conference attendees and introduce yourself in real life. Last year, at AMWA [2014], I didn't have the kind of connector cord I needed for my presentation. I tweeted to the conference attendees and had 2 offers of the correct cord within 30 minutes." Whitsell added, "For conferences with multiple sessions ongoing at the same time, if other attendees are live-tweeting podium pearls, live-tweeting allows you to get the highlights of 2 (or more) sessions simultaneously."

Other benefits that I have observed and experienced include:

- Speakers' presentations reach a broader audience.
- Networking opportunities improve as those following and posting to the conference hashtag begin to follow each other on Twitter.
- The live-tweet increases the buzz about a speaker or a session topic and may persuade an attendee to sit in on a particular session.

Storytelling Through a Live-Tweet

The most engaging aspect of live-tweeting at a conference is the art of storytelling. As a health communicator, I craft a story of tweetable moments through images, text, and sometimes video clips. I intersperse my personal reactions into some tweets: "Excited to attend #AMWA13 @AmMedWriters." Bringing a personality to your tweets draws in more followers to engage with you and can increase their desire to follow your Twitter feed on a more regular basis after the conference.

I select the top 2 or 3 key points from the presentation to live-tweet. Also, I retweet posts from other attendees who may be at the same session I am covering, particularly if they have pointed out valuable highlights I did not capture. The pace of live-tweeting is fast, so curating and retweeting from others is beneficial and adds to your story.

Tips for Live-Tweeting

For health communicators, I recommend:

- Check the conference guidelines and policies to ensure they do not have any restrictions or parameters on live-tweeting.
- Find out the time an embargo lifts on sessions that may have journal articles being released, which usually occurs concurrently with the session time.
- As a courtesy, inform speakers that you will be live-tweeting their presentations.
- Use the official hashtag for the conference or event.
- Consider volunteering to live-tweet at a conference on behalf of the organization, using the organization's Twitter handle. (Not all companies or organizations may be interested in this service, but convince them of the value of live-tweeting.)

Whitsell recommends, "If possible, add to or expand the conversation. For example, if a speaker is talking about a guidance and shares a pearl, quote the recommendation and insert a link to the guidance."

Also, if you are a freelance reporter paid to cover a medical conference, ask your editor if your coverage can include live-tweeting or suggest to the editor that you live-tweet at some of the conference sessions.

For conference organizers, O'Moore-Klopf recommends:

- Make announcements periodically during the conference to remind participants to live-tweet.
- At the end of the conference, to build goodwill, use your organization's Twitter account to send out separate tweets thanking those [actively live-tweeting] for their contributions.

When attending your next conference, make sure you have a fully charged phone or tablet, get the conference hashtag, and begin live-tweeting the latest medical findings.

Acknowledgments

The author thanks Katharine O'Moore-Klopf, @kokedit, and Robin Whitsell, @robinwhitsell, for their contributions.

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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Lay summaries *continued from page 63*

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FROM THE PRESIDENT
A Week in the Life of an AMWA President

By Karen Potvin Klein, MA, ELS / 2014–2015 AMWA President

It won't surprise you to learn that AMWA's volunteer leaders are also busy medical writing professionals. I'm no different. Although some of my AMWA activities are connected with my role as president, some are shared with other active AMWA members. Here's a rundown of a week in the (sometimes hectic) life of this AMWA president.

Each week, I speak with our president-elect, Steve Palmer, and Susan Krug, AMWA's executive director. In turn, I benefited greatly from this regular conversation last year, when I was president-elect and Brian Bass was at the AMWA helm.

Susan always has a lot to report, from what's on the staff's to-do list, to updates on ongoing projects, to things that have popped up since the previous week's call. We review possible items for our monthly conference call with the other AMWA officers (past president, secretary, and treasurer). There may be action items related to the *AMWA Journal*, chapter matters, or the certification commission. All 3 of us make this call a priority because good communication among us is essential to getting the association's business done. I'm happy to say that these are people I enjoy talking to, no matter what the topic, so the hour always flies by.

Ramping up for our face-to-face meetings is often part of our discussions. The Executive Committee meets 4 times a year, and the Board of Directors (BOD, which includes representatives from each chapter) meets twice a year. So conference calls often involve committee deliberations or other preparations for these in-person meetings. I try to join as many of these calls as I can. In this past week (mid-April), for example, I participated in the monthly chapter leaders' call facilitated by Chapter Relations Administrator Hilary Graham. This call focused on reviewing important items for discussion and decision at our spring 2015 BOD meeting. There were many thoughtful questions, and good information on a variety of topics was shared.

Good old-fashioned reading, note taking, and thinking about the import of various trends or issues are all big parts of my role as an AMWA president. Before beginning this column, I was reviewing chapter and committee reports submitted by those who will be part of the spring BOD and Executive Committee meetings. You'll be hearing more about these activities in the weeks to come.

