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GLOBAL MEDICAL COMMUNICATION

THE OFFICIAL JOURNAL OF THE AMERICAN MEDICAL WRITERS ASSOCIATION
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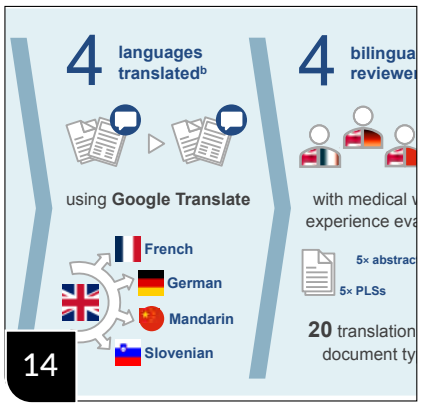

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL
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In support of the mission of the American Medical Writers Association (AMWA) and to advance the broader profession, the *AMWA Journal* publishes content that reflects the interests, concerns, and expertise of medical communicators. Its purpose is to inform, inspire, and motivate medical communicators.

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FROM THE GUEST EDITOR

Overcoming Obstacles and Building Bridges in Global Medical Communication

Elizabeth Kukielka, PharmD, MWC, CMPP / Oxford PharmaGenesis, Inc, Newtown, PA

Medical communicators are tasked with delivering scientific information to numerous stakeholders, including patients, caregivers, providers, researchers, policymakers, and payors, around the world. In recent years, content offerings have expanded beyond traditional scientific publications deliverables, such as abstracts and articles, to include enhancements that are more easily digestible by patients or busy clinicians, such as plain language summaries, infographics, graphical abstracts, and other multimedia formats. Global medical communications is a burgeoning field that involves the delivery of cutting-edge scientific research to a broader global audience. However, medical and scientific articles have historically been published only in English and kept behind journal paywalls, limiting accessibility by the global scientific community. In this special issue of the *AMWA Journal*, we explore some of these issues and consider ways that medical communicators are improving access to scientific data and bridging the gaps between stakeholders around the world.

In the first theme article of this issue, Amanda Xiaoqing Mao, PhD, an experienced bilingual Chinese medical communicator and translator, shares best practices for medical translators to ensure the best possible translations. To begin with, medical translators must possess strong writing skills and have a thorough understanding of medical terminology in both the source and target languages to ensure that a translation accurately conveys the intended message while maintaining the original tone and style. To support their work, medical translators may use existing tools or create their own when needed, such as bilingual glossaries or machine translators. In conclusion, Dr Mao posits that medical translation is an essential component of the global medical communications industry, alongside regulatory writing, scientific publications, health communication, continuing medical education, promotional writing, and grant writing.

In the second theme article of the issue, Jo Gordon of Oxford PharmaGenesis shares information about the history and mission of Open Pharma, which is a nonprofit-seeking collaboration that aims to improve the communication of research sponsored by the pharmaceutical industry. The article offers a wealth of information to medical communicators working in the field of scientific publications about the work and resources of Open Pharma and how they can get involved.

In the third theme article of this issue, Claire Beeby and Eleanor J. Raynsford of Oxford PharmaGenesis and Charles Pollitt of Ipsen present findings of a pilot study that evaluated a Web-based translation tool for translating scientific abstracts and plain language summaries (PLSs). Google Translate was used to translate abstracts and PLSs from 5 medical journal publications into 4 languages: French, German, Mandarin, and Slovenian. Bilingual reviewers with scientific backgrounds were tasked with assessing the translation quality of each abstract and PLS. The authors present the results of their study along with a discussion of their research in context and ways to increase accessibility of scientific content by non-English speakers.

I would like to note that the articles in this issue have been graciously contributed by medical communicators working outside the United States in Europe, Asia, and Australia, thus providing a different perspective on issues that may be important to medical communicators around the world. I invite both our current AMWA members as well as any new readers of our journal from around the world to share feedback about the content and consider contributing their own perspectives on global medical communications to future issues of the *AMWA Journal*.

Author declaration and disclosures: *The author notes no commercial conflict of interest in relation to this article. The views and opinions expressed in this article are those of the author and do not necessarily reflect the views of the author's employer.*

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THEME ARTICLE

Lost in Translation: The Vital Role of Medical Translation in Global Medical Communication

Amanda Xiaoqing Mao, PhD, CMPP[1] **and Ishani Thakkar, PhD** / [1]Acurit Medical Communications, Melbourne, Australia; [2]Boston, MA

ABSTRACT

In today's globalized world, translating scientific and medical content is vital to bridging language barriers and facilitating communication among diverse audiences. This article dives deep into the importance of medical translation and provides key best practices to ensure accurate and high-quality translations.

Effective medical translators must possess strong writing skills in both the source and target languages to accurately convey the intended message while maintaining the tone and style of the original document. Developing and finalizing content in one language before translation streamlines the process and enhances the quality of the translation.

Translators should seek clarification and ask questions during the translation process to deliver an error-free final version. Understanding medical terminology in both source and target languages is crucial, and staying updated with the latest terminology is essential for accurate translations. Utilizing a bilingual glossary or creating one in collaboration with the client helps ensure translation accuracy.

Although machine translations have limitations, computer-assisted translation tools like Trados, memoQ, Wordfast, and OmegaT improve efficiency and consistency. These tools, equipped with translation memory and terminology management features, support human translators in their work.

Medical translation plays a significant role in global medical communication, alongside regulatory writing, scientific publications, health communication, professional education, promotional writing, and grant writing. It is essential for effective communication and accurate information exchange in the scientific community.

In conclusion, accurate medical translation is crucial for effective communication and collaboration in the global scientific community. Adhering to best practices ensures precise and high-quality translations, facilitating the sharing of scientific knowledge across languages.

In today's globalized world, the need for accessible scientific and medical content is more important than ever before. In order to ensure that this information is available to a wider audience, including those who do not speak the same language as the original content, it is crucial to translate it. This can help bridge language barriers and facilitate communication among scientists, medical professionals, policymakers, educators, and the general public. Translating scientific content would be needed by individuals or organizations who want to communicate scientific and/or medical information to a diverse audience that speaks different languages. Some specific examples include

1. Researchers or scientists who want to publish their research findings in international journals or conferences and want to make their research accessible to a wider audience.
2. Science communicators who want to disseminate scientific information to the general public through various media channels such as websites, blogs, podcasts, or social media, and want to reach a broader audience.
3. Science-based industries or organizations such as pharmaceuticals, biotechnology, or environmental consulting firms who need to communicate scientific information to clients, stakeholders, or regulatory bodies in different regions of the world and want to provide multilingual content to facilitate understanding and compliance.

Hence, medical translation is an essential component of global health care communication.[1] However, Dr Mao, who is a bilingual Chinese medical communicator leading Acurit Medical Communications, believes that it is not as straightforward as it may seem. Acurit is focused on medical translations between English and Chinese, therefore Dr Mao led her team to translate the "AMWA-EMWA-ISMPP joint position statement on medical publications, preprints, and peer review" from English to Chinese. Dr Mao, who also serves on the executive board of the Australia China Business Council, believes that medical translators must adhere to

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several best practices to produce accurate, high-quality translations.

Medical translation may involve the translation of various medical documents, including clinical trial protocols, patient information leaflets, regulatory documents, medical device manuals, and research papers, among others. Although the types of documents to be translated are as diverse as those in medical writing, this article focuses mainly on medical translations targeting professional audiences.

A GOOD TRANSLATOR IS ALSO A GOOD WRITER

If a project requires translation, a translator must be good not only at writing in the target language but also comprehending the source language. If they are required to translate in both directions, then they should be good writers in both languages. They must be able to convey the intended message accurately while maintaining the tone and style of the original document. The aim is for the translated document to flow naturally, and for a third person to not be able to tell if it is a translation or original writing. This is only possible if the translator can produce good writing independently. Translators should actively work on their nonnative languages, and writing helps strengthen their language skills.

FINALIZING CONTENT IN ONE LANGUAGE FIRST

In order to ensure high-quality medical translations, it is best to develop and finalize content in one language before translating it into another language. This streamlines the process and ensures quality. Avoid developing content in both languages simultaneously. The choice of language for developing original content should depend on available medical writing resources and reviewer language preferences. A highly competent translator can ensure effective translation of complex messages such that the translated content appears to be produced in the target language.

TIMING YOUR QUERIES APPROPRIATELY

Indeed, the translation process is very distinct from manuscript writing or any other kind of medical writing. Translators are expected to deliver one and only one translation, so they must prioritize delivering a final version that is ready for immediate use instead of taking the multiple-draft approach. In order to deliver an error-free translation that meets the client's expectations, the translator should seek clarification and ask questions during the translation process, and not bombard the client with questions when the final translation is expected. Questions regarding individual word choices are expected during translation, unlike in other kinds of medical communication in which the entire document may need to be reviewed for context before further clarification. The mark of a good translation is minimal corrections at the end from the client's side.

GETTING MEDICAL TERMINOLOGY RIGHT

Medical documents are often complex and contain technical jargon, making them difficult for nonmedical professionals to understand. Therefore, a medical or life sciences background will greatly help a medical translator to accurately translate technical documents. More importantly, a thorough understanding of medical terminology in both the source and target languages is crucial in the translation process. Medical translators must also make efforts to stay updated with the latest medical terminology. Poor translation quality often results from incorrect translation of terminology. Asking the client to attach a bilingual glossary before the process or inquiring for clarification on terminology during the process can help produce high-quality medical translations that meet client expectations. If the client does not have a bilingual glossary, an experienced medical translator may help produce one during the first project and expand it when future projects come in from the same client.

To that end, authoritative sources in languages including but not limited to English include health and medical textbooks and scientific journal articles. Regulatory bodies in countries such as China, where the official language is Chinese, provide excellent resources in official medical terminology. Websites for organizations such as the World Health Organization also have official languages in addition to English. Such content can be very useful for looking up standard medical terminology.

MACHINE TRANSLATIONS VERSUS COMPUTER-ASSISTED TRANSLATION

Although machine translations may be an effective way to do some preliminary work, a human is always needed to edit and finalize a translation, especially in terms of medical terminology, tone, flow, and context.[2] However, using machines to translate medical and/or regulatory documents pose a bigger challenge than a lack of accuracy or flow.[3] Using online translation tools is not recommended for sensitive medical documents as it may put privacy and confidentiality at risk: an undesirable outcome in the life sciences industry. That being said, machine translation must not be confused with computer-assisted translation (CAT) tools designed to help translators with repetitive tasks and improve efficiency. Using translation tools like Trados, memoQ, Wordfast, and OmegaT is encouraged. These software tools assist human translators in translating written content between languages. They include features like translation memory and terminology management to improve speed and accuracy while ensuring consistent

terminology use. CAT enhances the work of human translators, allowing them to focus on complex and creative aspects while delegating routine tasks to the computer.

MEDICAL TRANSLATION IS A FORM OF MEDICAL COMMUNICATION

Based on the above information, the complexity and significance of the medical translation process in global medical communication are indisputable. According to the American Medical Writers Association, there are 6 major categories of medical communication deliverables:[4]

1. Regulatory writing
2. Scientific publications
3. Health communication
4. Education for professionals (Continuing Medical Education or CME)
5. Promotional writing
6. Grant writing

But it is important to recognize that medical translation is an additional crucial component of medical communication:

In conclusion, translating medical content is essential for effective communication and collaboration in today's globalized scientific community. Whether it is a part of the final deliverable or simply a behind-the-scenes aspect of the project, medical translation is a necessary step to ensure effective communication and accurate information exchange between international scientific entities.

Acknowledgment

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THEME ARTICLE

Open Pharma: Driving Positive Change in the Communication of Pharma-Sponsored Research

Jo Gordon, MA, VetMB, PhD / Medical Writer, Oxford PharmaGenesis, Oxford, UK

ABSTRACT

Open Pharma is a non-profit-seeking collaboration that aims to make the communication of pharma-sponsored research faster, more transparent, more accessible, and more sustainable, focusing on open science principles such as open access and plain language. Open Pharma includes 16 Member and Supporter companies representing the pharma and publishing industries and is facilitated by Oxford PharmaGenesis, a HealthScience consultancy. We believe that innovating the current publications model for pharma research is essential to accelerate medical progress, improve patient care, and increase trust in evidence from the pharma industry.

Open Pharma works as a think tank that seeks to "move the needle," a research hub that produces evidence, a knowledge-sharing "club," and a forum for member voices. Our research, resources, and events are designed to educate, broaden perspectives, and foster connections. We also seek to identify needs and solutions and to develop guidance that supports best practice and positive change across the sector.

Medical writers are uniquely positioned to understand the benefits of open science and to communicate them to their clients. They have an important part to play in promoting the innovations that will increase the quality, transparency, and accountability of medical research communication, which Open Pharma supports.

THE ORIGINS OF OPEN PHARMA

Open Pharma is a multisponsor collaboration that aims to drive positive change in the communication of pharma-sponsored research. Trust in pharma industry research was, and still is, estimated to be low,[1,2] despite pharma companies funding at least half of the biopharmaceutical research carried out in the United States and the United Kingdom.[3,4] Established in 2016, Open Pharma was set up in recognition that improving trust in pharma research publications is a goal shared by multiple stakeholders working across the pharmaceutical, publishing, and medical communication sectors, and one only realized through collective action.

Oxford PharmaGenesis, as an independent HealthScience consultancy working across these sectors, was well-positioned to listen to and connect conversations from different stakeholder groups that share a commitment to improving the pharma publications model. Thus, Open Pharma was launched as a member-led, non-profit-seeking project facilitated by Oxford PharmaGenesis. We strive to improve the pharma publications model by connecting pharma with innovations in publishing to increase transparency and broaden access to research outputs.

KEY OBJECTIVES AND MISSION

Open Pharma is a collaboration of forward-thinking representatives from organizations working across health care research communication. Members and Supporters contribute to Open Pharma financially at different levels. Members advise and vote on the strategic direction for Open Pharma, and both Members and Supporters are involved in discussions, events, and research projects. Current Open Pharma Members include AstraZeneca, Boehringer Ingelheim, Galápagos, Gilead Sciences, GSK, Janssen, Novartis, Novo Nordisk, Oxford PharmaGenesis, Pfizer, Takeda, and UCB, and current Supporters include Bristol Myers Squibb, Ipsen, Roche, and Taylor & Francis.

Nonpaying stakeholders include advisors and followers. Advisors represent policy groups, publishers, academic funders, patients, and open science innovators and take part in meetings and other activities. Open Pharma followers are the varied group of people who read our blog and newsletter, engage with us on Twitter, LinkedIn, and YouTube, take part in our public events, and use the information and resources available on our website.

Open Pharma has clearly defined aims (set out in a charter) that support the goal of improving the pharma publications model. We believe that pharma company–funded research should be published in a way that is transparent, accountable, accessible, and discoverable (Figure 1). Operationally, Open Pharma works on multiple levels: as a *think tank* that seeks to move the needle, as a *research hub*

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that produces evidence, as a *knowledge-sharing "club,"* and as a *forum* for member voices. A varied range of activities support our road map to open science in this space (Figure 2).

OPEN PHARMA: A THINK TANK

Open Access Position Statement

Open Pharma promotes publishing with open access to ensure that high-quality, peer-reviewed evidence is available to anyone who needs it, anywhere in the world, without charge. Publishing open access improves transparency, advances medical science, and, we believe, ultimately improves patient care (Figure 3). However, access to pharma company research is often more restricted by journal paywalls than research funded by other sources.

The first landmark achievement of Open Pharma was our open access position statement. In the statement, we highlight as an immediate priority the need to secure authors publishing company-funded research the same right to publish open access as authors publishing research funded by other sources so that all research can be made free to read from the date of publication. We also state that our long-term goal is to secure the same licensing terms for authors publishing company-funded research and authors publishing research funded by other sources, including using the most permissive Creative Commons license, Creative Commons Attribution license (CC BY), for all articles.

