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TOPICAL FEATURE

Understanding the Impact of Technology on Medical Writing: AMWA Survey Results from June 2023

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ABSTRACT

In July 2023, the American Medical Writers Association (AMWA) developed a survey to understand the impact of technology on the role of medical writers in clinical and regulatory document development. The survey was administered using SurveyMonkey to individuals responsible for leading, training, or developing a medical writing team. Respondents were mostly regulatory writers (96%) working in pharmaceutical/biotechnology/medical device or contract research organizations (88%). Most were using technology (65%) and almost all were planning to implement authoring technology (95%). New roles for medical writers, training methods for implementation of artificial intelligence (AI), and validation of the AI output were also discussed. Quality and accuracy of the AI output were the most important considerations of the respondents with transparency and disclosure as the least important. In general, the survey respondents felt that the impact of technology in the medical writing field was an important and timely topic for AMWA to address.

As the pace of artificial intelligence (AI) and related technology development and implementation increases in the medical writing field, the impact of this technology on the role of the medical writer is evolving. Global regulatory agencies such as the United States Food and Drug Administration,[1] European Medicines Association,[2] and Japan's Pharmaceuticals and Medical Devices Agency[3] are advancing positions and soliciting feedback on the use of AI in drug development.

Ultimately, the use of AI in scientific publications is likely to be dependent on the position of the editor(s) of the individual journals. To that end, journal editors are currently discussing the acceptable uses of AI in development of medical publications and requiring authors to attest to the use of technology when submitting manuscripts. The International Committee of Medical Journal Editors has added a section on the use of AI to its website defining the role of authors and contributors.[4] The American Medical Writers Association (AMWA) journal, along with other organizations, states that "AI tools cannot be listed as an author of a manuscript" and that "Authors should report the use of AI to create content or assist with writing or editing of submissions to the *AMWA Journal* in the Acknowledgment section."[5] Other professional medical writer organizations are publishing position papers on AI and discussing the use of AI by medical writers.[6-8]

The mission of AMWA is to promote excellence in medical communication and to provide educational resources in support of that goal.[9] Therefore, the AMWA Executive Advisory Council established a task force with the purpose of developing a survey to understand the evolving role of the medical writer in the face of AI technology advancements.

SURVEY PURPOSE AND METHODS

The overall purpose of the survey was to understand the impact of technology on document development to help ensure that medical writers acquire the skills to not only retain but also enhance their value. To make certain that all survey respondents were aligned on the terminology used in the survey, definitions (Table 1 on next page) were provided based in part on the definitions in the glossary of the US Food and Drug Administration's discussion paper *Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products.*[1] The survey was created, uploaded into SurveyMonkey, and distributed to AMWA members and other individuals who led, trained, or were developing a medical writing team in late July 2023.

SURVEY RESULTS

Respondents

Twenty-five respondents completed the survey. Most survey respondents (88%) were from pharmaceutical/biotechnology/medical device companies or contract research organizations/medical writing companies. Medical writing consultancies made up the remaining 13% of respondents.

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Table 1. Definitions of Technology Used in the Survey

Technology	Definition
Artificial Intelligence (AI)	A branch of computer science that focuses on building and managing technology that can learn to autonomously make decisions and carry out actions on behalf of a human being.
Bot	A computer program that can execute commands or automate certain tasks.
Machine Learning (ML)	A branch of AI and computer science that focuses on the use of data and algorithms to imitate the way that humans learn, gradually improving its accuracy.
Natural Language Processing (NLP)	The branch of computer science, specifically the branch of AI, concerned with giving computers the ability to understand text and spoken words in much the same way human beings can.
Assisted Authoring	A subset of NLP that generates human language text from data inputs.
Structured Content Authoring (SCA)	Structured authoring is a standardized approach to writing technical documentation in which the content is controlled by predefined rules.
Digital Data Flow (DDF)	Allows for information flow between systems or platforms eliminating the need for manual entry of data into documents.

The primary focus of most respondents (96%) was regulatory writing and communication; 4% were focused on scientific publications and other health communication. Most respondents (72%) worked in departments with ≥20 medical writers. More than half of the respondents (65%) were from companies using some form of technology to author content. Only 10% of respondents said that there were no plans to implement any technology in the next 2 years.