But some of my AMWA activities are the same things that many active members do—and I did some of those this week, too. Here are a few examples.

- This week I had some nice email exchanges from Carolinas Chapter leaders regarding my attending our annual chapter conference in Chapel Hill, North Carolina. I'll talk with members in the evening before the conference begins, hear from colleagues at a luncheon roundtable, and fit in a couple of open sessions in between. I look forward to these opportunities to listen to and learn from colleagues in my region and to share perspectives on AMWA and its value.
- Midweek, I participated in an AMWA webinar on rate setting for freelance medical professionals (like many of you, I work as a freelance in addition to my day job). I got excellent information from a thoughtful and seasoned professional, all while I was eating lunch at my desk. I now scan the schedule regularly for upcoming webinar offerings, whether on the AMWA website or in the monthly "AMWA Update" emails. These learning opportunities are a terrific member value and meet our common need: fitting high-quality continued professional development into our busy schedules.
- I completed the AMWA salary survey. I'm looking forward to seeing the results!
- Finally, I received 2 emails this week I'd like to share. One was from a member who wondered how best to demonstrate a skill set when she is early in her career. I suggested she look into both the new Essential Skills bundle of self-study modules and the medical writing certification examination that will debut in San Antonio this October. The second person had known about AMWA for some time and is now ready to join. In the past, she didn't see herself as a professional medical communicator, so until recently, she didn't see AMWA as a suitable professional home. I'm very pleased that now she does.

Each of you is a leader in AMWA, whether you see yourself that way or not. The professional standards you uphold in your daily work, your participation in AMWA at whatever level you choose, and your contributions to the profession—in whatever segment of our very varied profession—are how you document that leadership. So in the end, my "week in the life" has a lot in common with yours. We're all leaders in this organization, together.

Conference registration opens in June
Early rates are available until July 31

Remember the Alamo, Remember AMWA in San Antonio!

By Noelle Demas, MS / 2014–2015 Annual Conference Administrator

This September 30 through October 3, AMWA's 75th Annual Conference will feature education presented by the best minds in medical communication. The program is designed to challenge your thinking and provide you with new ideas to help build your expertise, all in an interactive, supportive, and inclusive environment.

Conference Program

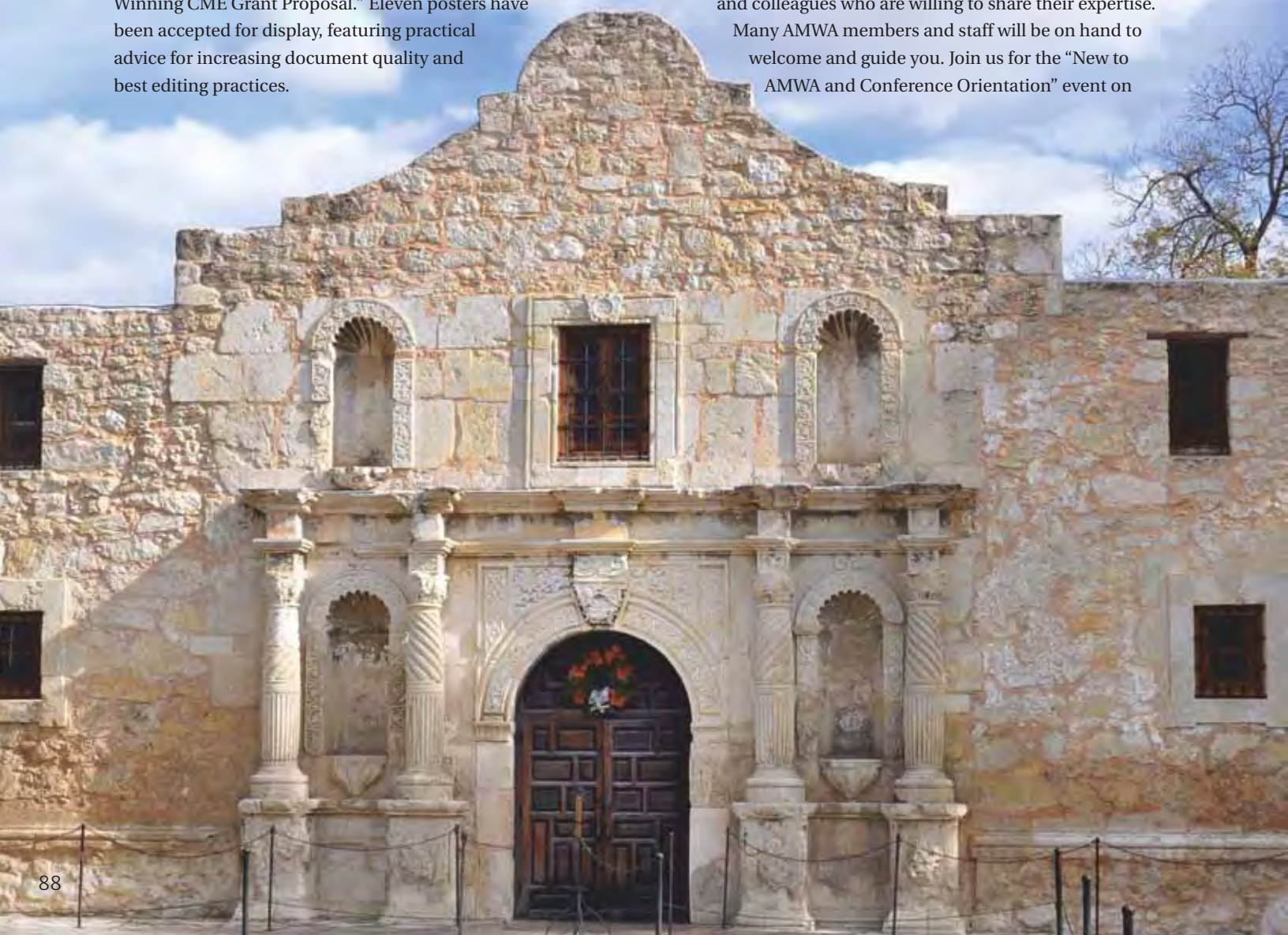
We're very excited about the wide variety of relevant and timely open session topics offered at this year's conference, from "Medical Writing for Digital Learning Programs" to "What to Consider When Writing for Global Audiences." You'll find a similar range of diverse roundtable topics for medical communicators at every career level, including "Science Education Resources for Humanities Majors" and "Editing a Winning CME Grant Proposal." Eleven posters have been accepted for display, featuring practical advice for increasing document quality and best editing practices.

