TRICKS AND TIPS FOR TIME MANAGEMENT

Speaker
Melissa Christianson, PhD, *Whitsell Innovations, Inc, Chapel Hill, NC*

By Jennifer L. Busch, PhD

"Imagine this: You are promised $86,400 per day for the rest of your life. You must use the money each day, or you will lose it; none of it carries over to the next day." Dr Melissa Christianson of Whitsell Innovations began her presentation with this attention-grabbing scenario. Each day contains 86,400 seconds, she informed her audience. She then offered suggestions for stewarding this nonrenewable resource.

The presentation was divided into 6 sections. Each section included a threat to time management, a challenge with which to confront each threat, and several strategies for each challenge (Tables 1 and 2). Dr Christianson encouraged the attendees to modify and personalize her strategy suggestions as needed. She concluded her talk with an admonition concerning time: "use it, don't lose it."

Table 1. Threats to Optimal Time Management and Challenges With Which to Combat Each Threat

Threat	Challenge
Inefficient use of time	Increase efficiency
Prolonged decision-making time	Start quickly and effectively
A self-reported 4-fold increase in procrastination within the past 30 years	Fight procrastination
Interruptions (They steal 90 minutes per day, and 23 minutes are needed to return to productive work after each one.)	Manage distractions
Unproductive time in meetings (Up to half of one's career is spent in meetings.)	Control your meetings
Scarcity mindset (The busier a person, the harder it is for him/her to decline a new request.)	Protect your time

Table 2. Strategies for Meeting Each Time-Management Challenge

Challenge	Strategy
Increase Efficiency	1. Keep track of project details (eg, OneNote). 2. Use organizational templates. 3. Maintain an accurate schedule of your projects.
Start Quickly and Effectively	*For starting your day…* 1. Before leaving work, plan a specific task for the beginning of the next day. 2. Work during your most productive working hours. 3. Jumpstart your day with an easy task or get a difficult task out of the way early. 4. Maintain big-, medium-, and small-picture plans of goals. *For starting a project…* 1. Plan time for getting organized. 2. Gather all needed materials before beginning. 3. Begin with easy tasks to familiarize yourself with the project. 4. Use a spreadsheet to track parts of the project.
Fight Procrastination	1. Work in small time chunks (<3 hours). 2. Enforce breaks to foster and enhance creativity. 3. Use mindless tasks as a break between projects. 4. Commit to working on an undesirable task for 5 minutes; this pledge tricks you into working longer. 5. Monitor time realistically to find time sinks. 6. Avoid procrastination pitfalls (eg, Facebook, perfecting PowerPoint slides).
Manage Distractions	1. Do one thing at a time. 2. Use a "to-do" checklist. 3. Only check emails at specific times of day. 4. Schedule known interruptions. 5. Postpone your response to nonurgent emails. 6. Use "do not disturb" digital functions when necessary.
Control Your Meetings	1. Schedule meetings with enough notice to allow for participants' preparation. 2. Provide a clear agenda. 3. Keep and disseminate accurate and detailed notes. 4. Schedule 15 minutes before and after a meeting to allow for final preparation and follow-up. 5. Follow up immediately after the meeting. 6. Communicate clearly.
Protect Your Time	1. Keep your calendar up to date; block off work time. 2. Say "no," if needed, yet offer a solution or an alternative. 3. Be clear about expectations (yours and client's) around a project. 4. Frontload your day or week.

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LOW-COST AND LOW-EFFORT WAYS TO CREATE INFOGRAPHICS AND VISUALLY APPEALING SLIDES

Speaker

Kelly Schrank, MA, ELS, *Head Bookworm, Bookworm Editing Services LLC, Canastota, NY*

By Raeesa Gupte, PhD

Many medical communicators are encountering a rising demand for visual-communication services from their clients and employers. Visual communication uses charts, graphs, and images to simplify and convey complex information or patterns in data. Infographics and slides use elements of visual communication to present concepts in a new way.

At AMWA's 2020 Medical Writing and Communication Conference, Kelly Schrank gave an introduction to and step-by-step tutorials for non–graphic designers on how to create visually appealing infographics and slides without the use of expensive software. "You need to have some patience, willingness to learn PowerPoint a little deeper or a new application, and some interest in breaking away from the words and thinking in a new way about how to present data," Schrank emphasized.

What Is an Infographic?

An infographic contains visual elements (color coding, graphics, and icons), content (time frames, statistics, and references), and knowledge (facts and deductions). It uses different colors, shapes, sizes, fonts, and icons to

- highlight main ideas,
- connect ideas or data, and
- compare and contrast information.

Color is used to accentuate important data or to separate sections of an infographic. Shapes of different sizes are used to make comparison easier. Icons may be used as bullets or for visual representation of ideas conveyed through text.

Types of Infographics

Infographics may appear in different formats:

- Images
- One- or 2-page handouts
- Rolling infographics that appear on websites and need to be scrolled through

Popular types of infographics include

- timelines,
- processes and how-to guides,
- comparisons,
- lists, and
- maps.

How to Create Infographics

An easy way to start building an infographic is to use a template. Templates make it easy to choose coordinating colors and fonts, thus ensuring style and consistency. In addition, templates can be customized by changing design elements and including the information you want to present.