Technology Applications in Use

Respondents were asked what technology applications their organization was using or planning to use (within 2 years) to improve the efficiency or speed of medical writing. Almost all respondents (95%) cited the use of authoring technology. Around half of respondents (53%) cited formatting technology. A little less than half of the respondents cited applications that performed document review/editing (47%) or quality review (42%). Less than a quarter of respondents cited the use of intelligent searching (21%) and electronic protocol builders (16%).

Stakeholders Using Technology

Information technology (IT) was reported as the highest user of technology for automation (53%) in the survey. Biostats and programming were cited as users by 42% of responders. Next was data management (32%); other (21%); and data analysis, submissions, and clinical (16% each). Respondents identified structured content authoring and assistive authoring (65%) as the most significant technology applications for medical writers in the next 3 to 5 years, followed by automated quality review (40%), and intelligent searching or digital data flow (30% each) (Figure 1).

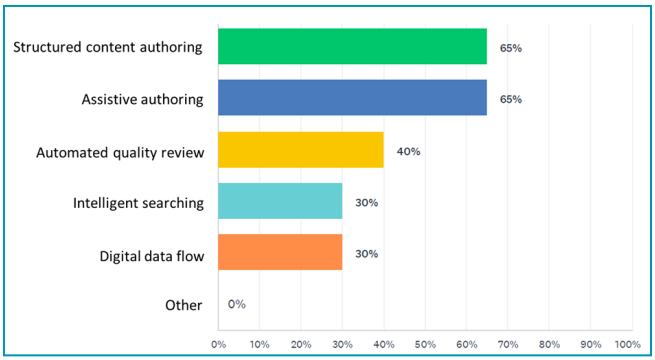

Figure 1. Future technology applications. Survey respondents were asked to select all technology applications that they saw as the most significant for medical writers in the next 3 to 5 years.

New Skills and Roles Medical Writers Need

The respondents identified training on and familiarity with the new tools/platforms as a need for medical writers to be successful in using technology applications for document development. Training that will be needed included how to use the tools and especially how to develop the appropriate prompts to produce the most relevant response. An understanding of how the tools work was cited as important to assess the accuracy and security of a new technology.

New roles will be needed for successful implementation and management of technology for document development. Effective trainers and implementation specialists who are experts in the technology (including software developers and IT support) were also deemed important and required for successful implementation and management of new technology tools. Quality control review of all AI-generated content was a critical component of necessary skills. Although the personnel for these roles may come from other disciplines such as IT departments, interested medical writers could also be trained to fill the new roles.

Validation of Technology

Human oversight was the most mentioned mechanism to validate technology. This included comparison of documents produced using AI, to manually generated documents, and development of standard operating procedures and processes based on ongoing experience with the tools. Some respondents said that there were no requirements or best practices (15%) for validation of technology or that

these were unknown (25%) in their organization. This illustrates the incredibly fast pace that technology is being developed and implemented in the medical writing field.

Training

Town halls, training sessions, and electronic communication were ways that management is approaching the implementation of new technologies used in document development. There was an interest in hands-on training for new technologies expressed by some respondents. No new or novel approaches to implementation were proposed by survey respondents.

Natural Language Generation and Assistive Authoring

Respondents suggested that the use of natural language generation and assistive authoring will enable medical writers to be more efficient, speed up the process of generation a first draft, decrease the time spent doing mundane tasks like copying and pasting, and increase productivity. This is predicted to shift the medical writer's time to evaluation of content.

Major Concerns and Considerations

One major concern expressed was that technology would be used without author input. Quality and accuracy ("hallucinations") of the output from these tools were also concerns along with protection of information and the integrity of information and/or data. Understanding the limitations of the tools and overreliance on the tools such that errors will be missed were also raised. Not fully understanding the critical need for medical writer review and quality control of the output was raised as a concern that could lead to unrealistic timelines. Some respondents also felt that company management may believe that these tools can replace medical writers, thus jeopardizing jobs.

Considering assistive authoring or other AI applications, survey respondents were asked to rank each item in order of importance or concern with 1 as the most important and 8 as the least important (Table 2). The top ranked concern was the accuracy of the generated content. Disclosure and transparency were ranked as the least important considerations.