Get on the Right Track

Education sessions and workshops will be organized into specialty tracks according to broad topics, such as freelance, regulatory writing, social media/technology, etc. We are posting the "Track Facts"—simple reference guides that include all workshops, open sessions, roundtables, and posters within each track. The Track Facts will help you demonstrate the value of the annual conference to your boss or to yourself and make planning your conference experience easy. Track Facts are available on the AMWA website at **www.amwa.org/events_annual_conference.**

New to AMWA or Attending for the First Time?

If you are a first-time attendee to AMWA's annual conference, you are in for an event that is filled with practical solutions and colleagues who are willing to share their expertise. Many AMWA members and staff will be on hand to welcome and guide you. Join us for the "New to AMWA and Conference Orientation" event on



Quest toward Brilliance

AMWA's 75TH ANNUAL CONFERENCE
SEPTEMBER 30–OCTOBER 3, 2015
SAN ANTONIO, TX

Wednesday, September 30, from 5:00 to 6:30 PM to hear from AMWA staff, chapter leaders, and conference mentors who will help you get the most out of the conference. In addition, we will share with you the most relevant information and resources AMWA has to offer.

Special Opportunities

The first examination for the Medical Writer Certified credential will be offered in the morning on Wednesday, September 30, 8:30 to 11:30 AM. Note that the application deadline is June 30. (For further detail regarding the application process, fees, and future exam opportunities, see page 91). The Board of Editors in the Life Sciences certification examination will be held the same day, 9:00 AM to 12:00 PM (application process and fees apply, see **www.bels.org**).

AMWA Awards

The annual conference is also a time to honor AMWA award recipients, and this year, recipients will be highlighted more than ever (see sidebar). AMWA awards will be presented in a variety of venues this year, offering you a greater opportunity to celebrate the recipients' accomplishments with them.

Celebrate 75 Years in Style

Dress up and shine or dress down and relax as we celebrate AMWA's 75th anniversary at our "Diamonds and Denim" themed celebration dinner. This upscale buffet dinner, free with registration, will be in a setting that allows for lots of networking, so do not miss it.

San Antonio Sights and Flavors

No visit to San Antonio is complete without remembering and experiencing the Alamo Mission, location of the pivotal Battle of the Alamo, and strolling down the River Walk with its charming bridges, restaurants, shops, and attractions such as Rio San Antonio Cruises and Marriage Island. Also, don't miss the spectacular bird's-eye view of the city from the top of the Tower of Americas and enjoy shopping at the River Center Mall. We encourage you to sign up near the conference registration desk to join your fellow conference attendees at these attractions, all within walking distance of AMWA's conference hotel. Also, remember Friday night dine-arounds will once again be a chance to get together with conference attendees and enjoy the nightlife of the host city. Attendees can sign up to enjoy live music venues, wine bars, martini bars, and much more along the San Antonio River Walk. The sign-up sheet tables will be near the conference registration desk.