Schrank shared information on applications that have templates available for infographics (Table 1). Both free and paid versions of these applications are available. However, the free versions may be watermarked or shared on the website's public domain. To protect client data and privacy, paid versions of the applications are preferred.

Table 1. Comparison of Websites Offering Infographic Templates

Site	Free Option?	Able to Export?	Public Publication?	Watermark/ Branding?	Paid Option (Individual)
https://www.canva.com/	Yes	Yes	No	No	~$10/mo
https://piktochart.com/	Yes	Yes	Yes	Yes	~$29/mo
https://www.visme.co/	Yes	Yes	Yes	Yes	~$39/mo
https://infogram.com/	Yes	No	Yes	Yes	~$19/mo
https://venngage.com/	Yes	No	Yes	Yes	~$49/mo

To avoid the constraints of commercial infographic software, Schrank relies on PowerPoint. She suggests using native PowerPoint templates available with Microsoft Office 365. Alternatively, you can download templates for free from websites like HubSpot.

Schrank provided a tutorial on how to customize infographic templates by changing shapes, colors, font sizes, and reordering or editing content. Detailed instructions can be found in the presentation handout (link in Resources).

How to Create Visually Appealing Slides

Visually appealing slides rely on the same basic elements as infographics; they

- make good use of color,
- put text into shapes or SmartArt,
- use different text size to show importance, and
- use icons to add visual interest and connect ideas.

Instead of using slides with standard bulleted lists or walls of text, thematically associated slides can be used to tell an effective story. To accomplish this, Microsoft Office 365 provides powerful tools such as

- templates,
- Design Ideas,
- SmartArt,
- icons, and
- stock images.

Older versions of PowerPoint do not have infographic templates or the Design Ideas function and have fewer options for SmartArt, icons, and stock images. Although websites like Canva, Piktochart, and Visme also provide templates and stock images, they are harder to export and may be watermarked.

Schrank shared the following tips and tricks for creating visually appealing slides:

- Convert bulleted lists to SmartArt.
- Convert SmartArt to shapes.
- Use shapes to make your own SmartArt.
- Get inspiration from the Design Ideas function.
- Adjust icons.
- Add stock photos.

Schrank provided a step-by-step tutorial for each of the actions mentioned above. Detailed instructions can be found in the presentation handout (link in Resources).

Closing

Kelly Schrank closed the presentation with ideas for infographics and visually appealing slides by sharing some of her own work. She also suggests performing a search on Google Images to learn more about the elements of good design, discover new design ideas, and see what is currently in vogue.

Resources

Websites for stock images:
https://pixabay.com/
https://unsplash.com/
https://thenounproject.com/
https://www.pexels.com/

Presentation handout:
https://headbookworm.com/wp-content/uploads/2020/10/AMWA-2020-Low-Cost-and-Low-Effort-Infographics-and-Visually-Appealing-Slides-Handout.pdf

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A POWERFUL COMBINATION: THE VALUE OF THE WRITER–EDITOR PARTNERSHIP

Speaker

Crystal Herron, PhD, ELS, *Managing Director, Redwood Ink, San Francisco Bay Area, CA*

By Christine Holzmueller, MS

Crystal Herron's goal in this presentation was not simply to deliver information to the audience. Her goal was to ask us questions to promote self-reflection on our capabilities and careers and to consider the "value a writer–editor partnership could bring to our professional endeavors." She acknowledged basic similarities between writers and editors but pointed to different qualities and functions of each role. For one, writers are creative with words whereas editors analyze and fix text. Writers also tend to research a subject, transfer knowledge, and become deeply knowledgeable about a subject. Conversely, editors focus on examining the writing and revising the text to improve it, and they may require less knowledge of the subject matter.

Medical communicators often both write and edit content. Herron questioned this dual role, noting most people are stronger in one area. She listed some pros and cons of being a generalist (both roles) compared with being a specialist, showing career value in the latter role (Figure). If you specialize and form a partnership, Herron believes "you can harness your strengths and focus on what you really enjoy" and let your partner complement your weak areas.

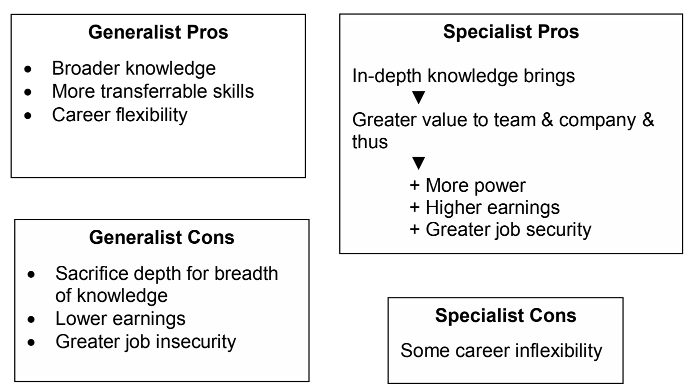

Figure. Pros and cons of generalist compared with specialist.

What Are Some Benefits of This Partnership?

One benefit Herron stressed related to the "curse of knowledge." The concept is that we omit information, unaware that we assume the reader knows what we know. A partner can identify these knowledge gaps in a document, find mistakes we overlook, and strengthen our writing. They can be a mentor. This person can give objective feedback and help divest our emotional attachment to our text. A partner can also save us time by taking on the refinement of documents. Importantly, a partner can make us look good and help us achieve our career goals and advancement.

