Introduction

Thank you for awarding me the 2019 Harold Swanberg Distinguished Service Award. I am very honored.

As I begin my presentation today, please know that the content and opinions expressed are solely my own and should not be attributed to any employer or other affiliated organization.

Today I will touch on several topics briefly, but know that they could all be discussed in day-long courses too. I have learned a lot about medical communication along my career journey to date. It is these insights that I want to share with you all today. I am hopeful that today's presentation may inspire some of you to stay in the medical communication field, expand your horizons as a medical writer, and enjoy the journey along the way. Today I am going to be talking about careers, medical communications, medical writing trends, communication channels, data visualization, structured and component authoring, and competency and certification.

I am speaking about these topics from a pharmaceutical industry perspective, but I believe it is nevertheless relevant to medical writers in general. It may be beneficial to think of a medical communicator in the broad sense beyond what is traditionally considered "medical writing." Trends in medical communications are leading to the need for expanding roles and breadth of expertise for medical writers. Medical writers are communicating medical data and information via new modes of content delivery that I refer to as "channels" in this presentation. For context, 1 example would be digital video abstracts.

Data visualization is now a focus, and it is now often replacing text. Structured and component authoring are becoming a reality, and I will define these for you later in the presentation. Although the core competencies needed for a successful medical writer have not changed, new knowledge, skills, abilities, and behaviors (KSABs) may be needed, and certification for professional medical writers now exists. These topics will be discussed in the context that new opportunities are available for scientific communicators to expand their horizons as they mature in their careers.

Career

I was asked to provide some details of my career background that led me to this stage, and I believe they make a nice segue into today's presentation topics. I earned a Bachelor of Science in Psychology at Iowa State University, but I felt that my undergraduate degree would not be useful without a postgraduate degree, so I pursued and earned a Doctor of Philosophy in Neuroscience at the University of Virginia. I wasn't sure being a laboratory scientist was what I wanted. However, I wanted to give the idea a full chance, so I completed a Postdoctoral Fellowship in Neurobiology at Duke University, which confirmed that I didn't want to work in a lab. So, I tried my hand at teaching at the University of Virginia, at a local community college, and at a few other institutions. I really enjoyed teaching, but I didn't think I wanted to do it full-time. I began to wonder, "What should I do?"

I knew nothing about medical writing at the time. Then I heard about it briefly from a fellow post doc who had recently gotten a medical writing job, and I thought ... this is perfect! It includes what I liked about my PhD experience, and it didn't have what I didn't like. I could be immersed in the science and presentation of research results in a variety of forms (manuscripts, oral presentations, abstracts, posters) while not having to work at a lab bench or be in a job that lacked daily variety.

So, I took a job as a medical writer at a Clinical Research Organization called Pharmaceutical Research Associates, where I wrote clinical study reports and protocols. Then I took a job as a medical writer in Global Scientific Communications at Eli Lilly and Company, where I wrote regulatory documents and publication documents of all types. Next, I took a role as a manager of a medical writing group with responsibility of staff oversight and development. I had a stint outside of medical writing in Lilly's Medical Affairs organization. I took subsequent roles as an operations and technical advisor for the medical writing department with responsibility for process, technology, and innovation. This all led to my second Global Medical Affairs role, with my current title being Principle...
Clinical Research Scientist, Global Medical Affairs, Eli Lilly and Company.

You may be thinking, what is the connection between my career path and today’s presentation? My medical affairs role had a significant overlap with a medical writing role: I authored protocols, publication documents, and medical information documents; I reviewed and approved cross-functional medical communication outputs; I added relevant KSABs and communicated clinical data and disease state information via new venues and channels (including advisory boards), promotional tactics (including print, Web, TV, and congress booths), and other promotional communications. I got the variety I was looking for and kept the scientific communications that in turn provided job satisfaction.

To bolster the day-to-day job variety and satisfaction, I have been involved in the medical writing external environment throughout my career. I have been a medical communications meeting chair, session chair, and/or topic presenter at both the American Medical Writers Association (AMWA) and the Drug Information Association (DIA). I have held leadership positions in both organizations. For example, I am currently the Medical Writing Certification Commission Chair for AMWA and am the recent past Chair of the DIA Global Medical Writing Community. Additionally, I have published several articles regarding medical communications, including on the topic of medical writer competency.

Medical Communications

So, when thinking about medical writing careers, perhaps think about being a medical communicator in the broad sense. Think of medical writing as an umbrella term, in which communication equates to transmitting medical information beyond writing alone and in which medical editing or writing roles can be a subcomponent of multiple job functions that are involved in medical communication. Roles or jobs focused on medical communications content creation include medical editors, medical educators, medical information communicators, and medical writers who are promotion focused, publication focused, regulatory focused, or nonclinical focused.

