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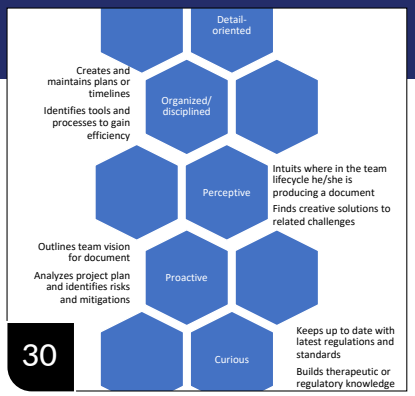

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In support of the mission of the American Medical Writers Association (AMWA) and to advance the broader profession, the *AMWA Journal* publishes content that reflects the interests, concerns, and expertise of medical communicators. Its purpose is to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

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FROM THE EDITOR & GUEST EDITOR

Communicating Science

Michael G. Baker, PhD, Editor-in-Chief and Thomas M. Schindler, PhD, Guest Editor

Michael G Baker, PhD
Editor-in-Chief

Thomas M. Schindler, PhD
Guest Editor

These are good times to be a medical communicator! Science keeps growing and so does the number of scientific publications. In the life sciences, the number of publications increases over 5% every year and the total number of publications doubles every 14 years.[1] This reflects the growing number of scientific articles intended for fellow scientists and peers. With the increasing involvement of medical writers in the preparation of manuscripts, this growth provides a multitude of opportunities for professional medical communicators. Thus, medical writers are part of a larger voice of researchers, medical practitioners, educators, and journalists who are conveying advancements clearly and objectively.

The audience many medical writers may primarily serve is the scientific/medical community. However, there is a growing demand of society at large and of patients in particular that the science they support with their taxes and with their out-of-pocket expenses is explained to them. They want to know what scientists work on and what relevance their work has. They want to understand why a new drug that comes at a higher price is apparently better than established cheaper products. With the growing demand of informing nonspecialists and the public comes an additional responsibility for medical communicators. We need to continue finding and defining best practices in communicating science to nonexpert audiences.

Although science is growing, there is a concerning percentage of society that mistrusts scientific expertise. Bubbles have emerged in which misinformation is spread, and opinions are presented as facts, particularly via social media. In this situation, medical communicators need to lend themselves to the struggle for objective and honest content and presentation. Communicating to the public needs to be embedded in a framework of sound ethical principles.

At a practical level, as medical communicators, we must continue to do our part by valuing the scientific method as the path toward advancements in our understanding of medicine, holding ourselves to high ethical standards, being mindful of potential personal biases while relentlessly striving toward objectivity, and ensuring our written contributions are always clear, precise, and complete. This applies whether our audience is a medical researcher or practitioner, student, regulatory body, patient, or the public at large.

In recognition of the growing importance of our role as medical communicators in conveying factual scientific information to our varied audiences, the theme for the summer 2022 issue of *AMWA Journal* is Communicating Science. In this issue, we tackle several topics relevant to our role in communicating science to our audiences, including

- the value of generating plain language summaries of scientific publications to help patients and other nonspecialists to understand the potential implications of clinical and medical research,
- the making of good lay summary practice guidance to help the public understand the results of clinical trials, and
- a proposed systematic approach to writing a scientific manuscript to increase the likelihood it will be used to further advance biomedical knowledge.

We are hopeful you will find the information in this issue helpful to you in your ongoing role in communicating science.

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V37 N2 / 2022

THEME ARTICLE

Generating Plain Language Summaries of Scientific Publications with Ethical Foundations: A Practical "How-To" Guide Cocreated with Patients

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ABSTRACT

Peer-reviewed scientific publications are written by scientists with peers in mind. However, there is a growing demand of patients and other nonspecialists to understand the potential implications of clinical and medical research. Research summaries of scientific articles in easy-to-read language—called plain language summaries (PLS)—are currently being developed to broaden the reach of scientific articles beyond expert audiences. While PLS can help nonexperts to understand and be informed about scientific articles, there is a risk that PLS contribute to publication bias and hence misinformation of patients and the public and thus achieve the opposite of their intention. Potential issues are an unbalanced selection of the scientific source articles for which a PLS is initiated, lack of alignment of the data presented in the PLS and in the source article, unbalanced reporting of efficacy and safety data, absence of reporting the primary endpoint, or over- or underreporting of secondary endpoint results. To objectively inform patients and to become a trustworthy source of information, the writing of PLS needs to be firmly embedded in a set of ethical principles. To safeguard balanced and fair PLS writing, the cocreated "How-To" Guide on PLS writing developed by the Patient Focused Medicines Development initiative comprises a set of 15 ethical considerations. These include the necessity for objective reporting, the need for balanced presentation, the importance of audience focus, the need to apply health literacy principles, and the importance of using inclusive and respectful language. The "How-To" Guide was developed in a stepwise process with several rounds of cocreation, public consultation (two rounds), internal review, and a final external review. The iterative development process ensured input from a wide variety of stakeholders (patient representatives, industry members, publishers, researchers, medical communications agencies, and public officials involved in research bodies). The final "How-To" Guide is a standalone, practical, ready-to-use tool to support multistakeholder cocreation of PLS.

Peer-reviewed scientific publications are the established channels through which researchers share results and data with their peers. These communications are typically written by scientists with peers and fellow experts in mind and are characterized by extensive use of technical language and complex graphical representations. Scientific articles are therefore often impenetrable for nonspecialist audiences. On the other hand, patients, patient organizations, and other nonexperts want to be informed about scientific research results that may impact on them or to whose generation they have contributed, eg, as participants in clinical trials or by anonymously being a included in health resource use study. Patients and their caregivers want to know what the research activity may mean for them and the conditions they are living with.[1-3]

Plain language summaries (PLS) are summaries of scientific articles written in easy-to-read, nontechnical language. They have the potential to increase the understanding of scientific data by making complex information more accessible to wider audiences. This includes patient organizations, patients, caregivers, healthcare professionals from different fields, and the public.[4-6] By improving knowledge and understanding of clinical research, PLS may facilitate patient–physician communication that could contribute to shared decision-making. Importantly, PLS are only of value when facts, numbers, and conclusions are conveyed truthfully and objectively, without promotional intent or spin. PLS can only fulfil their objectives if readers can fully trust that all relevant data—including information on the uncertainty of research conclusions—have been made available to them. Thus, the writing of PLS needs to be based on ethical considerations and requires a documented institutional framework.

The number of PLS associated with peer-reviewed publications is still relatively low, and there is currently wide variation in content, format, quality, and location (i.e., where people can access them) of PLS.[7] Efforts are

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ongoing to provide guidance, and minimum standards for PLS have recently been proposed.[8-10] However, previous guidelines do not address the need of ethical considerations for the generation of PLS nor do they provide guidance on cocreation with the target audience.

In line with key ethical principles formulated in the Declaration of Helsinki[11] that have become the basis for all clinical research in humans, members of the science communication continuum, ie, researchers, authors, sponsors, editors, and publishers, share the obligation to appropriately and ethically share the results of research (principle 36).

An ethical key consideration for PLS writing that expresses respect for potential and enrolled subjects of clinical research is the aspect of cocreation. PLS should be prepared in collaboration with members of the target audience to achieve an optimal outcome in respect to adequacy of content and presentation.[12] However, in current practice, patient involvement is often restricted to the late stages of PLS development, for example the review process.

The need for a practical "how-to" guidance that will ensure both ethical considerations and early involvement of patients was recognized by Patient Focused Medicines Development (PFMD).[13]

PFMD is a collaboration of health stakeholders, including publishers, patient organizations, and pharmaceutical companies, whose aim is to facilitate patient engagement (PE) across the medicine development lifecycle.

COCREATION OF THE "HOW-TO" GUIDE

For the development of the "How-To" Guide on PLS, an international working group was established, and members were required to have PE experience and/or expertise in generating PLS. The "How-To" Guide was developed in a stepwise approach using established cocreation methodology.[14-16] This included several rounds of cocreation, public consultation, internal review, and an external review. Feedback from each step in the review process was used to refine the draft "How-To" Guide, which was then validated through additional consultation. The first round of public consultation focused on the content, while the second public consultation gathered feedback on the usability and the associated user experience; a detailed description of the process is provided by Dormer et al.[17]

Ethical Considerations for PLS Writing

According to the Declaration of Helsinki,[11] a universally accepted ethical standard for medical research in humans, researchers, editors, and publishers have ethical obligations regarding the publication and dissemination of the results of research (principle 36). These actors in the biomedical communication continuum are accountable for completeness and accuracy of their reports and that negative and inconclusive as well as positive results are published or otherwise made publicly available (principle 36). Compliance with ethical principles is particularly relevant for PLS because they are intended for patients and nonexperts who are likely lacking the expertise to detect potential methodological flaws in scientific publications. In this regard, patients, caregivers, and other nonexperts constitute a vulnerable group that needs to be protected from harm inflicted by misinformation. While scientists are trained in presenting research in a structured way, the common format is alien to most patients and nonexperts. Hence, authors, editors, and publishers have the obligation to minimize the potential for misunderstanding of scientific results that are presented in PLS. This is supported by the 15 ethical considerations included in the "How-To" Guide.

The considerations cover the necessity for objective reporting, the need to apply health literacy principles, the importance of audience focus and the absence of any promotional intent, the need for balanced presentation, and the importance of using inclusive and respectful language. It is also essential for both sponsors and journals to have a consistent policy for the development and publishing of PLS. This means there should be transparent, prospective, and objective selection criteria for choosing publications from which to develop PLS and for deciding how and when they will be published to prevent publication bias. For example, one criterion from a sponsor could be a commitment to producing PLS for all phase 3 trials, regardless of outcomes. PLS on single trials need to include a disclaimer on the limitations and generalizability of the results. Details on the ethical principles are provided in Table 1.

Table 1. Ethical Considerations for PLS Writing

Any statement in the PLS should be objective and aligned with the data provided in the scientific publication.
Health literacy and numeracy principles should be applied in the writing and design of the PLS.
The choice of words should be neutral and factual. Superlative and emotional words, phrases, and metaphors should be avoided.
The PLS should be free of any commercial bias and must be strictly nonpromotional.
For PLS linked to primary scientific publications of clinical trials, there should be a balanced presentation of efficacy and safety data.
The overall objective (ie, the primary objective) of the research that is reported needs to be described in the respective PLS.
All data provided in the PLS should also be given in the scientific article. The data presented in a PLS should not go beyond the data provided in the scientific article.

Table continued on next page

Table 1. Ethical Considerations for PLS Writing (continued)

The results of the primary endpoint need to be described and explained in the PLS when reported in the scientific publication. Results of key secondary endpoints could be included if they have been prespecified in the study protocol or analysis plan, are statistically powered and analyzed, and are of particular relevance to patients.
The PLS needs to mention the important limitations of the research or study that is reported in the scientific article.
To make PLS accessible for patients whose native language is not English, appropriate translations should be done that faithfully reflect the content of the PLS. Translations need to be mindful of the cultural diversities between audiences and ideally reviewed by members of the target audience for each language.
The PLS should be inclusive of all genders, nationalities, and ethnicities.
The PLS should be reviewed by members of the public and/or by patients or patient representatives ideally with the condition that was studied in the scientific article.
The PLS should be approved by the lead author (the author who is named first in the author list) of the scientific article, as a minimum. All authors of the scientific article on which the PLS is based should be given the opportunity to review and comment on the PLS.
The authors of the PLS as well as the funding source of the research work and the funding of the PLS should be disclosed in the PLS.
Links to the scientific publication should be included in the PLS.

Cocreation of content expresses respect for the target audience and hence is an important aspect in generating PLS of peer-reviewed scientific publications. The methodology proposed in the "How-To" ensures adequate representation of the target population.

Seven Steps for Generating a PLS: Proposed Algorithm

The generation of PLS was broken down into seven steps that serve the overall aims of maximum audience focus and full cocreation with members of the target audience. A summary is provided in Table 2 below; a more detailed description is available in Dormer et al.[17]

DISCUSSION AND CONCLUSION

The field of PLS writing is evolving as more and more journals provide the opportunity for PLS.[5-7] Some guidelines for the content of PLS have been published by collaborative networks such as Cochrane[8,9] and Open Pharma.[10] Although these guidelines are applicable to all PLS, they do not explicitly provide ethical considerations, and they provide no methodology for cocreation of PLS with members of the target audience. It is very important to realize that PLS

Table 2. Seven Steps of Creating a PLS

Step	Action	Content
1	Have a rationale and scope for developing the PLS	The selecting criteria for the source scientific publication for a PLS must be clear before the writing is initiated. It is important to have a transparent process, such as a standard operating procedure, across an organization, to avoid publication bias by selectively providing PLS. Reasons for a PLS could be the impact of the data, the uniqueness of the scientific approach, or the needs of a certain audience.
2	Identify the target audience	The target audience should be defined before the start of the writing process. This choice will impact the resource needs in the cocreation process and will determine the administrative and operational complexity of the PLS writing.
3	Consider the dissemination channels	It is essential to consider the dissemination of the PLS based on the identified target audience. Free access is important to optimize distribution. The method of dissemination will influence the amount of aggregation and summarization of data from the source article. For example, if a manuscript and its PLS appear in the same issue of a journal, certain details may be omitted from the PLS and provided solely as reference to the source. Some journals may allow the inclusion of supplementary material, eg, for additional infographics.
4	Identify key stakeholders for cocreation	It is important to identify the key stakeholders for their engagement in cocreation before a PLS is written. It is desirable to have a broad range of stakeholders, including patients, caregivers, and others. The PLS cocreators should determine whether they have the appropriate reach into the target audience or whether new cocreation relationships need to be established. Resourcing (eg, contracting, payment, technical infrastructure) and any applicable legal requirements need to be considered to ensure that relationships can be maintained throughout the process.
5	Write PLS	PLS cocreators should establish an appropriate infrastructure and should agree on roles and interaction in the writing process. Based on the target audience, the PLS cocreators need to decide on the literacy level and the structure of the PLS and the use of visuals or infographics. It is highly recommended to have a member of the target audience review the draft PLS. The PLS must reference the source scientific article or contain a link to it.
6	Disseminate PLS	Once the PLS is published, it may be shared in print, in online repositories, or on relevant websites; the channels should be chosen based on target audience preference. The use of social media for dissemination depends on the legal restrictions in some countries and the corresponding compliance rules in large organizations.
7	Track dissemination and measure success	Ways to monitor the impact of the PLS should be developed to gauge future efforts. Various metrics may be available depending on where a PLS is located/hosted. The journal site/website/repository that hosts the PLS might provide metrics such as the number of views or downloads. Another measure is the attention the PLS or the source article has received on social media or in other commentaries. Posts on social media that link to the PLS may be liked or shared, and monitoring this activity can provide an indication of the reach of the PLS. It should also be measured whether the PLS is shared by patient organizations and healthcare providers in the respective disease area.

written without strict consideration of ethical principles bear the risk of contributing to misinformation rather than providing insight and understanding to nonexperts. To make this new format a trustworthy source for patients, caregivers, and others, a firm commitment to ethical conduct in PLS writing is mandatory. However, while not being explicit about their ethical considerations, the existing guidelines[8,9] stipulate a number of requirements that are in line with the recommendations of the PFMD guidance. For example, the Cochrane collaboration mentions consistency between the source and the PLS and the need to report the primary outcome as well as balanced reporting of efficacy and safety data as mandatory requirements.[8] Interestingly, in the latest version of the Cochrane guidance published in January 2022, the ethical considerations in regard to content of PLS, are substantially less explicit than in the previous version.[9] The Open Pharma collaboration mentions that PLS need to be nonpromotional and unbiased and that PLS need to include a link to the source publication.[10] In a recently published modified Delphi approach of stakeholders' perceptions of issues in generating PLS,[18] a number of items emerged as "important" that are in line with the ethical considerations put forward in the PFMD guidance. Stakeholders considered it "important" that the primary endpoint results are included in the PLS as well as mentioning the limitations of the study. Other obligations related to ethical conduct, such as having the authors of the source article approve the PLS, are only to be "considered" in PLS generation, according to this stakeholder group.

In summary, the "How-To" Guide developed by PFMD is the first one to more explicitly require compliance with a set of ethical considerations. The value of these stipulations was corroborated by the fact that the "How-To" Guide had been developed using an iterative and robust co-creation methodology with substantial public consultation.[14-16]

To ease implementation, selected resources for PLS development, complementary tools, and good-practice examples are available directly in the "How-To" Guide. The "How-To" Guide[19] has been uploaded onto the PFMD PE Management Suite, a central repository that allows open access to all PFMD tools.

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THEME ARTICLE

The Making of the Good Lay Summary Practice Guidance: A Multi-Stakeholder Document That Was Adopted Into Regulation – An Interview with Dr Ingrid Klingmann

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This interview describes how the Good Lay Summary Practice guidance (GLSP) came into existence. Its development had been initiated by a group of enthusiasts who wanted to provide guidance on how to plan, write, translate, and disseminate lay summaries and on how to best involve patients into the process. The GLSP is the result of a multi-stakeholder initiative with more than 60 contributing organizations, comprising patients, patient organizations, academic research networks, small and medium enterprises, and members from big pharmaceutical companies. The initiative collaborated over more than 3 years to arrive at a final guideline that was then accepted into regulation. Major steps were the development of an organizational structure consisting of a Core Management Team and 5 Task Forces that worked on the different topics, a large global public consultation of the draft document, and an intense discussion with the regulators in Europe. Dr Ingrid Klingmann, a physician, patient advocate, and cancer survivor, was at the helm of the Roadmap Initiative during the entire time and provides her insights on the challenges and results of this long and successful process.