As of May 4, 2023, our position statement has been endorsed >250 times by individual and institutional stakeholders – including publishers, pharma companies, patient

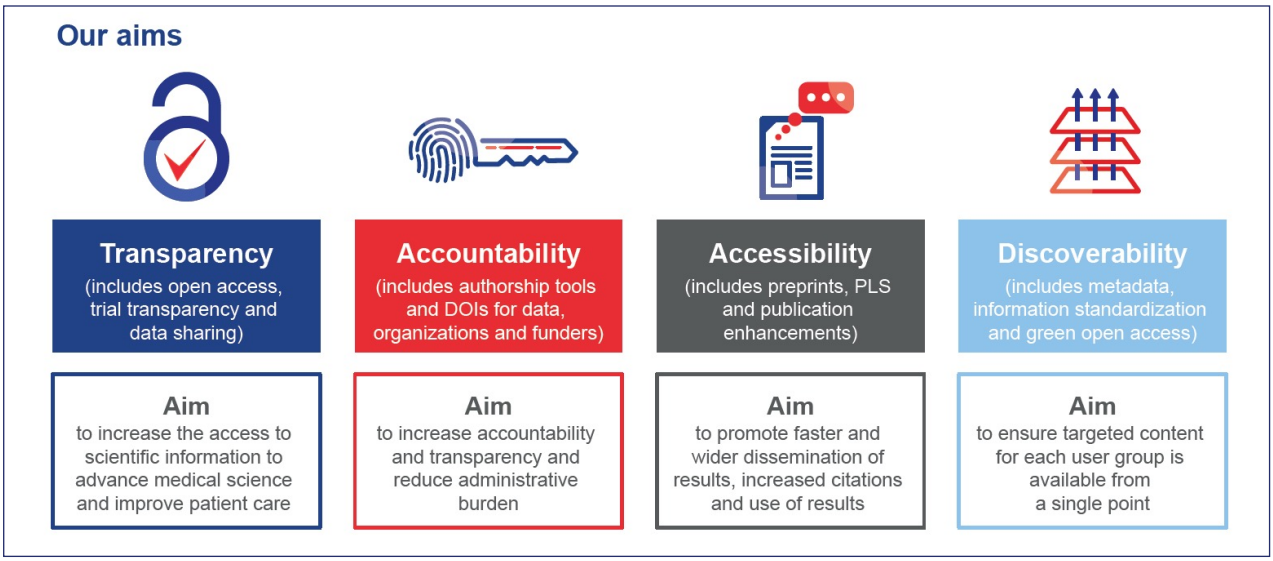

Figure 1. The aims of Open Pharma. PLS, plain language summary.

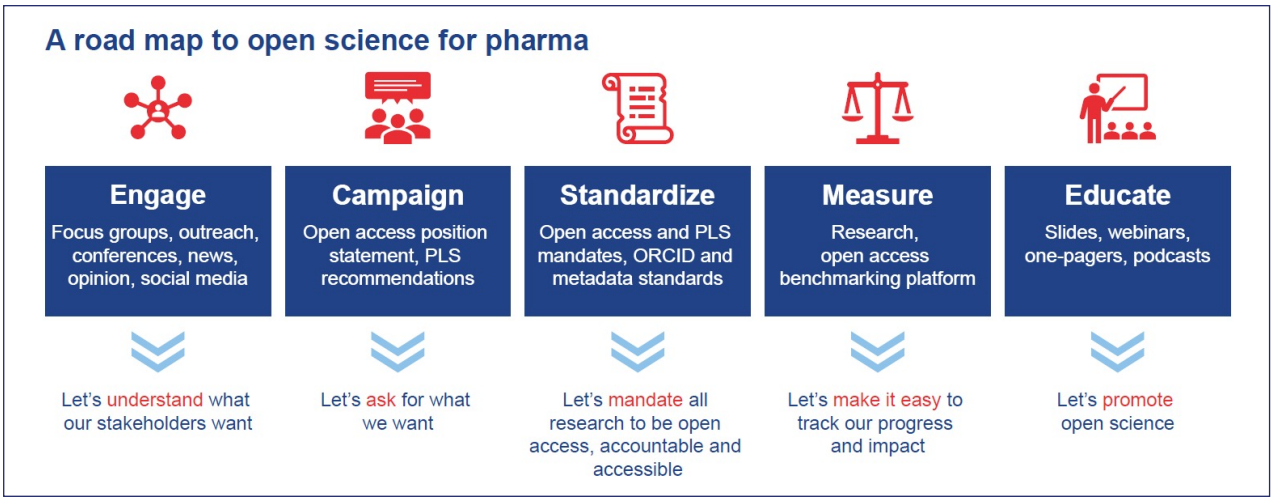

Figure 2. Open Pharma road map to open science for pharma research communication. ORCID, Open Researcher and Contributor ID; PLS, plain language summary.

Figure 3. Benefits of open access. Adapted from Kingsley D and Brown S.[11] CC BY, Creative Commons Attribution license.

advocacy groups, and organizations engaged in open scholarship. Many Open Pharma Members and Supporters have used the statement to raise awareness of open access within their companies and set open access targets, which is likely to have contributed to the rise in open access publishing observed across the sector in recent years.

Plain Language Summary Recommendations

Plain language summaries (PLS) are now an accepted way to make the content of medical research articles accessible to nonspecialist and time-challenged readers. Until 2020, however, consistent guidance on how to develop PLS was lacking, which limited their use.

Open Pharma recognized this unmet need and responded by organizing a roundtable of experts and a public consultation to discuss the issue and went on to develop and publish a PLS recommendations article and infographic (Figure 4).[5-7] With >10,000 views and 8 citations to date (as of May 25, 2023), we believe that our recommendations article is contributing to important changes in research publications, including an emerging consensus

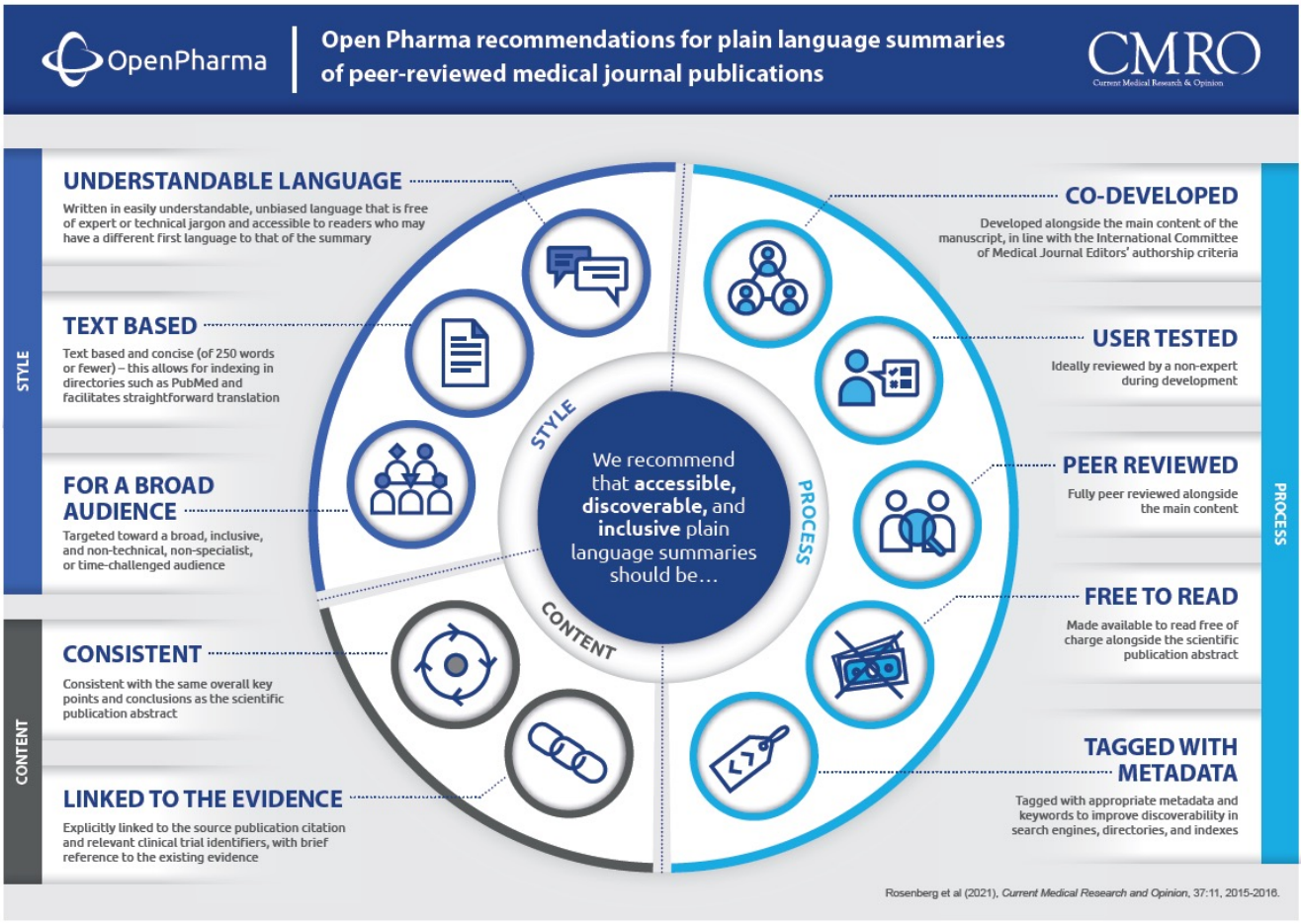

Figure 4. Infographic: Open Pharma recommendations for plain language summaries of peer-reviewed medical journal publications. Adapted/Reprinted from Rosenberg A et al.[6,7] PLS, plain language summaries.

about PLS best practice among some publishers,[8] adoption of mandatory policies or recommended PLS practices by pharma companies,[9] and an update to the Good Publication Practice Guidelines for Company-Sponsored Biomedical Research advising publication of PLS for all clinical research articles.[10]

OPEN PHARMA: A RESEARCH HUB

Educational Material

Open Pharma has developed a bank of resources that are freely available on our website for anyone to use. This material can help medical writers, pharma companies, and publishers to become more aware of open science and implement open science practices in their day-to-day work. Resources include a crib sheet for developing plain language documents, a toolkit for adopting Open Researcher and Contributor IDs (ORCID) in publications, and educational slides about open access.

Research Projects

Open Pharma research poster presentations are also freely available on our resources page. These posters summarize various analyses of open access for pharma company-supported articles, use of ORCIDs in pharma-affiliated publications, and discoverability of PLS. Here, we highlight 3 examples of recent or ongoing Open Pharma research.

Discoverability of PLS. Concise text-based PLS can assist a nonexpert and time-constrained audience to find and use published research. PubMed is one of the most widely used platforms for accessing biomedical research and, since 2019, text-based PLS hosted on this platform can be discovered when tagged (electronically labeled) with a PLS-specific label, the <plain-language-summary> metatag.[12] To assess how PLS are being indexed (labeled and organized) on PubMed, Open Pharma carried out an automated search of the presence and use of the PLS metatag. Our results uncovered an unmet need for explicit guidance on both the processes of indexing and the correct use of the <plain-language-summary> tag, which could help improve uptake and correct tagging.[13] The findings show an opportunity for everyone, including medical writers, to increase the impact of their content and reach a broader audience by ensuring article PLS are tagged appropriately on PubMed. A version of the conference poster presentation is available on YouTube.

Open Access Benchmarking. Open access publications are more likely to be discovered and accessed by a broad audience.[14] Since Open Pharma's launch and the publication of our position statement, the open access landscape has changed. Several major public research funders have implemented mandates requiring that their grant recipients publish their findings with immediate open access (eg, UK Research and Innovation, 2021; National Institutes of Health, 2023). In the private sector, pharma companies Takeda (formerly Shire; press release in 2018), Ipsen (press release in 2019), and Galápagos (press release in 2020), all part of Open Pharma, have also implemented open access mandates. However, a subset of high-impact journals do not offer open access or do not offer the least restrictive open access license, CC BY, to authors of pharma-funded research.

To investigate this possible open access bias, we needed to benchmark and track open access publication patterns in different research settings in an objective and automated way. Since 2018, we've analyzed and reported on open access rates of pharma-funded research using both manual and automated methods.[13,15-17] This year, we collaborated with the Lens platform to develop a free-to-use, publicly available open access dashboard that benchmarks and compares open access rates, types, and licenses between publications with authors affiliated to universities and those with authors from pharma companies. We presented a snapshot of the initial data as a poster at the 20th Annual (US) Meeting of the International Society for Medical Publication Professionals (ISMPP) (2023).[18]

Our research suggests that articles with university-affiliated authors are published with the most permissive license (CC BY) more often than articles with pharma company–affiliated authors. However, our analysis was not designed to determine whether this difference is driven by journal or author policy. The Open Pharma dashboard will now help us to assess how changing perceptions of open access translate into changes in practice.

Data Sharing Survey. The potential benefits of coordinated data sharing are undisputed (eg, improved research transparency and efficiency of research), but so is the importance of protecting patient privacy. In some instances, intellectual property and data ownership may also be relevant considerations.[19] Expanding access to clinical study results and source data has important implications for research sponsors, authors, publishers, and patients, and most biomedical research journals now have data sharing requirements as a prerequisite of publication.

Open Pharma designed a survey to assess the ease with which those involved in submitting pharma research for publication are able to implement current journal data sharing policies and to understand if there are barriers to implementation (eg, challenges in relation to certain study or data types) and related implications. To make sure our

survey was intuitive to complete and that we were asking the right questions, it was also reviewed by the ISMPP Global Transparency and Trends Committee.

Our results will help indicate whether there is a need to work with journals and publishers to optimize current data sharing policies for the benefit of all and, if so, where efforts should be focused.

OPEN PHARMA: A KNOWLEDGE-SHARING "CLUB"

Open Pharma Events

Many conversations about the communication of pharma research take place in the absence of the voices of important stakeholders. This makes it difficult to understand their challenges and needs and to come up with appropriate solutions. To help bridge this communication gap, Open Pharma seeks to develop events that stimulate debate between stakeholders who do not often have the opportunity to meet and to bring fresh voices into the conversation.

As an example, one of our highlights in 2022 was the Open Pharma Satellite Symposium held at the Association of Learned and Professional Society Publishers Annual Conference and Awards 2022. In the session "Who Can We Trust? Open Science and Pharma Research," presenters and audience members representing the pharma, publishing, and medical communication industries, as well as patient advocates, discussed the role of open science in building trust in pharma research, with a focus on open access publishing and accessible summaries.[20] A video of the symposium is available on YouTube, and a meeting report was published in a special issue of *Medical Writing* on the topic of "Open Science and Open Pharma."[21]

More recently, in February 2023, Open Pharma ran 2 virtual talk shows facilitated by Richard Smith (Open Pharma Chair, former Editor of the *BMJ*, and former Chief Executive of the BMJ Publishing Group) that brought together patient advocates, doctors, policy advisors, charitable funders, open access advocates, and publishers. Guests included Richard Horton (Editor-in-Chief, *The Lancet*) and Christine Laine (Editor-in-Chief, *Annals of Internal Medicine*). The discussions, which are available on YouTube, were energetic and thought-provoking.[22] Bringing together such a wide range of views made it a unique event that will continue to spark further debate and collaboration.

Presence at Congresses and Other Meetings

Open Pharma is a regular presence at international meetings and events involving pharma industry professionals, publishers, and medical writers. In 2022 and 2023, we've held roundtables, workshops, and session presentations on open access and PLS at the European and annual (US) meetings of ISMPP, the Council of Science Editors meeting, and the Berlin and Riga meetings of the European Medical Writers Association.

Open Pharma Blog

Open Pharma delivers open science news and commentary via our blog and e-newsletter. In addition to a weekly digest of short news stories, the blog features opinion and commentary pieces from expert guests (Table 1).

Our blog is a platform for discussing key issues and trends in open science for pharma research and to signpost everyone to events of interest and useful tools and resources.

Table 1. Highlighted Guest Blog Posts From the Open Pharma Blog

Guest Blogs in 2022
How Pharma Will Help Move the Needle on Open Research Mark Hahnel (Founder and CEO of Figshare)
Perceptions and Insights on Clinical Trial Participation: Results From the 2021 CISCRP Study Jessica Cronin (Center for Information and Study on Clinical Research Participation)
Open Science: Reflecting Upon Real-World Impact (podcasts) Martin Delahunty (Founder and Managing Director of Inspiring STEM Consulting)
Guest Blogs in 2023
Improving Equity Through Open Access Education Catherine Skobe (Senior Director, Pfizer Publications Innovative Solutions Lead), Adam Watson (Director, Pfizer Medical Excellence Lead in Inflammation & Immunology Medical Affairs), and J.R. Meloro (Global Head of Transparency, Pfizer Worldwide Medical and Safety)
The Changing Open Research Landscape: A Publisher's Perspective Priti Nagda (Publications Development Manager at Taylor & Francis) and Simon Horton (Policy and External Affairs Manager at Taylor & Francis)
Improve Research Discoverability to Support Health Literacy Catherine Skobe (Senior Director, Pfizer Publications Innovative Solutions Lead) and Sally Dews (Senior Medical Affairs Manager at Pfizer Patient Partnerships)

CEO, Chief Executive Officer; CISCRP, The Center for Information and Study on Clinical Research Participation; STEM, science, technology, engineering, and mathematics.

OPEN PHARMA: A FORUM FOR MEMBER VOICES

Topic Meetings, Roundtables, and Working Groups

Open Pharma has a program of discussion meetings that provide opportunities for Members and Supporters to explore specific topics internally and with external guests. Members and Supporters also take part in working groups, which develop projects in several areas of open science. All these activities help the group identify unmet needs and potential solutions in the communication of pharma research.

