
DELAWRITER

The quarterly newsletter of AMWA-DVC

Fall, 2024



Words of Hope: The Impact of Medical Writing on Rare Diseases

by Dena Aruta

When I transitioned my career from clinical microbiology to medical writing, my goal was to make a greater impact on patient's lives, more of an impact than I felt I could make when I was working in a hospital lab. At that time, I could never have predicted how my writing would evolve into creating awareness and advocacy for rare diseases, particularly sarcoidosis. In 2014, I was diagnosed with pulmonary sarcoidosis, a rare inflammatory disease that has a highly variable clinical course from mild disease to end-stage organ failure and death.

Although I do not have severe complications, sarcoidosis has changed the way I live and experience my life. The biggest challenge I have had since being diagnosed has been finding knowledgeable providers I can trust with my care and treatment. This journey, which has been frustrating, isolating, and at times, depressing, has been the catalyst and motivator for my passion to improve patient care and research into rare diseases. Medical writers play an important role in disseminating accurate, evidence-based information about rare diseases through a variety of resources including patient education, provider education, community advisory boards, and crowdsourcing. This article is the first part of a two-part series and will focus on defining rare diseases and educating providers.

What Is a Rare Disease?

Taken together, rare diseases are not that uncommon. The National Organization for Rare Diseases currently reports more than 10,000 known rare diseases affecting approximately 300 million people worldwide.¹ There is no gold standard for defining a rare disease. In the U.S., a rare disease is a condition that affects less than 200,000 individuals, but that definition varies among different countries. For example, the European Union defines a rare disease as one that affects fewer than 1 in 2,000 people.² Rare disease communities have historically been underrepresented and underserved in both clinical research and healthcare systems.

Diagnostic Challenges

Individuals with rare diseases frequently face being misdiagnosed, prolonged diagnostic delays, or remain undiagnosed altogether.³ The average time it takes to receive an accurate diagnosis of a rare disease is approximately 4-5 years, but in some cases, it can take 10 years or more.³ During this time, patients undergo extensive testing, invasive procedures, and visits to multiple providers. Patients and their families often report feeling unheard or dismissed by their healthcare providers, who may also lack motivation or refuse to investigate the root cause of their symptoms. In a community-based study, Harper et al examined barriers and facilitators to care in sarcoidosis by utilizing focus groups stratified by income.⁴ When asked about knowledge gaps in providers, one participant responded, “I ended up with fifteen doctors . . . and only one of them knew anything about sarcoidosis.”⁴ Several studies evaluating provider communication with patients found that 33% to 72% of participants reported dissatisfaction with the information given about their diagnosis: almost half of them did not understand what they were told.³

Addressing Knowledge Gaps and Educating Providers

Information Dissemination

Small sample sizes and the urgency of getting rapid FDA approval of novel drugs render conventional study designs like randomized clinical trials unrealistic.⁵ Case studies and single-arm clinical trials requiring the use of less common data analysis and statistical techniques are employed more often in rare disease research.⁵ However, these non-traditional methods can be unfamiliar to clinicians, making it challenging to effectively convey accurate information.

Medical writing comprises many different domains and specialty areas in which medical writers can disseminate new research findings targeting a

wide range of audiences. Determining the best strategy for delivering this information can be challenging, but the end goal is to maximize access for patients struggling with potentially life-threatening rare diseases. Having a multi-channel strategy utilizing resources like podcasts, social media, and videos to disseminate research findings is more effective at maximizing the coverage of rare disease research.⁵

Many journals now offer the option to publish articles as open access which makes research available to patients without a subscription.⁵ By developing plain language and graphical summaries in open access journals, medical writers can increase readability and ease of understanding of the content for patients and individuals without medical training or backgrounds.⁵

A Look to the Future: The FDA Rare Disease Innovation Hub

The FDA recently announced its commitment to its mission of engaging patients with rare diseases and understanding their experiences and perspectives when reviewing applications for approval of drugs and medical devices.⁶ The Rare Disease Innovation Hub (the Hub) has been established by the FDA to focus on products designed for small populations or diseases whose causes are not fully understood because developing treatments for these conditions is challenging. The three main functions of the Hub include:

1. Acting as a single point of contact for rare disease communities concerning medications, medical devices, and diagnostic tests.
2. Improving internal collaboration within the FDA and interdisciplinary strategies to address clinical and policy issues related to rare disease product development.
3. Advancing regulatory guidelines that consider innovative clinical trial designs, real world evidence, alternative statistical methods, novel endpoints, and development of biomarker assays.