Dr Ingrid Klingmann is a physician, patient advocate, and cancer survivor. She has been at the helm of the multi-stakeholder Good Lay Summary Practice (GLSP) Initiative that developed a guidance for writing lay summaries. Lay summaries are short documents understandable for the public that summarize the results of clinical trials. Lay summaries are now mandated for all clinical trials in the European Union (EU) based on European Clinical Trial Regulation (536/2014). They are also called Plain Language Trial Summaries, Patient Summaries, or Trial Result Summaries. Lay summaries are a novelty as they are the first regulatory documents that are meant to inform the public. Even more so, the GLSP Initiative was the first guidance that had been developed by a multi-stakeholder initiative that was then adopted as regulatory guidance. Some readers may be at odds with the use of the word 'lay' as for them it has a belittling connotation. However, as this is the official legal term in Europe, it has also been used in this article.

INTERVIEW

Schindler: Why did you and the European Forum for Good Clinical Practice (EFGCP) pick up the topic of lay summaries in 2018? At that time, several working groups had already been developing recommendations.

Klingmann: EFGCP had already been involved in the preparation of certain aspects of the European Clinical Trial Regulation. However, at that time there was no discussion on informing the public about the results of clinical trials. When the European Regulation was released in 2014, we were surprised to see the obligation to prepare lay summaries for all clinical trials. Apparently, this topic had been added very late to the legislation. The mandate to inform the public in a systematic way about the outcomes of clinical trials triggered a lot of interest and excitement, and EFGCP and the European Federation of Pharmaceutical Industries and Associations (EFPIA) decided to organize a workshop.

We wanted to clarify what it would mean for sponsors to prepare and disseminate lay summaries. During this first workshop in 2015, we became aware of the work of international collaborations such as Multi-Regional Clinical Trials (MRCT) and TransCelerate. It became clear that stakeholders would need more detailed guidance on the content and structure of lay summaries. When the European Expert Group issued their guidance on structure and content of lay summaries in 2017, we conducted another workshop

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during which we reviewed their guidance. We realized that it was not enough to know about the requirements and best approaches to present the content, but that an overall process for planning, preparation, translation, and dissemination was needed. Most importantly, producing lay summaries should involve patients in a systematic way. This aspect had not been included in existing guidances at the time. We had a very strong patient representation at this workshop, and they made it very clear that without patients, the process cannot be successful. As a conclusion from that workshop, EFGCP and EFPIA decided to create the "Roadmap Initiative to Good Lay Summary Practice" (the GLSP Initiative).

Schindler: What were the aims of the GLSP Initiative?

Klingmann: To bring together all the involved stakeholders—so, commercial and academic sponsors, patients, patient organizations, not-for-profit organizations, medical writers, lay language specialists, and translators. We wanted to involve all viewpoints and existing experience to jointly develop guidance on how to set up an overall lay summary process. We needed a bit of time to get our act together, but then our road map initiative was kicked off in 2019.

Schindler: What were the biggest challenges in getting the initiative off the ground and keeping it afloat?

Klingmann: Well, there were a lot of challenges. Firstly, we needed to give the initiative an organizational structure and we needed to identify the topics to work on. In total, we had over 60 organizations from Europe and the United States who participated in the initiative. To more efficiently manage the process an international Core Management Team was formed. Initially, after a lot of discussion, we settled on 5 task forces, each one led by a member of the Core Management Team and a patient or patient representative. The initial task forces were

1. Principles and processes of lay summary implementation beyond existing guidance.
2. Competencies required for development and translation of lay summaries.
3. Lay summary dissemination within and beyond the European Medicines Agency (EMA) Portal.
4. The issues of lay summary creation, translation, dissemination, and funding, particularly for academia and small and medium enterprises.
5. Suitable technology to reach patients, health care professionals, and the public including the development of lay summaries for trials in children.

It was difficult to get people to actively contribute to these different task forces. Participants were sometimes unaware that simply listening in was not going to help moving forward. The idea was to actively work out the content and to develop recommendations. Ultimately, we managed through a process of regular meetings, regular updates, and building up awareness in all the task forces to adhere to the timelines and to come up with proposals. In spring 2020, we had brought together a first draft of the GLSP that was then used in a very early discussion with the European Commission. They indicated that they were principally interested in collaborating toward a guidance and expressed that working on this aspect of transparency would be a good way to support the overall goals of the new European Clinical Trial Regulation. In line with the Core Management Team, the Commission supported the plan for a wide-spread public consultation on the draft in summer 2020. It was agreed to reconvene thereafter.

GLOSSARY

CTEG – the Commission Expert Group on Clinical Trials. They provide the Commission with advice and expertise on clinical trials in relation to the preparation and implementation of legislation and policy initiatives. The CTEG is part of the Directorate Sante and consists of delegates from all national authorities and ethics committees in Europe.

EFGCP – the European Forum for Good Clinical Practice. They are a not-for-profit organization established by and for those with an interest in the development of medicines and medical technologies.

EFPIA – the European Federation of Pharmaceutical Industries and Associations. They represent the biopharmaceutical industry operating in Europe.

European Commission – the executive branch of the European Union (EU). It operates as a cabinet government with 27 members (informally known as "Commissioners") headed by a president.

European Clinical Trial Regulation – the binding law that specifies the rules for conducting clinical trials throughout the EU.

MRCT – Multi-Regional Clinical Trials. They are a research and policy center that wants to identify and deliver ethical, actionable, and practical solutions for the global clinical trial enterprise.

TransCelerate Biopharma – a not-for-profit entity with a mission to collaborate across the global biopharmaceutical development community to identify, design, and facilitate solutions designed to drive the delivery of new medicines.

The GLSP draft was posted on the EFGCP website and disseminated by all Roadmap Members to their networks. We received a high number of comments on the structure and a lot of detailed recommendations from all stakeholders. And of course, like always, after such a public consultation, it takes time to consider and discuss and agree on the comments and write a revised draft. The workload associated with integrating the various comments and the preparation of a second draft was a major challenge for the initiative.

In addition, much to our surprise, one of the key messages was that the document that we had produced was far too complex and too long (about 100 pages), especially for academic sponsors and investigators, and that we would need a type of summary. In response to this, the team developed the idea of having a "Quick Guide," summarizing the principles and basic information, and a "Handbook" that contained the detailed guidance, recommendations, and experiences. And with that we went again to the European Commission. Keeping all stakeholders invested during the difficult discussions that ensued was a major challenge.

Schindler: Was it your idea to involve the European Commission at the draft stages?

Klingmann: Actually, it was an idea that was developed in the Core Management Team during one of our regular meetings. The team thought that the most effective way to support the implementation of good lay summary practice was a guidance that was issued by the regulators, ie, the European Commission. We believed that an official release and recognition would make it so much more powerful than when it was coming from a group of enthusiastic individuals who wanted to improve the world.

Schindler: In this long journey of the initiative, what were the moments of crisis? As a member of the Core Management Team, I remember a few. There were instances when it was difficult to keep the academic group engaged, and there were moments of distress when some colleagues in major pharmaceutical companies wanted to have some very specific points included. Most importantly, we had very critical discussions with the European Commission and the Clinical Trial Expert Group (CTEG).

Klingmann: Well, in fact, you listed them already quite correctly. I think the involvement of academia was an ongoing issue that came in different waves. Initially, it was difficult to get academia engaged at all because they were largely unaware of the new requirement. It became clear that the biggest issue for academia is that the writing of lay summaries is a very late-stage activity in a clinical trial. At that time, funding is often no longer available because conduct-related activities have subsided and given current funding procedures, writing a lay summary after the end of the project is not possible. Unfortunately, this situation is not solved. So, we agreed that we would also need to work with the large funding bodies to make them aware of the situation.

When we had submitted the revised draft GLSP to the European Commission, they forwarded it to the CTEG for comments and review. Because CTEG is a group of 54 representatives from national regulatory authorities and ethics committees of all European member states, we were afraid of receiving many comments and maybe even serious pushback. And, as expected, we received a substantial number of comments and a list of several topics with which they were not in agreement. One problem was that they insisted that the GLSP must primarily be a European document because it relates to the European Clinical Trial Regulation. So, the need for lay summaries for patients in international and global studies and the need of patients all over the world to have access to these lay summaries was not a priority for them. It was quite a tough discussion, and it was difficult to find agreement. Some representatives of global pharmaceutical companies were disappointed about this focus on the EU. However, building on the good will of all stakeholders, we were able to agree on a compromise.

The second topic that the European Commission absolutely did not want to go into was indirect dissemination—that is, dissemination of lay summaries via company or third-party websites. They felt that it was not appropriate to provide guidance in the GLSP because currently there is no broadly agreed standard for this type of dissemination. Also here, some representatives of large pharmaceutical companies were disappointed because they were hoping to get further guidance on how to disseminate lay summaries in a compliant way. In the Core Management Team, we agreed to tackle this topic again and work it out in full detail for another discussion with the regulators. This discussion in spring 2021 was one of the most critical moments when it was really unclear whether we would come to an agreed document.

Schindler: You really contributed a lot to steer the initiative through these crises and you skillfully managed the interaction with the regulators—your professionalism was truly important for the success of the initiative.

Klingmann: Well, many people contributed to this—not only me—and many members helped to overcome diffi-

cult moments. In addition, the Commission and CTEG had appreciated that this was a multi-stakeholder initiative with strong patient involvement. They were willing to accept that they could have not created something better. Whatever they would have done could only have been top down, and probably not as relevant and practical as the document that we have produced. Finding agreement on the various topics of concern was often difficult, but many members of the initiative and the Core Management Team contributed to a good outcome. Remember, we had 9 months of intense interaction between all the road map stakeholders and the European Commission to come to a final document.

Schindler: For me, one of the most fascinating things is that the GLSP is a bottom-up multi-stakeholder initiative that made it into law.

Klingmann: Yes, it is unique that an initiative that was started by a group of enthusiasts who wanted to provide clinical trial data in an understandable way was recognized by regulators and turned into an official guidance. The final document is posted on the EudraLex website, which is the place where all European laws are published. I believe it was of critical importance that the initiative was driven by a neutral body, and I am proud that EFGCP could serve in this capacity.

Another key factor was the ongoing substantial involvement of patients in the initiative. The role of patients was very practically worked out throughout the entire guideline without avoiding the complexities that this may create sometimes. So, it was not Big Pharma or academia who drove this guideline, but it was the balancing of all the efforts of the different stakeholder groups in an open and fair way. For academic research and for small and medium enterprises, it was important to be offered a stepwise approach of implementing the GLSP.

Schindler: You have been at the helm of the initiative for more than 3 years. What does it take on a personal level to make such an initiative successful?

Klingmann: First of all and foremost, it takes a lot of time and energy. I was working philanthropically for the initiative, and I still had to do my other work. During the intense phases, I had only very few weekends for myself. It requires a lot of energy to keep people engaged, which is sometimes difficult to muster. From time to time, I needed to give myself another push to advance the topic and to motivate the others and encourage them to deliver on the agreed topics. And of course, I was not alone in this. We were so lucky to have an exceptional group of dedicated individuals in the Core Management Team. Without their ongoing support and their critical input over several years, the initiative would have gotten nowhere. Also, I am very thankful for the ongoing support of all the members in the Task Forces and the entire initiative.

I believe we have a window of opportunity now to make the provision of lay summaries a part of the normal clinical trials process. With the COVID-19 crisis, there is so much interest in transparency and in the results of clinical studies. Our initiative will make those results more readily available for patients and the public.

Schindler: What are the next steps for the GLSP Initiative?

Klingmann: Most importantly we need to continue spreading the news about the availability of the GLSP to all parties that are potentially involved in the preparation of lay summaries. Webinars and workshops on a national level are planned. A next step could be to make the GLSP available in additional languages. The initiative is currently planning training programs for stakeholders and members of the public to learn about best practices in the preparation of lay summaries. And we will create an independent GLSP website that will become the central communication tool and repository for GLSP–related activities and content.

Another key issue we need to tackle is to encourage academic researchers to fulfill the obligation of writing lay summaries, especially because about 40% of all trials in Europe are conducted by academia. We need to continue the discussion with the European Commission, particularly the Directorate-General "Research and Innovation" that is providing funding for a lot of academic clinical research. In addition, we need to continue to inform national funding organizations about the requirement to write lay summaries and related resource needs. They need to change their requirements and their funding conditions to meet the costs associated with providing lay summaries.

We want to re-initiate the discussion with the regulators on the topic of indirect dissemination, ie, the option of sponsors to make lay summaries available on their websites. Although lay summaries are a European requirement, all patients in a global trial and the global public have the right to be informed about results regardless of their location. For this, we need to define the processes and develop an appropriate framework. And of course, the initiative should continue to provide a platform for best practices for example the provision of lay summaries for children.

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BIOS

Ingrid Klingmann, MD, PhD, FFPM, FBCPM

She is a physician specialized in clinical pharmacology with over 30 years of experience in different senior functions in the pharmaceutical industry focusing on clinical trial design, ethical, and regulatory aspects. She owns and manages a pharmaceutical development and site management support consulting company since January 2003 (Pharmaplex bv). The company creates networks of experienced specialists that work on diverse international projects such as drug development consulting, study management for pharmaceutical companies, teaching projects, and academic site support. Dr Klingmann is Chairwoman of the Board of the EFGCP. Based on her broad professional background, she facilitates the alignment between stakeholders in medicine development with the aim to develop patient-relevant treatments more efficiently.

Dr Klingmann is currently also Secretary of the European Federation of Exploratory Medicines and President of PharmaTrain Federation (EUFEMED), a not-for-profit organization focusing on global standardization and improvement of post-graduate training in medicine development. She teaches on topics like clinical research and regulatory affairs at the Universities of Bonn, Basel, and the Université Libre de Bruxelles.

Thomas M. Schindler, PhD

He is a biologist and linguist educated in Germany and the United Kingdom, holds a PhD in molecular physiology, and did postdoctoral research in the United Kingdom. He was the editor of popular science books in biology, geography, and astronomy. He then turned to medical writing and has over 25 years of experience in both medical affairs and regulatory medical writing, including the preparation of marketing authorization application dossiers in different jurisdictions. He founded, established, and led the medical writing function at Boehringer Ingelheim for almost 20 years, and he has recently focused on lay summaries, video creation, and AI-driven writing. He participated in the TransCelerate Return of Results work stream, is in the Core Management Team of the GLSP Initiative and has supported the development of the Patient-Focussed Medicine Development (PFMD) Plain Language Summary guidance. For many years, he is the editor of the statistics section, "Statistically Speaking," of the *AMWA Journal*.

FURTHER READING

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2021 CONFERENCE

Session Reports

A SYSTEMATIC APPROACH TO MANUSCRIPT EDITING

Speakers

Loretta Bohn, ELS, *Senior Editor/Writer, RTI International, Research Triangle Park, NC*

Kelly Schrank, MA, ELS, *Freelance Medical Editor, Bookworm Editing Services, LLC, Elberton, GA*

By Christine Holzmueller, MS

Loretta Bohn and Kelly Schrank share their experiences "in the trenches" when managing manuscripts, including editing and submitting to peer-reviewed journals. As experienced manuscript editors, they believe the overarching goal is to "shine the best light" on the research and the authors. To expand beyond their own experiences, the speakers also surveyed editors to learn what they look for when editing a manuscript and reported their findings (Figure).

What are editors looking for... (N = 12[a])
...in each section?
Editing standards (eg, grammar, punctuation, syntax, readability, and spelling) are met.
Content addresses the intended purpose of that section.
Section contains the components specified in journal guidelines.
...when evaluating the manuscript as a whole?
Terms and definitions are consistent.
Information flows coherently and logically.
Research methodology demonstrates good science.
Journal requirements are met (eg, word limit, reference format, title page components).

Figure. What are editors looking for...

[a]An 8-item survey was developed by Kelly Schrank and Loretta Bohn; it was posted on AMWA Engage and LinkedIn and emailed to the Board of Editors in the Life Sciences' mailing list and RTI International employees.

Manuscript Editing Checklists Are a Valuable Tool

A good checklist can help editors develop a plan, stay organized, and be more efficient when editing manuscripts and submitting them to journals. A highly recommended book that describes compelling reasons that checklists are valuable is *The Checklist Manifesto* by Atul Gawande, MD, MPH, a renowned surgeon.[1]

Checklists can be used for a single manuscript and can also serve as a dashboard to manage multiple manuscripts simultaneously. Bohn notes that checklist use shows your clients or employer that you are a professional and doing what you can to minimize errors on your part. Schrank shared her checklist as an online supplement on the conference platform. Also available to *AMWA Journal* subscribers, the checklist has sections for tracking/metrics, common manuscript features, abbreviations used, author instructions from the journal, notes, and final checks of the edited paper. A valuable tip when scanning the paper for the final check is to use "No Markup" in track changes to make issues visible (eg, extra spaces, typos).

Noted advantages of using a checklist when editing:

- **Consistency**—of acronyms, abbreviations, phrases or terms, nomenclature for key concepts, and other information
- **Structure**—ensures requirements from the particular journal are met, sections are in correct order, and the right data/information is in the correct section
- **Productivity**—keeps you on task, avoids wasted time scrolling pages to check for consistency, reminds you of where you left off
- **Tracking**—deadlines, authors' return of information you requested, metrics to estimate time required for future editing projects

Author Instructions Are a Gold Mine of Information

Bohn stresses the importance of abiding by the author instructions in manuscript preparation. Instructions can cover everything from the article categories accepted and word count limits to formatting of references and figures.

Several tips:

1. Add the URL to the author instructions in the manuscript checklist (or in your bookmarks for that client).
2. Thoroughly read the instructions.
3. If another person is formatting the manuscript, copy and paste pertinent instructions in an email to save them from sifting through information.

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Look for author instructions on the journal's home page, which may be in a tab near the top or a link along the side or near the bottom of the page. Note that submission instructions are usually different from author instructions. Submission instructions include the platform for uploading your manuscript files, any publication fees, and other relevant information.