Keep up to date on the conference by visiting the AMWA website (www.amwa.org).

2015 AMWA AWARD RECIPIENTS

Swanberg Award

Helen E. Hodgson, PhD
Professor of communications and director of the master's program in professional communication, Westminster College, Salt Lake City, Utah
To be presented at the Sablack Award Lunch

AMWA Fellowships

Catherine Magill, PhD, Northern California Chapter
Katharyn Spiegel, PhD, Michigan Chapter
Kristina Wasson-Blader, PhD, ELS, Empire State/Metro New York Chapter
To be presented at the Sablack Award Lunch

President's Award

To be named
To be presented at the Opening General Session

Eric W. Martin Award

Professional Audience: Kathryn Faguy, ELS, for "Imaging Foreign Bodies" in *Radiologic Technology* (July/August 2014)
www.radiologictechnology.org/content/85/6/655.abstract

Public or Health Care Consumer Audience: Seth Mnookin for "One of a Kind: What Do You Do if Your Child Has a Condition That Is New to Science?" in *The New Yorker* (July 21, 2014).
www.newyorker.com/magazine/2014/07/21/one-of-a-kind-2
To be presented at the Saturday General Session

Student Scholarship

To be named
To be presented at the Sablack Award Lunch

2015 Swanberg Award: Helen E. Hodgson

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 2015 award will be presented to Helen E. Hogson, PhD, at the annual conference in San Antonio, Texas. Through the twists and turns of her professional career, Dr Hodgson has taken a somewhat circuitous route to this award. While completing a PhD in 19th-century American literature, Dr Hodgson also fulfilled the requirements to attend medical school. During her study, she discovered that her passion was communicating about health care, not delivering it, and she abandoned her plans for medical school. When she didn't find an initial position as a college professor or medical writer, she parlayed her strong background in science into becoming a technical publications editor at the US Geological Survey. After she gained knowledge of the various genres of scientific writing, Dr Hodgson was singled out to teach geoscience writing at US Geological Survey offices throughout the country and to lecture on the topic at a number of conferences. During that time, she began a conscious effort to pursue her interest in biomedical communications by freelancing in the field.

Having learned of AMWA's existence through attending an AMWA mini-conference in Houston in 1983, Dr Hodgson, who was living in Denver at the time, questioned why no Rocky Mountain chapter existed. It seemed to be only minutes later that Judy Linn (AMWA's 1985–1986 president) was on the phone, and Dr Hodgson was soon gathering the signatures needed to establish the Rocky Mountain chapter. In that process, she met Dr Stephen Prather, a physician and AMWA member from Salt Lake City. They began working collaboratively on a variety of projects, including a workshop called "Caring for Difficult Patients." The goal of the intensive 4-day workshop was to guide physicians in understanding why their communication practices were leading to lawsuits and to provide techniques they could use to communicate more effectively with their patients. Their efforts led to publication of a companion book titled *Medical Risk Management* and to presentations on the topic throughout the United States.

In 1992, Dr Hodgson took her medical writing, editing, and marketing experience to Westminster College in Salt Lake City, where she has taught for 23 years. She is now a professor of communication and director of the master's program in professional communication. Her teaching responsibilities in the undergraduate and graduate communications programs have included courses on professional and technical writing, organizational communication, professional editing, writing for popular and peer-reviewed publications, advanced writing and research, writing about science, writing for the health care professions, proposal writing, business writing, business aspects of freelance writing and editing, and portfolio workshops. Dr Hodgson has been instrumental in the development of 2 master's programs in communication at Westminster: the master's program in professional communication, a traditional program that balances communication theory and practice, and the master's program in strategic communication, an innovative competency-based program that focuses on leadership and requires few on-campus meetings.

Dr Hodgson has always believed that students should be prepared for professional positions in the communication field, so her programs are geared toward the knowledge and skills students need when they become writers, editors, designers, or leaders in a constantly changing communications world. All of the traditional graduate students complete field projects for a variety of businesses, institutions, and nonprofit organizations. She insists that her students also learn how to think critically and to work with various clients and audiences—because of her background as a freelance medical writer and editor. With this broad focus, all of what Dr Hodgson teaches can be directly applied to a variety of jobs in biomedical writing.

Dr Hodgson's interest in wellness and in food and nutrition first landed her a column entitled *Food and Fitness* in a local monthly magazine and then a 10-year stint first as a health writer and then as the food editor at *Salt Lake* magazine. Using her expertise as a Utah Master Gardener, she has also coauthored articles on gardening and healthy food choices for the *Salt Lake Tribune*. Through her business, Professionally Write, she focuses on writing and editing related to health and wellness and a variety of medical topics.