Medical writers will have the opportunity to communicate data from the Hub regarding the development, review, and approval of safe and effective drugs and biologics for treating rare diseases. The goal is to improve patient outcomes and positively impact the rare disease community.

Summary

Medical writers and communicators are in a unique position to offer hope to patients and their families living with a rare disease. Navigating the healthcare system is not an easy task, but when armed with accurate and relevant information about their condition, patients can make informed decisions about their care and treatment. Let us, as a profession, work towards improving care for rare disease communities by increasing

awareness and advocating for change.

Dena Aruta has a BS in biology and medical technology. She has worked as a clinical microbiologist before transitioning into medical writing.

Living Your Legacy: An Interview with Joan Affleck, 2023 Harold B. Swanberg Award Winner - Part 2

by Mia Nagarajan

Joan Affleck, MBA, ELS, received the 2023 Harold B. Swanberg Award from the American Medical Writers Association (AMWA) at their National Conference. This award recognizes distinguished contributions to medical communication and is one of the highest honors from AMWA. Joan delivered an inspiring educational session about living your legacy and discussed the career journey for medical writers and opportunities to bring long-term goals to fruition.

The Spring edition of the *Delawriter* included Part 1 of the interview: Joan discussed her career journey, learnings over the years, and her advice for medical writers to think about and live their legacy every day. Below, Part 2 includes Joan's perspective on the meaning and significance of receiving the Harold B. Swanberg Award. In addition, she shares advice for medical writers to cultivate good habits, stay motivated and focused on goals, and keep up to date on the latest trends in the industry.



Joan Affleck, MBA, ELS

Mia:

What does receiving the Harold Swanberg Award mean to you?

Joan:

It's a great honor, and it recognizes not only my work but also the collective effort and support of the people around me. I have always been motivated to address the needs I see in the field and pay it forward in terms of service. Important aspects of my approach include innovation, opportunities to make things better, collaboration, and supporting people through change as

change is hard for people.

Anyone who becomes a medical writer knows that getting that first step in the door is the hardest part. The preferred background, prerequisites, and experience are often not clear. Sometimes people have no experience, but they know what they are good at and what they want to do. We started an apprenticeship initiative at Merck to facilitate their entrance. It has been transformative for the entire profession, including the industry of medical communication because it has cracked open access to all. We now are seeing more traditionally underrepresented groups being represented in medical communications, and that's been extremely meaningful. It's great to see industry partners coalescing around that common goal. I find it quite heartening that we've established this executive forum that, in several instances now, has been successful in collaborating on big ticket items in a noncompetitive way as we're trying to lift everyone up.

With the advent of large language models in artificial intelligence (AI), we are going to see some shifts. It's nice to know that we're working together on these issues and how to integrate them. It's about collaboration and cooperation and putting our heads together and seeing what works for the issues that we're trying to collectively solve and find common ground.

Mia:

How would you describe your leadership philosophy?

Joan:

I believe in being a servant leader, operating with the intention to benefit those I lead, and serving the greater good. And the greater good is a flexible idea. It can be the 10 people you're leading all the way up to global public health. I embrace the gray areas of problem-solving and am open to experimentation and flexibility. Being comfortable with revisiting decisions and evolving approaches is crucial. Coaching and actively engaging in discussions with my team members also plays a significant role and makes for a very rich and satisfying approach. Sometimes the decision that comes isn't my first choice and that's OK, it doesn't have to be.

Mia:

Can you talk about success habits that helped you stay curious, actively learn, keep an open mind, and try new opportunities?