Common Features of Manuscripts

Schrank toured the common features of modern manuscripts, showing both organization and what information goes where. Journals do vary in placement for some information; here are common things to check:

- Information required on title page
- Specific subheadings for abstracts
- Acknowledgements section—thank contributors (eg, statisticians, medical writers)
- Source(s) of funding
- Conflicts of interest—sometimes duplicated

Dummy Submissions Allow Editors to Discover What the Journal Requires

If the target journal is known, start a dummy submission in the online portal using the login ID and password of the submitting author. Gathering all information and materials from your authors ahead of time will avoid delays when it is time to submit the manuscript. Once you start the dummy submission, read the instruction prompts carefully for any surprises (eg, a cover letter is required and authors have not written one).

Common information requested on submission:

- Email addresses for all authors
- Biography of each author
- Suggested peer reviewers and email addresses; some journals require it and want up to 3 names
- Conflicts of interest/wording of statement for no conflicts
- Open access fees (do authors know this and want to pay for it?)
- Summary Box/Key Messages of the research

Once the manuscript is submitted, it will follow 1 of 3 paths (Table), and some authors will also engage the editor in this phase.

Table. Three Paths of a Manuscript

Path	Role of the Editor
Accepted	Read the article proofs carefully for issues introduced by the journal editors (eg, typos) and for behind-the-scenes comments that should have been removed Respond to queries/comments addressed to the authors Deter authors from requesting new revisions, as this could be costly (if it is allowed)
Revise and Resubmit	Ensure response letter is polite; thank the reviewers for suggestions (even if slightly off base) Help author pick the important battles; yield to suggestions and points when ethically possible Ensure that the revision is better, not worse, than the original text Explain to the reviewer what was changed and why Follow instructions for how the editor wants to see changes to the manuscript (eg, track changes visible, detailed cover letter)
Rejected	Submit to another journal Rework manuscript then submit elsewhere

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* * *

WHERE DATA, DESIGN, AND TECHNOLOGY MEET: EFFECTIVE INFOGRAPHIC STRATEGIES FOR HEALTH COMMUNICATION

Speaker

Kathleen Walker, *Content Strategist, Communicate Health, Fort Worth, TX*

By Sunali Wadehra, MD

What is an Infographic, and Why are They Important?

An infographic is a graphic visual representation of information, data, or knowledge that is intended to present complex information *quickly and clearly*. Slick graphics and data visualization are used to engage the audience, and visual storytelling is used to convey a concept. A well-designed infographic helps people find what they need, understand what they find, and remember what they read. Note that not just any chart or graph qualifies as an infographic; it must represent this criterion.

What is the value of an infographic? Likely, they can reach and engage audiences in a way that health information becomes easier to understand than another media. An infographic is 30 times[1] more likely to be read than a text article because users are more likely to engage with content that is presented visually. In addition, people following directions with text and illustrations do 323%[1] better than people following directions without illustrations, so infographics are particularly effective in conveying information that requires users to act. In addition, infographics stand out from the crowd, are easy to share, and may be more cost-effective than other media.

An infographic may be used to present statistical data, provide how-to guides, describe processes, illustrate timelines, map trends, make comparisons, and organize facts. Note that how-to guides are especially valuable for low literacy populations, as visual elements can help facilitate their understanding. This approach is particularly effective when you test them on audiences to make sure the infographic conveys the right takeaways.

Did You Know That Infographics May Facilitate Health Literacy?

Did you know that about 9 in 10 people have limited health literacy? They too should be able to access health information, and infographics help to facilitate that. The best practices for creating infographics are aligned with several key health literacy principles. What are some examples of these principles?

- State the main message up front.
- Use common, familiar words.
- Use "1 in X" language. (eg, "1 in 5")

Other recommendations specific to using infographics to promote health literacy include aiming for minimal text and using key messages, using images as cues to support understanding, and providing visual representations to help learners understand the meaning of data.

More Strategies, Tips, and Tricks

Writers and designers are key players in creating content and developing infographics. Those involved in the content development process—which should happen before the design process—should try to identify opportunities for the designer, whilst being open to their approaches. Even content designers sketch their visions out for the infographic. However, everyone else involved in the process should also understand its nuts and bolts to facilitate collaboration and communication. Here are 10 strategies for optimizing infographics:

1. **Start with an audience and a message.** This helps to hone in on the "why" and "how." More specifically, determine your audience, objective, goals, and method of distribution.
2. **Find data.** For example, data can be gleaned from internal, government, academic, and/or research resources. Note that it is okay to start with more data than needed and pare down during the development process.
3. **Write a story—meaningfully.** What is the story that needs to be told? How can that story be supported with data? Is there a hero statistic that can be featured? A few strong pieces of data to back the story up can be advantageous, with the hero statistic acting as a single takeaway piece of data that is the centerpiece of the story.
4. **Look for visual opportunities.** Evaluate the content and consider how the story can be conveyed through visualizations, including data that can be designed or content that can be reinforced with an icon. Also, use positive visualization when possible. For example, when designing an infographic about outdoor air quality, consider presenting someone exercising indoors.
5. **Be creative.** Consider questions such as, "Can I add an accompanying visual here?" "Does this deserve an icon?" "How can this data be displayed?"
6. **Choose meaningful design elements, including colors and fonts.** Even these elements should be strategic. For example, color palettes that include red can reinforce a message of danger.
7. **Keep it simple.** A major problem noted with many infographics is a design that fits too much content. Minimal content is the way to go, and visual elements should be the star.
8. **Organize and group content in logical ways.** Content should be split into clear, digestible chunks. Note that even 1 page of draft content in Microsoft Word can at times be too much for an infographic.
9. **Create a clear visual hierarchy.** This may guide the learner through the desired order of what should be read first, next, and last. Because many individuals tend to tackle visual information in chunks, they are likely to view this information in a sequence of how important it seems.
10. **Design for clarity and readability.** Make use of white and negative space to allow content to breathe, use appropriate and readable (sans serif) fonts, build with a grid in mind, and avoid styles that make content or imagery difficult to interpret.

Conclusion

This session covered what infographics are, why they are used, when they are used, and when they shouldn't be used. In general, they may help you identify your audience and goals, communicate data and other health information, reinforce your message visually, educate across barriers, create awareness, and encourage action.

Resource List

For inspiration

- designspiration.com
- good.is/infographics
- DailyInfographic.com
- abdz.do

For design assistance

- infogr.am
- piktochart.com
- easel.ly
- visual.ly

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THE IMPORTANCE OF DATA PRESENTATION

Speaker

Barry Drees, PhD, *Senior Partner, Trilogy Writing & Consulting GmbH, Frankfurt, Germany*

By Sampoorna Rappaz, PhD

The effectiveness of medical communication hinges on both the text and the accompanying data presentation being fit-for-purpose. Dr Barry Drees, in his presentation at AMWA's 2021 Medical Writing & Communication conference, explained how we can fulfill the ultimate purpose of data presentation, which is to tell a story clearly and simply. Using examples from the domain of regulatory writing, scientific communication, and medical and world history, he illustrated how good data presentation can help focus the message, correct misperceptions, and even save lives!

When done well, each element of data presentation within a document communicates 1 main message, which is determined by the question that the data are answering. Identifying this question and the message will help us decide how to best represent the data (Figure). Distinct data presentation types exist, each suited to a unique purpose. Once we have made a choice, we can use logical design principles to highlight and clarify the message.

Design Considerations for Tables

Dr Drees has the following advice for creating tables:

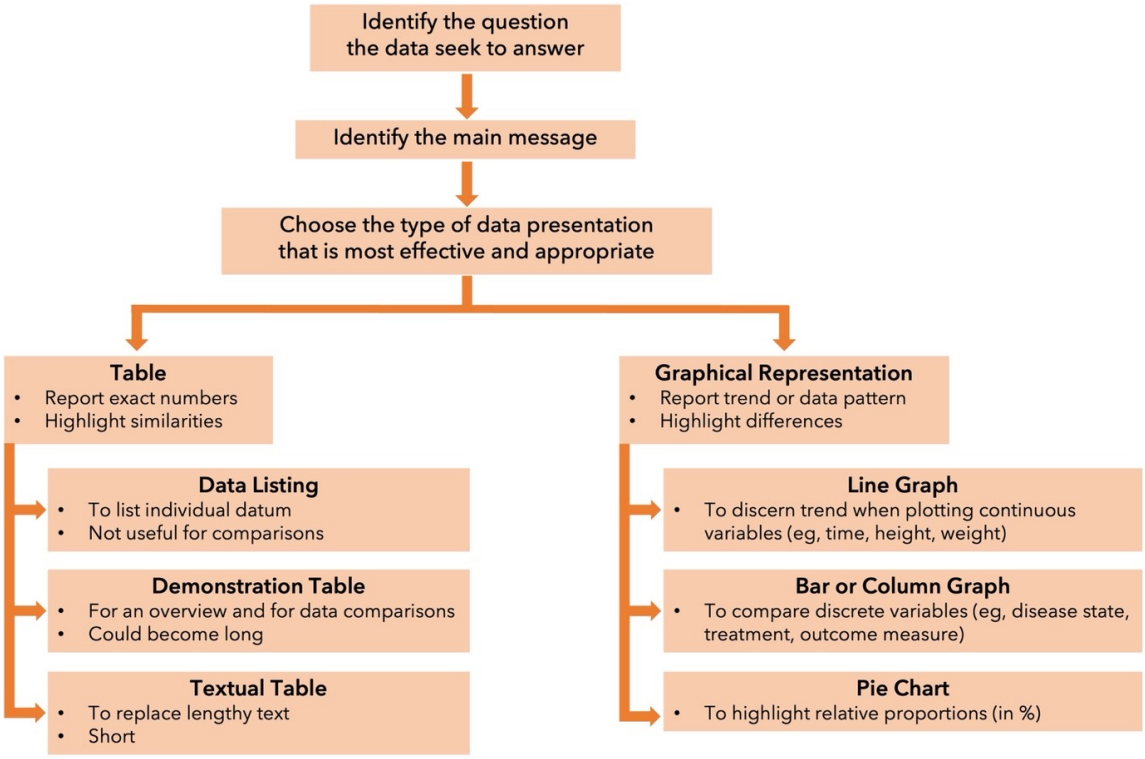

Figure. How to determine the right data presentation type. The purpose and message of the data presentation and the type of data variable will direct our choice.

- Choose a design that makes comparisons easy and keep the key comparators next to each other.
- Ensure column headings accurately describe the data within their respective fields.
- Ensure that the "total" presented at the *bottom* of the column is always the sum.
- Be consistent with text and number alignment. For easier reading, use the top alignment for column headings.
- Keep the table clutter-free. If adjacent data are identical, use a footnote. Use exponents when appropriate.
- Use an unambiguous footnote-labelling system. If the style guide allows it, use the alphabet, as this provides enough options and allows for logical organization. Avoid using a number-based system when data are numerical.
- Double-check for "footnote ghosts." All footnote symbols and abbreviations listed below the table must appear within the table field.
- Avoid empty cells. Blank spaces within a table field can confuse the reader (and the layout editor!).

Design Considerations for Graphical Representations

Dr Drees has the following advice for creating graphical representations:

- Ensure axis labels are clear, accurate, and legible.
- Ensure final figure is large enough for the details to be visible.
- Keep graphs as simple as possible so that differences are easily discernible. "Fancy" or "trendy" design principles (eg, too much "nondata ink") can be misleading.
- For line graphs,
  - Restrict use to continuous variables.
  - Ensure individual lines can be easily followed.
  - Use a trend line to improve clarity.
- For bar or column graphs,
  - Avoid stacked bar graphs, as they make comparing the nonflush variables (ie, those not aligned along the axis) difficult. Instead, use a grouped column graph and, if required, add a column for total.
  - Avoid using different shades of gray or striping to distinguish variables or categories, as these are affected by print quality.
  - Avoid adding numbers to the top of bars. If numbers are essential for clarity, then use a table.
- For pie charts,
  - Restrict use to instances in which percentage points add up to 100%.
  - Restrict use to instances in which the main message can be illustrated with *1 or 2* clear segment(s).
  - Make content user-friendly by starting segmentation at the 12 o'clock position, using appropriate colors or shades, and identifying the segments with a clear key or with labels on or next to segments.
- Avoid including many pie charts, as they are difficult to compare.
- Avoid three-dimensional graphs. These graphs create an optical illusion and can hide data points.

Focus on the Essential

Data presentation is a tool that should be used only when required, and each representation must be integral to the document. Good data presentation will make the accompanying text obvious and easy to write. We must not use data presentation for "data storage" or as means to show off the amount of data collected. We need to balance the quantity of information against the clarity of the message. Our focus should be on the story being told and on the impact of the data presentation.

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PRACTICAL MATTERS

Writing Your Paper from the Middle

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ABSTRACT

Communicating the results of research using concise, jargon-free language optimize its likelihood of being read and cited by other researchers. More than 3 decades of publishing scientific articles has convinced us that the most efficient approach to writing a scientific paper is one that starts in the middle and works outward. Such an approach means that the first items to finalize and polish are the actual tables and figures that will be included in the body of the paper (including supplemental tables and figures). This entails deciding on the order of these elements that, when viewed alone, should be able to tell the story of the paper. This first step is often the most difficult, requiring the most thought. However, once achieved, it is usually a straightforward process to write the Results section (that refer to these elements) followed by the Methods section. After these sections are proofed and polished, a quick review of the Methods, Results and associated figures and tables highlight the points that need to be made in the Discussion section. The last sections written should be the Introduction, to set up the entire Methods, Results and Discussion, and the Abstract, to summarize it all.

When this approach is combined with frequent proofreading of the article on some medium that is different from the one used to write it, experience has shown that the result will be a clear, uncluttered paper that is completed with a minimal number of drafts and that is most likely to be favorably reviewed and accepted for publication.

Good biomedical science requires good communication, and scientists who clearly and unambiguously communicate their observations, analyses, and conclusions in writing[1] are likely to reach a bigger audience. In our experience over the last 35 years, an approach to writing a paper that is adaptable to any topic, simple, reduces the number of drafts, and consistently results in a clear paper is one that starts in the middle and works outward.[2] Such an approach begins with the tables and figures of both the main paper and any appendix, continues with the Results, Methods, and Discussion, and ends with the Introduction and Abstract. Each of these steps is described below.

A: FIGURES AND TABLES

A paper generally includes figures and tables that clearly communicate the main message of the paper. Indeed, an approach to reading a scientific paper is to first read its title and Abstract and Conclusions sections and then flip to the figures and tables before deciding whether to read the full paper. Moreover, a paper's figures are often presented by other scientists when discussing their own work. It is for this reason that the creation of the figures and tables is an ideal place to start when writing a manuscript. This includes those that will be included in the main paper as well as in any supplement and that together will "tell the story" of the entire manuscript. As in any story, the order in which these elements are discussed needs to be carefully considered. Thus, before writing the Results section, it is best to decide the specific order of these elements (eg, Table 1, Table 2, Figure 1, Supplemental Table 1, Figure 2, Supplemental Figure 1, and then Table 3). Even if the author ultimately modifies this order, deciding on the initial order will facilitate writing the first draft of the Results section.

B: RESULTS SECTION

The Results section typically starts with a general description of the data that are analyzed, followed by the specifics of the analyses and findings with reference to the figures and tables. Brevity is a virtue for all parts of a scientific paper, and a succinct, clearly written Results section that tells the story that is shown in the tables and figures in a logical and uncluttered way will communicate the findings effectively. A supplement is the ideal spot for any information that does not directly address the study hypotheses.

C: METHODS SECTION

A clear set of figures and tables and a straightforward Results section facilitates drafting of a clear and concise

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Methods section. Although the amount of detail to include requires judgement, the guiding principle should be that it should be sufficient to describe what was done without confusing, irritating, or distracting the reader. Any other details can either be omitted or included in a supplement.

The Methods section, together with the Results, figures, and tables, represents the heart of the paper. Once it has been drafted, it is worth checking whether all the salient information, but no more, has been presented transparently. As with the any piece of writing,[3] we have repeatedly found that a good way to do this is to print a clean (unmarked) copy of the Methods, Results, tables, and figures as well as the supplement and review these sections as if they were written by someone else. Although one can never truly dissociate oneself from one's own writing, such an effort can help the writer identify confusing or distracting text that interferes with the flow of the written presentation of the information. It is also useful at this time to have a colleague read these sections before continuing, as it is not worth writing any more of the paper until these sections are polished.

D: DISCUSSION

The Discussion section of a paper presents an opportunity to contextualize the findings, show how they support or refute the hypothesis being tested, and show how they lead to new hypotheses or research. This is also the place where writers present their conclusions, which need to be consistent with the research design, the data quality, and the analytic approach used. For example, if a research finding is hypothesis generating, it is inappropriate to present it as hypothesis testing. In our experience, striving for clarity and brevity will reduce the likelihood of overstating the implications and relevance of a particular finding that happens to be consistent with a hypothesis and excusing or rationalizing an inconsistent finding.

The contents of the Discussion should directly flow from the Results section and should mainly focus on the findings that were observed. This can include citing other literature pertaining to these findings and suggesting possible explanations for the findings. Although every set of observations has limitations, a Discussion section that spends inordinate amounts of space on "explaining away" findings that do not support the investigators' hypotheses is usually unhelpful and distracting.

A simple structure for a Discussion section includes (a) restating the main findings, (b) a brief discussion of literature pertaining to these findings and how these findings advance an understanding of the hypothesis, (c) a possible explanation for these findings based on biologic mechanisms or methodology, (d) the strengths and limitations, and (e) the next steps and overall conclusion. It is important to note that a detailed literature review regarding the hypothesis best belongs in a review article, as such a review generally cannot be accommodated in the space available for the Discussion section.

E: INTRODUCTION

Perhaps the easiest section to write is the Introduction. The Introduction should state and briefly justify the hypothesis and its implications and generally foreshadow all the key points that are included in the Discussion section. A short 2-paragraph Introduction is ideal for many papers. As with the Discussion, the Introduction generally should include sufficient information to understand why the research was done. It should simply justify the reasons or motivation for doing the study, state the hypothesis in a few sentences, and provide a big picture as to what value this adds to science.