For example, the virtual roundtable meeting Pharma and Publishers Forum on June 24, 2022, cochaired by Caroline Sutton (Chief Executive Officer of STM Publishing)

and Richard Smith, brought together participants from the publishing and pharma sectors to discuss 4 core topic areas in open science – PLS, open access, discoverability, and data sharing. The participants identified several unmet needs and potential solutions in these areas (Table 2), which the Open Pharma working groups and other organizations can help to address.

ON THE HORIZON FOR OPEN PHARMA

As the open access movement taking place across the publishing industry reaches new heights, Open Pharma will continue to campaign for equitable open access opportunities for all researchers. Beyond open access, Open Pharma will continue to address other aspects of open science (and open research) by advocating for behaviors that promote greater transparency throughout the research life cycle.

A key topic of interest is how to make research more accessible and discoverable, with nonexpert public and patient audiences being increasingly recognized as valid audiences for pharma research. The growth in plain language documents within and beyond research publications will also require more precise use of the terminology used to refer to these documents.[20,23] Open Pharma will continue to champion best practice and cross-stakeholder collaboration in this area, working to expand the use and usefulness of PLS.

The use of natural language processing tools, including artificial intelligence (AI), in medical publications is a rapidly changing area, with many applications emerging for publication development, quality assessment, and regulation. Open Pharma will help keep our stakeholders abreast of this field and support them in using AI tools to improve research communication while maintaining publication integrity.

SUMMARY THOUGHTS

Medical writers can help to set standards of quality, transparency, and accountability in medical publications. Through their work with researchers, authors, pharma publication teams, and publishers, medical writers can under-

Table 2. Unmet Needs and Potential Solutions Identified at the Open Pharma Roundtable Pharma and Publishers Forum in June 2022

Open Science Topic	Identified Need	Possible Solutions
PLS	• Establish methods for evaluating how much easier it is for nonexpert audiences to find and understand publications when these are accompanied by PLS • Develop quality standards for PLS • Explore ways of reducing the extra work that PLS represent to publishers	• Continue to perform research and thought leadership on PLS value and readership • Convey the value of PLS to stakeholders by sharing these efforts at conferences and in the literature • Educate using Open Pharma's best practice recommendations article
Open Access	• Improve author appreciation of the value of open access publishing; reduce the traditional author focus on journal impact factor or citation score • Simplify, or educate authors on, open access licensing agreements • Explore issues of open access publication bias associated with article processing charges and possible solutions	• Provide evidence of the value of open access and existing bias through data-based research projects • Provide training on the different types of publication license and what each means in terms of reuse, distribution, and adaptation • Continue to promote mandatory open access publishing for industry-sponsored research • Campaign for fee-waiving schemes for small pharma companies or companies from lower-income countries that may not have the budgets to pay high article processing charges • Work with publishers on ways to update their systems to incorporate funder and pharma workflows for bulk publishing to reduce the administration burden and ensure use of intended licenses
Discoverability	• Explore search engine optimization for research outputs so that scientific data reach a wider range of audiences • Explore the use of article-level metrics for assessing publication impact	• Ensure that keywords are carefully chosen and provided during submission to optimize discoverability of articles through search engines • Promote use of text-based PLS that are fully incorporated into the main manuscript alongside the abstract so they are hosted in front of any paywall and indexed on PubMed • Discourage hosting of PLS in supplementary material or on third-party content sites that are less likely to be accessed and read unless explicitly distributed to readers through other means
Data Sharing	• Educate authors on optimal data sharing practices • Harmonize pharma and publisher perspectives on preferred data storage platforms • Explore the benefit of developing a universal data sharing guideline, including guidance around implications of – different data protection regulations among countries – disparities between pharma and publisher policies on data sharing	• Campaign for alignment to FAIR data management guidelines • Develop training toolkits for authors on data sharing early in the research process • Survey the industry to understand barriers to implementing current journal data sharing policies • Create and share universal data sharing guidelines to help to build researcher and institutional confidence in complying with data sharing best practices

FAIR, Findability, Accessibility, Interoperability, and Reuse of digital assets; PLS, plain language summaries.

stand the challenges of closed publications systems and witness the benefits of more open, collaborative, and audience-centric approaches.

We invite the readers of this article to engage with Open Pharma by endorsing our open access position statement, encouraging your clients to use our resources and tools, and staying abreast of developments in the field by signing up to receive our newsletter. Please contact us directly if you find any resources or activities that may be relevant to the Open Pharma audience or to discuss a collaboration.

We believe that the appropriate application of open research principles can improve the quality and transparency of pharma research communication and, ultimately, improve patient care and increase health equity globally. Everyone involved in the publication process can, and should, play a part.

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THEME ARTICLE

Science Without Borders – Can Translation Tools Bridge the Language Gap?

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ABSTRACT

Although access to scientific information has improved for the general public since the introduction of plain language summaries (PLSs) and the open-access publishing movement, language barriers still impede the widespread dissemination of information. Most scientific articles are published in English language only, despite English speakers comprising just 17% of the world's population. Here we present a pilot analysis that aimed to compare the translation quality of PLSs and abstracts translated by a selected browser-based translation software. We translated abstracts and PLSs from 5 medical journal publications into French, German, Mandarin, and Slovenian using Google Translate. Four bilingual reviewers with a scientific background assessed the translation quality using pre-defined survey questions that covered the appropriateness of word/phrase selection, grammar, and clarity. We assessed the number of errors of each type and used a 5-point Likert scale to measure the impact of these errors on the meaning of the text. Translations of both PLSs and abstracts were considered accurate and readable, although PLSs scored higher across most measures. For overall accuracy, translated PLSs scored higher on the Likert scale than translated abstracts (mean, 4.60 vs 4.30, respectively), with 60% of PLS translations considered to be "very accurate" compared with 45% of abstract translations. PLSs were also considered less likely to be misinterpreted (mean, 4.55 vs 4.25, respectively), with 60% of PLS translations compared with 45% of abstract translations reported as "definitely not" likely to be misinterpreted. Based on our findings, Google Translate potentially offers a quick and easy approach to translating scientific/medical information summaries for non-English speakers. However, before these articles can be translated, they must be discoverable by non-English speakers. Engagement and collaboration with medical publishers are needed to improve access for non-English speakers, including provision and PubMed indexing of PLSs that can be translated easily.

PLAIN LANGUAGE SUMMARY

Articles that report results from scientific studies are often written in technical language that can be difficult to understand. Scientific articles usually begin with a short summary, called an abstract. Sometimes, plain language summaries (PLSs) are also available which are written using straightforward language. The aim of including a PLS is to make sure that the scientific information can be understood easily by the general public. However, there is another language barrier that can make it difficult for people to read scientific articles: most are only written in English. Specialist services can be used to translate articles into other languages, but this can be expensive and time-consuming and so is not done often. In our study, we measured how well a free, online translation tool (Google Translate) could translate PLSs and abstracts from 5 English-language articles into French, German, Mandarin, and Slovenian. Four people who spoke English and one of the 4 languages read the translations and answered a survey about the translation quality. Overall, translations of both PLSs and abstracts were accurate and easy to read, but PLS translations were slightly better than abstract translations across all the measures. The results of our study show that Google Translate offers a free, quick, and easy way to accurately translate summaries of scientific information which could help people who do not speak English to understand the information. Importantly, before articles can be translated, non-English speakers need to be able to find them. To improve access to scientific articles, we suggest that scientists work with publishers to increase the number of articles that have PLSs, and to make sure that these can be found easily by people who do not speak English.

BACKGROUND

Accessibility of scientific information is an ongoing topic of discussion. Most scientific articles are written in technical language, which is not easily understood by all readers and is a barrier to the widespread accessibility of scientific information. In fact, evidence suggests that scientific literature

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is becoming less easy to understand, with long words, long sentences, and jargon preventing easy comprehension.[1] This is counterintuitive given the current focus on making science accessible to all. The proportion of freely available scientific literature has continued to grow since open-access publishing was proposed 20 years ago,[2,3] but if the average reader cannot easily understand the information, these efforts seem hollow. Plain language summaries (PLSs) offer a solution to this problem, and are increasingly popular with the aim of supporting nonspecialists (as well as time-poor readers) to understand the content of research articles easily, thereby further enhancing research accessibility.[1]

Although the volume of freely available scientific literature is increasing, as well as the number of articles that include PLSs, the proportion of articles published in languages other than English is decreasing. In the early 1900s, around one-third of scientific articles were written in English.[4] This had risen to around three-quarters of scientific articles published in English by 2013.[4] However, around 83% of the world's population is non-English speaking, leaving a huge accessibility gap for both lay people and the scientific community.[4]

To close this gap, there is a need to improve accessibility of medical information for non-English speaking physicians, researchers, policymakers, patients, and caregivers. Physicians who do not speak English may be at a disadvantage if they do not have timely access to important scientific information in their own language, for example results of clinical trials. Physicians who speak English as a second language may also find it harder to understand[5] or remember[6] scientific information that they have read in English than information supplied in their native language. Even high-profile research funded by non-English speaking governments is likely to be published in English, limiting accessibility within its country of origin if no translation is provided.[7]

Although specialist translation services offer high-quality translations of scientific text, time and cost may be barriers for most individuals and organizations to get articles they want to read translated regularly. Browser-based translation tools offer the potential for quick, easy, and free-of-charge translation of scientific articles. Free translation tools are largely trained on nontechnical language rather than scientific literature, and so may not translate scientific articles as clearly or accurately as plain language text.[8] Although abstracts provide a convenient condensed summary of a scientific article's content, most are written in highly-technical language. The rise in popularity of PLSs may therefore allow for enhanced access to scientific information for non-English speakers, provided that browser-based tools can accurately translate these summaries.

In August 2022, we performed a pilot analysis comparing the quality of translation of PLSs and scientific abstracts when carried out using a selected browser-based translation software. This analysis was presented as a poster at both the European and annual meetings of the International Society for Medical Publication Professionals (ISMPP) in 2023.[9,10]

METHODS

We selected 5 Ipsen-sponsored articles with accompanying PLSs for translation (Figure 1).[11-15] Our decision to use articles and PLSs from a single source was designed to limit any impact of differences in the quality of written English in

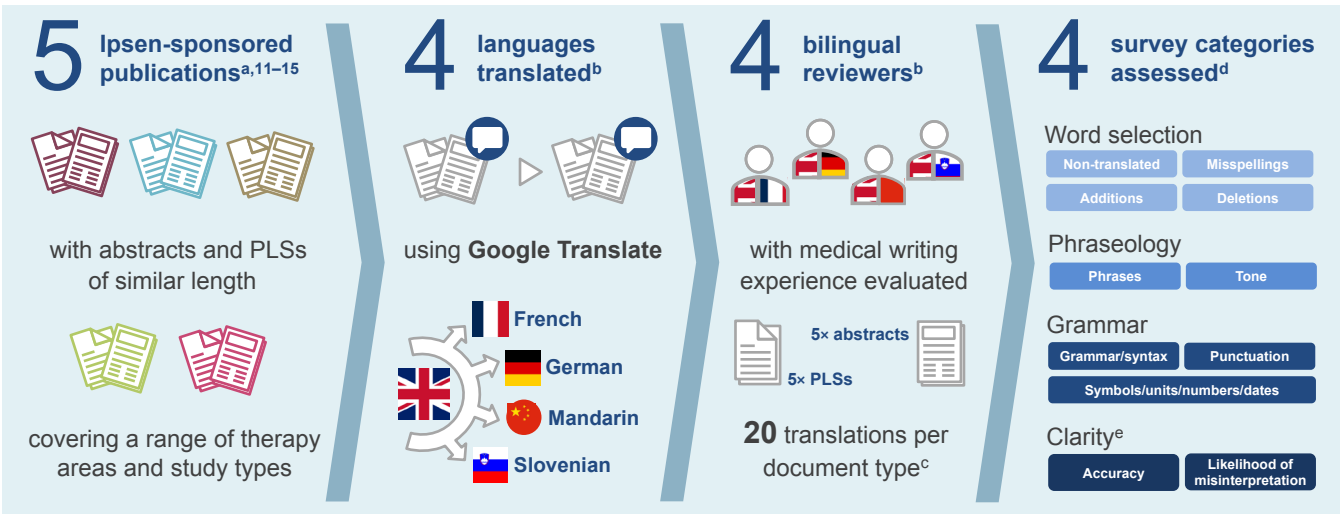

Figure 1. Study design. PLS, plain language summary.
[a]Ipsen-sponsored publications were selected because they were readily accessible and known to have both abstracts and PLSs.
[b]Languages were selected as representative of some widely spoken language families, and because these were the native languages of 4 in-house bilingual employees.
[c]One reviewer per translated language.
[d]Using standardized assessments, reviewers judged the impact of each category on the meaning, understanding, and readability of translated text.
[e]"Accuracy" and "likelihood of misinterpretation" were assessed using a 5-point Likert scale; 5 = highest accuracy and lowest likelihood of misinterpretation.

original documents on the translations. All of the selected publications had utilized medical writing assistance, ensuring that they were written in high-quality English.

Google Translate was used to translate the PLSs and abstracts into 4 languages that are representative of some widely-spoken language families (French, German, Mandarin, and Slovenian). Although other browser-based translation tools are available, we selected Google Translate because it is well known, free to use, and is incorporated in Google Chrome, the most widely-used Internet browser (as of July 2023).[16]

For each language, 1 bilingual reviewer with a scientific background assessed the translation quality using predefined survey questions that covered the appropriateness of word/phrase selection, grammar, and clarity. Reviewers assessed the number of errors of each type, and used a 5-point Likert scale[17] to measure the impact of these errors on the meaning of the text.

RESULTS

Word Selection

When assessed at the level of individual words, translations of PLSs and abstracts performed similarly (Figure 2). Inappropriate word insertion (0.2% vs 0.1% words), omission (0.2% vs 0.2%), and misspelling (0.05% vs 0.02%) rates were low in both translated PLSs and abstracts respectively, and most errors had little or no impact on the meaning of the text. However, translated PLSs had lower proportions of untranslated and mistranslated words than abstracts (both comparisons 0.6% vs 1.0%).

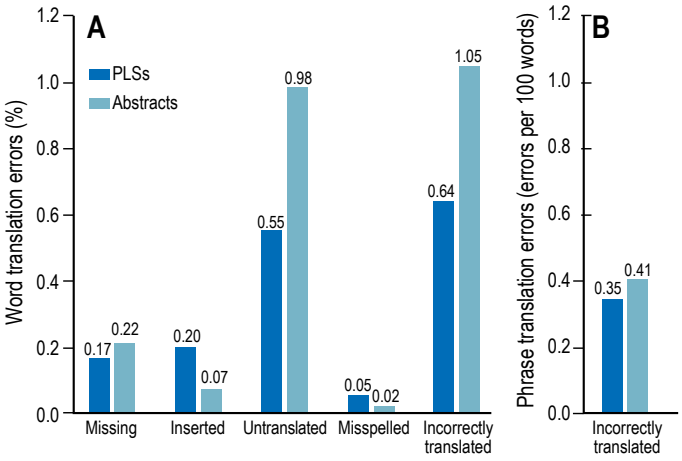

Figure 2. Translation errors (**A**. word selection and **B**. phraseology). PLS, plain language summary.

Phraseology

There were fewer incorrect phrase translations in translated PLSs than in translated abstracts (0.35 vs 0.41 errors/100 words).

Grammar

Translated PLSs had similar rates of grammatical/syntax errors to abstracts, but a lower proportion of these errors was identified as having the potential to lead to misinterpretation (17.2% vs 40%, respectively).

Clarity

On a 5-point Likert scale, translated PLS scored favorably compared with abstracts for overall translation accuracy (mean, 4.60 vs 4.30, respectively) and likelihood of misinterpretation (mean, 4.55 vs 4.25, respectively). For overall translation accuracy, the proportions of translations considered to be "very accurate" were 60% for PLSs and 45% for abstracts (Figure 3). Regarding how likely it was that translation errors would lead to misinterpretation of the information, 60% of translated PLSs and 45% of translated abstracts were scored as "definitely not" likely to be misinterpreted (Figure 4).

There were no notable differences in results between different languages, although the sample size was not large enough to detect inter-language differences.

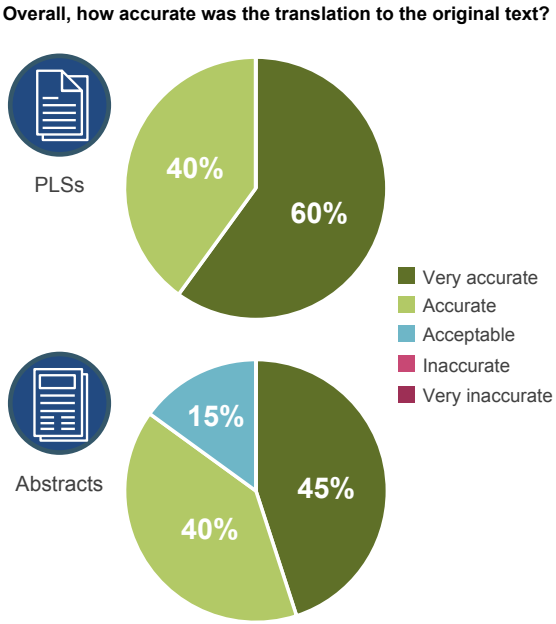

Figure 3. Translation accuracy. None of the reviewers found the translated text of PLSs or abstracts in any language to be "inaccurate" or "very inaccurate." PLS, plain language summary.

