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FROM THE GUEST EDITOR

The Future of Medical Writing: Gazing into the Crystal Ball

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Over the past eight decades, the role and perceived value of what we've come to know as the medical writer has evolved. As the process of document production became more complicated and time-consuming, a separate group of specialists evolved to serve the role of "medical writer." Although this role may not have been formally defined, and certainly not consistently so, this was the genesis of the professional we consider to be the medical writer.

When AMWA was founded, members were physicians who wrote. The documents that they generated were primarily manuscripts for publication, content for medical textbooks, and, perhaps, case studies. In 1940, there were only rudimentary documents created for submission to a fledgling Food and Drug Administration. Indeed, regulations, as we know them, had not yet been formulated.

As regulatory document requirements became more structured and went beyond case study descriptions, expertise had to be expanded from medical and scientific knowledge to an understanding of what would satisfy the requirements of regulators—requirements that were constantly evolving and becoming more stringent. At the same time, there was a move toward globalization and the need to serve at least two masters—FDA, the European Medicines Agency (EMA), the Japanese Pharmaceutical and Medical Devices Agency (PMDA), etc.

The world of publications has, likewise, undergone significant changes. At the outset, the end product was printed hard-copy articles in medical and scientific journals, the majority of which were only available by subscription to those with advanced degrees in the life sciences or to physicians. For most of the profession's history, there was no internet and, therefore, no access by the general public to this information. We now live in a technologically enabled environment where information is posted online, often unvetted, and assumes a life of its own—freely distributed, manipulated, misinterpreted, and all too often "weaponized."

Through the years, the role of the medical writer was often determined by corporate, or even team, culture. Depending upon the experiences, inherent biases, and personalities of your team members, the medical writer was viewed as a secretary, editor, wordsmith, or valued interpreter of data and expert communicator.

In preparing for this special topics edition of the *AMWA Journal*, I wanted to tap into a broad and varied spectrum of those who practice the trade of professional medical writing as well as some who collaborate with them. In eliciting thoughts, I decided to create a series of virtual panels, thus allowing for a more conversational and interactive experience among participants. What has resulted is a series of collective thoughts on where the profession is going, and which forces will shape the context within which we will ply our trade going forward. In one case, individuals formed their own "panel of one"; however, panels mostly comprised colleagues either from the same company or those who were invited because they were members of a particular professional organization (eg, the Drug Information Association (DIA)) or represented a particular viewpoint within the medical writing community.

I provided a framework for the panel discussions, based on my 2020 "crystal ball" predictions, on the occasion of AMWA's 80th year. I posited that the environment—scientifically, technologically, socially, and politically—will continue to evolve, although inexorably toward what end, it is impossible to divine.

My musings, below, apply to all segments of the medical communications community—regulatory medical writers, information specialists, publication professionals, teaching faculty…and others who represent the broad spectrum under the medical writing umbrella. Contributors were asked to choose one or more of the topics presented below and to share their perspectives, either as a consensus or as individual observations. The suggested overarching themes and subtopics follow; however, panelists tended to free-associate, and although some of the suggested topics were addressed, panelists sometimes elected to discuss topics of particular interest to them.

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TECHNOLOGY

- There will certainly be an increased use of artificial intelligence, automated templates, and eSubmissions to regulatory authorities.
- Data will become more available in real time as clinical studies leverage personal data interfaces, including "wearables" or even "implantables." This may result in the medical writer accessing, aggregating, interpreting, and communicating trends and signals throughout the course of a study, rather than only at the point of Last Patient, Last Visit.
- The current coronavirus pandemic has accelerated the work-from-home model. Technology will continue to enhance this practice, removing many of the barriers and inconveniences we now face. It may become an opportunity to be a "work-from-home planet."

WHAT ABOUT THE AUDIENCE?

- Information may be provided to a broader range of consumers. No longer will results of studies be limited to regulators and scientific/medical cognoscenti. With greater access to posted documents in a variety of portals, the public will seek and access information that is important for informed decision-making. The patient will have a stronger voice in determining their treatment, and this will extend to end-of-life decisions. Social media will amplify results and will spread misinterpretations and poor quality data. *Caveat emptor*!

ROLE EXPANSION

- Medical writers will assume a stronger role as "guardians" of best practices. Not only do regulations constantly evolve, but so do publication practices. The medical writer will have to maintain a high level of awareness and familiarity with current best practices and will have to serve as a "gatekeeper" to best ensure that these are not violated. This will require that the medical writer assume the role of educator, communicating the essence of these standards and the rationale for adhering to them.

GLOBALIZATION

- A single global regulator? Not likely, but a lot can happen in 80 years. The trend toward mutual recognition among regulators will continue, with common guidance and templates. Yes, there will still be regional differences; however, the core dossier will serve all masters.
- Our professional associations (eg, AMWA, EMWA, ISMPP, etc) have represented a "Balkanized" community, despite the significant overlap in membership profiles, educational program content, and common interests and goals. Recently, the three organizations mentioned have successfully collaborated to develop Joint Position Statements addressing systemic and institutional deficiencies. I trust that this will continue and hope that at some point, we will realize that we have a stronger voice through alliances not just within the medical writing community but with associated institutions (eg, academia, medical and scientific journals, regulators, etc). I have long been an advocate for the Intergalactic Medical Writers Association. Perhaps, one day!

OTHER THOUGHTS

- Pressure to release data in "real time" for publication – technology allows us to do so, particularly given the increase in use of patient-reported outcome platforms that gather data in real time and adapt to prior responses. This allows the release of "raw data" that may have been only minimally vetted.
- Society will determine that resources are insufficient to provide all services to all patients. This rationing of health care may seem Draconian; however, in a world of limited resources, algorithms will be applied to human healthcare. This will result in a greater need for medical communicators to develop materials to educate the public, including lawmakers, about the rationale for allocation decisions.

The panels represented participants from across the globe, and I thank them for their insightful observations and suggestions as to how the profession might best confront unmet needs, opportunities for growth, and the challenges that have been long-standing, are only recently emerging, or that we may imagine in a cloudy future.

The future will reveal itself over time. As one of my heroes, that great sage, Yogi Berra, likely said, "It's tough to make predictions, especially about the future."

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