An AMWA member since 1983 and a fellow since 1990, Dr Hodgson's contributions to AMWA extend over many years and are varied and stellar. Among the highlights of her service to AMWA, she cofounded the Rocky Mountain chapter; she served on the Executive Committee as secretary, treasurer, administrator of education, annual conference administrator, and administrator of publications; and she was president during 2001–2002. Dr Hodgson has also developed and taught many workshops for the annual conference as well as for chapter conferences and onsite programs; in 1997, she received the Golden Apple Award for her achievements. Dr Hodgson is also a life member of the Association of Teachers of Technical Writing and has been a senior member of the Society for Technical Communication. Her contributions to education and, specifically, to the education of professional medical communicators both through 29 years of teaching at AMWA and through her career are equally impressive, making her a very deserving recipient of the Harold Swanberg Award.

Update on Certification

First Medical Writing Certification Examination Set to Debut in San Antonio

By Marianne Mallia, ELS / Certification Commission Chair

AMWA members have been hearing a lot about the Medical Writer Certified (MWC) credential, which identifies professional communicators who have the essential competencies required for the work of a medical writer. By now, everyone should know that the first medical writer certified examination will debut at AMWA's 75th Annual Conference in San Antonio, Texas, on September 30, 2015. **The application deadline is June 30, 2015**. The second offering of the exam will be at the Spring 2016 Drug Information Association (DIA) Medical and Scientific Communications Annual Forum. The application deadline for the DIA meeting is December 15, 2015.

You can learn more about the examination by reading the *Applicant and Candidate Handbook*, which includes some example questions with annotated answers.

The Medical Writing Certification Commission has also recently posted FAQs and examination tips on the website. For example, 1 of the more-frequently asked questions (with its response) follows:

> **Q.** If I don't have experience in an area covered in the exam, should I apply? Would I have a chance of passing the exam?
>
> **A.** The exam includes some questions on specific areas of medical writing (for example, writing journal articles, writing for general readerships, and regulatory writing), in keeping with the breadth of medical writing as a field. However, it contains relatively few questions on any individual area, and many of the questions apply to multiple areas. If you are working as a medical writer, you should have much of the basic knowledge required for the exam. To gain background in areas where you lack experience, you can study material in the listed resources. So, in summary, you need not have experience in every area of medical writing to pass the exam.

Why should you consider taking the examination?

By earning the MWC credential, you can

- give an employer or client increased confidence in your credibility and knowledge of medical writing
- show your commitment to continued professional development in the field of medical writing
- increase your marketability and opportunities for career advancement

The certification commission will be happy to answer any questions you may have about the examination or the certification process. You can email your questions to certification@amwa.org. We are excited about this new opportunity for medical writers to distinguish themselves in the field.

➲ Visit **www.amwa.org/mwc** for the full details about the MWC certification.

Slate of Candidates for 2015–2016 Election

Each year, the slate of AMWA officers is chosen by the Nominating Committee, which consists of the president-elect (who serves as chair) and 6 voting members who are not members of the Executive Committee (EC). The Nominating Committee receives from AMWA headquarters the names and biographies of all members who meet the criteria for the 3 elected offices: president-elect, secretary, and treasurer. The EC interest form also was sent to qualified candidates, giving them an opportunity to express their interest in serving in an elected officer position. Members of the Nominating Committee discuss the potential candidates and select 1 candidate for each position. The names of these candidates are then presented to the Board of Directors for approval at its spring meeting.

The following candidates were approved by the Board of Directors at its spring 2015 meeting:

President-elect: Lori Alexander, MTPW, ELS
Secretary: Katharyn Spiegel, PhD
Treasurer: Christine F. Wogan, MS, ELS

The president-elect automatically assumes the office of president at the annual business meeting held during the annual conference of the following year. The 2015–2016 AMWA president will be **Stephen N. Palmer, PhD, ELS**. Steve is a senior scientific medical writer at the Texas Heart Institute in Houston. He earned a PhD in social and health psychology at the State University of New York at Stony Brook, where he also earned his master's degree. He holds a BA from Wesleyan University. Steve joined AMWA in 2002 and become a fellow in 2011. In addition to serving during the past year as president-elect, his previous AMWA service includes the following: administrator of awards, administrator of the annual conference, administrator of chapters and membership; annual conference roundtable and klatch leader; open session leader and speaker; member of many committees, including Medical Book Awards and Constitution and Bylaws; and, for the Southwest Chapter, program chair, president, immediate past president, and board delegate.