F: ABSTRACT

The Abstract of any paper should adhere closely to text written in the rest of the paper. Most biomedical journals have word limits for Abstracts ranging from 250 to 300 words. Generally, the most effective way to write the Abstract it is to summarize each of the other sections in 1 to 2 lines.

SUMMARY

Writing clearly is difficult and takes practice. This is as true for writing a scientific report as it is for writing a novel, play, technical document, or financial report. Regardless of what is being written, having a clear underlying structure that supports the document, and a systematic approach to building that document on that structure, can facilitate the process of writing a paper, ensure that the final product communicates clearly, and increase the likelihood that it will be used to further advance biomedical knowledge.

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FREELANCE FOCUS


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Jam Session for Seasoned Freelancers—Part 1

Brian Bass, with commentary from Melissa L. Bogen, Lori De Milto, Cathryn D. Evans, Gail V. Flores, and Phyllis Minick

A popular session during the annual conference was the Jam Session for Seasoned Freelancers. The session gives seasoned pros the chance to share experiences and discuss ideas, concerns, and challenges with peers who have the same or even more experience. A range of important topics were discussed at this year's session. These include managing stress, email issues, travel and security issues, sculpting your business, friendships with colleagues, referring clients, legal battles, and one of the costs of doing business. In this issue, we will cover the first 4 topics.

MANAGING STRESS

Saying *no* is probably the seasoned freelancer's greatest weakness. The no muscle can be strengthened by paying more attention to red flags that indicate a client may not be ideal to work with, such as being disorganized, and cutting that client loose. Giving yourself a day off every now and then, or better yet, a permanent 4-day work week, is another great way to take control of your freelance business and lower your stress level.

Another way to manage stress is to slow down. Delivering an assignment early is a great way to endear yourself to a client, but it can also set the expectation that you don't need as much time as other freelancers to get great work done. Slowing down doesn't mean you should start taking longer to complete assignments. Rather, you might sit on the completed project for an extra day or 2 before you deliver it—still early, but not as early.

Subcontracting is another option for managing heavy workloads. Seasoned freelancers who subcontract warn that subcontracting isn't easy and can actually lead to more rather than less work for the freelance business owner.

Tips from Seasoned Freelancers

Doing excellent work for our clients and delivering it on time and on budget while running a freelance business is often stressful. But with the right business practices, we can manage stress.

We need to say no to working with new clients that are likely to be bad clients and to unreasonable demands from current clients. If we are working with bad clients, we need to fire them. Although it's scary to do this, there are lots of great clients out there who need our help. If you're working with a client that depletes your energy and increases your stress, then you won't have the time or energy to find or work with better clients.

Training our clients also reduces stress. We need to set boundaries about when we work and require reasonable deadlines. If we answer emails or phone calls on evenings or weekends or agree to unreasonable deadlines, clients will always expect us to do this. Let your clients know your normal business hours and review each project carefully to ensure that you can make the deadline with your normal work schedule.

Make it clear to the client that if they do not do their part (eg, sending you source materials or reviewing your work), you cannot meet the deadline. Although it's always great to deliver a project a little early, don't turn it in too early or the client will always expect this.

All of the usual stress management techniques help too. Simple things like deep breathing, which you can do anytime, make you feel better right away. Meditation, exercise, being in nature, and eating healthily are other ways to manage your stress. I started meditating shortly after the start of the pandemic, using the Insight Timer app. Insight Timer has 100,000 free guided meditations on 200 topics, including stress and anxiety. I mostly do short meditations (3 to 10 minutes).

—Lori De Milto

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My answer: Managing stress daily is a high priority for me. By taking specific actions, I can maintain productivity and enjoyment of my work. If I am not vigilant about managing my stress levels, a sense of overwhelm can threaten to derail me.

Specific Actions to Manage Stress

- Exercise: A commitment of Pilates classes on Zoom twice a week keeps me accountable and somewhat active. I did a 6-week fitness challenge at a local gym, but COVID dissuaded me from continuing the challenge. Huffing and puffing into a mask at the gym while others didn't necessarily wear a mask wasn't to my liking, so I've replaced the gym with doing exercise programs on YouTube in my living room. Some programs I like are Yoga with Adriene (https://www.youtube.com/user/yogawithadriene), HAS Fit (https://www.youtube.com/c/Hasfit), and Fitness with PJ (https://www.youtube.com/c/FitnesswithPJ).
- Stay hydrated: Drinking water is important. My goal, 2 large glasses before and after lunch, forces me to take frequent trips to the bathroom. These short excursions are an ideal time to stretch and focus my eyes farther away than the monitor. I live on a lake, so there's always something pretty to see.
- Eat at regular intervals: I need to keep my body fueled to think and perform well throughout the day. If you're like me and don't have time to cook, consider a food delivery service, whether online like Hello Fresh (https://www.hellofresh.com/), Mosaic Foods (https://www.mosaicfoods.com/), etc, or simply local takeout. Keeping cut-up vegetables around helps me snack on something healthy.
- Maintain regular hours: Once I'm off the clock, I don't respond to work-related email and I tend to stay away from my computer. I need time when I am not working to relax.
- Engage in a hobby: Humans are not meant to just eat, sleep, and work. We need social engagement and creative outlets. Social engagements have been tricky during COVID. Participation in regular nonwork Zooms with friends from around the country and my family help me feel less isolated. But I also need to see people I know in person! I hike with local friends. Getting out in nature, even a simple walk around the block, invigorates me. I need creativity in my life—coloring in adult coloring books, dancing to music, or gardening (or looking at garden catalogs in the winter) are all restorative activities.

—Melissa L. Bogen

My best response to addressing this issue is a quote:
In speaking of the New Year, Richard Branson, although not an acknowledged sage but unquestionably a remarkable success, wrote that "every success is a tale of constant adaptation, revision, and change." So, my interpretation of that response is this: may none of us focus on fear. If something new or stressful is happening in your life, take courage. If you face anxiety, turn to the excitement of possibilities, because it takes only one step to begin breaking any barrier. Use the power of your ability for communication to change a system, a status quo, or even the heart of people to make a difference in this world. I am thankful for the spirit of learning and wisdom that AMWA fosters to help others, to share friendship, and to anticipate new beginnings.

—Phyllis Minick

* * *

ADDRESSING THE EMAIL ADDRESS ISSUE

Most seasoned freelancers have a hard enough time keeping up with their own email addresses. For them it would be onerous to have to constantly check other email addresses as well. They solve the problem by having their client addresses forwarded to their regular email address. Some seasoned freelancers prefer to keep their own email addresses separate from their client email addresses. One way to do this and keep your sanity is to manage each email address on a different browser.

Tips from Seasoned Freelancers

I hope others will describe how to maintain client-specific emails when they are forwarded to one email account.

In the past, I have been given up to 2 client email accounts. I preferred to not have those emails forwarded to my personal email address. For me, it was easier to maintain each email account separately by webmail.

Each morning I launch my personal email (on Mozilla Thunderbird). I also launch 2 tabs in my browser for the 2 separate client email accounts. I check email in my personal email account with immediate notifications. I keep my speakers off so the notifications are silent. These notifications appear as a small red number on my email icon in the taskbar (the icons at the bottom of my monitor). I can easily ignore or check my personal email as I see fit.

I keep track of each client's emails by switching through the accounts throughout the day. Typically, I check the client email accounts about 4 times per day: first thing in the morning, before and after lunch, and at the end of the day. I give my clients my cell phone so that if they have an urgent

need, they can always contact me immediately during my regular office hours. However, clients rarely text me. One client likes to use Slack (https://slack.com/), software that allows private chat rooms/groups and direct messaging. Slack's immediate notification means I never miss a timely communication.

—Melissa L. Bogen

In recent years, about half of my clients have required me to use an email account housed in their organization. I've set them all up in my Outlook along with my medical writing business email account, so I can scan my emails from all of my current clients at the same time. I've found it very helpful for organizing emails by project and client in my Outlook, and it allows me to filter out my other clients when I need to focus on correspondence related to active projects. The only email account I don't access through Outlook is my personal email account. I only check my personal email account through an Internet browser, so that I don't get distracted by personal emails during the workday.

—Gail V. Flores

In a recent email, purportedly from Costco, I was asked to answer 3 questions about customer satisfaction—a feature that Amazon and others use frequently (and I respond to those occasionally to express appreciation of good service). This time, I was offered a wristwatch with a "fall accident" feature. The only cost was postage. "OK," I wrote to accept. My son said, "Mom, you've been scammed. Cancel your credit card." I called Costco Visa and was told that the charge was $8.95 but that there was no need to cancel the card; Visa would protect me. Also, I was given the charge company's phone number. The agent who answered said, "your watch will be delivered tomorrow, and your earpods will soon follow for $35." I cancelled the earpods, charges, and (supposed) account. Incidentally, that call was my second scam email of that 1 day.

That said, I've done editing jobs by email in 6 countries for years. The only change I've added to my system is a separate email address for clients. I never use that email address to buy anything! Consequently, I never receive ads or unsolicited responses on that site. I also have a separate bank account to receive online payments for completed jobs. Immediately after payment arrives, I transfer the money to another business account.

—Phyllis Minick

* * *

TRAVEL SECURITY AND SANITY

Tapping into airport or hotel Wi-Fi can expose you to a host of security issues. When traveling, seasoned freelancers rely on their security software for protection. Norton, Trend Micro, and Malware Bytes come to mind. Some seasoned freelancers go so far as to have their own virtual private network (VPN) for travel security. And for both security and sanity, never check email on your phone when you travel, especially when you're on vacation. Set your out-of-office message and walk away from the inbox.

Tips from Seasoned Freelancers

For the last 2 years I have not stayed in a hotel and have traveled only by car. In the past, I took up to 15 trips per year: I have never worried about "security" vis à vis email or Wi-Fi while traveling—and I check my email by iPhone and iPad regularly. Even when traveling by air, I always sign on to the airport Wi-Fi and have never had a problem with hackers. Some of my clients like to send text messages regularly and of course I review these while traveling—sometimes I prefer text messaging, even if the messages are very long, because it is so much simpler while traveling.

—Cathryn D. Evans

* * *

BUSINESS SCULPTING

Freelance medical writers often get their start in one area of the business, like scientific publications, and over the years find their interests wander. Freelancing gives us the flexibility and the opportunity to explore other areas and sculpt our businesses accordingly. Rather than resist the urge to branch out, seasoned freelancers should embrace their passions and pursue other interests that can allow their freelance businesses grow.

Tips from Seasoned Freelancers

As a freelance business grows, it's common for seasoned freelancers to get so busy that we don't take time to think about the type of work we're doing. Then one day we realize that we'd like to add other types of medical writing or transition out of the work we're currently doing to other types of medical writing.

One of the joys of freelancing is that we do get to choose our clients and our projects. If you're not doing what you want to be doing, set aside a few hours when you can think strategically about your business and develop a plan. Consider other types of work you want to do and how you can make the

transition to those types of work. Can current clients give you new types of work? Who in your network does what you want to do and might help you? Continue doing the work you're known for as you add or transition into new types of work.

Every 6 months or so do another strategic planning session. Review your progress and the type of work you most want to do.

—Lori De Milto

This is truly an important question for all of us. I started out targeting "pharmaceutical industry" clients because I had worked for several years as a full-time medical writer for a drug company. Note, however, that during all those years, my experience included not only scientific publications and regulatory affairs but also marketing communication, sales-training projects, continuing medical education and patient education materials, writing and designing educational and scientific exhibits, writing press releases, and covering medical meetings. So my "focus" on pharma/biotech clients was by no means limited to clinical regulatory affairs.

I point this out here because I feel those who have worked in the industry may have a better advantage than they realize. An underpinning to *all* of these topic areas is understanding deeply the *process of the development of new drugs/biologicals as well as strong familiarity (experience) with Food and Drug Administration regulations*. No matter what you do in the pharma/biotech industry, regulations will be a ghost in the background—so learn the regulations as well as the product development process.

Over the years as a freelancer, I have also worked for hospital systems, creating or modifying website copy, writing practitioner profiles, or creating brochures, and for managed care companies, writing provider manuals, standard operating procedures, responses to patients, and educational material. The background in pharma/biotech enabled me to branch out this way quite easily.

Incidentally, I became a certified yoga instructor as well as a certified Acupressure/Shiatsu practitioner while freelancing. Thousands of hours devoted to classes for these certifications because I love both practices and did them part-time while freelancing as a medical writer.

Think about your present expertise and how/where you might branch out. Take classes in the new area, if you can. Do your homework and then move. But please . . . never, ever tell a client you have experience doing something when you do not! Study, learn, practice first—then do it for a client.

—Cathryn D. Evans

There's more to come from the 2021 Jam Session in next month's issue of the *AMWA Journal*.

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IN THE SERVICE OF GOOD WRITING

What's in a Name? (Diagnosis)

Laurie Endicott Thomas, MA, ELS / Madison, NJ

Shakespeare's Juliet asked, "What's in a name? That which we call a rose / by any other name would smell as sweet." (*Romeo and Juliet* Act II, Scene II, Line 46-47) But Juliet was a love-struck teenager. The Chinese philosopher Confucius gave advice that is more suitable for medical writers: "If names be not correct, language is not in accordance with the truth of things. If language be not in accordance with the truth of things, affairs cannot be conducted successfully." (*Analects* Section 3, Part 13) A diagnosis is a kind of name—a name that must be used accurately. Real estate professionals tell us that the value of a property is determined by 3 factors: location, location, and location. Likewise, the care that a patient receives will hinge on diagnosis, diagnosis, diagnosis. As medical writers, we need to understand what a diagnosis is, and what the process of diagnosis entails.

When I am sick, I want my clinician (physician, nurse practitioner, or physician assistant) to give me 4 vital pieces of information:

- What is wrong with me? (diagnosis)
- Why did this happen? (etiology)
- What can be done about it? (therapeutics)
- What will happen to me because of all this? (prognosis)

Sometimes, the answer to the first question will practically dictate the answers to the rest of the questions. If I receive a diagnosis of influenza, it means that my clinician thinks that my illness resulted from infection with an influenza virus. This diagnosis will affect how my illness will be treated and the predictions that will be made about what will happen to me next.

WHAT IS A DIAGNOSIS?

The word *diagnosis* came from ancient Greek. *Dia-* came from a root that meant "through, in different directions, or between," but could also mean "thoroughly," and *gnosis* meant knowledge. So, the word *diagnosis* implied a form of knowledge that was chosen from among a set of possibilities. Likewise, *pro-* meant "before," so a prognosis meant foreknowledge—a prediction. Many things can go wrong with the human body. A diagnosis implies that the clinician knows something about what has gone wrong in a particular case. A prognosis is the clinician's educated guess of what will happen in the future.

Diagnosis is a noun, but it has been transformed into the verb *to diagnose*. Thus, diagnosis can be viewed as a process, not just as the label that is applied to the patient's illness at the completion of the process. *Differential diagnosis* can mean the process of choosing from among 2 or more conditions that produce a similar clinical picture. However, a *differential diagnosis* can also mean the list of possible explanations for a patient's condition. Each item on the list is a diagnostic differential.

The ancient Greek philosopher Plato suggested that knowledge is a justified true belief.[1] A diagnosis is a belief that is (one hopes) justifiable. Ideally, there would be some consensus within the scientific community and the medical profession about how each diagnosis can or should be justified. Some diagnoses can be justified by some sort of pathognomonic sign or symptom (ie, something that is distinctively characteristic of that condition). Others are justified by the result of imaging or a laboratory test. The justification could be a formal case definition—a set of criteria that must be met. Yet even if a diagnosis seems to meet the appropriate criteria, it could still be wrong.

Medical students are taught heuristics for diagnosis. A heuristic is an approach to problem-solving. The word *heuristic* came from the Greek verb *heuriskein*, which means to discover. One approach is to consider the most common conditions first—yet rare diseases do occur, albeit rarely. Another approach is to try to find a single diagnosis that explains every aspect of the patient's condition, because the simplest explanation is most likely to be correct. This is in line with the principle called Occam's Razor: "entities should not be multiplied beyond necessity." Yet Occam's Razor must be balanced against Hickam's Dictum: "a patient can have as many diseases as he damn well pleases."

Clinicians can make errors in diagnosis for countless reasons. However, those errors all fall into 2 basic categories:

- A *misdiagnosis* means that the patient was given a diagnosis of a condition that he or she did not really have. A misdiagnosis is easy to make when several different

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diseases produce similar signs and symptoms. A misdiagnosis can also result from a false-positive result from a diagnostic test.

- A *missed diagnosis* (also known as a *failure to diagnose*) means that the clinician failed to provide the correct diagnosis. This problem can be due to a false-negative result from a diagnostic test. It can also result from a failure of imagination called premature closure of the differential: a failure to include the correct diagnosis among the differentials being considered.[2]

These individual errors can add up to a systematic under- or overdiagnosis of a disorder.

- *Underdiagnosis* means that the condition is being missed in a significant proportion of cases. Under-diagnosis is common when the population has poor access to medical care, when there is poor awareness of the condition among the population and/or the clinicians, or when the correct diagnosis is hard to make.
- *Overdiagnosis* means that too many patients are being given the diagnosis. The diagnosis is being given to patients who do not have the condition at all and/or it is being given to patients whose cases are too mild to warrant medical attention. Overdiagnosis can be a result of disease mongering, which is the practice of inappropriately widening the diagnostic criteria for a medical condition and aggressively promoting public awareness, to expand the market for diagnostics and treatments.

For the individual patient, an error in diagnosis can lead to bad treatment decisions and bad outcomes. On a societal level, these individual errors may result in poor public health and large-scale misallocation of resources.