What Are Key Features of an Ideal Partnership?
Herron showed a Venn diagram of 1 skill-based and 3 relationship-based features of an *ideal* partnership:

- Complementary skills that form a larger skill set that you could not accomplish alone.
- Confidence that you can trust and rely on each other.
- Chemistry in how you relate to one another. Both must respect and value their partner and work well around decision-making, disagreements, and conflict resolution.
- Similar values. Herron described this as a core feature to figure out ahead of time rather than waiting until "something pops up and values diverge." Some questions you need to answer are: Do you have similar work ethics (deadline-driven vs value-driven) and styles (prefer to work early in the morning vs later in the day)? Do you have matching communication styles and similar risk-taking behaviors? Do you share the same goals and have a similar vision for your partnership? Is there equal commitment to the work or a clear agreement on whether one person will do more work?

How Can You Find and Establish a Successful Partnership?
To find the right partner, consider colleagues you personally worked with that meet the key features of a successful partnership. Other approaches are networking at conferences and through professional online platforms (eg, LinkedIn), soliciting interest through professional organizations (eg, AMWA website), and simply being open and ready for a chance meeting in any public space.

You can establish a partnership at work by searching within your company for a viable candidate. Another option is to contract with a consultant for a trial period to see if it works well and then hire them or someone else as an employee. If you are self-employed, you might draw up a contract agreement and establish a formal partnership.

Herron ended with several questions to deepen our consideration of the value added from a writer–editor partnership:

1. What is your vision?
2. What are your strengths and weaknesses?
3. What are your interests and professional goals?
4. What are your company's goals?

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EDITING: HARD KNOWLEDGE, SOFT SKILLS

Speaker
Loretta Bohn, ELS, *Senior Editor/Writer, RTI International, Chapel Hill, NC*
Crystal Herron, PhD, ELS, *Managing Director, Redwood Ink, San Francisco Bay Area, CA*
Erica Goodoff, ELS(D), *Senior Scientific Editor, MD Anderson Cancer Center, Houston, TX*

By Kelly Schrank, MA, ELS
This panel of diverse editors provided their personal experience and advice in 5 areas: credentials, developing judgement, editing on a team and individually, managing expectations, and professional development.

Credentials
Although Herron has a doctorate, she doesn't think you need one to be an editor in our field; instead, she thinks you need to "be a master of the language and have an interest in the science." Neither Bohn nor Goodoff have degrees in the sciences, but Bohn says that you need to be curious, and she enjoys "learning about subject matter and learning about language, as it changes all the time."

Goodoff mentioned Editor in the Life Sciences (ELS) and ELS Diplomate [ELS(D)] as credentials that she thinks are well known in our field. The ELS credential helped her, she said, because "Those letters after my name did help me get interviewed for my current job." Bohn also mentioned that the AMWA Essential Skills certificates and other Medical Writing & Communication Conference (MWCC) workshops and sessions gave her ways to talk about what she is doing and why.

Developing Judgement
The panel posed the questions, "How do you know what to do *when*—how do you develop judgement about when to just change something, when to change and query, and when to just query, and how do you just let something go?"

Goodoff defaults to "If you aren't sure, ask." It's nice if you have someone to ask, such as a colleague or a message board, or you can query the author for clarification. As she and Bohn note, "People writing science manuscripts are happy to talk about their research." Bohn also brought up that if and when you query might depend on how long you have worked with an author or team. Herron added, "It helps to know who you are working with. If it's someone who is new, you want to be a little more careful."

Queries may also need to be changed over the course of a reading; Bohn, Goodoff, and Herron noted that they often find their queries answered by the end of the manuscript. They agree you should reread your queries before returning the document to the author.

Editing on a Team and Individually

Bohn, Goodoff, and Herron were all mentored by more experienced editors earlier in their careers; these senior editors provided feedback and helped them get up to speed with their companies' ways of doing things. More broadly, Herron also found it helpful to see how these more senior editors "edited documents and to learn from that."

Bohn discussed the advantages of editing and working with a team of editors as having others who "get" what you do, who can assist when you are overbooked, and who can help when you are struggling with questions or internal clients. As someone with her own business, Herron has a network of editors she works with, whom she can ask for assistance when she has too much work.

Managing Expectations

Bohn can ask editors on her team to assist if there is not enough time to meet an internal client's deadline. Goodoff said that in her work, she has to balance time with thoroughness and prioritize certain types of documents over others (for example, grants over manuscripts). She provides authors with a time estimate for editing that bakes in the other work ahead of the new project. Bohn said that one way to manage expectations is to stay in contact with internal clients through a monthly email to ask them about upcoming work. Herron's approach is to underpromise and overdeliver, so she has a cushion if things don't go as planned but leaves clients happy if the work goes well. All mentioned the helpfulness of discussing the levels of edit with authors/clients and which level can be accommodated within their timelines. Bohn's team also provides a calculator to authors so they can estimate their projects before submitting.

Professional Development

Goodoff started off this discussion with 3 things she tries to work on. She explains, "It's always a good idea to brush up on skills, especially things that you don't see every single day but that you see often enough," like statistics. Despite having a writing and editing background, she thinks brushing up on grammar gives her the vocabulary to explain to authors why she is making certain changes to their writing. She also likes to learn Word tips and tricks, saying she "finds some new little trick every single time."