Joan:

Discipline is essential for success, including in areas like exercise, eating, and sleep. All of these things contribute to one's ability to sustain activity in

many domains. It can sound boring, but it really does pay off. Mindfulness meditation has been powerful for me in staying focused. Staying connected to projects and actively engaging in dialogue with team members are also important habits. Every single project is different. It can be similar to others, but there will be nuances that are different, and if you're not paying attention, you can miss those nuances which can be very important for how you carry out your project, your deliverables, and your leadership of the team. It's really important that we stay in touch with and understand the strategy from all different kinds of perspectives and discuss it with our managers. These internal medical writing conversations make for a rich relationship and are helpful and meaningful. I think that's a good piece of advice to medical writers at any level.

Mia:

What are your tips for better health, mindfulness, and building discipline?

Joan:

Be compassionate with yourself, start small, and gradually increase the time for activities like mindfulness meditation. Find exercise routines that work for you and be flexible in adapting them to changing circumstances. Prioritize and find ways to meet various needs in your life with tradeoffs if needed.

Mia:

What qualities and skills contribute to success for medical writers?

Joan:

Medical writing demands proficiency in many competencies, and it's important to be patient and compassionate with oneself while learning. Some days your project management might not be that great, or your email writing might not be that great. But you knocked it out of the park with that efficacy section you were writing! There are a lot of competing skills, and they're only competing because of time and energy constraints. Finding joy in each project and appreciating the learnings and contributions they bring is crucial. Taking bold steps when opportunities arise and being open to unexpected possibilities are also important qualities.

Mia:

How can medical writers stay motivated and focused on their goals?

Joan:

Prioritizing and setting goals in different time frames or subject areas is helpful. Breaking goals down into manageable steps and celebrating achievements, no matter how small, is important. Things reinforce

themselves when we achieve a goal, even if it's a little tiny goal. Our hormones react to that and give us positive feedback, and that's a good habit. Being compassionate with oneself and being open to revisiting goals if they no longer align with priorities is also crucial. And let's not forget that one of our goals might be to have more downtime or to be a little bit more flexible with ourselves.

Mia:

How can medical writers stay updated on industry trends, best practices, and share knowledge within the community?

Joan:

Taking a collaborative approach to figure out how to share the burden a little bit, and the knowledge, is key. Volunteering to read relevant newsletters or publications in your area and reporting back to the group on important information is one way to stay informed. Active participation and defining best practices within the field, understanding methods and any controversies, are also important.

Mia:

How can medical writers get the most out of AMWA for their professional development?

Joan:

Getting involved at the local chapter level and taking on leadership roles within AMWA can provide valuable experience and growth opportunities. I think AMWA is also a really good place to practice both management and leadership that you might not be able to access in your corporate setting because it's very flat in some corporate structures with not a tremendous number of opportunities to move up. But if you have the interest and the inclination to do that kind of work, AMWA is always looking for people. You can volunteer and do it there, and you're not going to get paid for it in money, but you're getting paid for experience, and you can put that on your resume. And if you're being interviewed for some kind of leadership or managerial position, you've got perfectly valid, publicly available documentation of your capabilities. Participating in certificate programs, attending webinars, enlarging professional networks, and taking advantage of AMWA events and conferences are also beneficial.

Mia:

How do you think the industry will change in the coming years?

Joan:

AI will play a significant role, particularly in generating initial drafts of

documents. Medical writers who are used to writing those first drafts need to redefine their roles and actively engage with AI tools. It's important to focus on the aspects that AI cannot do, such as data interpretation and ensuring accuracy. They may need to sharpen some editorial skills. Now what's going to be the best practice for doing that? No one's defined that yet, but you could define it! That's important because you don't want to be in the position of someone else who doesn't understand what you do, tell you that you're no longer necessary. Look back at the value of medical writing articles from AMWA and see what's changed. And it's going to be more variable now because some documents lend themselves to AI, while others, not so much. Maybe that will change as AI evolves. But it's essential that the writers do not linger on the sidelines but define the best practices.

And maybe on the side, you're going to get a little bit better work-life balance. Take advantage of it! So theoretically, you should be able to do more with that. Managers can keep good metrics, so you know how much time is being saved and redefine resourcing algorithms. Also see if you can use the technological advances as a catalyst for other process improvements that you know would be beneficial by evaluating and dispensing of some steps that may no longer be needed.