DISCUSSION

The language barrier is a big hurdle for information accessibility in scientific publishing. One solution could be for English-language journals to provide alternative languages for abstracts. Nevertheless, there are many difficulties with this approach, not least the cost, workforce capacity, and expertise needed to review translations.

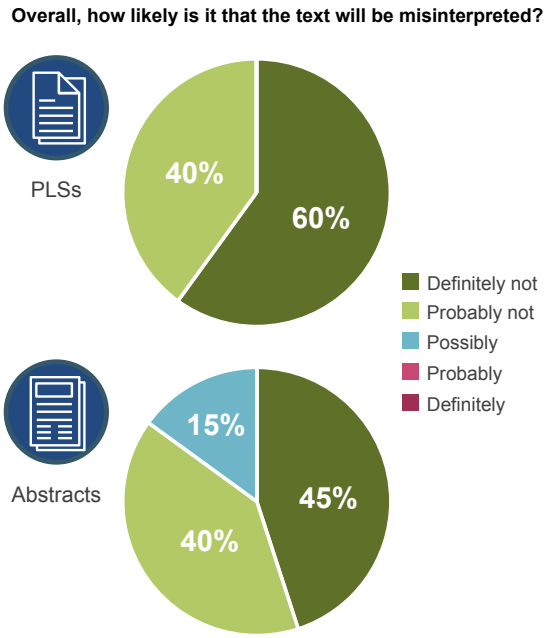

Figure 4. Likelihood of misinterpretation of translated text. None of the reviewers found the translated text of PLSs or abstracts in any language to be "probably" or "definitely" misinterpreted. PLS, plain language summary.

If freely available tools can translate scientific information clearly and accurately, non-English speakers could use these tools to read scientific abstracts in their own language. Our pilot study showed that, although not perfectly, both plain language and technical language scientific information were considered accurate and readable when translated using Google Translate. PLSs scored higher across most measures, possibly owing to the inclusion of complex sentences, abbreviations, and scientific terminology within the abstracts. However, the differences were generally small, and no statistical testing was conducted to establish whether the differences were statistically significant.

Based on comments provided by the bilingual reviewers in our study, there are potential considerations when writing PLSs and abstracts that may help to make the text more easily understood when translated via browser-based software. Translations of text that used the active voice were more readable and natural than those that used the passive voice. Acronyms were not translated consistently; although Google Translate could often recognize an acronym when it was first defined, acronyms were often lost in translation when used subsequently, or when an "s" was added to create the plural form. Practical guidance has previously been given for creating PLSs that are accessible for laypersons,[18,19] and a similar set of recommendations for creating translation-friendly summaries would go some way to helping non-English speakers have easier access to scientific information. Learnings from this study inform some initial recommendations, but more work will be needed to refine this list in the future.

Although this study focused on abstracts and PLSs, it highlights the importance of using clear and simple language in general. Ideally these learnings should also be applied to full-length articles. In 2020, Future Science Group was the first publisher to offer full-length PLSs of publications (PLSPs)—standalone summaries of entire articles written in nontechnical language.[19] Several of these summaries have been made available in several languages,[20-23] despite the original scientific article being published in English language only. Additional publishers have now also started to offer similar opportunities to publish in plain language. However, fewer than 100 PLSPs have been published to-date, so they do not yet offer a broad opportunity to make full-length plain-language texts available for translation by non-English speakers.[24]

These study results are promising, but are small adjustments to the way we write enough to enhance access to medical information for non-English speakers?

Some journals already offer translated abstracts, and multilingual journals publish abstracts in multiple languages. Other journals allow the opportunity to upload a translated abstract in the author's native language or in additional languages. Despite this, even when a translation is available, it is not always easy to find. Without knowing in advance which journals offer abstracts in their native language, non-English speakers must search for them, so how can we ensure non-English speakers can find the articles they need? Language filters are available on PubMed for articles written in non-English language, but for English-language publications, PubMed displays abstracts in English by default. When a translation is available, this must be accessed via a link.[25] There are tools available to help non-English speakers to use PubMed to find articles written in their native language. Technical solutions have been proposed to allow non-native English speakers to search for English-language articles on PubMed, for example, a Web-based tool that helps users to build PubMed searches in several languages (multilingual Query Builder).[26] However, to the best of our knowledge, these search tools are neither readily available nor in common use.

Whether they speak English or not, laypersons wishing to access scientific literature may not be experts in searching for scientific information. There may be additional need to ensure that PLSs are easily found. Although some PLSs are indexed and tagged in PubMed, there may be a need for a lay-friendly database or search engine dedicated to PLSs that would ideally be searchable in any language. Additionally, publishers and the scientific community

should work together with providers of translation software to ensure that, when professional translations of technical-language publications have been provided, these are made available for training of machine translation software.

It is likely to be some time, if ever, before Google Translate (and similar software) is sufficient for people to remove the need for specialist translation of scientific articles. This is particularly pertinent to the pharmaceutical industry, in which companies must comply with professional standards, regulations, and laws to ensure clinical trial results are reported accurately. Currently, translations from browser-based software could not be used without professional review of the translation.

Study Limitations

With only 5 publications, 4 languages, and 1 reviewer per language, the sample size in this study was limited. Although efforts were made to include different therapy areas and study types, the publications were developed by a single sponsor and were of uniform quality, and the writing style was similar across the 5 publications. For the most part, there is a lot of Internet content written in the languages we used in the pilot study, and Google Translate is likely to have been trained extensively in French, German, and Mandarin. Browser-based translation tools may not perform as well with languages that have a smaller Internet presence. Although multiple alternative tools are available for automatic translation (DeepL, Microsoft Translate, and ChatGPT), Google Translate was the only software used in this study. Although all these popular translation tools employ machine learning techniques (a subset of AI),[27-29] there is currently a lot of public interest in ChatGPT and future advancements in similar large language models. Recent studies suggest that the current iteration of ChatGPT does not yet consistently outperform Google Translate or Microsoft Translator, and performs worse with less widely spoken languages.[30] Although there is a lot of excitement about the future of ChatGPT in many fields, it is still reliant on the availability of training data.

The results of this study may not easily be extrapolated to other publication types because we included only short text-based summaries. These were easy to handle using Google Translate, but this approach may be less practical for longer texts or articles in which a lot of the information is embedded in figures and tables. Although Google Translate does have capabilities for translating whole documents, the complexity of the document formatting can affect how successful this is.

Finally, a survey-based approach was used to assess translation quality. The quality assessment could be expanded to also include the reverse translation method, in which Google-translated abstracts and PLSs are translated back to English by a translator who has no knowledge of the original text, with the results compared with the original to check for equivalence of the wording.

Although there has been recent focus on making scientific information more widely available, there remains a gap for non-English speakers. Ideally, professional translations would be available for all English-language scientific research, but this is not a practical solution. It is possible that, with technological advances, it will get easier for non-English speakers to search for, find, translate, and understand literature originally published in English. In the meantime, we propose that the publishing community should increase its commitment to PLSs, including improving their discoverability (eg, ensuring correct indexing on PubMed). Wider availability and accessibility of these lay-friendly summaries should not only provide an accessibility benefit to English-speaking readers but should also improve access for non-English speakers by enhancing the accuracy of translations using browser-based tools.

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SCIENCE SERIES

The Gut Microbiome–Human Body Symbiosis: Relevance of the Ubiquitous Microbial Community on Health and Development, Part 1

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ABSTRACT

There appears to be a collaborative nexus between the human body and its resident microbes. Research shows strong associations between this parallel universe of microorganisms and our overall health, immunity, and behavior. The human microbiome consists of microbes that flourish in different parts of the body. Our gut with all its projections spans nearly 7 kilometers in length and contains the largest number of microorganisms within the human body. An imbalance in the gut microbiome is strongly associated with allergies, metabolic diseases (eg, diabetes, obesity), neurological conditions (eg, depression, autism), respiratory diseases, liver diseases, and cancer. The development of the gut microbiome is a dynamic process that begins either during gestation or at birth and continuously evolves with human growth into adulthood. The gut microbiome is part of an intricate metabolic and signaling network in the human body. It communicates through biochemical pathways or axes with the skin, brain, lungs, kidneys, breast, and liver. A key motivation behind gut microbiome research is to confirm the cause-and-effect role of the gut microbiota on host health homeostasis. Today, gut microbiome research is generating excitement due to its potential to prevent and treat several interrelated health conditions. Conclusive evidence of the role played by the gut microbiome on human health will furnish new avenues of treatment and better insights into the influence of diet, environment, antibiotics, and genetics on the body. This article, the first of a two-part review, will discuss the relevance of the gut microbiome and its prominent constituents, the developmental trajectory of the gut microbiome from infancy to adulthood and its mutualistic relationship with the human host.

Today, medical research is dominated by an overwhelming interest in the human microbiome.[1] Because advances in health and medicine are of genuine public interest, results related to microbiome research are popular. In North America, there is a hype about the microbiome where nearly 94% of articles discuss only health benefits, whereas very few articles provide critical assessments or limitations of microbiome research.[2] Microbiome is a term that refers to the ecosystem that comprises genes, metabolites, and associated products of bacteria, fungi, viruses, phages, and archaea (Box 1).[3-7] There is a symbiotic relationship between human cells and the microbial community that dwells in the human body.[8] In humans, there are approximately 39 trillion microbial cells, encoding nearly 20 million microbial genes.[3,9-12] In contrast, human bodies with approximately 30 trillion human cells possess a little more than 20,000 human genes.[12-14] This vast difference of a factor of 10^2 to 10^3 in microbial gene number has an impact on immunity, behavior, and health in humans. Although studies on the effects of the microbiome on human health have been around for more than 50 years, a dedicated human microbiome project was initiated in 2007 by the National Institutes of Health to

Box 1.

Microbiome
An ecosystem of microorganisms (bacteria, viruses, phages, fungi, archaea), their genes, and metabolites in a particular environment.

Microbiota
The microorganisms living in a particular environment, which include bacteria, viruses, fungi, archaea, and phages.

Dysbiosis
Changes to the composition of the gut microbiome (eg, function and taxonomy) cause dysbiosis as presented in a disease state. Drastic disturbances to the gut microbial balance are linked to diseases, such as inflammatory bowel disease, obesity, type I diabetes, asthma, autism, and allergies. Gut dysbiosis causes inflammation and immune reactions.

Alpha Diversity
The intraspecies diversity in a particular environment in an individual.

Vertical Transmission
Transfer of bacteria and genes directly from mother to child

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understand the physical and genetic structure of the microbiome.[1,4,15] The first phase of this project studied the composition of different microbiomes (eg, skin, buccal mucosa, gut, feces, vaginal wall, tongue, outer ear cavity, and other sites) in the human body.[15] A second integrative human microbiome project is studying the impact of 3 conditions–prediabetes, inflammatory bowel disease, and pregnancy–on the dynamic interaction between microbiomes and the human body.[4,15] There is evidence of biased reporting of gut microbiome benefits on human health. By reporting results before they have been verified in large sample studies or randomized controlled trials, the public may be misled about the impact and benefits of the gut microbiome on our health.[16,17] The following evidence-based review aims to provide a balanced overview of the gut microbiome and its role in the human body.

RELEVANCE OF THE GUT MICROBIOME IN THE HUMAN BODY

The gut or intestinal microbiome accounts for 99% (~ 1,000 to 4,500 species) of the entire microbial flora in the human body (Table 1),[5,11-13,18,19] making it the densest organ of metabolism on our planet. Research has demonstrated the significant role of the gut microbiome in immune system maturation, vitamin production, energy production from dietary components, breakdown of complex sugars from plant-derived products and human milk, protection of the body against pathogenic bacteria, maturation and development of epithelial cells, and neurotransmitter production to facilitate communication with the brain.[20-22] Processed foods, high-fat diet, high- protein diet, low-fiber food, antibiotics, alcohol, and diseases cause inflammation and create an imbalance in the composition or dysbiosis of the gut microbiome.[23,24] Gut dysbiosis (Box 1) appears to be associated with long-term impacts on the individual's health in the form of allergies (eg, hay fever), gastrointestinal diseases (eg, inflammatory bowel disease [IBD], Crohn's disease), metabolic diseases (eg, obesity, diabetes, and cancer), neurological conditions (eg, depression, autism, Alzheimer disease), and respiratory tract infections (Figure 1).[4,20,25,26]

ORIGINS OF THE GUT MICROBIOME

The First Stage: Seeding

The development of the gut microbiome is a dynamic process.[27] Two theories explain the seeding of the gut microbi-

Table 1. Types of Microbiota in the Gut

Bacteria		Fungi		Viruses and Bacteriophages		Archaea
Major Phyla (Term Infants)	**Major Phyla (Preterm Infants)**	**Children**	**Adults**	**Infants**	**Maternal Gut**	*Methanobrevibacter smithii* *Methanosphaera stadtmanae* Order Methanobacteriales
Proteobacteria *Firmicutes* *Actinobacteria* *Bacteroidetes* *Verrucomicrobia*	*Firmicutes* *Actinobacteria* *Bacteroidetes*	*Aspergillus* *Tremellomycetes*	Phyla *Basidiomycota* *Ascomycota* Genera *Saccharomyces* *Penicillum* *Aspergillus* *Candida*	*Myoviridae*, *Podoviridae*, *Microviridae*, and *Siphoviridae* families	*Microviridae* *Circoviridae*	

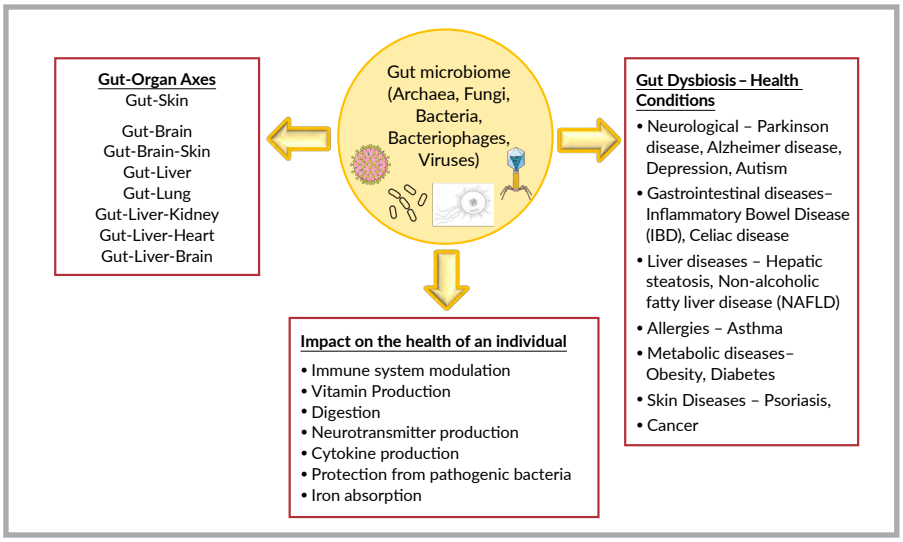

Figure 1. The relevance of the gut microbiome in the human host. The 3 main roles of the gut microbiome are outlined in the figure. Parts of the figure were drawn by using pictures from Servier Medical Art. Servier Medical Art by Servier is licensed under a Creative Commons Attribution 3.0 Unported License (https://creativecommons.org/licenses/by/3.0/). Archaea cells icon by SwissBioPics https://www.swissbiopics.org/ is licensed under CC-BY 4.0 Unported https://creativecommons.org/licenses/by/4.0/.

ome in humans.[8,23,28] Bacteria initially colonize the immature gut of infants followed by viruses and fungi.[23,29,30]

Sterile womb hypothesis. This hypothesis states that the uterus of a pregnant person is a sterile environment, and microbial colonization of the fetal gut begins at birth during labor.[8,31,32] When the amniotic sac ruptures in a vaginal birth, the fetus is exposed to and enveloped by the mother's vaginal microbiome as it makes its way through the birth canal. Babies born via elective cesarean section have a gut microbiome that resembles the mother's skin microbiome.[3,8,13,33] Infants born from an emergency C-section have gut microbiota that resemble the mother's skin and vaginal microbiomes.[3,8,13,33]