DISCUSSION

Technology is here to stay and will provide benefits to medical writers. But it is clear that the medical writing community should be part of the discussion on what, how, and when to use technology. The respondents ranked the accuracy of the generated content as the most important consideration as AI is implemented in the medical writing field. The least important considerations were disclosure and transparency, likely due to the fact that these are currently being addressed by journal editors and regulatory agencies. The survey respondents called the use of technology in medical writing an important and timely topic for discussion within the medical writing community.

To understand role of AI in medical writing from a different perspective, the authors queried ChatGPT version 3.0 with the prompt, "What is the role of AI in medical writing?" The final paragraph of the output contained this disclaimer:

> *While AI offers numerous benefits to medical writing, it is important to note that human expertise and oversight remain crucial. Medical writers should use AI tools as aids and validation mechanisms, understanding their capabilities and limitations in the context of the specific writing task. Additionally, ethical considerations, data privacy, and regulatory compliance should be carefully addressed when integrating AI into medical writing processes.*

Table 2. Concern or Importance of AI Considerations

	Rank								
AI Considerations	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	Avg Score
Accuracy of generated content	47%	26%	21%	5%	–	–	–	–	7.16
Acceptance by regulatory authorities	21%	–	37%	16%	11%	11%	–	5%	5.47
Ability to protect confidentiality of company and patient data	5%	32%	5%	21%	16%	11%	11%	–	5.16
Traceability during audits or inspections	–	26%	5%	26%	16%	16%	11%	–	4.79
Developing processes to support the use of technology	16%	5%	16%	16%	16%	11%	5%	16%	4.58
Ethical considerations/legal concerns	5%	11%	11%	16%	21%	21%	–	16%	4.21
Transparency to other functions/communication of use across stakeholders	–	–	5%	–	21%	16%	47%	11%	2.68
Disclosing use of technology to stakeholders	5%	–	–	–	–	16%	26%	53%	1.95

Considering assistive authoring or other AI applications, survey respondents were asked to rank each item in order of importance or concern with 1 as the most important and 8 as the least important. Percentages are based on the 19 respondents who answered this question. AI, artificial intelligence; Avg, average.

This again illustrates that the medical writing community needs to be included in the development, deployment, and implementation of AI. Medical writers can increase their value by facilitating adoption of AI in the field, taking on new roles to support the use of AI in medical writing, and by working to improve the quality and pace of AI use to produce medical writing output.

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References

1. *Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products: Discussion Paper and Request for Feedback*. U.S. Food and Drug Administration; 2023. Accessed December 4, 2023. https://www.fda.gov/media/167973/download
2. *Reflection Paper on the Use of Artificial Intelligence (AI) in the Medicinal Product Lifecycle*. European Medicines Agency; 2023. Accessed December 4, 2023. https://www.ema.europa.eu/en/documents/scientific-guideline/draft-reflection-paper-use-artificial-intelligence-ai-medicinal-product-lifecycle_en.pdf
3. Chinzei K, Shimizu A, Mori K, et al. Regulatory science on AI-based medical devices and systems. *Adv Biomed Eng*. 2018;7:118-123. doi:10.14326/abe.7.118
4. Defining the role of authors and contributors: artificial intelligence (AI)-assisted technology. ICMJE. Accessed December 4, 2023. https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html
5. Submission preparation checklist. AMWA. Accessed December 6, 2023. https://amwajournal.org/index.php/amwa/about/submissions
6. DeTora LM, Lane T, Sykes A, DiBiasi F, Toroser D, Citrome L. Good Publication Practice (GPP) guidelines for company-sponsored biomedical research: 2022 update. *Ann Intern Med*. 2022;175(9):1298-1304. doi:10.7326/M22-1460
7. International Society for Medical Publication Professionals (ISMPP) position statement and call to action on artificial intelligence. *Curr Med Res Opin*. 2024;40(1):9-10. doi:10.1080/03007995.2023.2273139
8. Parisis N. Medical writing in the era of artificial intelligence. *Med Writ*. 2019;28:4-9. https://journal.emwa.org/artificial-intelligence-and-digital-health/medical-writing-in-the-era-of-artificial-intelligence/
9. AMWA home page. AMWA. Accessed December 6, 2023. https://www.amwa.org/