Herron believes it "improves your work" to put in the time for professional development. She believes that if you get certificates, you can make up for the cost by giving yourself a pay bump. To make sure she spends time on professional development, she adds it to her calendar on her historically slower days. Sometimes she just spends an extended lunch time reading up on something or squeezes in just 15 minutes of reading here and there.

Bohn liked Herron's idea of "making it bite-sized" and focusing on 1 idea and what you can read/learn in 15 minutes.

Tips:

Erica Goodoff: If you're early in your career, the ELS credential is worth it.

Loretta Bohn: Always go back and reread your queries when done editing the full document.

Crystal Herron: Keep a file of boilerplate comments: just copy and paste into comments. (Bonus from chat: use AutoCorrect to insert boilerplate comments or create macros to insert them into docs.)

Crystal Herron: Focus on one thing a month to learn/brush up on skills. (Bonus: teach it to others on a blog to learn it better.)

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COLLABORATIVE WRITING: ENSURE SUCCESS WITH AN EFFECTIVE STRATEGY

Speaker

Crystal Herron, PhD, ELS, *Managing Director, Redwood Ink, San Francisco Bay Area, CA*

By Sadie van Dyne, PhD

Collaborative writing projects often stir up a mix of emotions in the writing professionals tasked with their completion. While these collaborative projects can provide an opportunity to learn new skills, generate new ideas, and gain new perspectives, negative feelings can overwhelm those involved and hinder the writing process. However, before memories of collaborative project-induced dread could set in attendees of AMWA's 2020 Medical Writing & Communication Conference, Crystal Herron, PhD, ELS, highlighted strategies to use in three key phases of the writing process to help rein in those overwhelming negative emotions.

The Planning Phase

Deriving all the benefits collaborative writing can offer begins in the planning stage. Herron recommended attendees use a project-management approach. This approach includes creating a feasible schedule that takes the project scope, work style of team members, and prior obligations into consideration. Team members should agree on a file naming convention that works well for everyone. Creating an organized storage structure (Figure) can also help streamline the writing process. Herron also offered this helpful organizational tip: archive older versions of files and store the most up-to-date version of a document in each version folder.

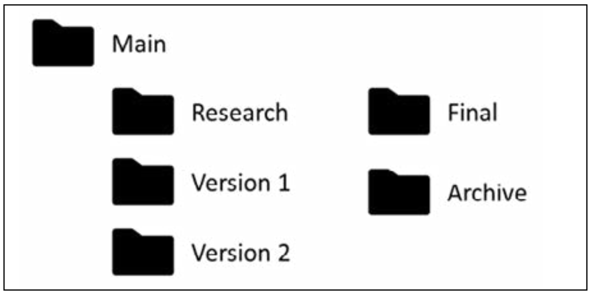

Figure. Example file structure.

Identifying a strong leader who can take on responsibility is also a necessity during the planning phase. General duties of the team leader include the following:

1. Managing deadlines
2. Updating team members
3. Scheduling and directing meetings
4. Combining drafted sections
5. Coordinating with editors
6. Proofreading
7. Submitting final product
8. Following up with client

The Writing Phase

Herron discussed three different collaborative writing methods: layering, combining, and stitching. The layering method involves the team meeting to discuss the content and overall direction of the project while one person (usually the team leader) writes the first draft. The draft is then sent to the team members, who then weave, or layer, their ideas into the existing text. This method allows for a more continuous writing style.

The combining method of writing allows for each team member to contribute written content. The team meets to discuss content and outlines major themes or sections. Each section is delegated to a team member and returned to the team leader. The leader then combines each section into a comprehensive document. This method is time-efficient and allows for each writer to use their strengths.

Finally, the stitching method takes a highly structured and focused approach. The team meets to discuss content and outlines each paragraph, including topic sentences. Team members are assigned a specific paragraph and the team leader stitches each paragraph together. The stitched document is then returned to the team to refine. While this method does require more meetings to plan specific content, the time invested up-front can ultimately help save time later.

The Editing Phase

Establishing an efficient editing process is critical in collaborative writing. Herron discussed the pros and cons of two different review styles. First, she described in-parallel editing as a process in which the team leader sends the document to each team member to review simultaneously. The leader is then responsible for incorporating revisions into one document. Incorporating and keeping track of each author's edits can be challenging for the team leader. Similarly, team members may make duplicate edits or edit an old draft. This can introduce inefficiencies, as each team member is unable to see other authors' perspectives and may not be updated about the status of the project. Overall, Herron discouraged attendees from using this method of editing.

In-series editing is a time- and effort-saving alternative. The team leader sends a draft to Author 1 to make edits. In turn, Author 1 sends the edited draft to Author 2 for review. The series continues until each author has edited the document, which is then returned to the leader. This method eliminates the possibility of duplicate edits. Furthermore, each author can see the revisions other authors suggest, making for a more efficient process.

Conclusion

Overall, Herron reminded attendees the best process to follow in collaborative writing projects is the one that works for your team. Considering the members of the team, knowing their strengths and weaknesses, and knowing each team member's professional goals can help identify the most appropriate methods to use throughout all major phases of the collaborative writing process.