President-elect criteria: *The president-elect (1) must have served on the Executive Committee for a minimum of 2 full years and (2) must be a current member of the Executive Committee when his or her name is being considered by the Nominating Committee.*

Lori Alexander, MTPW, ELS, is currently serving on the executive committee as secretary. She served as annual conference administrator in 2013–2014 and also filled that role in 2012–2013. Previously, she had served for 10 years as the *AMWA Journal* editor. A member of AMWA since 1998, Lori is a past president of the Florida Chapter and coordinated several chapter conferences for both the Mid-Atlantic and Florida chapters. She has served on numerous AMWA committees, including the job analysis and item writing committees supporting the development of medical writing certification. She has contributed to the annual conference as a roundtable leader, open session moderator and speaker, and workshop leader. She was recognized with the AMWA President's Award in 2009, an AMWA fellowship in 2010, and a special award for her service to the *AMWA Journal* in 2012. Lori received a bachelor's degree in English (concentration in journalism) from the University of New Hampshire and a master's degree in technical and professional writing from Northeastern University in Boston. Lori has more than 25 years of experience in medical communication, first as a medical editor at Lahey Clinic and at the *Journal of Bone*

and Joint Surgery and then as a writer and editor in the publications department at the American Society of Clinical Oncology. She is president of Editorial Rx, Inc, an independent medical writing and publishing company in Fort Myers, Florida.

Secretary criteria: *The secretary must have served on the Executive Committee within the 3 years immediately preceding his or her consideration by the Nominating Committee.*

Katharyn (Kathy) Spiegel, PhD, an AMWA member since 2006, is currently on the Constitution and Bylaws Committee and has been a member of that committee since 2012. She was the EC chapter relations administrator in 2012–2013. She also served on AMWA's EC as the chapters and membership administrator and Michigan Chapter delegate to the board. At the chapter level, she served as president, past president, board member, and vice president. Her annual conference activities have included roundtable leader, special interest session coordinator, open session moderator, open session panelist, and workshop leader. Kathy received her BS in chemistry from Duke University and PhD in pharmacology from Cornell University Medical College. Kathy is senior manager of regulatory writing at Amgen, Inc, in Grass Lake, Michigan.

Treasurer criteria: *The treasurer must have served at least 1 year on the Budget and Finance Committee within the 5 years preceding his or her consideration by the Nominating Committee. It is also desirable for the treasurer to have served on the Executive Committee before assuming the office of treasurer.*

Christine F. (Chris) Wogan, MS, ELS, an AMWA member since 1989, has been AMWA treasurer since 2012. She previously served on the EC as the awards administrator and was a member of the Budget and Finance Committee. She has served as a contributor and peer reviewer for the *AMWA Journal*. At the annual conference, she has served as editing/writing section chair, roundtable leader, workshop leader, and open session chair and panelist. At the chapter level, she served as Southwest Chapter director-at-large, chapter treasurer, chapter president, and immediate past president. She received the AMWA President's Award in 2010 and was awarded an AMWA fellowship in 2012. Chris is publications manager in the Division of Radiation Oncology at MD Anderson Cancer Center in Houston.

Procedure for Additional Nominations

According to AMWA's bylaws (Article III.2d), additional nominations for president-elect, secretary, or treasurer may be made by any member whose dues and special assessments are current, provided that any such nomination is submitted in writing to the secretary of AMWA at least 30 days before the annual business meeting (which will take place October 3, 2015, at the annual conference in San Antonio, Texas). Any individuals so nominated must meet the criteria outlined in the bylaws (Article III.1.a through III.1.d) for their names to be placed on the ballot. Such a nomination must clearly state the qualifications of the candidate, must be signed by 50 members in good standing as of the date of the receipt of the nomination, and must be accompanied by a letter from the candidate stating that he or she is willing to serve if elected.

Thriving at Work Through Emotional Intelligence

By Sam Clapp[a] and Laura Town[b]

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In our individualistic culture, we tend to associate leadership with qualities such as intelligence, resilience, and vision. Take a moment, though, to think about a person in your life who really spurred you to accomplish something difficult. Was it a teacher, a family member, a friend, or a compassionate boss? No matter who encouraged you, he or she almost certainly pushed you to succeed with excitement rather than stress. True leaders lead by inspiring, by being in tune with their own strengths and the feelings of the people they lead.

Writers attending the 2015 Indiana Chapter AMWA Conference were treated to an incisive keynote speech on true leadership by Dr Annie McKee, *New York Times* bestselling co-author of *Resonant Leadership and Primal Leadership*, internationally renowned executive coach as cofounder of the Teleos Leadership Institute, and current director of the University of Pennsylvania Graduate School of Education PennCLO doctoral program and medical education master's program. She calls genuinely inspiring leaders "resonant leaders." These agents of change spur us to action through mindfulness of their own emotions, compassion, and ability to use emotional knowledge in practice. These abilities together compose emotional intelligence, the core skill McKee sees as distinguishing average leaders from resonant leaders.