DIAGNOSES ARE LABELS

A diagnosis is a label that is applied to a patient's illness. This labeling allows clinicians and scientists to sort cases of illness into categories and to sort patients into groups, which makes it possible to do clinical studies. Some diagnostic labels imply the kind of knowledge that the clinician believes that he or she has about the patient's condition. Others refer to the process through which the clinician's belief was justified (see Types of Diagnosis).

Types of Diagnoses

admitting diagnosis—the diagnosis reported by the clinician who decided that the patient needs to be hospitalized. The admitting diagnosis may be tentative because the patient has yet to undergo examinations and testing. The admitting diagnosis is recorded for administrative purposes.

biologic diagnosis—a diagnosis based on a test performed on a laboratory animal (eg, inoculation of a cell culture, egg, or laboratory animal with a patient's specimen to isolate a virus).

clinical diagnosis—a diagnosis based on the patient's symptoms and clinical signs at examination, as well as the patient's history. Symptoms are phenomena (eg, pain) that are subjective (ie, only the patient can observe them). Clinical signs are phenomena (eg, swelling, heat, or redness) that are objective (ie, the examining clinician can observe them). The term *clinical diagnosis* can also mean a diagnosis that was based on all the information (including laboratory and imaging results) available during the patient's lifetime, as compared with the autopsy findings.

cytologic diagnosis—diagnosis based on examination of exfoliated (shed) cells.

definitive diagnosis—a final diagnosis based on the results of confirmatory testing.

diagnosis of exclusion—a diagnosis made by eliminating all of the other known differentials.

diagnosis ex juvantibus—a diagnosis based on the result of treatment, such as antibiotic therapy.

direct diagnosis—a diagnosis made by observing structural lesions or pathognomonic signs or symptoms. Pathognomonic means distinctly characteristic of a particular disease.

discharge diagnosis—the diagnosis recorded when the patient leaves the hospital.

etiologic diagnosis—a diagnosis that implies the underlying cause of an illness (eg, a diagnosis of measles means that the clinician believes that the patient has a measles virus infection), or the process of identifying the underlying cause of the illness (eg, isolation of a particular strain of bacteria in the case of an infection).

faux diagnosis—a false diagnosis that is made for some administrative purpose.

laboratory diagnosis—a diagnosis based on the results of tests or examinations performed in a laboratory on specimens (eg, of tissue or bodily fluids) taken from the patient.

niveau diagnosis—localization of the exact level (*niveau* in French) of a lesion, such as in the spinal cord.

pathologic diagnosis—a diagnosis based on the observed presence of structural lesions. The clinicopathologic method meant comparing the records of the patient's condition during lifetime with the autopsy findings.

physical diagnosis—a diagnosis based on looking at (inspection), feeling (palpation), tapping on (percussion), and listening to (auscultation) the patient's body.

presumptive diagnosis—a diagnosis based on the known probability of a known condition, such as the antemortem diagnosis of a disorder that can be confirmed only at autopsy. (Compare with **definitive diagnosis**.)

provocative diagnosis—a diagnosis based on a provocative test, such as exposure to an allergen to confirm an allergy.

radiologic diagnosis—a diagnosis based on the results of imaging, such as x-ray imaging, computed tomography, or magnetic resonance imaging.

serum diagnosis—a diagnosis based on testing of serum (the fluid left after a blood sample coagulates).

syndromic diagnosis—the recognition of a group of signs and symptoms that characterize a clinical condition that might not always result from the same cause. The word syndrome came from the Greek for "occurring together." If research shows that a particular syndrome always results from a particular cause, the syndrome becomes a disease.

wastebasket diagnosis—a vague and possibly meaningless diagnosis given when a patient's condition cannot be easily classified.

working diagnosis—the differential (or set of differentials) that is considered most likely to be the true diagnosis.

Cause or Effect?

Diagnoses are labels that allow us to sort cases. However, diagnostic labels themselves can be sorted into categories, such as etiologic (ie, pertaining to cause) vs syndromic (ie, pertaining to the pattern of observable effects). Some diagnoses (eg, the classic exanthems) start off as a syndromic diagnosis, only to become an etiologic diagnosis as its cause is revealed. An exanthem is an acute, sudden illness that involves a widespread rash along with other symptoms (eg, fever and headache). By the early 10th century, the Persian physician Abū Bakr Muhammad ibn Zakariyyā al-Rāzī (known in the West as Rhazes) knew that smallpox and measles were separate diseases. Yet the causes of those 2 diseases remained unknown for another millennium. In the early 20th century, pediatricians assigned numbers to the most common childhood exanthems (Box: The Classic Exanthems).[3] These disorders began as clinical syndromes. But in the 20th century, researchers found that each of these classic exanthems (except for fourth disease, which might not exist as a separate entity) was due to a different infectious agent. Thus, 5 out of the 6 classic exanthems became diseases, and the diagnoses changed from syndromic to etiologic diagnoses.

The Classic Exanthems

In the early 20th century, pediatricians numbered the most common childhood exanthems (diseases that caused a rash and other symptoms, such as fever)[3]:

- **First disease** was rubeola (measles)
- **Second disease** was scarlet fever
- **Third disease** was rubella (German measles)
- **Fourth disease** was Duke's disease (unknown today)
- **Fifth disease** (erythema infectiosum or slapped cheek syndrome) is still called fifth disease
- **Sixth disease** was roseola infantam.

Measles, rubella, fifth disease, and roseola are caused by viral infections. Scarlet fever results from a bacterial infection (group A *Streptococcus*).

Names and Numbers

Medical conditions often had 2 names: the popular name and the scientific name (eg, measles and rubeola). A medical condition was often named after the person who first described it in the medical literature (eg, Cushing's syndrome). Today, AMA style requires us to drop the 's after the person's name (Cushing syndrome). Sometimes, the name of a condition changes. For example, *dementia praecox* became *schizophrenia*, and *manic-depression* became *bipolar disorder*. Sometimes, the name is changed because the cause is discovered (eg, "De Vivo syndrome" became "glucose transporter type 1 deficiency syndrome"). In May 2015, the World Health Organization recommended that new diseases should not be named after persons or refer to geographical locations, animals, foods, cultural or occupational groups, or populations or industries and should not include terms that incite undue fear (eg, *fatal*).[4] If you are uncertain of the current name of a condition, you might look it up under the Medical Subject Headings thesaurus of the National Library of Medicine (https://www.ncbi.nlm.nih.gov/mesh). Genetic disorders are catalogued in Online Medical Inheritance in Man (https://www.omim.org/), a joint effort between the National Library of Medicine and Johns Hopkins University.

To make it easier to record medical diagnoses and compile statistics on public health, the World Health Organization introduced the International Classification of Diseases and Related Health Problems. The 11th edition, which is currently being implemented, provides roughly 55,000 unique alphanumeric codes for diseases, injuries, and causes of death. For example, the code for a distal fracture of right radius with dorsal tilt and joint involvement after falling on the sidewalk would be NC32.50 & XK9K & XJ5GS / PA60 & XE53A.[5] Similarly, the American Psychiatric Association's *Diagnostic and Statistical Manual*, currently in its fifth revision (DSM-5), is used in the United States for coding mental disorders.

Binaries, Scales, and Spectrum Diagnoses

Many common diagnoses involve some sort of binary. A binary is some variable that can have one of 2 values: on or off, yes or no, alive or dead, male or female, pregnant or not pregnant. Yet in practice, even a yes-or-no question has 3 possible answers: yes, no, and no answer. Although a binary involves 2 categories that are separate conceptually, the boundary between the 2 categories may be fuzzy in practice. Thus, it can be hard to classify some individuals. For example, a child's biological sex is a diagnosis that used to be made at birth but is now often made much earlier, during an ultrasound examination. Nearly every human being can easily be classified as either male or female on the basis of their phenotype (their anatomy) or their karyotype (presence or absence of a Y chromosome). Nevertheless, there are a few cases (about 1 in 5,500 live births)[6] in which a newborn's external anatomy does not match the chromosomal sex or cannot be easily classified. These rare cases do not prove that sex is nonbinary. Rather, they just illustrate that the boundary between the 2 categories is slightly fuzzy.

Even if the boundary between categories is a single clear criterion, some cases can be misclassified if the criterion is

hard to document. For example, a woman is either pregnant or not pregnant. By definition, a pregnancy begins when an embryo implants itself on the inner lining of the uterus. Yet the pregnancy cannot be detected by blood or urine tests until a few days after implantation.

Many diagnoses depend on some sort of measurement (body weight, blood pressure measurements, IQ scores) that falls somewhere on a scale. This kind of diagnosis raises important questions: is the measurement accurate? Is the scale meaningful? Where should the lines between categories be drawn? Consider the diagnosis of obesity. Obesity means that the body contains too much fat. Yet body fat content (adiposity) is rarely measured directly. Instead, clinicians measure body weight (in kilograms) and divide it by the square of the height (in meters) to calculate the body mass index. Body mass index provides a useful rule of thumb. However, bodybuilders can have a body mass index in the obese range despite having very little body fat. Also, the body mass index tends to underestimate body fat in short people and overestimate it in tall people.[7] Yet even if you developed a better metric than body mass index, you would still have to decide where to draw the lines between the categories of underweight, normal weight, overweight, and obese. Even if you draw those lines in reasonable places, someone whose weight falls close to the boundary between categories could switch from one to the other and back within the course of a single day.

Sometimes, differences in magnitude can seem to produce differences in kind. If a patient receives a different diagnosis than another patient received, the difference in labeling seems to imply that the 2 patients have different *kinds* of problem. Yet the 2 patients might have the same underlying kind of problem but at different levels of *severity*. A spectrum disorder is a set of conditions that look different but are believed to represent the same underlying problem at different levels of severity,[8] just as light at different wavelengths looks like different kinds of light.

Psychiatric Diagnoses and the Biopsychosocial Model

Psychiatric diagnoses pose a particularly thorny set of problems. In general, a mental illness can be any problem that involves one or more of the following: cognition (perceptions and thoughts), emotion (feelings), or action (behavior). To be considered a mental disorder, a mental illness must cause distress or disability, must not be an expectable or culturally sanctioned response to a particular event, and must not be primarily a result of social deviance or conflict with society. Unfortunately, these concepts are broad and lack precise boundaries.

Key Points

When writing about any diagnosis, think carefully about what that diagnostic label means.

- Is the diagnostician asserting something about the cause of the patient's condition? Or does the diagnosis simply mean that the signs and symptoms follow a familiar pattern?
- How is that diagnosis justified? Is it supported by physical examination findings, radiologic findings, or the results of laboratory testing?
- How meaningful are the criteria for making the diagnosis, and how reliably are they being applied?
- How severe must a case of a condition be to qualify for the diagnosis? How were the boundaries between normal and abnormal values determined?
- Is the diagnostic label saying something true about the patient? Or is it sending a misleading message that undermines the patient's interests?

Some mental disorders may have a purely biological cause. Others seem to result from a combination of biological, psychological, and social causes. The biopsychosocial model accepts that all 3 kinds of causes can contribute and may be interrelated. Psychiatry is part of medicine because many mental disorders are believed to have at least some basis in biology. Yet once a particular condition is shown to have a clear biological basis (eg, psychosis due to anti-*N*-methyl-D-aspartate receptor encephalitis), that condition tends to get reclassified as a neurologic disease as opposed to a mental disorder. As a result, psychiatry is left with a set of conditions whose etiology is unknown or is so complicated that it might never be untangled. For this reason, psychiatric diagnoses are generally syndromic (ie, based on a pattern of signs and symptoms) as opposed to etiologic (ie, a statement of cause). Thus, psychiatrists use diagnostic testing to rule out medical diagnoses, as opposed to confirming psychiatric diagnoses.

When trying to figure out the cause of a mental disorder, some psychiatrists prefer to err on the side of biology whereas others prefer to err on the side of psychosocial causes. Medical writers should be alert for either kind of bias. In particular, medical writers should be skeptical whenever a diagnostic label suggests that a patient's physical symptoms are psychological in origin.[9] Conversely, medical writers should also be skeptical of the use of medical-sounding diagnoses for social or educational problems. In 1851, Samuel A. Cartwright argued that slaves who tried to escape from slavery were exhibiting a mental illness that he called *drapetomania*.[10] Today, children who have trouble with the "3 R's" (reading, writing, and arithmetic) are routinely given the diagnoses of dyslexia, dysgraphia, and

dyscalculia. This use of these medical terms implies that the cause of the problem is in the child's brain, when the cause of the child's poor academic performance could very well be in the child's schooling (eg, bad methods for teaching reading and math and a refusal to teach penmanship). If we are using a medical label for a problem whose cause is pedagogical, not medical, then (to paraphrase Confucius) our language is not in accordance with the truth of things, and our affairs cannot be conducted successfully.

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EDITOR-AT-LARGE

A Shoe in the Door: Regulatory Writing Internships for Promoting Diversity and Building the Talent Pool

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ABSTRACT

Demand for qualified medical writers is high and expected to continue to grow. With competition for experienced writers getting fierce, the need for alternative pools of talent has become evident. This article describes a pilot internship program developed at an independent clinical and regulatory consulting company designed to allow an alternate path for entry into the field of medical writing and to foster and retain talent. The internship will provide novice writers with relevant training, connections, and job experience to aid in attaining a position in regulatory writing. We discuss the challenges and opportunities discovered during the inaugural internship year and provide lessons for developing an internship program.

Demand for qualified medical writers is high and expected to continue to grow, with the global medical writing market expected to reach 7.7 billion US dollars by 2027.[1] This market growth is driven in part by increasing investments in research and development by pharmaceutical companies and the rise in contract research organization outsourcing.[1] Despite the demand for medical writers, there are few degree or professional development programs that prepare students directly for medical writing. Existing training programs comprise a combination of degree and certificate programs and include the American Medical Writers Association (AMWA)'s Essential Skills Certificate program, the University of California San Diego Extension's medical writing certificate program, and the University of Chicago's medical writing and editing certificate program. Although these programs are useful for building technical knowledge, they often do not provide students with training in the soft skills or practical skills necessary for day-to-day work as a medical writer, including project management, professional communication, emotional intelligence, time management, and conflict resolution (Figure 1).

Medical writing and the biotechnology industry generally have been experiencing a significant degree of staff turnover as part of the "Great Resignation" phenomenon that has followed the economic turmoil of the COVID-19 pandemic.[2] This competition for top talent, combined with significant growth, has left the biotechnology industry looking for ways to increase interest in the field, create alternate tracks for entry, and retain talented employees. These include mentoring college students interested in science, technology, engineering, and mathematics careers, hiring

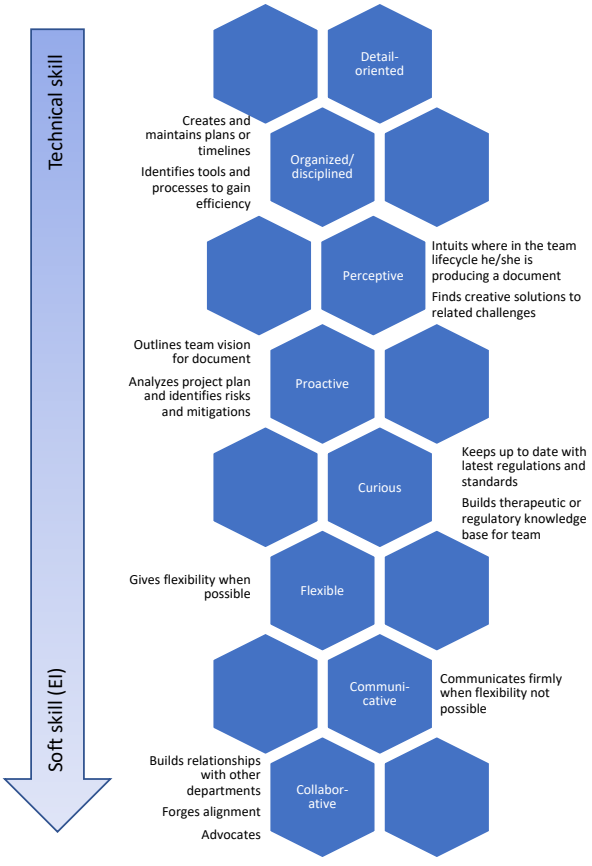

Figure 1. Key attributes of successful medical writers. Figure previously presented at AMWA New England Brunch Roundtable Meeting, March 21, 2021.

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foreign-born talent, and developing a robust corporate culture of inclusion.[3]

Many job positions in medical writing require multiple years of industry experience. A search of job postings on April 26, 2022, on Indeed.com for entry-level medical writing positions found that 14 of the first 15 listings required either an advanced degree (master's or above) or more than 1 year experience; 7 of 15 required both. One job listing did not specify experience requirements.

As is true for other medical writers in the field who are advanced in their careers, the senior leaders in our consultancy benefited from colleagues who were willing to provide mentoring early in their careers, which has engendered a sense of corporate responsibility in contributing to the development of the next generation of medical writers. Thus, Synterex has developed a medical writing internship program to foster new professionals and help medical writers enter the field of regulatory medical writing.

Synterex partnered with a local agency promoting engagement in the life sciences for Massachusetts residents to create an in-house medical writing internship. This program provides sponsorship for 2 students from local colleges and universities. Two additional students may be sponsored if chosen from an associate degree program or from historically Black colleges and universities (HBCUs).

Our findings from the first year of the internship program indicated that the internship provided a potential pipeline for talent acquisition and retention. We hope that this outline of our experience may serve as a base model for implementation of an internship program for companies of any size considering starting a program and will lower the barriers for entry into the field for medical writers, in particular those from diverse backgrounds and historically disadvantaged communities.

METHODS

In early 2021, our team observed that there was a concurrent increase in requests from associates of staff and consultants for mentoring and tips on how to enter the medical writing field, a higher demand for medical writing resources, and fewer contract medical writing resources available for ad hoc projects. Although historically we had not hired many entry-level medical writers due to the fast pace of the work and lack of demand from clients for medical writers with less than 5 years of experience, we began thinking of ways we could expand the medical writing talent pool in the long-term to eventually align client demand with interest from entry-level potential candidates.