Mia:

Hopefully we can get the AI tool to do those tedious things that have been painful for us and do the more pleasurable things that we really like, like data interpretation and key messaging and bringing in the connection and the flow between all the different parts of a submission. **Is there something that the AI tool cannot do that we should focus on?**

Joan:

So, think again about how you're going to ring fence those sections and this is human-only activity. There are also going to be cases where the juice isn't worth the squeeze. If it's too hard to teach the AI tool to make those connections between a series of documents like the first, second, third and final CSR, don't have the tool do that. Let the human do that and keep your value in the game.

Mia:

Joan, thank you for all your candid and open conversation today and for sharing a lot of great information and advice.

Joan:

My pleasure. Thank you.

Mia Nagarajan, PhD, is a Director, Medical Writing in Merck & Co., Inc. in New

Exciting Programs Proposed at the Annual Business and Networking Meeting

by Courtney Lepping

The evening of Juneteenth provided a warm and quiet atmosphere in rural PA, where the sun set over acres of manicured land. Water fountains, post clocks, pops of colorful flowers, and elaborate golf courses hugged the Sandy Run Country Club. At the Annual Business and Networking Dinner Meeting, new and long-standing AMWA-DVC members mingled and talked about the various specialties and facets of medical writing.

Members enjoyed a light buffet dinner and dessert during the evening's program, which offered the space to discuss thoughts about future chapter activities. Program Chair Laura Sheppard discussed past program highlights and introduced the program topics for the evening. Debbie Anderson, the 2023-2024 AMWA-DVC President, recognized current and future committee volunteers and then announced AMWA-DVC's incoming officers: Jennie Jacobson, PhD, CMPP as President; Suzanne Bujara BA, MBA as President-Elect; Don Harding, MA, MS, ELS, CHCP as Treasurer, and Jasmine Moore PharmD as Secretary. The raffle winners were announced and given prizes such as free entry to the annual freelance workshop.

Jennie Jacobson, incoming President of AMWA-DVC proposed the possibility of AMWA-DVC sponsoring a mentoring program for those interested in becoming medical writers or current medical writers seeking to advance in their careers.

Mentoring programs are invaluable for mentees new to the medical writing industry. Effective mentors can provide insights into their specialties and trends in the industry, as well as advice about succeeding in such a role. With several avenues to explore, including regulatory writing, freelance writing, and medical education, the medical writing field can be challenging to navigate as a newcomer. A successful mentoring program would enhance soft and technical skills, professional development, and the ability to produce successful deliverables.

The field of medical writing often requires advanced degrees, as well as experience as a pharmacist, researcher, or technical writer who has a strong grasp of verbal and written communication, grammar, spelling, and medical terminology. Even entry level roles can have strict requirements, such as several years in the industry, expansive portfolios of previous work,

strong project management skills, and direct knowledge of artificial intelligence platforms, Microsoft Word, Adobe Acrobat, and content management systems.

Attempting to stand out in this crowd of highly specialized experts can be incredibly challenging, even for writers who have publications in prestigious journals or a pharmacology background in the pharmaceutical industry. Part of the struggle also involves distinguishing between various job titles, such as medical technical writer, lead medical writer, regulatory specialist, and junior technical writer, which can have many different meanings. In this challenging environment, seasoned medical writers can clear up any confusion and guide novices in the right direction.

For the AMWA-DVC chapter, launching a new mentoring program requires determining how it will be assessed for its effectiveness. This involves monitoring adherence to clearly defined roles, conducting surveys about metrics and belonging, and requesting feedback about the quality of the deliverables, such as regulatory submissions, produced as a result of the program. Members discussed the potential program's purpose, scope, strategies for engaging future mentors and mentees, and reasonable awards/recognition.

Although the core components of the program will need to be detailed, members can aim to bring more ideas to upcoming meetings and enjoy a sense of shared cohesiveness and engagement. Future AMWA-DVC meetings can be expected to fully flesh out the length and budget of the program, expected portfolio items, structure of the groups or one-on-one meetings, and overall needs and outcomes. In the meantime, new volunteers, such as Jennie G. Jacobson who is assuming the president position, will contribute to the structure and future direction of AMWA-DVC's latest offerings.