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STRATEGIES FOR EFFECTIVE RISK COMMUNICATION

Speaker

Melissa Christianson, PhD, *Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC*

By Núria Waddington Negrão, PhD

Good risk communication is key for empowering patients and the public in general to make informed decisions about their health. However, since risk communication involves an interplay of complex mathematical concepts, personal beliefs, and emotions, effective risk communication can be hard to achieve. For example, if we compare some of the things that people are most afraid of, such as terrorist attacks, gun crime, and bird flu, with the things that cause the most deaths, cardiovascular disease and cancer, we see that there is a disconnect in society between perceived risk and actual risk.

In her talk, Dr. Melissa Christianson, a Medical Writer and Consultant at Whitsell Innovations, Inc., defined risk as "the probability of the occurrence of an event or outcome" and emphasized that risk communication is "the open, two-way exchange of information and opinion about risk, leading to a better understanding of the risk in question and promoting better (clinical) decisions about management" with no clear right answer.[1] "Successful risk communication points out hazards and helps navigate crises and avoid danger."

In medical communication, we typically talk about incidence, the number of new cases, prevalence, the total number of cases, absolute risk, the probability of an outcome in a population, and relative risk, a comparison of the absolute risk between 2 populations. The role of medical writers is to bring clarity in how these concepts are presented to the target audience.

Dr. Christianson identified 4 major obstacles for clear risk communication. The first is that the math involved is hard and many people, even college-educated individuals, do not have the numeracy skills to "do the basic computations that are necessary to understand risk."[2–4] This leads to general overestimation of risks and inconsistent interpretation of equivalent data.

The second obstacle to effective risk communication is that we are inconsistent in the way we assess risk.[2,5,6] Many variables influence our assessment of risk, such as the statistical measure used to present the risk, the framing of the data, mental shortcuts, emotions, and our numeracy and literacy skills.[7] The speaker gave various examples of how the way the risk is described affects the audiences' perception of the risk and consequent decision-making. People understand absolute risk better than relative risk, but presenting the relative risk leads to an overestimation of the effect and, therefore, to treatment acceptance.[3,5,8,9] Studies have shown that how we frame the data is extremely important. For example, when told that "32% of patients were dead 1 year after treatment," more patients chose to take the treatment than those told that "68% of patients were alive 1 year after treatment," even though these 2 statements represent the same risk of death.[10]
The last 2 obstacles to risk communication are that doctors and scientists speak a different language than the public and that personal beliefs enter the mix as well. Dr. Christianson emphasized the need to be careful with the word "significant," which is normally interpreted as meaning "clinically significant" by the general population.

Finally, Dr. Christianson presented 6 strategies for better risk communication. **Strategy number 1** is to start basic, to not assume that your audience already understands the background information, and to clearly define the risk, the time interval, and the population. **Strategy number 2** is to make the math as easy as possible to increase the chance of the appropriate interpretation of the numbers. Best practices are to use natural frequencies (2 out of 100 people), to use a mix of numeric and verbal descriptors (low risk—10%), to present the absolute risk or combine it with the relative risk (risk of A was 10% and risk of B was 20%), to use visual aids, and to build up to multiple levels of precision. **Strategy number 3** is to be consistent when comparing between different treatments and to use the same statistical measure, population, time interval, denominator, and framing. **Strategy number 4** is to give context, be careful when presenting risk comparisons, and consider using an incremental risk format. For example, present the background risk of an outcome regardless of intervention. **Strategy number 5** is to reduce the emotion by eliminating emotive language, using balanced framing, and being open about what is known and what is not known. **Strategy number 6** is to write to the audience. Take into consideration the socioeconomic makeup, concerns, habits, and knowledge of your audience when writing and "proactively intervene if your audience will have trouble assessing or acting on the risk." In summary, Dr. Christianson advises us to "use our tools wisely" when communicating risk.

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MENTORING PROGRAMS: ONE SIZE MAY NOT FIT ALL

Speaker
Mary Burder, PhD, *Senior Medical Writer, Parexel International, Durham, NC*

By Niada Niederhauser, BS

As the demand for skilled medical writers increases, medical communication and regulatory medical writing companies are seeing the value of mentorships; however, different mentorships fit different situations. At AMWA's first virtual conference, Parexel International's Senior Medical Writer, Mary Burder, described 3 different mentoring programs and highlighted how they can benefit both employees and their companies. The 3 mentoring programs included new hire mentoring, project mentoring, and role shadowing. The benefits of mentoring and best practices for implementing mentoring relationships were also discussed.

Mentoring programs benefit both companies and employees:

- Mentees can learn new knowledge-based skills, build confidence, and advance their medical writing career.
- Companies can see improved productivity levels and increased employee retention and satisfaction and facilitate a culture of growth.
- Mentoring relationships can foster cross-cultural exchange and understanding while improving communication skills.

When implementing mentoring programs, best practices should be developed first to ensure the programs are beneficial and to clearly define the mentor/mentee responsibilities. Some practices are specific to certain mentorships, but others are applicable to all programs. The most important general best practice, according to Burder, is to define the goals of the mentorship based on the needs of the mentees before the first meeting. During the mentorship, mentees should proactively disclose their needs to their mentors to assure the appropriate knowledge and skills are conveyed. Scheduling regularly occurring meetings is a must; both mentees and mentors should commit to attending. Mentors should encourage mentees to propose job-relevant topics for their meetings. Mentors should willingly share experiences, both positive and negative, as well as be approachable and accessible outside of meetings for support and feedback. As the program continues, mentoring style should adapt to the mentees' advancing skill level and job responsibilities.