In the term infant, the gut is randomly colonized initially by pioneer colonizers or microbiota (Box 1) from different sites of the mother's body (eg, skin, mouth, gut, vagina, breastmilk).[28,30-32] In the first week of birth, the infant's gut is aerobic and has a neutral pH. Facultative anaerobic bacteria (growing with or without oxygen) act as pioneer colonizers (Box 1, Table 2).[28,31,32] They then reduce in number as obligate anaerobes (Table 2) begin to proliferate in the gut. As the infant grows, the pH of the gut changes. Facultative anaerobes become predominant in the gut, signaling a shift in oxygen conditions. These robust microbes are vertically transmitted (Box 1) from the mother to the child.[32] After 6 days of life, there is a transition to *Bifidobacteria* species that use human milk oligosaccharides (HMOs) as a source of carbon (Figure 2).[3,23]

Table 2. Seeding Microbes

	Facultative anaerobes	Obligate anaerobes
Term Infants	*Prevotella melaninogenica, Haemophilus parainfluenzae, Enterobacteriaceae members, Alistipes putredinis, Staphylococci, Streptococci*	*Bifidobacteria, Clostridia, Eubacteria spp, and Bacteroides*
Preterm Infants	*Staphylococcus, Enterococcus, Enterobacteraceae, Bifidobacterium*	Delayed colonization – *Bifidobacteria, Lactobacillus, and Bacteroides*

In utero hypothesis. In contrast, this controversial hypothesis suggests the fetal gut microbiome is seeded during gestation when the fetus is exposed to the microbiota of the placenta or amniotic fluid. Placenta, amniotic fluid, and meconium–once considered sterile–are now being shown to be occupied by microbial communities. Preterm babies are exposed to amniotic fluid microbiota due to urinary infections (premature rupture of membranes) or chorioamnionitis (infection within the amniotic sac and the surrounding fetal membrane) during gestation.[25,34-38]

Controversies. Critics argue against the presence of microbiota in these sterile sites and suggest that laboratory contamination may be the potential source. These microbiota could also seed the neonatal gut via vertical transmission from the mother to the fetus (eg, breastmilk).[6,25,34,39]

The Second Stage: Weaning

The infant's gut microbiome undergoes a significant change during weaning when they are introduced to a solid diet.[3,23,40] The gut microbiome is compelled to mature and increase in diversity when the complexity of carbohydrate and starch components increases. There is a decrease in *Bifidobacterium* and other obligate anaerobic species. This stage of maturation sees the predominance of the phylum

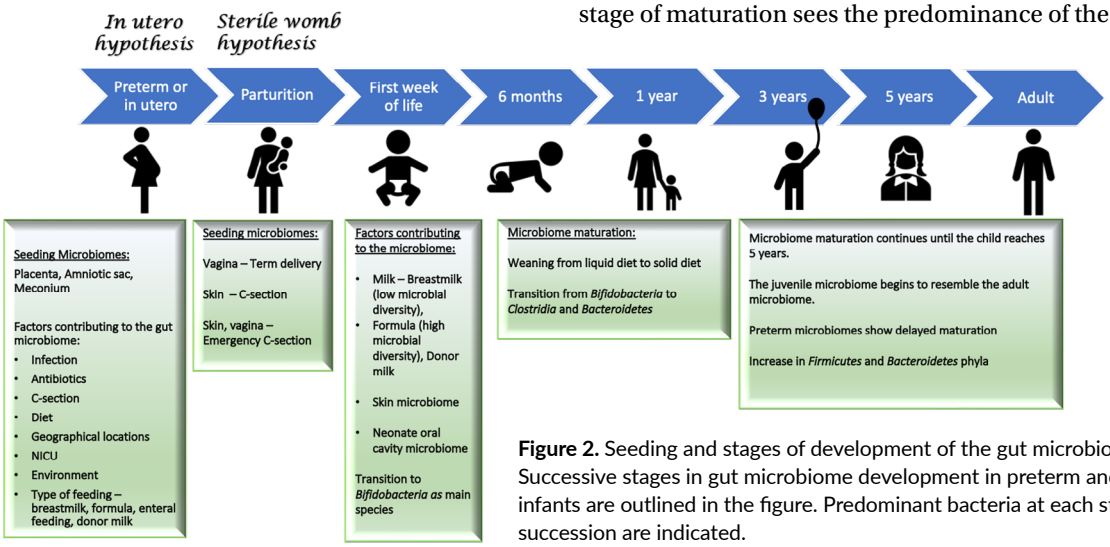

Figure 2. Seeding and stages of development of the gut microbiome. Successive stages in gut microbiome development in preterm and term infants are outlined in the figure. Predominant bacteria at each stage of succession are indicated.

Bacteriodetes and *Clostridia* species.[23,28,31,40] The gut flora is distinctly different in children aged 4 months, 12 months, 3 years, and 5 years.[3,23,29,41] As the infant grows through the first year of life, the alpha diversity (Box 1) increases when solid foods are introduced in the diet (Figure 2).[25,27,37]

The Third Stage: Stabilization of Gut Flora During Growth Into Adulthood

There is limited information on the gut microbiomes of children and adolescents. The evolution of the gut microbiome stabilizes in children after 5 years of age and appears to resemble that of adults. The 5 major phyla in an adult gut are *Firmicutes, Proteobacteria, Bacteroidetes, Actinobacteria*, and *Verrucomicrobia*. Microbial content, however, differs and is influenced by diet, geographical location, and use of antibiotics.[3,8,29,41-43] Bacterial genera of the adult gut do not resemble the genera found in children younger than 3 years.[29] With the progress to adulthood, *Bifidobacteri*a abundance reduces along with subsequent enrichment of *Firmicutes* and *Bacteroidetes* in the adult microbiome.[44]

FACTORS INFLUENCING GUT MICROBIOTA

Normal development of the gut microbiome with increasing species diversity from birth is essential to the future health of the individual.[27] Several factors enhance or impede the microbial balance in the gut.

Term Infants

In a term neonate, vaginal birth, good maternal health, breastmilk, and probiotics enhance the diversity of gut flora. Antibiotics, hospitalization, and smoking (Table 3) give rise to antimicrobial resistance genes and facilitate the growth of facultative anaerobic pathogenic bacteria.[8,13,39,45,46] The type of mother's diet, c-section birth, formula feeds, bovine-milk-fortified human milk, and the environment (eg, living with family members, daycare, pets, rural or urban lifestyle, an industrialized environment) influence gut flora maturation in different ways.[8,28,30] Gut microbiota of infants born via c-section and/or fed formula are very diverse and closely resemble mature microbiota of adults.[23] In addition, chemical factors (pH, bile acid, mucus), microbial factors (adhesion capability, metabolic pathways, bacterial enzymes), and bacteriophages influence gut microbiome diversity.[5,21]

Preterm Infants

Preterm infants show delayed development of microbial diversity and a distinct difference in species composition (Table 4) from those of age-matched term infants before 6 months.[25,37,47] Microbial colonization may occur prior to birth because of complications during gestation.[13,33,36] Gestational age plays a major role in the initial colonization and microbial diversity of the preterm infant's gut.[47] Other factors include genetics, sex, the mode of feeding (enteral; parenteral; breastfeeding), type of milk (breastmilk; formula, donor milk); pumping and storage of milk, and the environment (hospital; intensive care unit; medical interventions; antibiotics; family members).[13,27,33,37,44,45,48-51]

IMPACT OF CHANGES IN MICROBIAL DIVERSITY

Gut microbiomes of children are more susceptible to changes in diet, environment, and antibiotics than those of adults. Babies born via c-section appear to be predisposed to developing obesity and celiac disease.[8,41] Antibiotic treatment reduces microbiota diversity, leading to antibiotic-related obesity, multidrug resistance, and asthma. Gut health could be restored when treated with beneficial bacteria.[23,41] The quality of microbial diversity in the gut is

Table 3. Gut Bacteria in Term Infants

Vaginal	*Escherichia coli*, *Lactobacillus spp*, *Enterococcus Bifidobacteria (eg, Bifidobacterium breve, Prevotella spp, Bifidobacterium bifidum, Bifidobacterium adolecscentis, Bifidobacterium longum), Sneathia spp, Streptococci, Atopobium vaginae* and *Gardnerella vaginalis*, *Bacteroides, Fecalibacteria, Parabacteroides, Lachnospiraceae, Ruminococcaceae, Christensenallaceae, Roseburia, Anaerostipes*
C-section	*Klebsiella, Clostridium, Staphylococcus, Haemophilus, Veillonella, Propionibacteria, Proteobacteria, Enterococcus spp, Corynebacterium spp,* other *Ruminococcaceae variants, Bifidobacterium spp*↓, *Lachnospiraceae, and Bacteroidaceae* species↓
Breastmilk	*Enterobacter, Streptococci, Acinetobacter, Staphylococci, Bifidobacteria,* lactic acid bacteria, *Pseudomonas*
Formula	*Clostridium difficile, Bacteroidetes (Bacteroides fragilis), Staphylococci, Atopobium, Enterobacteria, Enterococci,* and *Firmicutes Lactobacilli, Escherichia coli*

Table 4. Gut Bacteria in Preterm Infants

C-section	*Enterococci, Enterobacteraceae, Staphylococci, Klebsiella, Mycoplasmataceae (↑ in chorioamnionitis), Bacteroidetes*↓, *Escherichia, Bifidobacteria* ↓, *Veillonella, Lactobacilli* ↓, *Coprobacilli, Desulfovibrio, Carnobacteria, Phascolarctobacteria, Gammaproteobacteria, Firmicutes, Shigella, Clostridia* ↓, *Atopobium* ↓, *Sneathia sanguinegens, Fusobacterium nucleatum*
Breastmilk	*Staphylococci, Corynebacteria, Pseudomonas, Streptococci, Acinetob*
Formula	*Bifidobacteria* and *Clostridiales*
Antibiotics	*Firmicutes* and *Proteobacteria*
Hospital-associated	*Klebsiella pneumoniae, Yersinia, Enterococci, Serratia, Granulicatella, Proteus, Enterobacter aerogenes, Escherichia coli*
Diet-associated	*Ruminococcus bromii, Bacteroides vulgatus, Lactococci, Ruminococcus obeum*
Butyrate producers	*Eubacterium hallii, Anaerostipes caccae, Coprococcus eutactus*

crucial and dependent on the interplay of different factors. Despite breastfeeding, malnutrition reduces alpha diversity (increased prevalence of *Proteobacteria*) and slows down growth in children.[3,23,29,43] A Western diet of low-fiber and high-fat processed foods increases the presence of *Bacteroides* and reduces overall alpha diversity. Numerous health conditions (eg, obesity, IBD, cancer) appear to be associated with reduced alpha diversity.[23,52] In contrast, high-fiber diets increase microbial diversity and overall health in rural populations in Asia and Africa.[23,40,41,52] Geographical location appears to influence microbial diversity. People living in industrialized urban areas exhibit lower gut microbial diversity than those who live in rural areas.[42,52]

GUT MICROBIOME NETWORK

The gut microbiome does not act in isolation. Instead, microbiota or its metabolites travel to other sites of the human body and interact with their microbiomes through bidirectional or multidirectional pathways. This complex network explains the influence of the gut microbiome on our immunity, health, and even our emotions (Figure 1). Some of the gut axes are gut-liver,[24] gut-lung,[10,24,53,54] gut-brain, gut-skin, gut-liver-kidneys,[24] and gut-brain-liver.[24] Disruption to the normal functioning of these axes results in diseases such as chronic kidney disease, hepatic encephalopathy, and cardiovascular disease, nonalcoholic fatty liver disease, chronic obstructive pulmonary disease, asthma, and cystic fibrosis.[10,24,53,54] These conditions are often linked to gastrointestinal diseases. This article will focus on the gut-skin, gut-brain, and the gut-breastmilk axes.

Gut-Skin Axis

The biochemical interactions between the skin and gut microbiomes are bidirectional.[28] A dysbiotic gut microbiome may induce changes to the skin microbiome with the release of proinflammatory cytokines. This allows gut bacteria or their metabolic byproducts and toxins to enter the systemic blood circulation. The gut bacteria reach the skin and affect the integrity of the skin barrier. The resulting inflammation has been linked to chronic skin disorders (eg, psoriasis, acne, alopecia).[55,56]

Gut-Brain Axis

According to preclinical research, there are bidirectional interactions between the gut, brain, and the gut microbiome (GBM). The gut-brain axis comprises the autonomic nervous system, the gut microbiota with its metabolic products, the enteric neuroendocrine system, the hypothalamic-pituitary-adrenal system, the enteric nervous system, and the gut-associated immune system.[36,57] Research has shown that bacteria, their metabolites, and immune cells have access to the brain through the blood brain barrier (BBB).[22,58] Gut bacteria belonging to the genera *Bifidobacteria, Streptococci, Escherichia, Lactobacilli*, and *Enterococci* regulate the production of neurotransmitters (eg, GABA, serotonin, and acetylcholine), which pass through the BBB and modulate brain signaling directly or indirectly. Interactions between the nervous system and the immune system are also affected. People suffering neurological, psychiatric, and degenerative conditions (eg, depression, anxiety) also display perturbations in the diversity of their gut microbiome (eg, IBD, chronic abdominal pain).[22,57-59]

Gut-Brain-Skin Axis

The gut-brain-skin axis is gaining relevance in the consistent link between skin conditions (psoriasis, acne) and mental health (depression). The central nervous system (CNS) is regulated by neurotransmitters transmitted from the gut microbiota through the vagus nerve. Neurotransmitters facilitate the interactions between the nervous system and immune responses to skin inflammation. Mental health conditions (eg, depression) and skin conditions (eg, psoriasis) generate cytokines (eg, IL6) from the brain and the skin. This causes inflammation. Simultaneously, CNS conditions (eg, depression or anxiety) appear to cause gut dysbiosis and increase the permeability of the gut epithelial cells (leaky gut). Gut microbiota and their metabolites enter the bloodstream and trigger inflammation on the skin and in the brain.[58,60]

Human Breastmilk – Enteromammary Hypothesis

Breastmilk may play a role in seeding the infant microbiome. A quarter of the infant's gut microbiota is obtained from breastmilk, which influences its development over the individual's lifetime and protects against potential allergies.[61,62] The enteromammary hypothesis suggests that bacteria travel from the mother's gut to the lactating breast and create the breastmilk microbiome. However, this hypothesis is based on a small sample size.[51,61,63] Human breastmilk contains bioactive compounds (secretory immunoglobulin A,[64] growth factors, >200 HMOs, cytokines), immunological compounds, nutrients, and maternal gut microflora. Bioactive compounds help to develop a robust immune system in the infant.[8,44,61] As prebiotics and a source of bioactive compounds, HMOs are digested by microbiota, such as *Bifidobacteria*, in the large intestine because humans lack the enzymes to metabolize HMOs in the small intestine. HMOs (elaborate sugar complexes) are a major source of brain nourishment and prevent the growth of infectious pathogens.[8,44,61] The components of breastmilk change dynamically at each developmental stage of the infant.[65]

CONCLUSION

Despite strong associations, the vital question persists: does a health condition cause gut dysbiosis, or is the reverse true?[22,23] This topic is ripe for debate as misinformation influences public opinion. Unfortunately, it has been noted that the general population prefers to acquire information from nonmedical independent sources.[17] Popular content (eg, articles or videos) lack reliable peer-reviewed sources to support their claims on the benefits of products, such as probiotics or yogurt, on human health.[2,17] However, responsible reporting is warranted. Accurate data interpretation could influence future health policies.[1] To preserve scientific integrity, it is our responsibility as medical writers to ensure that facts and research findings on the gut microbiome are validated and appropriately disseminated. Data from large randomized clinical trials should be cautiously interpreted by assessing the relevance of statistical tests used or by distinguishing associations from cause-and-effect. When statistical data are accurately interpreted in the larger context of the human population, the significance of the results is more convincing. Although gut microbiome research is under the influence of the "health halo," we cannot deny the existence and the involvement of this extensive microbial community in human health.[2] Established as an integral part of the complex, interconnected human signaling network, the gut microbiome and its manipulation could soon form a key aspect of the diagnostic and treatment landscape.

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FREELANCE FOCUS


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Q1: What are the potential benefits and limitations of using ChatGPT in medical writing, and how can these be mitigated?

Many writers in the continuing medical education (CME) field who have been exploring ChatGPT as a tool to generate ideas see at least 3 possible use cases. First, if you are unfamiliar with a disease state or therapeutic area at the beginning of a project, ChatGPT can be a valuable research assistant that rapidly finds information to help organize your thinking, generate feedback on your work, and summarize research literature. You can ask ChatGPT to provide a targeted overview and an "at-a-glance" perspective on the basics. But that's what you'll get. You'll still need to do a much deeper dive into the peer-reviewed and evidence-based clinical practice literature. Second, some writers are using ChatGPT for efficiency gains. They create detailed prompts for ChatGPT to generate outlines for needs assessments and ideas for practice gaps. Writers I've spoken to who are experimenting in this way then validate and build out practice gaps using the literature. Third, ChatGPT is being explored to support adaptive learning by generating patient cases, providing responses to learner questions about those cases, and prescribing relevant resources for additional feedback and remediation.