In May of 2021, our executive leadership team initiated development of an internship program. The team discussed goals and gathered requirements for the internship program, including

- The scope of the program: did we want the internship to be focused on just medical writing, or would we open it up to other business functions?
- The geography of the program: did we want a national search, or did we want to anchor the program near headquarters?
- The logistics of the program: did we want a program that had a database of candidates we could search, or did we want applications to come directly to us to vet? Did we want to consider only students studying medical writing, or would we consider students studying in adjacent scientific fields?

Ultimately, we decided that we wanted at least one of the intern roles to be open to IT and business operations in addition to medical writing because we felt providing opportunities on those sides of the business would be equally beneficial for potential internship candidates as well as being areas of the clinical trial talent pool that also need development and that may have potential employment needs in our company in the future. We also decided to anchor the internship program at our headquarters in Massachusetts, given the high concentration of our clients and staff in the state and the potential for in-person interaction (pandemic permitting) within our primarily virtual workforce. In addition, given that we wanted to ensure our first internship program would be successful and manageable in scope because we are a company comprised largely of working subject matter experts with lean administrative/operational staff to vet applications, we opted for a program that had an existing database of interns we could search. Although this may present some limitations because the database is finite and not tailored to our core services, we felt this would be more manageable for us in the timeframe given to start up the internship program. Lastly, for medical writing interns, we opted to search for students in any scientific studies and try to identify writing-related or clinical trial-related experience or interests on their profiles, rather than limit our search to only medical writing-related applicants, as we did not want to bias our resourcing pool to those students who already had exposure to medical writing as a career choice.

In selecting an institution to partner with for internships, we wanted to select one that would be consistent with our hiring goals as a woman-owned and disability-owned

business in terms of making sure that our workforce represents the people who will ultimately receive the medicines we work on. Massachusetts Life Science Center's (MLSC) Internship Challenge program appealed to our mission because this program provides sponsorship of up to $8,160 ($17 per hour for up to 12 weeks) for 2 students from local colleges and universities as well as 2 additional students if chosen from an associate degree program or from HBCUs.

Massachusetts, where our headquarters is, has a particularly robust life science industry that provided us with multiple partner organizations to consider. These partnership opportunities may vary in areas with less biomedical infrastructure.

A full-time employee was identified to act as the Internship Coordinator. This person acted as the main contact for the intern to answer questions and direct programming. In our case, a junior staff member was chosen as someone who was able to relate to recent entry into the field. This team member also had more availability for ad hoc meetings, questions, and hands-on direction.
The Internship Coordinator then applied to the MLSC Internship Challenge program and searched in their database for intern candidates who would fit our consultancy's needs (educational background in the life sciences or information technology, career goals in line with our areas of expertise, experience with relevant software systems, etc). Any student who meets the MLSC program requirements of Massachusetts residency and enrollment in an accredited college or university in Massachusetts or at an HBCU can submit a resume and cover letter to the program database for companies to search. Six potential applicants were identified for each internship, and the executive team reviewed their application materials. None of the medical writing internship candidates were from associate degree programs. Two of the IT internship candidates were from associate degree programs. The Internship Coordinator reached out to one applicant for the medical writing position and 4 applicants for the IT position and signed formal agreements with the medical writing intern who confirmed her interest in the program. None of the IT applicants contacted chose to pursue the internship opportunity.

A single intern was hired for our pilot internship season. The intern was selected for her interest in pursuing regulatory writing professionally and her educational background in a regulatory affairs master's program. She was assigned to work 40 hours per week for the 12-week period with pay sponsored by the MLSC internship program.

The executive leadership team worked with the Internship Coordinator to develop a curriculum that involved meetings and shadowing sessions to pair the intern with team members in various departments. This allowed the intern exposure to various facets of the business (Figure 2).

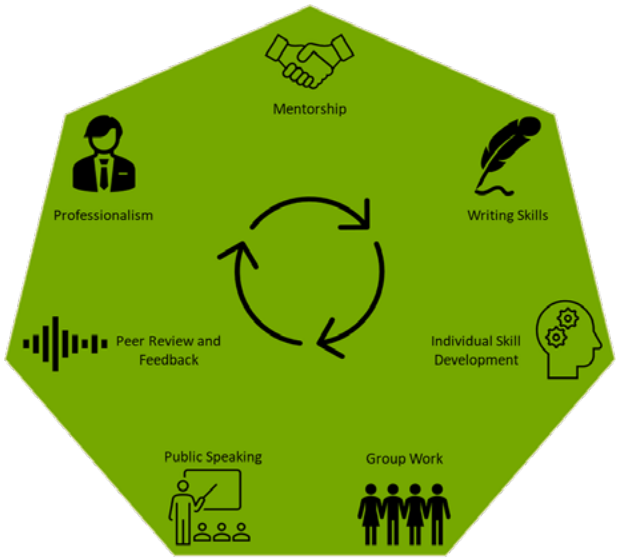

Figure 2. Components of the pilot internship.

We also agreed on critical success factors for the internship, including

- exposure to the concept of peer review and feedback,
- review and tips on developing their CVs for future opportunities,
- practicing summarizing medical content (eg, a regulatory guidance of interest),
- practicing public speaking (eg, discuss a science-related webinar they attended), and
- general work tips and day-to-day expectations for how to work and communicate in an office environment.

The Internship Coordinator set up an orientation to convey these success factors, our company values and organizational structure, and expectations to the intern. The Internship Coordinator also set up a Microsoft Teams channel in which the extended team could create a queue of projects that would be both appropriate for the intern to work on and meaningful in terms of gaining experience. We also sent a company-wide email introducing the intern so that the wider team could get to know and connect with her.

The intern was invited to weekly business operations meetings and assigned various internally facing projects such as the development of a company style guide. The intern was also assigned to externally facing projects with the supervision of a staff medical writer including social

media blog posts on health-related projects. These projects allowed the intern to gain experience with professional writing tools and reference citation management software.

Although the intern did not work directly on client materials, she was involved as an observer in several active documents with Advance permission from the client and an active nondisclosure agreement. This allowed the intern to experience the collaborative authoring process and comment resolution meetings. After the meetings, the intern met with the Internship Coordinator to discuss professional communication and conflict resolution tools.

At the beginning of the internship, an exit interview was put on the calendar with the intern, as well as prospective regular meetings with select other team members to discuss specific business functions outside of the medical writing function. In addition, our own impressions and reflections on the internship were discussed at a regular internal meeting at the end of the internship period. The intern completed training in Good Clinical Practice and our company standard operating procedures. Our intern provided feedback at her exit interview on the aspects of the program that worked and things that could have been done better. This feedback is reflected in the lessons learned section below.

LESSONS LEARNED

Consider Work Environment

Our company is a fully remote workplace, with team members spread across the United States. This remote set-up may be an advantage for interns from areas without a developed biotechnology industry or for individuals without reliable transportation to and from work. The remote workplace can present a challenge, however, as the intern will not organically get to meet the team in the course of their work, and at this juncture in their career development they most likely do not have existing in-office experience to draw from to make their own connections. We had to go out of our way to encourage team members to interact with the intern and to include her in ongoing projects.

When hiring interns for remote work, recognize that in order to participate fully, interns may need to be provided with laptops and other tools to access company resources.

Setting Expectations

It is important that both the intern and the company set realistic expectations at the beginning of the internship both in terms of requirements and availability. Although our intern had 40 hours of availability in the week to dedicate to the internship program, it was understood and agreed at the outset that she also had a part-time job and a capstone project that cut into some of our regular business hours. This arrangement may not be feasible for all companies and all individuals, as it puts the onus on the intern to communicate their availability and the hosting company to work around it.

Have a frank conversation with the intern prior to hiring on the expected hours and commitment that will be required in order to provide real, meaningful work for the company. In retrospect, we decided to make a formal job description for the internship position to state these expectations in writing. Recognize that if your internship requires full-time hours but does not provide a living wage or benefits, many individuals will need to maintain outside employment. Restricting outside concurrent employment or expecting interns to work for experience rather than pay will limit applicants to only those privileged enough to be supported by family or external means. The more you are able to invest in your intern, the more they will be able to invest in your company.

Provide Depth and Breadth in Programming

We found success with assigning the intern a mix of group work and independent projects. This allowed her to stay busy while allowing for feedback from other team members on rotations through each department. Having a long list of possible tasks, longer than you think you will need, ensures that the intern has other work to focus on if the Internship Coordinator is not immediately available to direct the intern to a new project.

Try to identify independent, low-pressure tasks that are conducive to skill-building. We assigned our intern to writing blog-style health posts for our social media site. We challenged her to write the piece for different audiences (graduate level peers, high school students, children) and to bring the reading level of her work within range for each group. These assignments also allowed her to also practice using citation management software in a low-risk environment before applying those skills in a client-facing document during collaborative authoring.

A limitation of our program was having only one intern in our pilot program. In the future, we hope to host a cohort of interns at the same time. This would allow for more group work and collaborative learning between interns of similar skill levels.

Provide Resources for Learning

In order to facilitate independent work from your intern, curate resources for self-guided learning. Note that many of these resources already exist and do not need to be created in-house. There is a wealth of tutorial videos available on

the Internet for the different software systems typically used in medical writing. Online training modules are available through AMWA and the DIA (see Additional Resources)

Additional Resources

DIA Learning Solutions: https://www.diaglobal.org/en/learning-solutions

AMWA Courses: https://info.amwa.org/medical-communication-essential-skills-for-success

Provide regulatory guidance documents for the intern to review. If you can show a redacted example completed document similar to the one under development, this will allow the intern to build context for the current assignment. Consider building a library (analogue or digital) for your intern and other staff members to peruse. Try sending your intern on an Internet search for additional resources on a certain topic; you may be surprised at what useful tools they are able to bring back to the team.

Allow Time for Feedback and Questions

After periods of independent and group work, it is important to allow the intern time to digest and process the learning experience. We established a standing weekly meeting between the intern and the Internship Coordinator to discuss recent work. We also planned weekly meetings with each department to allow for broader exposure to the company. Given how busy team members are, it is strongly recommended to set these meetings up in advance so that programming for the intern can be prioritized. We were limited in the quick development of our internship program, and more advanced planning would have allowed for a more regular meeting schedule.

Not All Assignments Have to be Directly Related to Medical Writing

Medical writers often wear many hats in the course of their normal work. Foster these adjacent skills in your interns as well. Provide time to discuss soft skills such as professional development, time management, and remote working strategies. Interns may have little experience with professional workplaces. Recognize that you may need to discuss and model professionalism in written and verbal communication as well as business etiquette. This may take the form of role-playing professional communication and conflict resolution scenarios. Consider offering training in emotional intelligence courses that will serve the intern in their future career, regardless of what they pursue.

Consider Future Benefit to the Intern

Try to provide the intern with experiences that will not only benefit the company but will benefit the intern going forward. This may take the form of resume-building experiences such as authorship or editing credit, industry connections for future professional development opportunities, or, more tangibly, a position within your company if possible. We had a very positive experience with our first intern, and we were able to hire her into a part-time project management position while she completed her graduate degree. She now works for us as a full-time employee. She has been able to smoothly transition into these new roles due to her previous experience during her internship and was able to make an immediate impact on our team. If you are not able to hire your intern, consider remaining in contact so that you can continue to provide mentorship, advice, or job references after the internship is complete.

PLANS FOR FUTURE INTERNSHIP DEVELOPMENT

We found our pilot internship program a resounding success. We are looking to expand the program in 2022 to take on multiple medical writing interns and have developed a pilot information technology internship position as well. We are looking to partner with other local life science outreach programs to reach a more diverse student base of first-generation college students. We also hope to partner directly with local colleges and universities to identify interested students. Many students plan their summer and semester experiences months in advance, and it is important to get your internship information to them early if you would like to be considered.

In the future, we would like to expand outside of our local area to partner with HBCUs, tribal organizations, and international student groups to cast a wider net for our internship candidates and provide opportunities for entry into medical writing to communities that have previously been under-represented.

Building on the success of our internship program, we are also developing a fellowship program to function like a medical writing apprenticeship. This program would be longer-term, a full year as compared with the 12-week internship. The fellowship is targeted to individuals who have completed an advanced degree in life sciences within the previous 2 years. This program provides a full-time, benefited fellowship position for individuals who are committed to entering the medical writing profession but do not have relevant job experience for entry-level positions.

CONCLUSIONS

Given demand for experienced medical writers and the dearth of qualified applicants, we have presented a basic model that small- to medium-size companies can customize to develop an in-house training and internship program to attract and retain medical writing talent from a diverse background.

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V37 N2 / 2022

BIOGRAPHY

Maud Mellish-Wilson – Librarian, Editor, Visionary

Tom Lang / Principal, Tom Lang Communications and Training International, Kirkland, WA

ABSTRACT

Maud Mellish-Wilson was an early and influential voice in biomedical communication. In the early 1900s, she was hired by Mayo Clinic to set up its first library, but she accomplished a great deal more. A competent editor, she established the Clinic's Division of Publications, which helped establish the Clinic as a world-renowned health care and research center, and probably the craft of author's editing as well. The Division still supports authors during all stages of scientific publishing and remains a model for research centers around the world. She started *The Collected Papers of Mayo Clinic*, which summarized the articles published by Clinic authors each year; wrote an important book on medical writing and editing; and began what would become *Mayo Clinic Proceedings*. The Mayo brothers considered her to be 1 of the founders of Mayo Clinic, along with their father. Here, I describe her life and accomplishments to recognize her achievements and to contribute to the history of the profession of medical writing and editing.

Maud Mellish-Wilson was the first editor at Mayo Clinic (Figure 1). She headed the Division of Publications from its creation in 1914 to 1926 and continued to edit for the Clinic until she died in 1933.1 As an early and visible author's editor, she is credited with greatly increasing the quality and consistency of manuscripts leaving the Clinic. In her 26 years there, she set new standards for scientific publishing, wrote a book describing those standards, initiated and edited the first 24 volumes of the *Collected Works of the Mayo Clinic*, launched what would become *Mayo Clinic Proceedings*, and became a legend both at the Clinic and in the scientific community.

Figure 1. Maud Mellish-Wilson. Date unknown. Born Annie Maud Headline, she dropped the name Annie during her marriage to Dr Ernest Mellish, who died in 1905. She kept his name when she remarried to Dr Louis Wilson. (Used with permission from Mayo Foundation for Medical Education and Research.)

HER EARLY YEARS

Annie Maud Headline was born to Swedish immigrants on February 14, 1862, the youngest of 7 children.[1] The family lived in a log cabin near the small town of Faribault on the plains of Minnesota, 50 miles from Rochester to the southeast and 50 miles from Minneapolis to the north.[1,2] The Civil War had begun the year before, and in a few months, the short but bloody Dakota War of 1862, which pitted settlers against the Santee Sioux Indians, would begin not far from town.

In her childhood, she was curious, strong-minded, and practical to the point that her parents often followed her advice.[1,2] She wanted to be a doctor, but women were not generally allowed in medical school at that time, and money was scarce. Instead, she went to nursing school in Chicago, auditing lectures at Rush Medical School at the same time.[1] At Rush, her persistence and intelligence were noted by 2 prominent physicians, Dr Moses Gunn, Head of Surgery at Rush, and Dr Charles Parkes, Surgeon-in-Chief at Augustana Hospital. She developed close and lasting friendships with both men.[1,3] Shortly after graduating from the Illinois Training School for Nurses in 1887,[4] she went to work at the 50-bed Maurice Porter Memorial Hospital for Children, eventually becoming the superintendent of the hospital.[2,4]

In 1889, at age 27, Maud married Dr Ernest J. Mellish, a promising young surgeon teaching at Rush Medical School.[1,5]

Ernest had contracted tuberculosis before they married, and his health problems were to last throughout the marriage. They moved to Michigan, where Ernest built a successful surgical practice with Maud as his surgical assistant. During the marriage, she dropped her first name, Annie, and went by Maud.[2]

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In 1893, they moved back to Chicago. Despite a severely depressed economy, Ernest found work at charity hospitals and returned to teaching at Rush. During this time, Maud began to edit his articles.[2] Ernest later wrote, "Maud is of inestimable aid to me in revising my papers. I am sure they are much more readable for the revision. There are no superfluous words left in them."[1]

Ernest's disease went into remission in 1897, and for 4 years, he was able to build his practice again. When the disease recurred in 1901, he and Maud moved to El Paso, Texas, where they hoped the arid environment would be beneficial. He died of tuberculosis in 1905, cared for by Maud until the end.[1,2]

After her husband's death, Maud returned to Chicago and found work organizing the library at Augustana Hospital where she had friends.[2,4] There, at age 43, she met Dr Albert Ochsner, the chief surgeon at the hospital and an increasingly famous and prolific writer.[2,6] (Later, he would help found the American College of Surgeons.[6]) He hired Maud to edit his manuscripts, and her skill and intellect led them to become good friends and trusted colleagues.[3] (Dr Albert Ochsner mentored Dr Alton Ochsner, a distant relative, who would establish the Ochsner Clinic in New Orleans in 1942. In 1963, Dr Alton Ochsner was made a fellow of AMWA.[7])

Mayo Clinic was founded in 1889 as part of Saint Mary's Hospital and in cooperation with the Franciscan sisters who ran it.[8] The original medical staff consisted of Dr William W. Mayo and his 2 sons, William and Charles (affectionately called "Dr Will" and "Dr Charlie" by everyone at the Clinic).[9] The 3 introduced the integrated, multidisciplinary approach to medical care now common throughout the world. The Clinic grew rapidly in size and reputation—in 1904, the 2 brothers operated on more than 4,000 patients[8]—and was developing its medical specialties, laboratory facilities, educational programs, and other support services.