The first mentoring program discussed in Burder's presentation was the new hire program, which enables new employees to acquire specific skills and knowledge needed to excel in their job. New hire mentoring differs from onboard training, as the latter is the core information conveyed to all new employees. By contrast, new hire mentoring is focused on helping the mentee acquire the knowledge, skills, and understanding of the processes and workflows specifically relevant to the new job. Mentors should provide examples of well-written documents, which should be closely reviewed to highlight key features that make the document effective. Mentors should also incorporate hands-on training, perhaps allowing mentees to work on small parts of the mentors' projects while the mentors provide guidance and feedback. Effective new hire mentoring programs should enable mentees to become self-sufficient more quickly, boost confidence, and ensure a smooth adjustment to the new job's responsibilities.

Project mentoring, the second program presented by Burder, focuses on ensuring current employees achieve specific new levels of knowledge and skills to take on more challenging roles so that they are equipped to skillfully complete projects and meet clients' needs. Burder pointed out that line managers or team leads usually assign their employees to the project mentoring program. Mentors are responsible for guiding mentees on specific document preparation and providing feedback on performance. Effective project mentoring programs enable mentees to acquire new project/role-related skills, promote professional development, and may increase employee retention and satisfaction.

Role shadowing, the last program discussed by Burder, differs from the other mentoring programs in that mentees request the opportunity to acquire knowledge and skills needed to transition to new responsibilities or positions within the company. Role shadowing exposes mentees to new roles, projects, and complex processes while conveying how to apply certain job-related skills. It can be either observational, in which mentees observe meetings and interactions, or hands-on, which allows mentees to perform small tasks to be reviewed by mentors.

Burder closed the presentation with a summary of mentoring programs while emphasizing how their success depends on determining mentoring objectives before implementation.

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ANALYSIS OF MENTORING: FROM MARGINAL TO MAXIMAL

Speaker

Susan Morris, MEd, CPCC, ACC, *Susan Morris Coaching*

By Christina Barnes, MSN, RN, CPNP

One of the most important business relationships is the mentoring relationship. Traditionally, the mentoring relationship has been innately hierarchical, with the mentor as the expert and the mentee as the junior or apprentice. Morris classifies this type of mentoring as traditional or minimal mentoring. "Learning goes in one direction, from the mentor to the mentee," Morris says. "The mentee is dependent on the mentor." Morris advocates for moving away from this minimal model and instead adopting a mentoring relationship that opens possibilities for both the mentor and the mentee. Morris calls this mutually beneficial model of mentoring "maximal mentoring," and she encourages professionals to cultivate this type of mentoring relationship within their own network.

What is maximal mentoring? Maximal mentoring is a professional relationship between a mentor and a mentee that is mutually beneficial. The expectations of both parties are exceeded. The mentoring process is not generic, but rather is highly customized to the needs of the mentee. There is an emphasis on the mentee as a whole person; the focus goes beyond career-related needs and goals. The relationship is transformational, as both the mentor and mentee change as a result of this style of mentoring.

Traditional or minimal mentoring, in contrast, is a generic professional relationship. The mentor has a standardized way of mentoring others that is not tailored to the needs of the specific mentee. This is usually a tr ansactional relationship or exchange; the mentee needs a job, and if the mentor helps the mentee find a job, the mentor hopes for access to the mentee's network. The focus in this relationship is solely on career development. The mentee is dependent on the mentor, and the 2 are not considered to be equals.

Maximal mentoring requires mentors and mentees to move away from the mindset of traditional mentoring. In doing this, mentors and mentees can enjoy a relationship founded on equality, respect, and trust. "Learning is a two-way street" in maximal mentoring, says Morris. The mentor and mentee are equals, and there is the expectation that they will learn from each other. Both the mentor and mentee can experience personal and professional growth as a result of this relationship. Maximal mentoring can be "positive, uplifting, appealing, attractive, and fun," Morris says. The mentor and mentee can expect to have conversations about both professional and personal matters. Morris quotes a maximal mentor who describes these conversations: "I am very close with my mentee. There are few things that we don't talk about. … Our mentoring relationship helps me grow and learn as much as my mentee."

So, how do you create a maximal mentoring relationship? What is the "secret sauce?" According to Morris, there are 4 important ingredients to establishing and maintaining this valuable connection:

1. **Relationship:** In maximal mentoring, friendship comes first, and the professional relationship comes second.
2. **Connection:** It is important for the mentor and mentee to have a strong connection. They must care about each other's success, be responsive to communication, and create a safe space for each other. A firm commitment is required, with many maximal mentoring agreements and logistics outlined in a document or contract.
3. **Acceptance:** The mentor and mentee must accept each other for who they are with no judgment. There is no hidden agenda or pretending to be someone else; the "masks are off." The mentor and mentee can discover their best selves, and both are able to take risks within the privacy and safety of the relationship.
4. **Preferred traits on the part of the mentor and mentee:**
   a. Trust and mutual respect
   b. Interdependence
   c. Authenticity
   d. Vulnerability
   e. Patience

If maximal mentoring does not sound feasible, Morris suggests starting with reverse mentoring. Reverse mentoring is when a younger, inexperienced employee is paired with a senior executive who is *willing* to learn. The younger employee exposes the executive to issues important to the younger generation and addresses gaps in the executive's technology skills. This style of mentoring helps the organization retain young talented professionals while increasing representation of the younger demographic throughout the organization.