Courtney Lepping, MS, works in the pharmaceutical industry and has over 7 years of combined experience in the sciences and technical writing.

Optimizing CME Through AI

By Parul Yadav

Alana Brody, MBA, CHCP, Executive Director, Projects In Knowledge, Powered by Kaplan moderated a stimulating lunch session on "Navigating AI Integration in Continuing Medical Education: A Strategic Approach" at the Spring 2024 CMEpalooza. The panelists included David Setiadi, PhD, Chief Technology Officer, Projects In Knowledge, Powered by Kaplan and

Prior to the session, 13% of respondents (supporters) were unlikely to support AI in CME activities. After the session, no respondents remained opposed, with 25% very likely and 75% somewhat likely to support AI-integrated CME in the future.

The adoption of AI tools varies widely among CME professionals, from performing basic search functions to more advanced tasks like data analysis and insight generation. One's reliance on AI varies and depends on the level of success achieved with it. For this reason, knowledge of using AI tools in content creation is necessary.

Natural Language Processing vs Generative AI

While natural language processing (NLP) and generative AI are related, they represent two distinct approaches. NLP focuses on understanding and interpreting information, such as analyzing patterns in language and data and then making predictions based on these observed patterns. Generative AI takes this a step further by predicting patterns in addition to generating new data, text, or content.

The panelists highlighted that while several AI tools, such as neural networks and linear regression, are available, the key is to use the right tool for the task at hand. It is important for those new to AI usage to utilize it with caution and learn about the best applications.

Strengths and Limitations of AI

The panelists pointed out that the strength of AI lies in its ability to uncover hidden patterns and relationships, trends, and correlations that are not readily apparent from raw data alone. However, AI's generative capabilities often mimic the human brain, leading to the potential for mistakes. Furthermore, "synthetic data" generated by AI models might appear real but may not be accurate, and it needs human validation to ensure reliability. Both speakers concurred that though Generative AI can produce appealing results, it is currently unreliable and inconsistent due to its reliance on broad internet data. AI models perform better with closed data sets or within controlled environments like data lakes. The panelists emphasized that its accuracy depends on the data provided, and human oversight is necessary to improve and validate performance.

The key to using AI tools is understanding their limitations, ensuring that they are built on vetted data sources, providing continuous feedback for improvement, and critically evaluating their outputs using human judgment

rather than blindly accepting them.

Input Defines Output

To improve an AI output, the panelists recommended that one should begin by providing the AI system with a base set of questions and correct responses to train AI based on the initial knowledge. As the AI system is utilized over time and is provided feedback on its 'right' or 'wrong' responses the chatbot's accuracy and relevance improves. Additionally, retraining the AI system with the latest data when new information becomes available, such as updated guidelines or new research, aids in keeping the system up to date. The more high-quality training data and feedback the AI receives, the better it will get at providing accurate and reliable responses.

The Million-Dollar Question—Will AI Replace CME Professionals in the Industry?

About 12 % of attendees were concerned that AI might replace CME professionals. However, one key takeaway from the discussion was that AI, in its current state, is intended to augment and assist rather than replace CME professionals. However, CME professionals who develop skills in using AI tools effectively will have a competitive advantage over those who do not. Understanding how to leverage AI effectively is crucial for CME professionals to gain a strategic edge.

Creation of CME Content

Generative AI models today, while advanced, should not be used to fully automate the creation of CME content. Instead, it should be used to assist and augment the creation of CME. It can help with tasks like literature searches, concept extraction, and initial content generation. However, any AI-generated content still requires thorough vetting, validation, and editing by subject matter experts before being used in a CME program. This ensures that the content is evidence-based, accurate, and meets educational standards. The panelists stressed that defining clear boundaries and using prompt engineering to guide AI responses effectively is important. While prompt engineering aids in setting boundaries, it currently lacks the ability to specify the exact information needed to generate high-quality responses. In order for AI to improve, there should be a focus on understanding and incorporating the right components into the system to ensure the responses meet the desired standards, rather than just producing synthetic outputs.