Dr Will was looking for someone to organize and develop a library to "run the literary end of the business."[4,10] He asked his friend, Dr Albert Ochsner, if he knew someone suitable for the job. Dr Ochsner immediately recommended Maud.[1,2] In early 1907, after Maud had visited the Clinic at the invitation of the brothers, Dr Will wrote to her, saying "We want you, we want you badly, and the sooner the better... We want you to develop a library and to do editorial work on scientific publications."[1,2,4] Having recently lost her husband, not wanting to return to nursing, and feeling that it was too late to go to medical school at age 45, Maud joined the Clinic 3 months later.[1,2,11]

HER YEARS AT MAYO CLINIC

When Maud arrived at the Clinic, the library consisted of "three small book cases, a few journals on a small reading table, and the books owned by various members of the staff."[1,12] She also reportedly found copies of dozens of publications by the Mayo brothers and their father stored in a basement coal bin.[1,2,11] She pulled the papers from the coal bin, cleaned and organized them, collected books and articles from around the Clinic, ordered missing journal volumes, arranged for interlibrary loans, and, in general, created order out of chaos.[1]

She built the collection carefully to meet the specific needs of the Clinic. After WWI, many European libraries were sold, and the Clinic was able to add several rare and important books to fill gaps in its collection.[1] She also visited medical libraries around the country to collect ideas for the design of a new library that opened in 1914.[2] Within a few years, she had increased the library holdings to more than 4,000 volumes.[13] When she died in 1933, there were 40,000.[1]

Dr Louis B. Wilson (1866-1943) was brought to the Clinic to develop its laboratory services as Chief of Pathology, a position he held from 1905 to 1937.[14] He met Maud shortly after she began working at the Clinic, when they were given the task of designing the new library for the 1914 expansion of the Clinic. Maud said of him, "I have met few men his intellectual equal. In addition to his scientific abilities, he has a most pleasing personality."[1] Louis's first wife died in 1920, and he and Maud married in 1924.[2,4] Louis would become the first director of Mayo Foundation and was a national leader in graduate medical education in the 1920s and 1930s.[15]

The Division of Publications

When Maud became the Clinic's first professional editor,[13] she had had close to 20 years of experience helping authors prepare manuscripts for publication which, in her view, "did not stop at checking grammar and punctuation."[13] (An understatement, to be sure.) When Dr Will noted that the quality of the articles written by Clinic staff "was not up to the standard of their clinical work,"[2] he asked Maud to help authors improve their writing. Soon, in addition to managing the library, she became head of the new editorial office and later, the head of the new Division of Publications in 1914.[1,4,12] Advances in printing had improved the reproducibility of photographs and medical illustrations and made them less expensive to publish. In time, 4 photographers (Maud made a point of hiring women photographers) and 2 medical illustrators were added to the Division.[1,11,16] She designed a clin-

ic-wide system for registering, editing, submitting, revising, and tracking manuscripts through the publication process, a centralized service that continues today.[12]

According to one biographer, Maud "set herself the task of seeing to it that the Rochester men said what they meant to say, that they were accurate in their facts and, as far as she could ensure it, straight in their thinking."[1] One story goes that Dr Charlie left a paper for Maud to edit while he was away for several weeks. He returned to find an article on his desk, read it, liked it, and wondered who had written it—until he realized it was his paper made better by Maud's editing.[2,13] (Dr Charlie, as Editor-in-Chief of *Postgraduate Medicine*, received AMWA's 1958 Honor Award for Distinguished Contributions to the Medical Literature.[7])

In fact, between 1909 and her death in 1933, not a single manuscript left the Clinic until it met her standards.[13,14] She gave recalcitrant authors a choice: bring your paper up to standard or publish it under your own name, without the Clinic's support. Or, as her future successor, Dr Richard Hewitt, said, "The paper... either descended by slow degrees into desuetude [a state of disuse] or was elevated to the heavens and has a star named after it."[12]

This policy paid off as journal editors noticed that every paper they received from the Clinic was technically sound and unusually well prepared.[1] There is little doubt that Maud's efforts greatly improved the Clinic's publications, which substantially advanced its reputation, as well as that of its staff at a critical period in the Clinic's history.[13] (This reputation has persisted for more than 80 years. Ed Huth, then Editor-in-Chief of the *Annals of Internal Medicine*, told me in the early 1990s that, "When you get a manuscript from Mayo Clinic, you just know it's going to be tightly edited, formatted correctly, and a pleasure to read." If ever there were an argument for insisting on rigorous editing and high standards, this is it.)

The Collected Papers of Mayo Clinic

In the early 1900s, physicians and hospitals generally did not advertise because such promotion was considered improper if not unethical. As a result, the Mayo brothers kept a low profile—including turning down an interview with *Life* magazine—to avoid the appearance of impropriety.[2] However, they were aware that physicians built their reputations by publishing in scientific journals, which of course was why they hired Maud. With Maud, however, they got more than just a librarian and an editor: they got a visionary.

In 1909, Maud selected the most important papers written by Clinic authors since 1905 (apparently including some rescued from that coal bin) and published them as the *Collected Papers by the Staff of St. Mary's Hospital Mayo Clinic*[1] "to present adequately the work of the Mayo Clinic and the Mayo Foundation."[17] The volume was the first of a series that continued for decades as *The Collected Papers of Mayo Clinic*.

The *Papers* increased the Clinic's professional visibility in a way that individual articles could not. For example, volume 1 was 686 pages; volume 15, published in 1924, was 1,420 pages. Of "629 papers published [in volume 46] between December 1, 1953, and November 30, 1954, 63 are republished in full, 52 by abridgement, 20 by abstract, and 495 by title."[17] Maud edited and published at least 1 volume every year until her death in 1933. The volumes she edited represented more than 6,000 articles.

The Writing of Medical Papers

In 1922, Maud published *The Writing of Medical Papers* (Figure 2).[18] Although it was not the first book on the topic,[19-21] it appears to have been among the most popular, going through 3 editions in 1922, 1925, and 1929. The book itself is a grammar and usage guide, a style manual, a textbook on preparing scientific articles, a reference for journal abbreviations, a summary of proofreader's marks, and an explanation of publication practices.

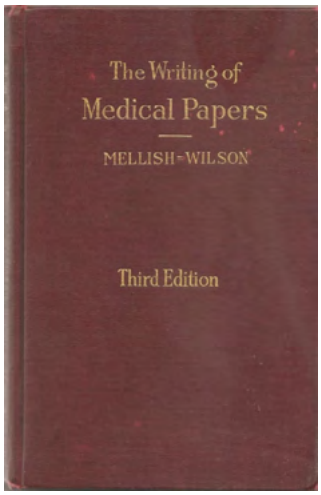

Figure 2. Maud's book, *The Writing of Medical Articles*.[18] The book appears to be one of the earliest and most popular guides for preparing medical articles. Much of the content is still relevant. Used with permission of Mayo Foundation for Medical Education and Research.

Of the 20 chapters, 7 are devoted to grammar and usage in medical publications (describing many conventions still followed today), and the last 13 concern preparing the scientific article and its parts, including the use of abbreviations, scientific style, and the importance of revising. In a summary at the end of each chapter, the topics were "reduced to a minimum, and rules have been made definite, even dogmatic, that they may be easy to refer to and follow" (Box on next page).[18]

The text is strictly utilitarian, but Maud's humor often comes through. Many sentences are statements about what authors should do when writing, such as "use standard abbreviations only," "writers should not be too ready to

Quotes from *The Writing of Medical Papers* by Maud Mellish-Wilson[18]

"A good writer addresses persons who have to comprehend, to decide, and to act." [This sentence is the very definition of technical writing.]

"It is quite possible for the casual writer to be wholly inappreciative [sic] of the time and care expended by editors in recasting and checking tabulated data."

"Don't fail to go over your pages diligently; relentlessly 'thin out' words. A good writer takes a hint from a good gardener."

"Don't rise to poetic heights except when describing genuinely poetic subject matter."

"Many writers pay little serious attention to their introductions… At no time is bewilderment more fatal for the reader than at the start… starting is as much more difficult than continuing for a reader as it is for a locomotive attached to a heavy train."

"Don't estimate measurements [of tumors] in terms of cocoanuts, oranges, fists, eggs, beans, and so forth; use the metric system." (Gotta love that one.)

"… few realize the amount of earnest effort and painstaking labor which a conscientious editor bestows upon many a paper to make it readable and worthwhile." (Well said!)

follow others in the misuse of terms or words," and "do not submit a manuscript for publication until it has been made as perfect as possible."

Chapter 7, titled simply "Don'ts," includes sound advice:

- "Don't say *case* when you mean patient."
- "Don't say *due t*o when you mean *attributable to* or on *account of*. *Due to* is inaccurate and slovenly."
- "Don't begin as many as ninety-five percent of your sentences with *thus*."
- "When writing a medical paper, don't always go back to the Garden of Eden and review the literature to date." (Elsewhere, she explains this advice: "The order of development of a subject is rarely the order in which it should be studied… review the more recent articles first.")[22]
- "Keep down your *that's*, for they multiply like lower organisms."
- "Do not invent words."

In the 3rd edition, she writes, "It would seem that an impression is abroad among the writers of academic essays that the first person is indecent."[23] Her endorsement of using first-person pronouns in medical texts is consistent with the recommendation of George Gould, an important early journal editor and one of the founders of what would become the American Medical Library Association, who gives the same advice in S*uggestions to Medical Writers*, published in 1900.[19] Her book may also have influenced George Simons and Morris Fishbein, then the editors at the *Journal of the American Medical Association*, in their book, *The Art and Practice of Medical Writing*.[24]

Chapter 18, titled "The Manuscript," reads like the instructions for authors found today in every journal. She recommended a variation of the Harvard (name-date) referencing system in which articles are alphabetized by the first author's last name in the reference list, numbered sequentially, and then the numbers placed in the text, not the first author's last name and date of publication as they are in the Harvard system.

Mayo Clinic Proceedings

As the Clinic grew, not every staff member could attend all meetings. In 1919, Maud and her division began to prepare short, daily summaries of the meetings in an in-house newsletter called the *Clinic Bulletin*.[9,11] In 1926, the focus of the *Bulletin* was narrowed to the topics covered in what appears to have been weekly grand rounds.[9,11,25] The name was changed to the *Proceedings of the Staff Meetings of the Mayo Clinic* in 1927 and to Mayo *Clinic Proceedings* in 1964, when an editor-in-chief and an editorial board were appointed to make the *Proceedings* a separate, monthly, peer-reviewed medical journal.[9]

HER LEGACY

Today, the main library of the Clinic stands where Maud's library stood. It now includes 400,000 volumes. In fact, the Clinic runs 15 other libraries in 4 states and employs more than 30 professional librarians and 40 library associates. In 2021, the 5,300 physicians and researchers throughout the Mayo Clinic Health System published 12,500 articles and case reports and an unknown number books, chapters, letters, comments, and other publications. (Personal communication with LeAnn Stee, Head, Scientific Publications, Mayo Clinic, 4 April 2022.) The *Collected Papers* went through 60 volumes before publication stopped in 1969. In 2019, the *Proceedings* was sent without charge to 130,000 people around the world. In 2020, it ranked eleventh among 154 general internal medicine journals indexed in *Journal Citation Reports*.[26]

When Maud died in 1933, Dr Hewitt became Head of the Division of Publications. In 1957, he became President of AMWA.[7] In 1964, the Clinic created the Department of Biomedical Communications. Its first director was a prominent physician named Dr Charles Roland, who became President of AMWA in 1969.[7]

MAUD REMEMBERED

Maud was described as "a tall, handsome woman, regal in appearance and in manner"[1] who had "the ability to do well a great deal in a short time."[12] "She was a severe critic, never minced words in expressing her opinion, and was inclined to be high-handed in correcting and revising."[1] (My favorite quote from her book is, "Don't think that [grammatical] atrocities are pardonable."[23])

Dr Will said of her, "Staff members, faculty, and fellowship men alike received much aid in the preparation of their written contributions. They were taught where and how to obtain references from the library, to be accurate and concise, with proper literary form, and, above all, to give credit to other workers, and not by half-truths to over-emphasize unimportant details, which might lead to misconstruction."[12] Maud was made an honorary member of Mayo Clinic faculty in the late 1920s.[1,14]

Actress Megan Cole portrays Maud in a 30-minute documentary on her life.[3,13] To prepare for the part, she studied Maud's life and work. Curiously, Maud, who contributed so much to the field of medical writing, did not like to write and rarely wrote anything down. As a result, most of what Ms Cole learned about Maud came from others.[13] (The 2 best sources being those by Clapesattle[1] and Wright-Peterson.[2])

According to Ms Cole, it is clear that Maud "was a gentle powerhouse, a compassionate taskmaster, and an intimidating scholar who didn't boast about her accomplishments."[13] Vitally important to the growth of the Clinic and in building its reputation, she was "a brilliant editor and a woman far ahead of her time, one who raised a fairly traditional position to heights not previously imagined."[13]

On the day of Maud's funeral, the Clinic was closed in her honor.[3] But perhaps the most appropriate honor was given by Dr Will himself, who considered Maud to be the 4th founder of the Clinic, after he, his brother, and their father.[1,2] He wrote that she "was endowed with exceptional ability, untiring perseverance, sound judgment, and indomitable courage," and "dedicated her life to the literary development of Mayo Clinic."[2] Indeed, the profession of medical writing owes much to her contributions.

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

FROM THE PRESIDENT

A New Day

Katrina R. Burton, BS / 2021–2022 AMWA President

As I write this article, it's been a few weeks since the AMWA Board of Directors (BOD) met for an in-person board meeting in Washington, DC. After two years of virtual meetings and numerous phone calls handling the organization's strategic priorities and pertinent business, it felt good to be at an in-person BOD meeting. This was not my first travel experience since the world opened back up for business. I've traveled twice before, and on each trip, I had the same mixed emotions- trepidation, excitement and a bit of normalcy.

One thing I can say is that my recent in-person experiences has rejuvenated me, and I'm motivated more than ever to get back to traveling. As I attend several in-person celebratory events and make plans to travel with my family this summer, I am reminded of how truly blessed I am to not only survive through a pandemic, but also thrive in this new day.

Speaking of thriving, AMWA also continues to thrive. We've seen an increase in membership when other organizations have seen a decline. Recruiting and maintaining members continues to be one of our most important strategic priorities. AMWA is here because of our members, and our commitment to serving our members' needs stays foremost in my mind. I am deeply appreciative of the members that join the organization and jump right into learning and sharing their skills and talents with other AMWA members. I believe AMWA's warm and welcoming atmosphere even during the virtual environment has attracted medical communicators from a variety of areas and locations around the world.

As part of our discussion at the AMWA Spring Board meeting, we reflected on the some of the threats and challenges to our profession, celebrated the wins of the organization, and made plans to initiate opportunities that will further benefit our members and continue to propel the organization forward.

Much of the AMWA BOD and staff's work has centered around supporting and implementing our priorities and strategies to enhance our members experience, sharpen educational member tools and resources, and develop a digital footprint for the future of the organization. We've continued to work at an accelerated pace to keep up with the delivery of educational materials and resources most important to our members. We are excited about the continued growth of member resources and the work to come from the Education Committee, and I look forward to seeing what's next for the Diversity & Inclusion (D&I) Assessment Task Force.

Like many of you, I try to stay focused, keep up with technology, and develop new skills to stay relevant in my field. Being open to learning new skills and transitioning your skillset into more opportunities is one of the reasons why AMWA has been so important to my growth. Being able to transition to new technology and platforms also has been an important part of AMWA's growth, and I am thrilled to see it. As you are aware, the *AMWA Journal* transitioned to a digital format in Open Journal Systems (OJS) and launched the first digital issue in March. Not only is the *AMWA Journal* team working to align publication content with the organization's content strategy, they have initiated theme-based issues and have incorporated guest editors for each issue. I hope you've had an opportunity to see the *Journal* in its digital format and read some of the rich content.

Throughout the first half of my term as President I've witnessed some great educational programming delivered at the chapter level. I'm excited to see innovative and interesting content being offered through virtual programming and networking events. Many chapters hosted Spring virtual conferences across the AMWA platform, and I am happy to know that some members of AMWA's Executive Committee (EC) were able to attend or participate in some of the conferences.

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Speaking of conferences, I look forward to attending and presenting at AMWA's Southeast Regional Conference in Fort Myers, Florida this summer. The collaborative conference between the Southeast, Florida, and Carolinas chapters' will be the first in-person AMWA conference in more than 2 years, and the conference will offer a variety of educational sessions and workshops. I will join other AMWA faculty in presenting content from my skillset applicable to medical communicators in different phases of their careers.

As we continue to transition and get back to in-person events at both the chapter and national level, I am most excited about the upcoming 2022 Medical Writing & Communication Conference taking place in Denver, Colorado, Nov. 2-5. This year's annual conference theme—Elevating Health and Well-Being through Medical Communication—perfectly aligns with what we as medical communicators strive to do every day.

With the 2022 Medical Writing & Communication Conference taking place in person this year, some things may change with logistics and protocols for safety reasons; however, the rest of the annual conference experience will remain the same. In addition to networking with your peers, and enjoying the local fine dining, conference attendees can expect to feel AMWA's warm and welcoming environment; experience a variety of workshops and sessions; and celebrate this year's John P. McGovern, Walter C. Alvarez, and Harold Swanberg award recipients, and more.

I hope we will see you in Denver, healthy, thriving and ready to have a great experience because you deserve it!

AMWA NEWS

AMWA Annual Financial Report, 2020-2021

Julie Phelan, MD, MBA / 2020-2021 AMWA Treasurer

As Treasurer for the American Medical Writers Association (AMWA), I am providing a financial report for the 2020-2021 fiscal year which ended June 30, 2021.

AMWA continued to experience the impact of the pandemic during this year. Staff transitioned back to working in the office on a part-time basis; however, in-person meetings and travel did not resume. AMWA held its first-ever virtual conference that was very successful and well-received. In addition, several staff positions were unfilled during this time.