Morris summarizes the most important aspects of building a meaningful mentoring relationship as follows:

1. Build a **relationship** based on candor and **trust**.
2. Look for opportunities to explore **professional** goals and **personal** dreams.
3. Be open to give and receive critical feedback, sharing successes and **mistakes**.

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KNOWING WHICH BUTTON TO PUSH: COMMUNICATING THE VALUE PROPOSITION OF MEDICAL WRITING

Speaker
Robin Whitsell, *Whitsell Innovations, Inc, Chapel Hill, NC*

By Lisa English, PhD

As medical writers, it is essential to understand that everything we do communicates our value. Our emails should be free of spelling and grammatical errors and highlight our writing expertise. Our presentations should have well-prepared slides based on a solid understanding of the science involved. We need to show others that the document is safe with us and that they can put their confidence in us. Scientific knowledge and writing expertise alone aren't enough to do that. There is more.

Understanding Team Dynamics

We need to understand our teams. To own the document, we need to influence without authority, which is challenging, especially when team members may be more senior. Understanding team dynamics allows us to own any situation and shepherd the team and the document toward success.

Mastering Our Reactions

It is equally important to understand what our actions might be saying to the team. To do this, we need to be observers of our reactions. Try taking private notes during a meeting. When something uncomfortable happens, write it down. Include only observations, no judgments. After the meeting, evaluate the information critically. Understanding our feelings and how they manifest in us gives us the power to change them to improve our interpersonal effectiveness.

Seeking the Gift of Feedback

What if others seem concerned about our value? In those situations, it is vital to own the disconnect and ask to reset. When seeking feedback from an individual, compliment the person on something specific and real to create a connection and confirm commitment. If the person does not provide feedback, lead them to it, explaining the behavior that's creating the disconnect and asking to learn more. But what if the disconnect is with the team? The same basic principles hold, but it's probably best to address it at the beginning of a meeting: "Hi, it seems we're experiencing a rough patch. I'd appreciate your advice about the best way to move forward."

Putting It All Together

Let's look at a few stereotypical examples of team dynamics and how being aware of our feelings and mastering our reactions can help.

Captain Obvious. What happens when a team member says something obvious? How do we feel? How do we react? Understand both and then own the situation. Try pulling Captain Obvious more fully into the conversation. Ask him a question related to his expertise and make room for him to answer.

The Interrupter. What happens when someone consistently interrupts? Often, if the interrupter is more senior, we think we must allow the behavior, but we should not. Again, identify the feeling and reaction elicited. Then own the situation. Try practicing neutral phrases to address this situation. One example is "I promise we will get to that, Jack; please, let's complete this discussion point first."

The Combative. How does a combative team member make us feel, react? Owning this situation requires staying neutral, being succinct, and redirecting the individual. For example, one might say, "Catherine, I hear how important this is to you. Maybe we can address it in Section 11. Right now, we need to move to comments from Clarice."

Skill at Leading and Motivating a Team

Although disagreeing may make us feel combative, respectful disagreement is often necessary to get the documents right. In this situation, we need to maintain a neutral tone and remain matter-of-fact. Try posing the disparity as a question. For example, one might say, "It seems we are missing a source for the data on page 82. How should we resolve this?"

The value proposition of a medical writer is multifold. It is about scientific knowledge and writing expertise, understanding team dynamics, and understanding (and being willing to change) ourselves. It's about getting the document right, not being right; about conveying empathy, respect, and dedication; and about giving others the benefit of the doubt. As medical writers, we need to show up every day as our best selves to do our best work because that invites everyone to do the same.

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WHAT THE BEST MEDICAL WRITERS KNOW ABOUT NONCLINICAL DATA

Speaker
Beth Krause, MS, MBA, *Senior Medical Writer, RRD International, LLC, Rockville, MD*

By Stacie Marsh, MPA, CPH, GPC

Medical writers specialize in a variety of fields, such as continuing medical education, patient education, scientific publications, regulatory documents, and research-grant applications. Writers pursuing Medical Writing Certification (MWC) must at least be familiar with each of these areas, and even those not pursuing certification benefit from cross-disciplinary understanding.

Ms Krause's presentation at the AMWA's 2020 Medical Writing & Communication Conference explained the importance of nonclinical data and studies from a broad context, resonating with medical writers from all areas, including those with and without expertise in regulatory documents.

Overview of the Drug Development Process

The life cycle of drug development occurs through 4 phases, some of which can occur simultaneously. These include

- phase I (relatively small studies focused on establishing safety, and clinical pharmacology studies),
- phase II (larger studies focused on evaluating clinical efficacy),
- phase III (pivotal, large, randomized, placebo-controlled studies with clinical trials to prove clinical efficacy prior to marketing authorization), and
- phase IV (large studies to establish processes for ongoing safety and efficacy surveillance after a drug is approved and marketed).

The most important function of nonclinical data is to establish that a drug is safe to be administered to humans. These data are submitted with an Investigational New Drug application prior to initiating studies in humans. However, the data from nonclinical studies may impact the clinical development, and thus, clinical documents, throughout a drug's life cycle.