In all these potential use cases, the key to any degree of success is prompt engineering that shares sufficient detail and clear parameters with ChatGPT at the outset. The downside is that there is absolutely no guarantee that the information ChatGPT returns will be in any way accurate, and it certainly won't be supported by evidence. Several journalists and scientists have now drawn attention to inaccuracies and false citations that ChatGPT generates because no one is fact-checking. If we cannot attribute claims to published sources, then we cannot use the content. So, if you are exploring ChatGPT, you'll need to find and corroborate the sources and rigorously fact-check the integrity of information it returns. In my mind, the time to check facts will swallow any efficiency savings. Using ChatGPT and other artificial intelligence (AI) tools to generate ideas and content could also nudge writers into sloppy habits. It'll be easier to lose track of your source material if that material is not anchored to specific references. Another limitation is that ChatGPT does not have the capacity to notice and process context and cannot provide nuance or perspective. These are human characteristics. As a result, medical writers will and must remain the primary drivers of content integrity in CME and continuing education for health professionals.

—Alex Howson

ChatGPT is a program focused on language-related tasks that "understands" natural language and can answer questions and requests. GPT stands for "generative pretrained transformer." ChatGPT was developed by OpenAI and released to the public in November 2022. The public interface was trained on information taken from the internet up through September 2021; thus, the information is slightly out of date, unless you input more recent information during a conversation.

The public interface is free and requires no setup. Once you provide your email address and a password, you can type in a question or a request. The best answers come from questions that are as specific as possible.

Benefits of ChatGPT

ChatGPT has several potential benefits for medical writing. In a webinar I attended, attendees from a medical communication (med comm) company noted that ChatGPT can be used as an *initial research tool*, for example, to ask for background or an overview of a therapeutic area. Here are some examples:

- "Provide peer-reviewed references for US colonoscopy guidelines within the last 10 years"
- "Explain current treatments for acute myeloid leukemia to an oncologist in fewer than 500 words"

ChatGPT can help *overcome writer's block* by providing a starting point, summarizing a group of paragraphs you upload, or suggesting ideas for slide titles. Here are some examples:

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- "Summarize the introduction and conclusions of the following publication as bullet points <insert content>"
- "Rephrase the following sentence to be more concise <insert content>"

ChatGPT can help repurpose material for different audiences. It can rewrite scientific material in lay language; adapt training modules for physicians to ultrasound technicians; or write a key opinion leader's bio for a medical meeting from a resume that you upload.

- "Write a 200-word biography of this professor of radiology to be shared with peers <insert complete resume>"
- "Rewrite this text to be language-appropriate for children ages 9-12 <insert abstract>"
- "Turn this journal abstract into a slide presentation <insert abstract>"

ChatGPT helps spark the creative process by providing an initial summary of information but not final draft material. Humans are needed to apply thought and judgment to the proposed answers. It's not doing all the work for you, but it can make some tasks easier.

Limitations of ChatGPT

You need to check all facts and the quality and accuracy of all references. By OpenAI's own admission, ChatGPT may produce inaccurate information about people, places, or facts. In other words, it *can say things that are not true*. In a recent email exchange on AMWA Engage, participants noted that *ChatGPT created fake references*.

Because of nondisclosure agreements in place, medical writers should upload only public data to this third-party application.

ChatGPT uses personal information you provide to provide, administer, maintain, improve, and/or analyze its services. Although ChatGPT provides information in its privacy policy on how you can opt out of their use of your content to train the models, uploading patient data and other private information would be a mistake.

—Melissa L. Bogen

In my opinion, the benefits of ChatGPT are in the eyes of the beholder. I don't personally see any benefits from the medical writer's perspective because the role of ChatGPT is to do the job of the medical writer. If we're not doing the research, reading and synthesizing what we find, and distilling what we learn into clear, concise, and accurate language that is accessible to our target audiences, then what are we doing? In that vein, ChatGPT has the potential to turn medical writers into reviewers, which may not be many medical writers' cup of tea.

ChatGPT has vastly deeper, broader, and faster access to information than medical writers will ever have. But currently, ChatGPT does not have the ability to filter information from misinformation, and it cannot take responsibility for its content as medical writers and authors must. If a reviewer wishes to question a sentence or a paragraph written by ChatGPT, who is there to ask? ChatGPT currently doesn't have the capacity to explain or justify itself. It simply is. It is the medical writing equivalent of "because I said so."

So, who do I think can currently benefit from ChatGPT in the medical writing space? To a large degree, content mills, because they already don't care about accuracy or accountability. Predatory publishers are another unscrupulous group that I think can immediately benefit from the speed and power of ChatGPT. But I do think there's a legitimate side to ChatGPT's potential as a medical writing tool by limiting the information it can source and what it can do with that information.

For example, limiting ChatGPT to only the information contained within a specific set of resources and giving it a prescribed template in which to apply that information is a task for which I think ChatGPT is potentially well suited. But the content ChatGPT produces must still be reviewed, scrutinized, and when necessary, questioned. This may, in turn, create more opportunities for medical writers and medical editors who love to fact-check.

—Brian Bass

Benefits of ChatGPT include helping to amalgamate information related to some of various research questions. An IT friend put >10 questions to ChatGPT on my behalf (because I have not yet started using it on my own computer). The questions related to medical/science issues, political topics, philosophical/religious topics, and simple pragmatic queries. Many *factual errors* as well as errors of "narrowness" resulted! As well, it was clear that the AI may provide biased answers.

Serious questions, in my opinion, should not be put to ChatGPT (at least not at this time). Other alarming impediments include not providing published, bona fide (respectable) reference citations for ChatGPT's opinions; one must specifically ask for references to be included; moreover, when we asked ChatGPT to include reference citations, some of them were *incorrect*! Another danger is the risk/temptation for a person to plagiarize ChatGPT (which has already plagiarized someone else, of course, with no attribution). I suspect much of this is already taking place without attribution.

I did, however, receive helpful information in response to a certain question: I had Googled and done other searches about growing a potted rosemary plant indoors. After several unsuccessful results, we finally got a very

helpful reply from ChatGPT, which not only amalgamated replies I had received elsewhere but elaborated more specifically on my geographic location, the dry climate, and high altitude. (In the end, after killing 6 rosemary plants, I learned that, in fact, the conditions inside my home are not amenable to growing rosemary. ChatGPT was the preferred source. So, I stopped wasting money on these plants.)

At this time, I do not think we should be using this AI program for serious professional medical writing. Nor do I think we can do much to mitigate the problems other than to commit ourselves to doing our homework, maintaining our integrity and ethics, and not succumbing to the temptation of laziness, ie, allowing ChatGPT to do work for us that our human critical thinking/intuitive minds should be doing.

—Cathryn D. Evans

AI technologies such as ChatGPT have unleashed a Pandora's box. Recently, Congress had the opportunity to hear from Sam Altman, the founder of OpenAI, the organization behind ChatGPT. Altman expressed concern about the potential for AI to spread misinformation, highlighting the genuine threat it poses. In his address to Congress, Altman emphasized the urgent need for regulation to mitigate these risks. Although regulations are currently lacking, hopefully they will be implemented soon.

As medical writers, we must grasp both the advantages and limitations of AI technologies. Despite the absence of regulation, AI is here to stay. We can harness the power of ChatGPT as an advanced search engine, but importantly, exercise caution and fact-check all the generated content. ChatGPT exhibits inaccuracies in developing references for its text; thereby, a critical evaluation of its generated references is necessary. Some have drawn comparisons between ChatGPT and Wikipedia, with arguments against ChatGPT reminiscent of those once made against the reliability of Wikipedia. Nonetheless, Wikipedia has persevered and flourished despite the initial skepticism. Similarly, ChatGPT will continue to propagate and evolve, irrespective of whether we choose to employ it.

To illustrate the power of ChatGPT, I generated my response without the help of ChatGPT, and then I put my response in ChatGPT and asked it to expand on my answer. ChatGPT was able to summarize and expand on what I wrote while maintaining my ideas, focus, and flow. I did edit what ChatGPT generated, and what you read in the previous paragraphs is the result.

Although AI may not yet replace medical writers, medical writers who utilize AI effectively could outperform their peers. AI should be viewed as a tool that complements and enhances our capabilities rather than directly threatening our profession. Adapting to this technology will enable medical writers to capitalize on the opportunities that AI provides while ensuring our continued relevance and success in an increasingly AI-driven world.

—Ruwaida Vakil

* * *

Q2: What ethical considerations need to be taken into account when using ChatGPT for medical writing, particularly in relation to patient privacy and data protection?

Bias, copyright, and informed consent around data use are serious ethical concerns with ChatGPT. AI like ChatGPT is trained on speech, text, and images it scrapes from real-world content that is already in the public domain. Much of this content is structured by an existing inbuilt text and image bias that obscures heterogeneity in terms of gender, race/ethnicity, and other characteristics. Researchers like Timnit Gebru, founder and executive director of the Distributed Artificial Intelligence Research Institute, note that the data that large language models like ChatGPT encode are more likely to represent the perspectives of people who already occupy considerable internet real estate compared with women and people of color, who spend less time and have less access to determining online content. So, the idea starters and writing prompts that initially seem appealing as efficiency levers might already be culturally and racially biased, or at least lack cultural sensitivity and specificity. Unless medical writers are intentionally using ChatGPT and other AI tools through an equity and inequality framework, we will unwittingly reproduce bias.

Copyright implications for both image and text are also pressing. On the one hand, who owns AI-generated material? The US Copyright Office is actively exploring this question via a new initiative, but at the moment, if writers are using generative AI tools to create content, they do not own that content. Also, although many medical writers create content as employees or are bound by work-for-hire contracts, if you use AI-generated content to write blogs or books in your own name, anyone can reproduce it without your permission. On the other hand, although copyright is meant to protect material that is the product of human creativity, various ongoing lawsuits point to the ways in which copyrighted materials are already being used to train AI tools like ChatGPT without attribution, compensation, or credit to their creators.

Another problem concerns the information we, as users, feed into ChatGPT. For instance, some clinicians have posted on social media how they are "testing" ChatGPT's diagnostic capacities by feeding it anonymized history of present illness (HPI) data. Even if HPI data are anonymized, the data enter the public domain and are available to others

without patients giving consent for their own data to be shared publicly.

We cannot be Luddites and push against the tide of technology. AI is going to change communication processes and practices whether we like it or not. But the direction that AI takes is not inevitable. We can and must influence how tools like ChatGPT are applied in practice.

—Alex Howson

I think there are several important ethical considerations to be taken into account with the use of ChatGPT for medical writing. First and foremost, ChatGPT lacks a moral compass. Information that's accessible is information that's usable, whether it is accurate or inaccurate, biased or unbiased, public or confidential. This is of particular concern with respect to protecting patient privacy and proprietary data in medical writing. I'm not a programmer, but it seems to me this challenge is potentially surmountable because the types of information that can reveal a patient's identity are themselves identifiable and should therefore be able to be targeted as "off limits" to ChatGPT. It then becomes the job of reviewers to ensure that sensitive information is edited out of documents before they're published.

Another big ethical consideration with the use of ChatGPT in medical writing is accuracy. ChatGPT has every electronically accessible resource at its disposal from which to develop content, and as we all well know, not all that information is accurate. Furthermore, there's growing evidence that ChatGPT can, and does, lie. This places an additional burden on reviewers to check and double-check ChatGPT's work.

But this brings me to my third big ethical concern regarding ChatGPT: accountability. No one—not even its inventors and keepers—knows how ChatGPT does what it does. Without the ability to question ChatGPT's writing or hold it accountable for what it's written, medical publishing ethicists like the Committee on Publication Ethics (COPE), organizations including the World Association of Medical Editors (WAME), and publishers such as the JAMA Network have all said that AI tools such as ChatGPT cannot be listed as the author of scholarly papers.

Developers have put ChatGPT out there with all its faults and shortcomings, anticipating that real-world experience will teach and improve it. I'm sure it will. However, in a field as reliant upon sound ethical practices as medical communication, I think we currently have too much to lose by putting too much faith in ChatGPT.

—Brian Bass

The 3,000 Springer-Nature journals, Elsevier's 2,800 journals, Taylor & Francis, JAMA Network, WAME (and *British Medical Journal*), and the International Committee of Medical Journal Editors (ICMJE) ban the listing of ChatGPT as an author. The Lancet Digital Health (owned by Elsevier) published a commentary entitled, "Generating scholarly content with ChatGPT: ethical challenges for medical publishing," complete with a response from ChatGPT in its supplementary material on the effect of AI on publishing ethics in medical publishing.

These updated journal guidelines require that authors report the use of ChatGPT during manuscript preparation in the acknowledgement section. The burgeoning popularity of ChatGPT will undoubtedly lead to the development of more policies around its use and increase the importance of using human fact checkers.

—Melissa L. Bogen

* * *

Q3: How can ChatGPT be used to assist medical writers in creating patient education materials, and what challenges need to be addressed in this context?

Despite the caveats I put forth earlier in Question 1, I do feel there may be some interesting uses of ChatGPT in this context. (Assuming, of course, that one maintains personal and professional integrity and does one's own work prior to querying and relying on ChatGPT.)

First, let me point out that I include in the category of "patient education" the following types of medical writing tasks with which I have personal experience—all of these require the simple clear language one should use for patients/consumers:

- Pharma/biotech regulatory affairs: Informed consent forms; lay summaries (plain language summaries); standard operating procedures; and other "instructional documents" for in-house or outside use
- Pharma/biotech med comm, marketing communication, sales, and public relations (corporate communication): Patient education materials of all sorts; slide presentations or other company website information targeted to the general public (and perhaps to investors as well); sales training materials; collateral advertising materials directed toward patients
- Health maintenance organizations or managed care organizations: Letters to members and provider offices explaining services clearly; policies & procedures (P&Ps)
- Hospitals, medical centers, doctors' offices: Patient education materials; website copy intended for the layperson

- Nonprofit health care organizations: Parts of grant applications and their interim reports; patient education fliers for their clients; P&Ps; other medical information documents they may create for their clients
- Medical journalism: Articles for publication in lay magazines and trade journals reporting new information about diseases and medicines; website copy targeted to the layperson

Certainly, there are other areas, but all the mentioned examples require a voice similar to that required for "patient education" materials.

One might use ChatGPT to assist in formatting and organizing a plain language summary—first by asking for samples of various companies' formats for such summaries (some of which are offered on the Food and Drug Administration website and elsewhere, but ChatGPT would offer several samples). This could help an inexperienced medical writer to understand how such summaries are best designed. One might also submit to ChatGPT the summary one has already written and request improvement.

One might submit a less simple example of any of the mentioned documents one has already written and ask ChatGPT to revise it—just to see if the AI program does indeed offer improvement in structure or language (always, of course, being careful not to allow plagiarism to creep in).

The main challenge, it seems to me, relates to discrimination in fact-checking and ensuring that plagiarism has not occurred. Likely there are other caveats, but I have not used the AI program(s) extensively enough to identify other difficulties or challenges.

—Cathryn D. Evans

Additional Information: A Developer Interface

In addition to ChatGPT, OpenAI also has a developer interface available for US $20/month. In a webinar I attended, attendees from a med comm company noted this private interface could be used by pharmaceutical or medical communication companies on behalf of clients. Its advantages are that data could be kept confidential, larger data sets can be uploaded, and the user has more control over the responses. Here are some uses and examples.

The developer interface could generate internal reports from multiple data sources and summarize advisory boards (eg, executive summaries). However, it will be a while before it can be trained to ignore the nonsensical chatter in an ad board transcript.

The developer interface could be trained to act as a medical information chatbot (not for public release). The user could input prescribing information, a clinical study report, and published studies. These data could be used to draft medical letters or answers/replies. The interface could rewrite existing content from, say, a pharmacist geared toward another audience.

The private interface could also provide consistency to omnichannel materials. It could ensure that the information is relevant to different audiences and could repurpose material into new formats (eg, from video to slide deck) much faster than a person could.

But again, with the noted limitations, humans are needed for their thought, judgment, and discernment for accuracy and relevance.

—Melissa L. Bogen

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CONSCIOUS WRITING

3 Common Phrases That Tarnish Credibility in Medical Writing

Crystal R. Herron, PhD, ELS / Redwood Ink, LLC, San Rafael, CA

Credibility is integral to good science. And medical writers support the credibility of science with credible writing. They base their logic on previous findings, clearly describe the methods and results, and distinguish their interpretations from the data. In other words, they show the data and logic to strengthen credibility—and build trust with readers.

But sometimes medical writers use vague language to describe their logic and interpretations. This vague language can undermine the content and tarnish the credibility of the work and the writing.

Although vague language can take many forms in medical writing, 3 phrases stand out as the most common phrases that tarnish credibility: "little is known," "to our knowledge," and "first to show."