Reframing emotional capability as the key ingredient for exceptional leadership unlocks the potential for each of us to become a resonant leader. You don't need an official title to be a leader: we can each use our skills, combined with emotional intelligence, to make a contribution to healthy organizational culture. Compassion doesn't always come easily. To accurately gauge your impact on others, you must first assess your strengths. Honest self-reflection provides a venue for discovering latent abilities and any potential emotional limitations that may introduce an element of dissonance into teamwork. Dissonance can be dangerous, particularly considering fundamental shifts in work driven by new technology, laws and regulations, and financial pressures. Creating a healthy organizational culture driven by resonant leadership, ethical behavior, and innovation at all levels is essential to succeeding in the 21st century knowledge economy.

If it's common sense that knowing your own strengths and the feelings of others leads to healthier relationships, what organizational pressures are holding us back? Dr McKee points out a few prevailing myths that prevent our organizations from promoting emotional intelligence. The first myth is that intellect is sufficient to set leaders apart. Our society tends to put an undue emphasis on IQ as a measure of ability. In reality, IQ only measures pattern recognition, whereas 85% to 90% of the difference between outstanding and average leaders is linked to emotional intelligence. The second myth is that mood doesn't matter. In reality, emotions are contagious, and as human beings, we feel before we think. Research has shown that culture and climate account for nearly 30% of organizational performance. The third myth is that great leaders are tough enough not to complain under even the most intense stress. Our culture expects us to be superheroes, even though we'd all be better off admitting our weaknesses.

Once you've recognized the importance of employing emotional intelligence and reflected on your own strengths as a leader, you must use your emotions properly. Emotions are contagious. Both positive and negative emotions can spread between people, so it is essential to moderate your own emotional state. Reflect on what makes you angry, what stresses you, and what engages you, and project the emotions you know will inspire people. Don't cover over negative emotions, though. Recognize and move through them.

When individuals strive to remain emotionally in sync, they produce healthy organizational culture. Research has demonstrated time and again that teams with positive organizational cultures that foster employee growth are far and away more productive. One study of 229 businesses demonstrated that a positive climate was the most significant factor associated with company performance, growth, and revenue over a year-and-a-half period.*

So what are the practical implications of emotional intelligence for leaders and team members? We should try to incorporate a wide range of emotional intelligence competencies into hiring and training practices. We should encourage emotional competence in managers through continuous monitoring and evaluation by superiors, peers, and team members, a process known as 360-degree feedback. Of course, practicing emotional intelligence on a practical basis is not easy. Every day, we go to

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**Ozcelik H, Langton N, Howard Aldrich H. Doing well and doing good: the relationship between leadership practices that facilitate a positive emotional climate and organizational performance.* Journal of Managerial Psychology. *2008;23(2):186-203.*

LETTER TO THE EDITOR

Defining Our Professional Identity

Thank you for the article addressing the important issue of establishing our identity as medical writers.[1] As a medical writer trained in science journalism who writes for a variety of audiences, I appreciate the delineation of medical (technical) writing from journalistic and literary writing. However, I think the article overstates some distinctions (below) and is remiss in recognizing medical writing for patients and the clinicians who care for them daily.

> Also—critically—the conventions in one tradition do not always apply in another. In medical writing, we don't need to tell "stories," require engaging "writing styles," "spice up" leads to create interest, or worry about "spatial and economic inflections on genre change."

Medical writing for patients and clinician providers requires specialized skills in addition to other skill sets. In patient education, we often talk about providing content in terms of distinguishing between what patients need to know and what's nice to know. Similarly, in scripting content for clinicians to deliver to patients or in developing clinician training materials (toward gaining knowledge and improving patient outcomes), we need to distinguish between providing only evidence-based facts and how to apply such knowledge and why.

Such nuances, I believe, do not preclude engaging writing or spiced-up leads to create interest, or additionally, empathy or acknowledgment of conditions in order to enhance patient engagement and activation. For example, many people know they need to eat healthy foods or be more physically active. What lead in the content will grab their attention and get them to start *and* finish reading what they need to know to understand and act on information? What about ensuring an individual's belief in his or her clinician's concern about a devastating diagnosis, not just treatment options? How do you craft a respectful patient letter about repeated missed appointments that expresses concern about individual health and meets a clinician's schedule needs and economic realities?

Such nuances, in fact, require—critically—engaging and "real-voice" writing, but in a different realm from other engaging or literary writing, or conventional instructional design writing. We need to do more than "just need to give readers the information they want." We also often need to convince patients to read the information, and we need to present the information in a way they can best understand and act on it. Meeting health literacy standards, which include language, formatting, and design principles, is key, whether writing directly to patients or for clinicians on behalf of patients.

Understanding "Who is my audience?" when writing anything is first and foremost. But sometimes in patient education, you have multiple audiences that present unique challenges. Solutions are complicated with potentially conflicting needs. Effective, high-quality medical writing often can best be advanced (written) by using both journalistic and literary techniques as well as technical writing based on formal analysis, development, design, implementation, and evaluation with all audiences considered.