Some jobs are focused more on direct-to-audience content delivery than on content creation, but a medical editor or writer can be involved in all these spaces, including delivery-focused areas like medical affairs or medical liaisons. In my medical affairs roles, I have heavily utilized my medical writing competency for editing, educating, informing, and promotional and publication writing.

Some roles may have unique competencies and KSABs, but core medical communication competency domains are relevant across roles: deliverables (manuscript compared with continuing medical education presentation); channels (scientific congress compared with television commercial); and audience (health care provider compared with patient). Thus, all these roles are generally involved in planning, creating, reviewing, and delivering medical communication content; they may just be doing it via different venues and channels. As such, moving from 1 part of the medical communication umbrella to another can be a way of maintaining career variety while expanding one’s competency and skill sets, and thereby personal marketability.

Medical Writing Trends

Pharmaceutical companies still submit content to regulatory authorities in static portable document format (PDF), which is the equivalent of e-paper. This method is extremely antiquated. For regulatory submissions, the industry is working toward providing digitized data tagged with metadata for interactive review. For publications, the industry is working toward moving from static to digital content, and by digital, I mean programmed or coded content. Digital content is not new for other industries communicating data, or even for marketing within the pharmaceutical industry, but it is new within the scientific medical communications umbrella.

Audiences do not have time to read voluminous content. On average, readers only read 20% to 28% of text-based content. Visualization is our number 1 sense for learning, bolstered significantly by interactivity. We only remember 20% of what we read but up to 80% of what we visualize and interact with; thus, as visualization significantly improves engagement, understanding, and retention, the trend is for visualization to replace text and long prose.

Component authoring, at a high level, refers to chunking content for reuse. Particularly for regulatory writing work, to handle the volume and variety of documents that contain much the same information, component-based authoring tools are now being utilized. This is not a new concept, but the standardization and technical advancement needed is finally making it a reality, and it will continue to become more robust over time.

Interactive data analysis and visualization tools such as Spotfire are now being used for clinical statistical analyses to aid data review and interpretation of study data and to enable
statisticians to deliver analyses and data outputs in new and advanced ways.

Finally, an increasing number of writers are getting certified, and certification is now being recognized by employers. Although not an absolute requirement, I would contend that to be a successful medical writer, you would need to have a working understanding of these topics with some level of expertise in elements relevant for your medical writing niche. Now I am going to provide a little more insight into each of these trends.

Channels
As medical communicators in a time of advancing technology, our venues and content delivery channels continue to morph. For example, infographics and visual abstracts are becoming more commonplace. These new channels address data visualization needs and meet customer needs for concise summary information that provides take-home key points.

Venues such as scientific congresses are moving from paper to static e-posters and, eventually, to interactive digital posters. The future example shown here is advanced, but digitally based content for medical communications is now here and advancing in complexity and commonplaceness. Meanwhile, publications are moving in the same direction. A paper poster developed into a digital poster is another example of content moving to a digital channel. Digitization allows for inclusion of the following:

- graphic design and data visualization principles,
- icons and infographics,
- video and audio,
- user interactive installations,
- computer-generated imagery (CGI),
- animation,
- augmented reality,
- virtual reality,
- gamification, and
- integration into Web and mobile applications.

In the future, medical communications will provide disclosure-ready tables and figures that can be used in component authoring across internal and even external medical communication functional groups. Through validated interactive tools, customers will be able to customize the data visualization to meet their needs, removing back-and-forth communication, medical writer rework just to meet nuanced needs, and voluminous revalidation work.

Data Visualization
Data visualization is moving from raster nonscalable and noneditable file formats to vector scalable and editable file formats, from static to animated and interactive tables and figures, and from content lacking data visualization principles to incorporation of visualization and graphic design principles. Data analysis and visualization tools like Tableau, Power BI, SAS VA, and Spotfire can help authoring teams with data interpretation when reviewing study data, which can aid authoring teams in figuring out what needs to be written. And, as noted already, content delivery is moving from electronic paper to digital formats.

One example is a key figure in a published manuscript reporting changes in the Psoriasis Area and Severity Index, which is a measurement of plaque psoriasis clearance. This static figure was published in the article and shows only the final portion of the data in PDF format. An animated version was published as a supplemental figure cited and housed online: https://www.tandfonline.com/doi/suppl/10.1080/09546634.2018.1473551 (Supplemental Figure 2; click play). Every patient in the clinical study across 3 treatment groups is represented over time in this one animated figure. Data points are color-coded based on efficacy category reached and linked to stacked bars to aid in data summary. The animated manuscript figure is an example of data visualization. As medical publications become more digital, this figure would move from being supplemental to being embedded.

Structured and Component Authoring
Document authoring refers to the writing of text-heavy documents. Structured and component authoring each utilize a different approach to medical writing. Structured authoring is a rules-driven writing technique to deliver simplified, focused content that increases readability and the ability to find information. Structured authoring enables component authoring.