LITTLE IS KNOWN

"Little is known" is not a very convincing argument for a few reasons. First, most topics have had many papers published on them, so we likely know a lot about a particular topic. But medical writers are often writing about work that aimed (or aims) to answer an important question, fill a gap, or solve a problem. And that question, gap, or problem is bounded by what is known about the topic. "Little is known" does a poor job of defining a specific question, gap, or problem. If you use this phrase, readers may think that you do not know the literature well or that you are overstating your case.

Second, "little is known" is often preceded or followed by more in-depth descriptions of what is known. These descriptions contradict the case for "little is known." And these contradictions tarnish credibility.

Finally, "little is known" is not clear. A reader may wonder, "How little is little?" Is there only one paper published on the topic? Are there a dozen papers on the topic but none that answer the specific question that this work aimed to answer? Is there an extensive body of literature on the topic, and the work aimed to confirm that a new tool will validate those findings?

To craft a convincing argument, you need to define the specific question, gap, or problem that the work aimed (or aims) to fill.

Example

Avoid: Little is known about how the drug reduces cell proliferation in lung cancer.

Preferred: Although we know that the drug reduces proliferation of A549 cells, we do not know the mechanism by which the gene regulates this process.

TO OUR KNOWLEDGE

"To our knowledge" is also not a convincing statement. This statement implies that others may know certain information, but you may not be aware of it. By using "to our knowledge," you may cast doubt in your reader's mind about whether you really know the literature or field.

What's worse is that "to our knowledge" suggests that you do not want to be held accountable if that information becomes known. This lack of responsibility can damage your reputation and tarnish your credibility and the credibility of the work.

To give readers confidence in the writing and the work, omit "to our knowledge" and only share known information.

Example

Avoid: To our knowledge, researchers have not uncovered how the drug reduces cell proliferation of lung cancer cells.

Preferred: Although we do not fully understand how the drug reduces cell proliferation in lung cancer, researchers have linked the drug to cell mitosis in other cancer cells.

FIRST TO SHOW

"First to show" may seem like a convincing statement. Some writers believe that this phrase highlights the novelty or significance of the work and, therefore, is persuasive. But "first to show" suggests that you know *everything* in the field—published or unpublished. This conviction is difficult to guarantee. Rather than persuade readers, "first to show" may lead readers to perceive that you are overconfident or overstating your case for novelty.

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Unless you are indisputably certain that you are the first to show something, avoid using "first to show" in your writing.

Example

Avoid: We are the first to show that activation of the gene increases proliferation of A549 cells.

Preferred: We showed that activation of the gene increases proliferation of A549 cells.

TRIPLE THREAT TO CREDIBILITY

When used alone, these three phrases—"little is known," "to our knowledge," and "first to show"—can tarnish credibility. Yet, writers often use all three phrases in the same document. They will try to build the case for the work with "little is known," protect their reputation with "to our knowledge," and claim the novelty or significance of the work with "first to show."

But when used together, these phrases can have a cumulative effect that erodes credibility in the writing and in the work.

To support credibility, avoid using all three phrases—alone or together—in your writing.

Example

Avoid: Little is known about how the drug affects plaque formation associated with Alzheimer's disease.... To our knowledge, this study is the first to show that the drug slows plaque formation, reducing the risk of Alzheimer's disease.

Preferred: Although the drug reduces beta-amyloid, we do not know if the drug slows plaque formation associated with Alzheimer's disease.... In this study, we showed that the drug slows plaque formation, reducing the risk of Alzheimer's disease.

MAKE THE CREDIBILITY SHINE

Credibility is key to building and maintaining trust in science. And the phrases you use can strengthen or tarnish that credibility and trust. But with some mindfulness and intention to the phrases you use (or omit), you can polish your writing to ensure that the credibility shines.

Author declaration and disclosures: *The author notes no commercial associations that may pose a conflict of interest related this article.*

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AMWA NEWS

FROM THE PRESIDENT
It's a Journey

Elise Eller, PhD / 2022-2023 AMWA President

It's hard to believe that summer is over, and the 2023 Medical Writing & Communication Conference is coming soon. I am looking forward to being in Baltimore. The conference offers wonderful content, including General Session presentations by our McGovern Award and Alvarez Award recipients. Other articles in this issue of the *Journal* have more information on the 2023 award recipients and what the conference has to offer. I am excited for the opportunity to learn and connect with you there, while also recognizing that the annual business meeting at the conference marks the transition of our governance year.

With my year as AMWA President nearly over, I have been reflecting on how much the organization has accomplished this year. Thanks to the AMWA Board of Directors (BOD), our volunteers, and AMWA staff, we have made great strides with 2 major initiatives that began during the presidency of my predecessor, Katrina Burton.

First, our diversity and inclusion (D&I) initiative continues to move forward. The BOD has engaged a diversity, equity, and inclusion consultant to guide the development of a strategy to implement inclusion, equity, and diversity enhancements throughout the organization. This strategy will include a vision and overarching goals and objectives. Based on the recommendations of the D&I Assessment Task Force, we will develop plans to operationalize those goals, measure outcomes, and create systems to monitor progress and improve our processes. This is a multiyear effort, and I am grateful that the BOD has approved the resources to support this important work.

Second, the new Health Communication Curriculum Development Task Force has begun its work to develop an AMWA health communication curriculum. This initiative will support our efforts to recognize and honor the legacy of Lori L. Alexander, who did so much for AMWA and the medical writing profession at large. Lori had a passion for health literacy and clear medical information and believed that clear communication is essential to scientific research, meaningful patient–health care professional interactions, and better health outcomes. AMWA's expanded health content will include topics such as tactics for creating effective communication about health, science, and medicine; strategies for presenting information on health and medicine to a variety of audiences; how to develop inclusive health communication; the use of inclusive language in medical communication; and health equity and health disparities issues. I thank the task force members for their hard work and for sharing their professional expertise.

I have never seen AMWA do so much at one time. Keep in mind that AMWA has other priorities as well, including organizing the annual conferences, creating and updating educational content and our online learning platform, and enhancing the member experience. I am confident that these initiatives will strengthen the organization. In addition, the BOD already has a list of future initiatives to consider. The continuous work to improve organizational effectiveness, promote excellence in medical communication, and increase member value never ceases… It's a journey.

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AMWA NEWS

Officer Candidate Slate for the 2023-2024 Election

R. Michelle Sauer Gehring, PhD, ELS / 2022-2023 AMWA President-Elect

This year, I am honored to serve as President-Elect for the American Medical Writers Association. As such, I chair the Nominating Committee, which is charged with selecting a slate of officers for the upcoming governance year. Each year, any interested AMWA member is invited to submit a board interest form for consideration of 1 of 3 elected offices: President-Elect, Secretary, and Treasurer. The Nominating Committee reviews the forms and qualifications of candidates who meet the criteria and collectively agrees on a candidate for each officer position to submit to the AMWA Board of Directors (BOD) for consideration.

I want to extend my gratitude to those who volunteered their time and expertise to serve alongside me as committee members:

- Cyndy Kryder, MS, MWS
- Tenille L. Lawson, PharmD, BCPS
- Brian Bass, MWC
- Gail V. Flores, PhD
- Theresa E. Singleton, PhD
- Leslie Nielstat, ELS
- Susan Krug, MS, CAE (ex officio, nonvoting member)

This year's committee consists of past AMWA presidents and board members as well as members who have served in leadership positions in the medical communication field. We received multiple strong applications for the executive committee, and the Nominating Committee's insightful feedback and critical analysis allowed for robust discussion and a strong slate of officer candidates.

I respectfully present the following candidates who were presented to and approved by the AMWA BOD at the June BOD meeting:

- **President-Elect:** Shawn Watson, PharmD, PhD, BCPS, RPh, BSPharm
- **Secretary:** Kimberly Korwek, PhD
- **Treasurer:** Julie Phelan, MBA, MD

PRESIDENT-ELECT

Shawn Watson, PharmD, PhD, BCPS, RPh, BSPharm, has been an AMWA member since 2012. He has served on the board as a Director at Large since 2019. Shawn has served on the Diversity and Inclusion Assessment Task Force and as the Liaison for the Engage Committee. He has assisted with the virtual conferences and publications on salary surveys. Dr Watson has also served on the National Nominating Committee (2018-2019) and the National Educational Committee (2018-2019). At the chapter level, Shawn served as President (2017-2018), Immediate Past President (2018-2019), and Chapter Delegate (2015-2017) of the New England Chapter; he also served on the Chapter Nominating Committee from 2017 to 2019. Shawn has authored or contributed to multiple *AMWA Journal* articles and has led roundtables and sessions at the chapter and national conference level. Shawn is currently a Senior Director of Clinical Development, Program Team Lead, and Interim Head of Medical Writing at Recursion Pharmaceuticals.

SECRETARY

Kimberly Korwek, PhD, an AMWA member since 2010, has been on the AMWA BOD for 4 years. She is currently the 2022-2023 Secretary. She previously served as the Chair of the 2022 Annual Conference Program Committee. During the 2019 2020 term, she served as the Chapter Advisory Council Chair on the BOD, and prior to that, she was a member of the Chapter Advisory Council (2017-2019). From 2016 to 2019, she was a section editor, serving on the Editorial Board for the *AMWA Journal*. Kim

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was President of the AMWA Southeast Chapter (2016-2017), serving previously as President-Elect (2015-2016). She also served as a Chapter Delegate to the AMWA Board (2016-2017) and the Website Coordinator for the Southeast Chapter (2018-2019). Kim is the Manager of Scientific Communications within the Clinical Operations Group of HCA Healthcare. In this role, she is responsible for the management of the portfolio of comparative effectiveness research projects that seek to use data collected within the course of clinical care to improve health care delivery and patient outcomes. Kim also manages the development of scientific publications, including manuscripts, abstracts, presentations, and white papers, to facilitate the distribution of research findings to internal and external audiences.

TREASURER

Julie Phelan, MD, MBA, an AMWA member since 2009, is in her seventh year as Treasurer on the BOD and as Chair of the Budget & Finance Committee (2016-2023). She was previously a member of the Budget & Finance Committee (2015-2016), the Communications Committee (2014-2015), the 2015 Salary Survey Task Force, and the Online Community and Social Media Committees (2012-2014). At the chapter level, she was President of the Greater Chicago Area Chapter (2013-2016), serving previously as President-Elect (2012-2013). She also served as Membership Chair for the chapter (2011-2015) and as a Chapter Delegate to the Board (2013-2016). She has authored articles for the *AMWA Journal* and currently serves as AMWA's Registered Agent. She was awarded an AMWA fellowship in 2017. Julie is the Founder and President of Biomedisys, Inc, a medical communication and strategy consulting boutique in Chicago, IL. She has more than 20 years of medical communication and business strategy experience, including working as a Biotechnology Equity Research Associate Analyst at Robert W. Baird & Co, Medical and Strategic Advisor for an insurance corporation, and Medical Communication Consultant.

PROCEDURE FOR ADDITIONAL NOMINATIONS

As required by AMWA's Bylaws (Article IV.2e-f), these nominations were announced to the AMWA community by email more than 60 days before the annual business meeting. A nominee who is unopposed for any office is declared automatically elected at the annual business meeting. As stated in the bylaws, additional nominations for President-Elect, Secretary, or Treasurer may be made by any member provided the member meets the criteria set forth by the BOD. The criteria and process are listed as follows:

- Member dues must be current, and the member must be in good standing.
- The nomination must be submitted in writing to the Secretary of AMWA at least 30 days in advance of the annual business meeting. This year's annual business meeting is scheduled for October 28, 2023.
- The nomination must clearly state the qualifications of the candidate and be signed by 50 members in good standing as of the date of the receipt of the nomination.
- The nomination must be accompanied by a letter from the candidate stating that they are willing to serve if elected.

Author declaration and disclosures: *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

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AMWA NEWS

AMWA Fellowships for 2023

Abbie Miller, MWC / 2022-2023 Chair, Member Awards Recognition Committee

AMWA Fellowships are awarded to members in recognition of their significant contributions to the goals and activities of AMWA. The 2023 Fellows are leaders within AMWA with distinguished service at chapter and national levels.

Barbara O. Lightfoot

Barbara O. Lightfoot has been an AMWA member since 2009 and has served in many positions in the Indiana Chapter, including president-elect, president, secretary, treasurer, education committee co-chair, and program chair. In 2019, she received the Indiana Chapter Leadership Award.

At the national level, Barbara has served as a chapter delegate to the AMWA Board of Directors (BOD), a member of the National Chapter Advisory Task Group, and a chapter representative on the national Chapter Advisory Council. She has also given presentations at local chapter educational events and Indiana/Ohio Valley AMWA Conferences.

Currently, Barbara is a manager in Science Communication and Regulatory at Eli Lilly and Company.

Anita Misra-Press

Anita Misra-Press, PhD, attended her first AMWA meeting in 2010 and has since been an active and engaged member. Anita served in many positions in the Northwest Chapter before it dissolved, including president, president-elect, treasurer, and chapter delegate. She also served on and led several chapter workgroups.

At the national level, Anita is an active member of the AMWA Constitution and Bylaws Committee. She has led roundtables and educational sessions for the AMWA Conferences and contributed to the *AMWA Journal* as a peer reviewer. Despite the loss of her chapter, Anita has remained active and has continued to seek out meaningful contributions.

Anita has worked as a freelancer for 13 years.

Shawn Watson

Shawn Watson, PharmD, PhD, BCPS, RPh, has been an AMWA member since 2012. At the chapter level, Shawn served as president, immediate past president, and chapter delegate of the New England Chapter. He also served on the Chapter Nominating Committee.

Shawn has served on the board as a director at large since 2019. As a director at large, he has served on the Diversity and Inclusion Task Force and as the liaison for the Engage Committee. He has assisted with virtual conferences and publications on salary surveys. Shawn has also served on the National Nominating Committee and the National Educational Committee. He has authored or contributed to multiple *AMWA Journal* articles and has led roundtables and sessions at the chapter and national conference levels.

Shawn is currently a senior director of Clinical Development, program team lead, and interim head of Medical Writing at Recursion Pharmaceuticals.

Please join AMWA in congratulating Barbara, Anita, and Shawn as they receive their awards this fall at the Medical Writing & Communication Conference in Baltimore, MD.

The Member Awards Recognition Committee members were Abbie Miller, MWC (chair), Loretta Bohn, ELS (BOD liaison), Elizabeth Brown, MS, PMP, Joanne McAndrews, PhD, Christina Barnes, MSN, RN, CPNP-PC, Jerm Day-Storms, PhD, MWC, and Susan Aiello, DVM, ELS. Diane Noland served as staff liaison, and Susan Krug, MS, CAE, served as ex officio.

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AMWA NEWS

2023 John P. McGovern Award Recipients Jessica B. Steier, DrPH, PMP, and Andrea C. Love, PhD

Elise Eller, PhD / 2022-2023 AMWA President

The John P. McGovern Award is named in honor of John P. McGovern and is presented to a member or nonmember of AMWA to recognize a preeminent contribution to any of the various modes of medical communication. The McGovern Award is presented during AMWA's Medical Writing & Communication Conference.

One of the perks of being the AMWA president is selecting the recipient of the McGovern Award. I am thrilled to announce that our 2023 McGovern Award recipients are Dr Jessica Steier and Dr Andrea Love in recognition of their work to communicate science on social media and via their *Unbiased Science* podcast, which critically appraises available evidence on health-related topics relevant to the public in an approachable way.

Dr Steier and Dr Love began their *Unbiased Science* podcast during the pandemic as a way to counter misinformation and misconceptions about COVID-19. The podcast has expanded to other topics, ranging from mammograms to vaping to health and wellness trends on social media. The podcast has a Substack as a permanent repository of their sources, allowing their audience to delve into the details and reliably return to content. For those of you into infographics, you should check out their unbiasedscipod Instagram, which has a wealth of health-related infographics.

In addition, Dr Steier and Dr Love's work involves training the next generation of science communicators. Their Unbiased Science team includes several interns who do research and infographic design. Furthermore, Dr Steier and Dr Love have founded the Unbiased Science Institute to improve science literacy, help people be better consumers of scientific information, and train the next generation of science communicators. The institute works with public health leaders, students in science, technology, engineering, and math, and community organizations, and its programs include education, training, and community engagement to build health and scientific literacy.

Figure. Dr Andrea C. Love (left) and Dr Jessica B. Steier (right), cofounders of the Unbiased Science podcast and the Unbiased Science Institute.

Although Dr Steier and Dr Love work on health issues in different ways—macro (public health) and micro (immunology/microbiology), respectively—their areas of expertise enable them to provide a comprehensive perspective on various scientific topics. Please join me in congratulating our 2023 McGovern Award winners, and I hope you join me in hearing their talk at the 2023 Medical Writing & Communication Conference in Baltimore.