AMWA also obtained a second round of funding from the Small Business Administration Payroll Protection Plan (PPP) loan to help retain staff and keep major programs running. AMWA successfully applied for and was granted forgiveness of the first and second rounds of PPP funding.

FINANCIAL PERFORMANCE

AMWA's net income for the 2020-2021 fiscal year was $837,466 with significant investment gains and grant income from the PPP loan forgiveness contributing to these positive results.

REVENUES

Overall, program revenues exceeded budget expectations by 16%. This was largely because of the conservative income budget estimates that were used due to the uncertainty surrounding the pandemic. Membership, annual conference, and education/certificate program income continue to be AMWA's major sources of revenue, providing 86% of AMWA's program revenue. Net investment income, shown in Figure 1 in all other revenue, of $115,074 accounted for 5% of AMWA's total revenue.

EXPENSES

AMWA invests in programs, products, and services that bring value to members and the medical writing community. Overall, program expenses were under budget by 15% for the fiscal year. Total program expenses for the fiscal year were $1,373,546, with 31% of the expenses being used to fund membership benefits, 17% of expenses were used to produce the virtual annual conference, 21% of expenses funded educational programs including the Essential Skills Certificate Program and online education, and 8% was used to produce the journal (Figure 2).

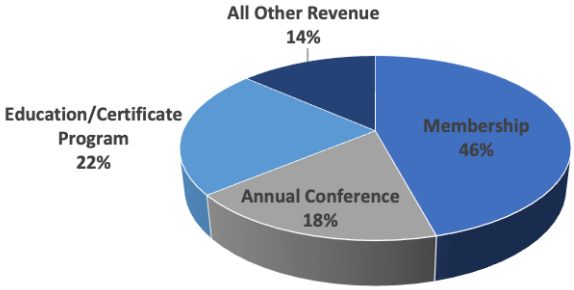

Figure 1. Sources of program revenue for the fiscal year that ended June 30, 2021.

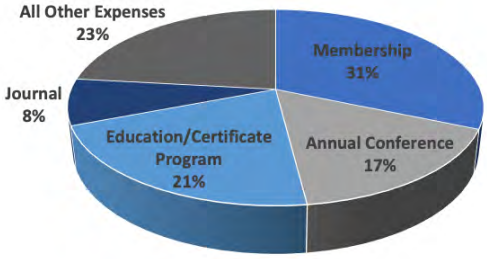

Figure 2. Sources of major program expenses for the fiscal year that ended June 30, 2021.

RESERVES

Reserves are the accumulation of funds over time that enable an organization to withstand an emergency or to invest in new mission-related initiatives. Unrestricted reserves of 6 to 12 months of annual operating expenses represent a standard target for not-for-profit organizations. With budgeted annual operating expenses of $1,678,950 for the fiscal year from July 1, 2021, to June 30, 2022, the target for AMWA's reserves ranges from $800,000 to $1,600,000. AMWA's unrestricted short- and long-term investment reserve level of $2,526,739 on June 30, 2021, exceeds this targeted range.

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AMWA's restricted Endowment and McGovern funds totaled $246,612 and $199,665, respectively.

FINANCIAL POSITION

An organization's financial position is reflected in its asset and liability holdings. AMWA is well positioned to pay its obligations and plan for the future. Total assets were $4,137,522 as of June 30, 2021, and the organization's liabilities totaled $701,598.

FINANCIAL STATEMENT AUDIT RESULTS

Abercrombie and Associates, AMWA's independent auditors, expressed an unqualified opinion regarding their audit of the financial statements for the fiscal year that ended June 30, 2021. An unqualified opinion states that the financial statements present fairly in all material respects, an entity's financial position, results of operations, and cash flows in conformity with generally accepted accounting principles. AMWA continues to be in a secure financial position as it continues expanding member benefits and resources into the next fiscal year. The full audit report is available to AMWA members upon request.

Acknowlegment

I thank Calibre CPA Group, PLLC, for providing the financial data, and the members of the 2020-2021 Budget and Finance Committee for their review of reports and budgets: June Baldwin, Adriana Caballero, Alice Pappas, Leena Patel, Whitney Smalley-Freed, and Christine Wogan (as well as ex officio members Gail V. Flores [2020-2021 AMWA President], Katrina R. Burton [AMWA President-Elect], and Susan Krug [AMWA Executive Director]).

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

2021 Annual Business Meeting for AMWA Members

November 12, 2021, 12:30-1:00 PM EST

R. Michelle Sauer Gehring, PhD, ELS / 2020-2021 AMWA Secretary

AMWA President Gail V. Flores, PhD, called the meeting to order and provided a report about the accomplishments of the organization over the past year. She expressed gratitude to the 2020-2021 Board of Directors (BOD), committee and task force members, and volunteer leaders, who devoted their time and energy to lead AMWA during a challenging year.

Julie Phelan, MD, MBA presented a financial report for the period of July 1, 2020, to June 30, 2021.

Dr Flores announced that in accordance with the AMWA bylaws, the nominating committee presented the following slate of officers for 2021-2022 to the AMWA BOD:

- President-Elect: Elise Eller, PhD
- Secretary: Michelle Sauer-Gehring, PhD, ELS
- Treasurer: Julie Phelan, MD, MBA

The AMWA BOD approved the slate, and the membership was notified of this slate 60 days before the annual meeting. The AMWA bylaws contain a provision for additional nominations to be made in writing and no additional nominations were received. Nominees who are unopposed are elected automatically at the annual business meeting.

Dr Flores declared the slate to be the elected officers for 2021-2022 led by Katrina R. Burton, who as President-Elect automatically assumes the office of President.

Dr Flores passed the gavel to AMWA's incoming President, Katrina R. Burton, and Ms Burton thanked the former for her leadership during continued challenging times. Ms Burton introduced the 2021-2022 AMWA BOD and shared highlights from her inaugural address scheduled for publication in the *AMWA Journal*. Ms Burton announced the launch of a new Diversity and Inclusion Task Force, the organization's plans to transition the *AMWA Journal* to a digital platform, and the continuance of efforts in place to elevate the value of medical communicators.

Officers:

- Immediate Past President: Gail V. Flores, PhD
- President: Katrina R. Burton, BS
- President-Elect: Elise Eller, PhD
- Secretary: R. Michelle Sauer Gehring, PhD, ELS
- Treasurer: Julie Phelan, MD, MBA
- Executive Director: Susan Krug, MS, CAE

At Large Directors:

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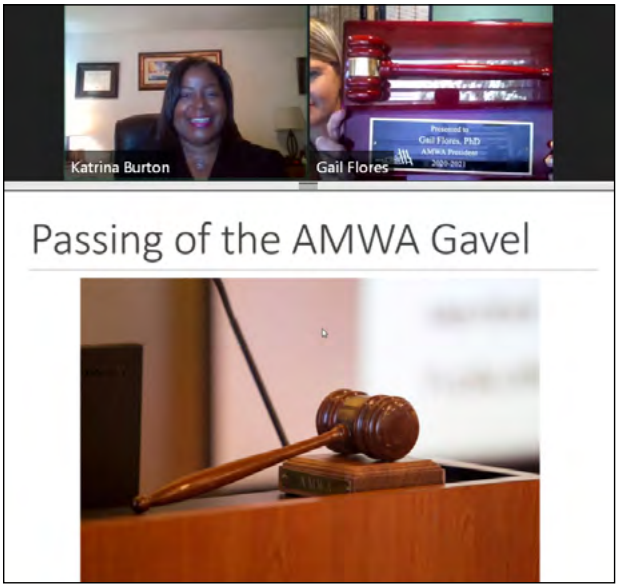

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AMWA NEWS

2022 Walter C. Alvarez Award Recipient: Dr Leana Wen

Kimberly Korwek, PhD / Chair, Annual Conference Program Committee

*The **Walter C. Alvarez Award** is named in honor of Walter C. Alvarez, MD, a pioneer in the field of medical communication. The award is presented to either a member or nonmember of AMWA to honor excellence in communicating health care developments and concepts to the public. The Alvarez Award is presented during AMWA's Medical Writing & Communication Conference.*

The 2022 Walter C. Alvarez Award is presented to Dr Leana Wen in honor of her many contributions in health communication, including regular columns in the Washington Post, the patient advocacy book *When Doctors Don't Listen: How to Avoid Misdiagnoses and Unnecessary Tests*, and the memoir of her career in public health, *Lifelines: A Doctor's Journey in the Fight for Public Health*. She has also authored dozens of articles in scientific publications including *Health Affairs*, *Lancet*, *PLoS Medicine*, and the *American Journal of Public Health*.

During the COVID-19 pandemic, Dr Wen served as a CNN medical analyst and anchored a new Washington Post newsletter "The Checkup with Dr Wen" to provide help on navigating this and other public health challenges. As a consistent voice for using scientific evidence to guide policy decisions, these columns have aided many in understanding the numerous changes to guidelines and requirements. She brought this expertise to Congress in June 2020, testifying in front of the in front of the US House of Representatives Select Subcommittee on the Coronavirus Crisis on racial disparities and COVID-19.

Dr Wen's career has focused on public health as a fundamental force in our individual lives and well-being. Previously, she served as Baltimore's Health Commissioner, where she led the nation's oldest continuously operating health department in the United States to fight the opioid epidemic, treat violence and racism as public health issues, and improve maternal and child health. She directed the public health recovery efforts of Baltimore after the 2015 riots, working to ensure access to prescription medication after pharmacy closures and working to develop the city's mental health and trauma recovery plan with crisis counseling, youth health and wellness, and violence prevention programs. As she states in *Lifelines*, "Public health saved your life today—you just don't know it."

As an expert on patient advocacy and patient-centered care, Dr Wen has long encouraged transparency in medicine. She began this work during in medical school, serving as the national president of the American Medical Student Association and leading campaigns to decrease health disparities and combat conflicts of interest between physicians and pharmaceutical companies. She has campaigned for voluntary disclosure of such conflicts of interest, and her TED talk on this topic has been viewed over 2 million times.

Dr Wen obtained her medical degree from Washington University School of Medicine and studied health policy at the University of Oxford, where she was a Rhodes Scholar. She completed her residency training at Brigham and Women's Hospital and Massachusetts General Hospital, where she was a clinical fellow at Harvard Medical School.

Dr Wen currently works as an emergency physician, professor of health policy and management at George Washington University, and a nonresident senior fellow at the Brookings Institution. She lives with her husband and their 2 young children in Baltimore.

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AMWA NEWS

2022 John P. McGovern Award Recipient: Peter J. Hotez, MD, PhD

Katrina R. Burton, BS / 2021-2022 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.*

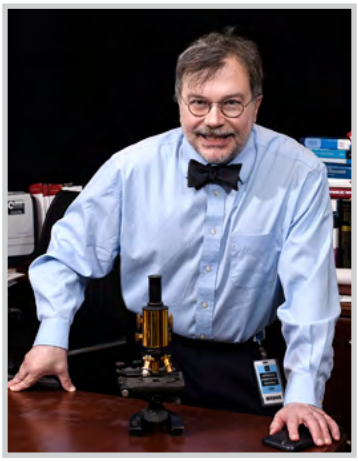
The American Medical Writers Association (AMWA) is pleased to recognize preeminent contributions to the various modes of medical communication through the John P. McGovern Award. The AMWA president presents the McGovern Award, named in honor of renowned allergist and philanthropist John P. McGovern, MD, during its annual Medical Writing & Communication Conference.

It is an honor to name Peter J. Hotez, MD, PhD, an internationally recognized physician–scientist, global health advocate, accomplished author, and 2022 Nobel Peace Prize nominee, as this year's John P. McGovern Award recipient.

Considered a pioneer in his field, Dr Hotez is an expert in neglected tropical diseases, global health, and vaccinology. Based in Houston, Texas, he is the founding Dean of the National School of Tropical Medicine and is a Professor of Pediatrics and Molecular Virology and Microbiology at Baylor College of Medicine. In addition, he is a University Professor at Baylor University and is the Co-Director of Texas Children's Hospital's Center for Vaccine Development.

Dr Hotez has a passion for developing new interventions for global diseases of poverty, developing vaccine diplomacy–communicating science, and combatting rising antiscience sentiment, and his passion is reflected by many prestigious awards, roles, and honors. He holds the Endowed Chair in Tropical Pediatrics at Texas Children's Hospital, for example, and served as a US Science Envoy during President Barack Obama's administration. He is an elected member of the National Academy of Medicine and American Academy of Arts and Sciences.

I first met Dr Hotez in 2017 when I served as president of AMWA's Southwest Chapter. I had the honor of presenting Dr Hotez with the chapter's John P. McGovern Award in recognition of his research and vaccine development. Since then, his advocacy for health equity among underserved populations, continued work on vaccines and COVID-19, and passion for communicating science have continued to resonate with medical communicators.



Dr Hotez's scientific publications and advocacy have addressed treatment needs for millions of underserved populations afflicted with neglected tropical diseases around the world. He has co-led efforts to develop new "antipoverty" vaccines for neglected tropical diseases, including a new recombinant protein COVID-19 vaccine for global health. His contributions to the field of medical communication include more than 650 peer-reviewed journal articles and 5 single-author books, such as his most recent and timely *Preventing the Next Pandemic: Vaccine Diplomacy in a Time of Anti-Science*. His other books include *Blue Marble Health: An Innovative Plan to Fight Diseases of the Poor Amid Wealth* and *Vaccines Did Not Cause Rachel's Autism* (Johns Hopkins University Press); the latter publication is Dr Hotez's personal reflection on his journey as a pediatrician, vaccine scientist, and father of an autistic child.

During the COVID-19 pandemic, Dr Hotez has regularly appeared on national platforms to educate the world on vaccines and to address the spread of misinformation. His research on coronaviruses began a decade prior to the pandemic. Through this knowledge and diplomacy, he has become a regular contributor and trusted source to media outlets such as CNN, NBC News, CBS News, ABC News, NPR, and *The Washington Post*.

I will be honored once again to present a much-deserved award to this leader in medical communication on behalf of the entire AMWA membership as we gather on November 2-5 in Denver, Colorado, for this year's conference. Together, we will extend our sincere congratulations and gratitude as Dr Hotez joins an esteemed group of McGovern Award recipients at the national level as AMWA's 2022 John P. McGovern Award recipient.

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CONFERENCE

Resiliency on Display in Denver: AMWA 2022 Medical Writing & Communication Conference

Kimberly Korwek, PhD / Chair, Annual Conference Program Committee

The global challenges of the past 2 years have resulted in a myriad of changes in our personal and professional lives. As the world begins to recommence, medical communicators will again be called to elevate health and aid in crafting messages that promote well-being both in ourselves and others.

#AMWA2022 marks a return to in-person conference activities. The 2022 Medical Writing and Communication Conference will be held November 2-5, 2022, in Denver, Colorado. The resiliency and commitment of the AMWA community will be on full display in Denver as we once again are able to learn and connect face-to-face. Public health guidance and local event best practices will be followed during the conference. It is our top priority to create the safest possible environment, and we will do this by proceeding with the current best practices and information available to us. We are continuing to review and evaluate the outlook for in-person events and will provide updates as they become available. As we get closer to the event, we will post more information about what you can expect on-site.

Member feedback has consistently praised the connection and development opportunities at the Medical Writing and Communication Conference, and we are working hard to ensure this warm and welcoming learning environment is present at #AMWA2022. Educational sessions will feature topics chosen to meet the current professional development needs of attendees presented as interactive workshops, presentations, panel discussions, and small-group roundtables. Plenary sessions will highlight trend-setting topics in medical communication and honor the accomplishments of

AMWA members and other influential medical communicators. Networking will be plentiful with opportunities for members to reunite and make new connections.

The conference location in beautiful Denver, Colorado will also provide attendees with plenty of options for extramural activities. Denver features one of the most walkable downtowns in the nation and 300 days of sunshine per year, which makes it a great location for partaking in the multitude of top restaurants and craft breweries. Art galleries and history museums also call downtown Denver home, as do many amazing coffee shops. The surrounding area with 200,000 acres of parks in the nearby mountains will tempt you to extend your stay and explore!

➔ Registration is now open for the 2022 Medical Writers and Communication Conference. Join your colleagues in Denver to learn, connect, and reinvigorate your professional and personal development!

Left: Morrison Red Rocks Park ten miles west of Denver.

Right: Denver's Big Blue Bear sculpture by Lawrence Argent peering into the Convention Center.

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CALENDAR OF MEETINGS

Asian Council of Science Editors
8th Annual Meeting of the ACSE
August 21, 2022
Virtual
https://theacse.com/2022/

International Conference on Communication in Healthcare
September 5-9, 2022
Glasgow, Scotland
https://each.international/eachevents/conferences/icch-2022/

Regulatory Affairs Professionals Society
September 11-13, 2022
Phoenix, Arizona
https://www.raps.org/regulatory-convergence

International Society of Managing and Technical Editors
November 1-3, 2022
Virtual
https://www.ismte.org/events/EventDetails.aspx?id=1630533&group=

AMWA Medical Writing & Communication Conference
November 2-5, 2022
Denver, Colorado
https://www.amwa.org/conference

American Public Health Association
November 6-9, 2022
Boston, Massachusetts
https://www.apha.org/events-and-meetings/annual

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2022 AMWA

Medical Writing & Communication Conference

NOVEMBER 2-5, 2022
DENVER, CO

Trends and Opportunities for Medical Communicators

Elevating health and well-being through medical communication.

REGISTER NOW!

Join us November 2-5, 2022 in Denver, CO. Gain new perspectives and reach new heights in medical writing and editing.

#AMWA2022 education sessions will include timely and topics such as

- Advancing medical communication and building value
- Emerging trends in the regulatory writing environment
- Health communication strategies for elevating health literacy
- Medical writing and editing for continuing education in the health professions
- Preparing the next generation of medical writers and leaders
- Progress and developments in scientific publications
- Technology and innovation in medical communication
- The medical communicator's role in diversity, equity, and inclusion

#AMWA2022 | Register Now!
www.amwa.org/conference