Component authoring revolves around creating content in chunks with downstream reuse in mind. As mentioned, this is not a new concept, but standardization and improved technology is finally making it a realistic approach to authoring. It utilizes parent-child relationships and structured templates to make easy changes to documents and increases consistency across documents. Component authoring is necessary for content reuse platforms, and it enables the automation of document creation. A content platform is a software application that enables the integration of component content.
Structured and component authoring enable machine learning, artificial intelligence, and automation to aid in document development. This is particularly useful for regulatory documents, and indeed the current application is within regulatory medical writing.

A lot of the push for such ideas is related to searching for efficiency gains in a time when medical writers are continually asked to do more with less. Automation can accelerate content creation, increase consistency, and reduce resourcing effort. This requires doing work somewhat differently, but it is more about embracing innovation to allow the medical writer to focus on what is actually important, which is the writing of narrative that accurately describes their medical data and information while providing the key points.

**Competency and Certification**

Competency means a person is qualified to perform a specific role, has the ability to perform that specific role successfully, and uses their KSABs to satisfactorily perform their role. A competency model defines the functions, tasks, and activities, as well as KSABs that define the profession.

When asked what is needed for a medical writer to be successful, I always respond that they have to be able to

- understand and speak the language of science,
- write a document (knowing what to include, how to include it, and where to include it to meet audience needs), and
- manage a project team that doesn’t report to you and is often challenging (requiring good soft skills and people skills).

More recently, I have begun to add that one has to be able to understand the strategy behind communication plans, the different aspects of the medical communications umbrella, concepts of structured authoring, and data visualization principles.

Importantly, however, one cannot and does not need to be an expert on everything nor be an expert on all technology and tools. Take data visualization as an example. A medical writer should

- know the best type of data display needed for the data or information being conveyed;
- understand and advocate use of data visualization and basic graphic design principles;
- hand off creation of the data visualization to a data analyst, graphic designer, or digital creator; and
- learn how to create basic low-complexity visuals such as basic infographics or visual abstracts, or, at a minimum, know who can do it for them.

Certification tests an individual’s competency, which requires professional experience, and involves a formal assessment process leading to a professional designation. AMWA's Medical Writing Certification Commission (MWCC) in collaboration with a testing agency, developed the Medical Writer Certified (MWC) credentialing program that is an exam-based professional certification. Professionals who hold this credential have demonstrated their understanding of medical writing core competencies through successful completion of an examination. To be eligible for the program, the medical writer must have at least 2 years’ experience. The program also requires continuing education for recertification. All of this shows a medical writer’s dedication to their profession and identifies a professional medical writer compared with someone just looking for a job.

Certification is awarded by a third-party standards organization. The standard is set via a defensible job analysis process that outlines the required knowledge and skills necessary, but not sufficient, to be competent. An individual’s competency is measured by a standardized test.

The DIA Medical Writing Competency Model is linked to the MWC examination. Certification examination domains and the associated knowledge tested is based on the competency model, which can be a great road map to expanding horizons for beginners, for those changing their specialization area, and for those wanting to expand their development plans. The certification domains focus on gathering, interpreting, evaluating, organizing, and presenting, with the topic of ethics built into each domain. The KSABs associated with these domains are core to what all medical communicators do, regardless of their niche or specialty or job title.

The certification examination tests a medical writer’s core foundational knowledge needed for success in the workplace and shows a medical writer’s breadth of knowledge. Successful certification provides a designation (credential) to use with one’s name. Ongoing requirements are needed to maintain the certification, which provides robustness over time.

Certification can look good on a medical writer’s resume and is now showing up in job postings under preferred qualifications.

So, I recommend that medical writers be medical communications experts in addition to being medical writing experts. Learn what is under the medical communications umbrella and embrace innovation. This can keep career doors open,
which is nice, even if you choose not to step through, and it can bring variety to career paths while keeping medical communications and medical writing a core focus, which can lead to a high level of job satisfaction.

**Summary**

Working across medical communications roles brings variety to the job. There is a medical communications umbrella that is made up of medical editing, education, and information; promotional, publication, and regulatory writing; and medical affairs and medical liaison activity.

Medical writing trends include increasing digital content, data visualization replacing verbose prose, viable component-based authoring tools, interactive data analysis and visualization tools to aid clinical study data review, and medical writing certification.

Medical content delivery channels are increasing in variety and complexity. Ensuring the integration of data visualization and graphic design principles in medical communications content is important. Structured authoring can help focus written content, and component authoring can enable efficiency through content reuse and automation. Strong medical communications competency opens doors. Certification shows professional dedication, and employers are starting to recognize it.

Embracing innovation trends is important for staying competent, competency in overall medical communications opens doors to opportunity, and medical communication expertise can expand horizons for medical writers and other medical communicators.

In closing, let me again thank AMWA for the honor of this Harold Swanberg Distinguished Service Award and for allowing me to share my thoughts with you today.

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