The Importance of Nonclinical Data in the Drug Development Process and Placement of Nonclinical Data in Clinical Regulatory Documents

Ms Krause set the stage for writers unfamiliar with regulatory documents by explaining the lifecycle of drug development within the framework of the "Common Technical Document" (CTD) Triangle (Figure).

Endorsed by the International Council for Harmonisation, the CTD Triangle is a standard framework for applications for approval of new medical drugs to regulatory authorities in the United States, Europe, and Japan. The CTD Framework is organized into 5 modules. Most medical writers with regulatory document expertise focus on Module 5 (Clinical Study Reports). However, the preceding module, Module 4 (Nonclinical Study Reports), includes valuable content that impacts the documents in Module 5.

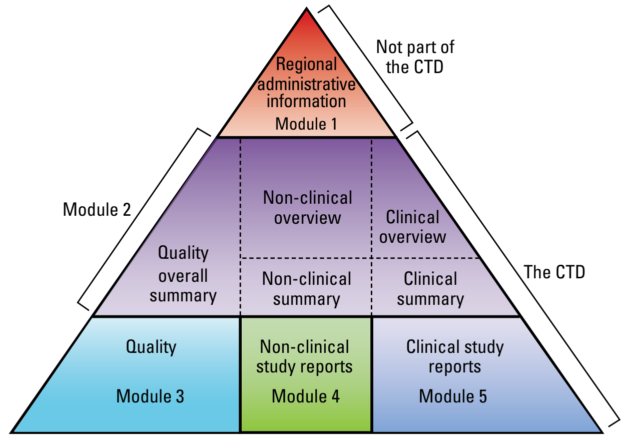

Figure. The CTD triangle. The CTD is organized into 5 modules. Module 1 is region specific, and modules 2, 3, 4, and 5 are intended to be common for all regions. CTD, Common Technical Document.

> "Nonclinical data enrich the overall understanding of a drug during the development and approval process, starting well before new drugs are first tested in humans."
> —Beth Krause

As Ms Krause explained, the most important role of nonclinical information in regulatory documents is to provide basic safety support for a new chemical entity (drug) before it is tested in humans, including a detailed assessment of benefits and risks. Thereafter, nonclinical information is required throughout development and marketing, including the medication packaging.

Nonclinical data impact risk language, dose selection, design elements, and development. For example, nonclinical studies inform risk language in clinical documents such as informed consent forms, clinical protocols, general investigational plans, and investigator brochures. Nonclinical studies also predict potential side effects when it is too difficult or unethical to test in humans (ie, reproductive side effects).

Nonclinical data are also valuable in informing first-in-human dose selection by establishing starting doses and safety margins, as well as dosing regimens, on the basis of findings in toxicology studies. Additionally, nonclinical data inform the rest of the drug development process by determining the need for additional clinical studies, identifying potential new indications/targets, and even terminating development if the safety profile is poor.

Following an overview of the basics of the drug development process and the value of nonclinical data therein, Ms Krause provided a detailed explanation of the role of nonclinical data within Module 4. The 3 main categories in Module 4 include

- pharmacology (how a drug works, how a drug may affect organ systems secondary to its main target, and how coadministration of drugs may affect how they work),
- pharmacokinetics (how a drug is absorbed, distributed, metabolized, and excreted from the body as well as the potential for drug interactions), and
- toxicology (how a drug may cause adverse effects, including single-dose toxicity, repeat-dose toxicity, and the potential for genotoxicity and carcinogenicity).

Ms Krause explained how to link nonclinical data in Module 4 to clinical documents with which regulatory medical writers may be more familiar (typically Module 5) by using a fictional example of a new chemical entity compared with a drug that is repositioned for a new indication.

Importance for All Medical Writers

Even medical writers who focus on other areas of medical writing, with little or no experience with regulatory documents, benefit from this presentation by its comprehensible overview of drug development and how nonclinical data fit in.

Although regulatory writing is a popular area of the medical writing profession, it is often limited to those with medical or pharmaceutical backgrounds or early-career experience and can be intimidating to those who specialize in other areas. The content in Ms Krause's presentation is particularly salient for writers without a medical or pharmaceutical background, given the myriad aspects of the drug development and approval process that require proper placement of nonclinical data.

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The Medical Writing Certificate program at the University of California San Diego (UCSD) Extension is designed to provide graduates with the foundational knowledge and skills needed to work as a medical writer in the commercial sector, government agencies, and/or academia. The certificate equips scientists, communication professionals, and others with a strong biomedical and/or life-sciences background to write specifically for scientific, education, or regulatory audiences and to fully understand the profession.

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For more information on the UCSD Extension Medical Writing program and our faculty, visit https://extension.ucsd.edu/courses-and-programs/medical-writing-courses.

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Oxford University Press is the proud publisher of the *AMA Manual of Style*, 11th edition, the must-have resource for anyone involved in medical, health, and scientific publishing. Written by an expert committee of JAMA Network editors, this latest edition addresses issues that face authors, editors, and publishers in the digital age. Extensive updates include examples of how to cite digital publications, data repositories, and social media. Full-color examples grace the chapter on data display, with newer types of graphic presentations and updated guidance on formatting tables and figures. The usage chapter has been revised to bring the manual up to date on word choice, especially in writing about individuals with diseases or conditions and from various socioeconomic, racial/ethnic, and sexual-orientation populations. In sum, the answer to nearly any issue facing a writer or editor in medicine, health care, and related disciplines can be found in this 11th edition.

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