Dr Jessica Steier is a public health scientist with expertise in public health policy, biostatistics, and advanced analytics. Dr Andrea Love is an immunologist and microbiologist, with expertise in infectious disease immunology, cancer immunology, and autoimmunity. Dr Steier and Dr Love believe strongly in scientific education and health literacy and the translation of research for the general public, and their Unbiased Science podcast is devoted to the objective, critical appraisal of available evidence on science and health-related topics relevant to listeners' daily lives.

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AMWA NEWS

2023 Walter C. Alvarez Award Recipient Katelyn Jetelina, PhD, MPH

Michele W. Sequeira, MS, MBA, MWC / 2023 Annual Conference Committee Chair

The Walter C. Alvarez Award is bestowed on a member or nonmember of AMWA to recognize excellence in communicating health care developments and concepts to the public.

As chair of the 2023 Annual Conference Committee, I have the honor of bestowing this year's Walter C. Alvarez Award upon Katelyn Jetelina, PhD, MPH.

Like many of us, Dr Jetelina discovered her love for writing and for sharing scientific concepts with the public almost by accident. In 2020, during the COVID-19 pandemic, she worked as a senior scientific consultant at Meadows Mental Health Policy Institute, a nonpartisan health policy think tank, and she also consulted with several organizations, including the US Centers for Disease Control and Prevention.

But at night, after her children went to sleep, Dr Jetelina started writing about public health science. Her passionate work to bridge the communication gaps between the public, patients, doctors, and researchers led to a newsletter to help ordinary people be "well equipped to make evidence-based decisions."

And what started as a side hustle driven by passion and compassion grew over the next 3 years. Dr Jetelina's Substack publication, "Your Local Epidemiologist," now reaches more than 190,000 subscribers in 126 countries.

Now renowned for translating public health science into everyday language, Dr Jetelina is taking a break from her scientific work. She is focusing full-time on processing and translating scientific knowledge for the public.

Dr Jetelina's newsletter topics range from infectious diseases and vaccines to reproductive health and violence to mental health and public health emergencies. The thread that runs through them all is her clear explanation of statistical analysis that transforms the profound scientific ideas into understandable chunks of information and actionable suggestions.

Please join me in congratulating Dr Jetelina, our Walter C. Alvarez award winner, and listening to her talk on Saturday, October 28, at the 2023 Medical Writing & Communication Conference in Baltimore.

Dr Jetelina's newsletter topics range from infectious diseases and vaccines to reproductive health and violence to mental health and public health emergencies.

Author declaration and disclosures: *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

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AMWA NEWS

2023 Harold Swanberg Distinguished Service Award Recipient Joan Affleck, MBA

Abbie Miller, MWC / 2022-2023 Chair, Member Awards Recognition Committee

Named in honor of one of the founders of AMWA, the Harold Swanberg Distinguished Service Award is given to an active member who has made distinguished contributions to medical communication or rendered unusual and distinguished services to the medical profession.

This year's award goes to Joan Affleck, MBA. Her contributions to the field of medical writing have impacted not only AMWA but also organizations and individuals around the globe.

Joan is an associate vice president at Merck & Co, Inc, where she leads the Medical Writing Department. She earned her MBA from Columbia University in New York, where she is a Lang Center Innovation Fellow and a regular guest lecturer.

Over the past 25 years, Joan has built several medical writing departments from the ground up in the United States, Europe, Asia, South Africa, and South America. These experiences in pharma, biotech, and contract research organizations give her a broad and international perspective of medical writing. Beyond the influence of her skills on organizations at large, her leadership and interpersonal skills have supported, encouraged, and molded many individual medical writers in their professional journeys.

Joan has used her adaptive global leadership experience to help support AMWA's strategic planning, development of innovative solutions, and prioritization of key needs. As chair of the Executive Council from 2018 to 2021, Joan led medical writing leaders to develop Executive Forum events and projects. In 2019, upon Joan's recommendation, AMWA formed a Workforce Training Committee to identify the educational content needed to prepare and develop the careers of medical communicators in pharmaceutical and biotechnology settings and to provide guidance on the development of new educational content. In 2020, Joan received the AMWA President's Award, and she has been a member of the Board of Directors since 2021. Joan was

also instrumental in conceiving and implementing the Value of Medical Writing Work Group. This group has worked diligently to define and quantify the value of medical writing, producing numerous peer-reviewed publications in support of the medical writers' role in the industry.

Joan has had an active role in shaping the evolution of medical writing over the last 2 decades, and her leadership has extended beyond AMWA and her employers to help the field at large. She has served as an advisor to the Healthcare Businesswomen's Association and is a member of the University of Virginia Darden School of Business Leadership Communication Council.

Join AMWA in congratulating Joan when she receives her award this fall at the Medical Writing & Communication Conference in Baltimore, MD.

The Member Awards Recognition Committee members were Abbie Miller, MWC (chair); Loretta Bohn, ELS (Board of Directors liaison); Elizabeth Brown, MS, PMP; Joanne McAndrews, PhD; Christina Barnes, MSN, RN, CPNP-PC; Jerm-Day Storms, PhD, MWC; and Susan Aiello, DVM, ELS. Diane Noland served as staff liaison, and Susan Krug, MS, CAE, served as ex officio.

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AMWA NEWS

2023 Golden Apple Award Recipient Hope Lafferty, AM, ELS

Abbie Miller, MWC / 2022-2023 Chair, Member Awards Recognition Committee

The Golden Apple Award is given to an AMWA member in recognition of their consistent and outstanding excellence in leading AMWA workshops.

This year's Golden Apple recipient is Hope Lafferty, AM, ELS. Hope joined AMWA in 2003 and has been leading workshops, roundtables, and hands-on intensives since 2009. She has taught 14 workshop sessions spanning 3 workshop curricula for AMWA. Participants in her workshops consistently give Hope high ratings and excellent feedback.

Hope's involvement in AMWA is truly on a national scale. Beyond her national conference workshop leadership, she's served 2 terms as the annual conference workshop coordinator and participated in the education committee. She also has been a member of at least 5 chapters, and in chapters where she wasn't a member, she has led workshops and talks at AMWA chapter events.

Her dedication to learning, teaching, and growth is evident in her career path and contributions. Hope received her certificate in medical writing and editing from the University of Chicago—where she also received her master's degree specializing in group psychotherapy and cognitive-behavioral therapy. She is a past president of the Board of Editors in the Life Sciences and has served on the editorial board of the last 2 iterations of the *AMA Manual of Style*. Hope is a faculty member of the medical writing certificate program at the University of California, San Diego. The bulk of her medical communication work centers on the academic and research space—with 100% of the grants on which she worked receiving fundable scores.

In 2015, Hope made a career pivot by stepping out from behind the desk to teach communication skills, scientific writing, public speaking, and leadership. In 2016, she received her training certificate from the Association for Talent Development. In 2020, Hope completed the Habit Finder coaching program, which is the foundational work behind this year's AMWA Medical Writing & Communication Conference intensive, "How to Think Like a Leader." Hope also holds instructor member status at the Robert S. Hartman Institute, a nonprofit that focuses on value theory, which is the math and science behind the Habit Finder assessment and Hope's work as a coach. Hope made another career pivot—from writer and coach to playwright and performer—which led her to enroll in the Professional Training Program at the Dell'Arte International School of Physical Theatre at the age of 57. In 2019, Hope qualified to join the Dramatists Guild of America, the lead professional organization for playwrights and lyricists, and is an individual member of the American Association of Community Theatre. She is currently touring 2 solo shows across North America.

Please join AMWA in congratulating Hope as she receives her award this fall at the Medical Writing & Communication Conference in Baltimore, MD.

The Member Awards Recognition Committee members were Abbie Miller, MWC (chair); Loretta Bohn, ELS (Board of Directors liaison); Elizabeth Brown, MS, PMP; Joanne McAndrews, PhD; Christina Barnes, MSN, RN, CPNP-PC; Jerm-Day Storms, PhD, MWC; and Susan Aiello, DVM, ELS. Diane Noland served as staff liaison, and Susan Krug, MS, CAE, served as ex officio.

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AMWA NEWS

2023 President's Award Recipient Don Harting, MA, MS, ELS, CHCP

Elise Eller, PhD / 2022-2023 AMWA President

The recipient of the President's Award is selected by the AMWA President, and each year this award is bestowed upon a member of AMWA who has made distinctive contributions to the association at the chapter or national level.

I am honored to recognize Don Harting, MA, MS, ELS, CHCP, as the recipient of the 2023 AMWA President's Award. Don is a professional medical writer with master's degrees in journalism and biology, 20 years of experience in print journalism, and 15 years of experience in continuing medical education (CME) writing. He is also a board-certified editor in the life sciences (ELS) and a certified health care CPD professional (CHCP). Don is the president of Harting Communications LLC and specializes in developing needs assessments for education grant proposals and instructional content for accredited continuing education in the health professions. Since 2008, he has worked with many accredited CME providers as well as nonaccredited medical education companies to win more than $4.8 million in education grants, mostly in oncology.

A dedicated CME professional, Don has published original, collaborative research on best practices for writing needs assessments and shared his results in the *AMWA Journal* and as posters, workshops, and a mini-tutorial for AMWA members. Currently, Don and several collaborators are developing the first-ever competency model for the next generation of medical writers who wish to excel in developing content for continuing education in the health professions. The new CME writers' competency model will be presented at this year's Medical Writing & Communication Conference in Baltimore.

A member of AMWA since 2007, Don has been involved in the Delaware Valley Chapter in a variety of roles and currently serves as programs chair. He notes that during the pandemic, he was instrumental in helping the chapter transition to Zoom meetings for networking events, and he and the other attendees learned how to use the breakout room feature together. At the Delaware Valley's in-person chapter conference this year, Don organized a panel discussion on training the next generation of medical writers. Don has also served on several committees at the national level, including the certification task force.

When I reached out to Don to congratulate him on receiving this award, he said, "I would just like to remind readers (including myself!) of what we already know: AMWA is a wonderful, well-built organization, and its future will be what we make it. Our profession depends on people helping people, and not always in ways that yield direct financial benefits. If we give generously, AMWA will gain strength, and we will all benefit. If we withhold our gifts, AMWA will weaken, and we will all suffer. So, let's all encourage each other to keep volunteering and giving back to our profession through AMWA. We'll be glad we did!"

I couldn't agree more. Thank you, Don, for your passion for CME, your expertise, and your support of AMWA.

It is my pleasure to present Don with this well-deserved honor for his contributions to AMWA and to the medical writing and editing profession at large. Please join me in congratulating Don as this year's President's Award recipient.

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2023 CONFERENCE PREVIEW

Continuous Learning and Connection at the 2023 Medical Writing & Communication Conference

Michele W. Sequeira, MS, MBA, MWC / 2023 Annual Conference Committee Chair

Before you know it, the AMWA 2023 Medical Writing & Communication Conference will be here. This year's conference is scheduled for October 25 through 28 in Baltimore, Maryland, just an hour's drive from AMWA's home offices. Register now for the conference at the Annual Conference website (https://www.amwa.org/page/conference).

The Annual Conference Committee has worked hard to pack the schedule with a variety of different topics in scientific communication, regulatory writing, health communication, and more. From educational sessions, workshops, posters, speed networking sessions, and roundtables to new learning modes such as vendor showcases and learning circles, the conference will offer something for beginner, intermediate, and experienced medical communicators. We'll also have breaks and snacks to keep attendees refreshed.

Be sure to stick around until the end to listen to all our excellent speakers. This year's McGovern Award winners are the team of Dr Jessica Steier and Dr Andrea Love, and the Alvarez Award winner is Dr Katelyn Jetelina. All are making important contributions to bring medical science to lay audiences and will share their great insights on the importance and role of medical communicators.

One of the best features of these conferences is the ability to meet and socialize in person with other medical communicators from around the country. Networking sessions, breaks, sunrise walks, and dinners offer attendees ample opportunities to meet each other. Attendees come from a variety of backgrounds, and we bring vastly different experiences to our medical communication. (I myself have had a long, nonlinear career path.) Learning from each other can take place in any moment, with anyone, at the conference. I've received some of the best insights and advice about medical communication during relaxed conversations over breaks and dinners.

Thankfully, Baltimore has plenty of attractions—or distractions—to help attendees enjoy some downtime, too. The conference schedule will allow for visits to the city to take in the historic sites, museums, and oceanfront scenery.

I encourage you to take advantage of your time in Baltimore, and I hope to connect with you at the 2023 Annual Conference.

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CALENDAR OF MEETINGS

Council for Programs in Technical & Scientific Communication
"2023 CPTSC Conference"
September 22-23, 2023, Charleston, SC
https://conference.cptsc.org/

American Copy Editors Society/ACES: The Society for Editing
"VCON23"
September 27-29, 2023, Virtual
https://aceseditors.org/conference/vcon23-central

Plain Language Association International
"Connecting Cultures: Creating Bridges with Clear Communication"
September 27-29, 2023, Buenos Aires, Argentina
https://plainlanguagenetwork.org/conferences/2023-buenos-aires-argentina/

International Society for Medical Publication Professionals
"ISMPP Academy: PREP! Practical Resources to Elevate Publications"
September 28-29, 2023, Philadelphia, PA
https://whova.com/web/sBiNx2Ue7Txb9UYY4biTSgqEUaBq69mvUmfDult4edA%3D/

Society of Clinical Research Associates
"2023 Annual Conference"
September 29-October 1, 2023, Montreal, Quebec, Canada
https://www.socra.org/annual-conference/2023/2023-annual-conference-information/

Regulatory Affairs Professionals Society
"RAPS Convergence 2023"
October 3-5, 2023, Montreal, Quebec, Canada
https://www.raps.org/events/raps-convergence-2023

National Association of Science Writers
"ScienceWriters2023"
October 6-10, 2023, Boulder, CO
https://www.nasw.org/events/nasw-science-writers-national-conference-sciwri23-annual-meeting-2023-boulder-colorado

Academy of Communication in Healthcare/International Association on Communication in Healthcare
"International Conference on Communication in Healthcare"
October 22-25, 2023, Rio Mar, Puerto Rico
https://www.achonline.org/ICCH2023

Regulatory Affairs Professionals Society
"RAPS European Clinical and Risk Management Conference"
October 24-26, 2023, Brussels, Belgium
https://www.raps.org/events/raps-european-clinical-and-risk-management-conference

American Medical Writers Association
AMWA Medical Writing & Communication Conference
October 25-28, 2023, Baltimore, MD
https://www.amwa.org/page/Conference

Drug Information Association
"DIA Japan 2023"
November 5-7, 2023, Ariake, Japan
https://www.diaglobal.org/en/flagship/dia-japan-2023

Drug Information Association
"DIA Canada Annual Meeting"
November 7-8, 2023, Gatineau, QC, Canada
https://www.diaglobal.org/en/conference-listing/meetings/2023/11/canada-annual-meeting

European Medical Writers Association
"56th EMWA Conference"
November 9-24, 2023, Virtual
https://www.emwa.org/conferences/future-conferences/

American Public Health Association
"APHA 2023 - Creating the Healthiest Nation: Overcoming Social and Ethical Challenges"
November 12-15, 2023, Atlanta, GA
https://www.apha.org/events-and-meetings/annual

AFDO/RAPS Healthcare Products Collaborative
"Artificial Intelligence Summit"
November 14-16, 2023, Cincinnati, OH
https://www.raps.org/events/artificial-intelligence-summit-11-2023

AFDO/RAPS Healthcare Products Collaborative and the Food and Drug Administration
"Combination Products Summit 2023"
November 28-December 2, 2023, Fort Worth, TX
https://www.raps.org/events/combination-products-summit-2023

International Society for Medical Publication Professionals
"2024 European Meeting of ISMPP"
January 23-24, 2024, London, UK
https://www.ismpp.org/european-meeting

Alliance for Continuing Education in the Health Professions
"The Alliance 2024 Annual Conference"
February 5-8, 2024, New Orleans, LA
https://www.acehp.org/Your-Learning/Events

American Association for the Advancement of Science
"Toward Science Without Walls"
February 15-17, 2024, Denver, CO
https://meetings.aaas.org/

Drug Information Association
"DIA Europe 2024"
March 12-14, 2024, Brussels, Belgium
https://www.diaglobal.org/en/flagship/dia-europe-2024

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2023 AMWA

Medical Writing & Communication Conference

OCTOBER 25-28, 2023
BALTIMORE, MD

Trends and Opportunities for Medical Communicators

REGISTER NOW

AMWA 2023

Your home for continuous learning and connection.

Join us October 25-28, 2023 in Baltimore, MD.

#AMWA2023 education sessions will include expert advice, relevant research, and engaging discussions on timely topics:

- The value of medical communication
- Advances in regulatory writing
- Excellence in scientific publications
- Health communication strategies
- Preparing the next generation of medical writers
- Technology and innovation in medical communication
- Trends in medical grant writing and editing
- The medical communicator's role in diversity, equity, and inclusion

Explore the Program

https://www.amwa.org/conference