—Ruth Taswell, MA
Manager, Editorial and Production, Patient Education, Park Nicollet Institute, and Editor, Media Reviews, AMWA Journal*, Minneapolis, Minnesota*

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AUTHOR REPLY

In responding to my article,[1] Ruth Taswell notes that writing for patients includes asking, "What lead in the content will grab [readers'] attention and get them to start *and* finish reading?" and that "We need to do more than 'just give readers the information they want.'" Implicit is that the lead will be provocative or entertaining; that, in addition to medical information, writing should validate readers' experience, support them emotionally, promote healthy behaviors, and so on; and that medical information, by itself, won't keep readers engaged.

Having written patient education materials for years at the Cleveland Clinic, studied health communication in graduate school, and taught AMWA's patient education workshop a dozen times,[2,3] I agree with these implicit assumptions. I also agree that patient education writing is medical-technical writing, to the extent that it involves communicating "the information needed to use health care technologies" and that its purpose is "to help a specific audience achieve a specific purpose."[1]

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However, much patient education writing is—appropriately—promotional. It has—appropriately—elements of selling and advertising. When writing addresses readers' emotional and psychosocial needs, it crosses the line into literary or journalistic writing, which justifies using literary devices. Technical writing is also persuasive writing, but it persuades with fact and logic. It need not be stilted, but what keeps readers engaged is the intrinsic value of the information, not emotional support.

Effective patient education writing must cross the line into literary or journalistic writing. In fact, medical writers would do well to study the principles of marketing, behavior change, persuasion, and so on that would make such writing even more effective. However, Ms. Taswell's statement that "multiple audiences present unique challenges" because "solutions are complicated with potentially conflicting needs" applies to all forms of writing, although I think only technical writing has dealt with it systematically and comprehensively from an author's perspective.[4-7]

What matters for us professionally, as suggested in my article, is that we define medical writing by its unique characteristics, not by its content. Just because patient education writing concerns medicine doesn't mean that it is always medical writing. We also need to focus on the skills specific to medical writing and not confuse them with those of literary or journalistic writing if we want to have a professional identity. Finally, we need to know when, why, and how we cross the line into literary or journalistic writing. We don't want medical writers "spicing up the lead" of a clinical study report, "exploring character defects" in a scientific article, or going insane trying to understand the meaning of "spatial and economic inflections on genre change."

—Tom Lang, MA

Tom Lang Communications and Training International, Kirkland, Washington

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work with a new set of challenges, as well as resentments that compound over time. It is important to correct destructive behaviors early: if you suffer through several confusing and painful episodes with a coworker, you'll be less likely to have the capacity for empathy later. To build sustainable organizations and to improve our own work, we must approach difficult conversations with compassion and understanding rather than anger.

Author disclosure: *In 2010, Pearson Education hired Laura Town to edit* Management: A Focus on Leaders, *written by Annie McKee.*

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CALENDAR OF MEETINGS

Quest toward Brilliance

AMWA's 75TH ANNUAL CONFERENCE
SEPTEMBER 30–OCTOBER 3, 2015
SAN ANTONIO, TX

AMWA Chapter Conference
Greater Chicago Chapter Conference
July 24, 2015
Evanston, IL
www.gcac-amwa.org

Society for Technical Communication
June 21–24, 2015
Columbus, OH
http://summit.stc.org

Committee on Publication Ethics
North American Seminar
August 19, 2015
Baltimore, MD
http://publicationethics.org

International Society of Managing and Technical Editors
August 20–21, 2015
Baltimore, MD
www.ismte.org

Plain Language Association International
September 17–20, 2015
Dublin, Ireland
www.plainlanguagenetwork.org/

National Association of Science Writers
October 9–13, 2015
Cambridge, MA
http://nasw.org

New Horizons in Science
October 11–12, 2015
Cambridge, MA
http://casw.org/

American Public Health Association
October 31–November 4, 2015
Chicago, IL
www.apha.org

Health Literacy Annual Research Conference
November 2–3, 2015
Bethesda, MD
www.bumc.bu.edu/healthliteracyconference/

European Medical Writers Association
November 5–7, 2015
The Hague, Netherlands
www.emwa.org

Celebrate in Style

AMWA's Diamonds and Denim
75th Anniversary Reception and Dinner

Saturday, October 3, 2015
San Antonio, TX

You are cordially invited to join us as we blend our wonderful 75th annual conference location of San Antonio, TX, with the celebration of our diamond anniversary during this special event. As the theme implies, choice of attire is wide-ranging: from cowboy hats and boots to cocktail dress. Please wear what makes you most comfortable. Dinner is included with full conference registration or one-day conference registration. Single dinner tickets are also available.