Additionally, AI-powered CME platforms allow for more sophisticated analytics, personalization, and improvement in continuous educational content and activities. These platforms transform CME from a one-way

dissemination of information to an interactive learning experience that can be customized to the needs of individual learners. Key benefits include improved question-to-content matching using semantic AI search, better engagement through learner behavior analytics, identification of unexpected target audiences, and pattern detection in learner questions. This can help create valuable longitudinal datasets that can be used for improvement. This mixed-methods approach can provide powerful insights to internal stakeholders.

Overall, the focus should be on integrating AI thoughtfully and judiciously into the CME development workflow while maintaining human oversight, expertise, and quality control.

AI is here to stay, and incorporating it into your toolkit may eventually provide a competitive edge.

Parul Yadav, MD, is a physician medical writer who partners with various healthcare stakeholders, including medical education organizations, pharmaceutical companies, biotech firms, and medical device manufacturers, to create impactful and accurate communications tailored to clinical professionals and general audiences.

CALL FOR VOLUNTEERS

Volunteer Opportunities with AMWA-DVC Freelance Workshop Committee

Volunteering for the AMWA-DVC Freelance Workshop is a great way for you to:

1. Make key contacts
2. Get referrals or leads for freelance work
3. Build new skills.

We have opportunities for several committee members.

Committee members help with tasks such as:

- Content coordination (speaker and roundtable leader communication)
- Promotion of the Freelance Workshop (conference brochure, LinkedIn posts, etc.)
- Day of workshop activities such as on-site registration.

Committee members can expect to spend from about 2-15 hours on the

workshop, depending on the tasks.

Interested in volunteering for the Freelance Workshop or learning more? Email Lori DeMILto at loriwriter@comcast.net with “Volunteer for Freelance Workshop” in the subject line.

Help advance your career. Call for Abstracts and Opportunities for Volunteers to Co-Chair and Help with the Program for the Online Princeton Forum.

Although experience counts for much when seeking to break into or change the direction of a medical writing career, leadership in the field can make a candidate stand out from the increasing competition. A proven way to demonstrate leadership is to be a member of a conference committee. To that end, in addition to submitting an abstract for a presentation, there are opportunities to join the AMWA DVC online Princeton Forum Conference Committee.

This year, the Forum will be held on 3 May, 2025. The Princeton Forum focuses on how to write different types of documents, such as regulatory documents, continuing medical education, publications, grants, and sales training. Open positions include 2 volunteers in the program and marketing committee. Responsibilities include identifying topics and speakers, follow-up with presenters before the conference, advertising to colleagues, other chapters and the national organization, registration management, and online management on the day of the conference.

Interested in volunteering for the Princeton Forum or learning more? Please email Dan Benau, Conference Chair at d.benau@icloud.com with “Volunteer for Princeton Forum” in the subject line.

Quotes of the month:

“Go confidently in the direction of your dreams! Live the life you’ve imagined” – Henry David Thoreau

“It is better to fail in originality than to succeed in imitation” – Herman Melville

Jokes for the Quarter:

“I have an immunology joke, but it may sound inflammatory to some” – Soumen Basak

“What do all virus jokes have in common? They’re catchy” – Unknown

Even while using the Editor Function, check for common misspellings!

Chromogenes instead of chromogens



Delawriter Editorial Team

The *Delawriter* is published quarterly by the American Medical Writers Association-Delaware Valley Chapter

Executive Editor: Jennie Jacobson, PhD

Managing Editor: Courtney Lepping, MS

Designer: Tara Rachinsky, PhD

Editorial Consultants: Ann Volk, PhD, K. Molnar-Kimber, PhD

Please direct change of address/information to AMWA Headquarters Staff:

American Medical Writers Association

9841 Washingtonian Blvd, Suite 500-26,

Gaithersburg, MD 20878

(240) 238-0940 (telephone)

(301) 294-9006 (fax)

email: amwa@amwa.org

Visit our AMWA-DVC
website

AMWA-DVC | AMWA National 9841 Washingtonian Blvd Suite 500-26 | Gaithersburg, MD
20878 US

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