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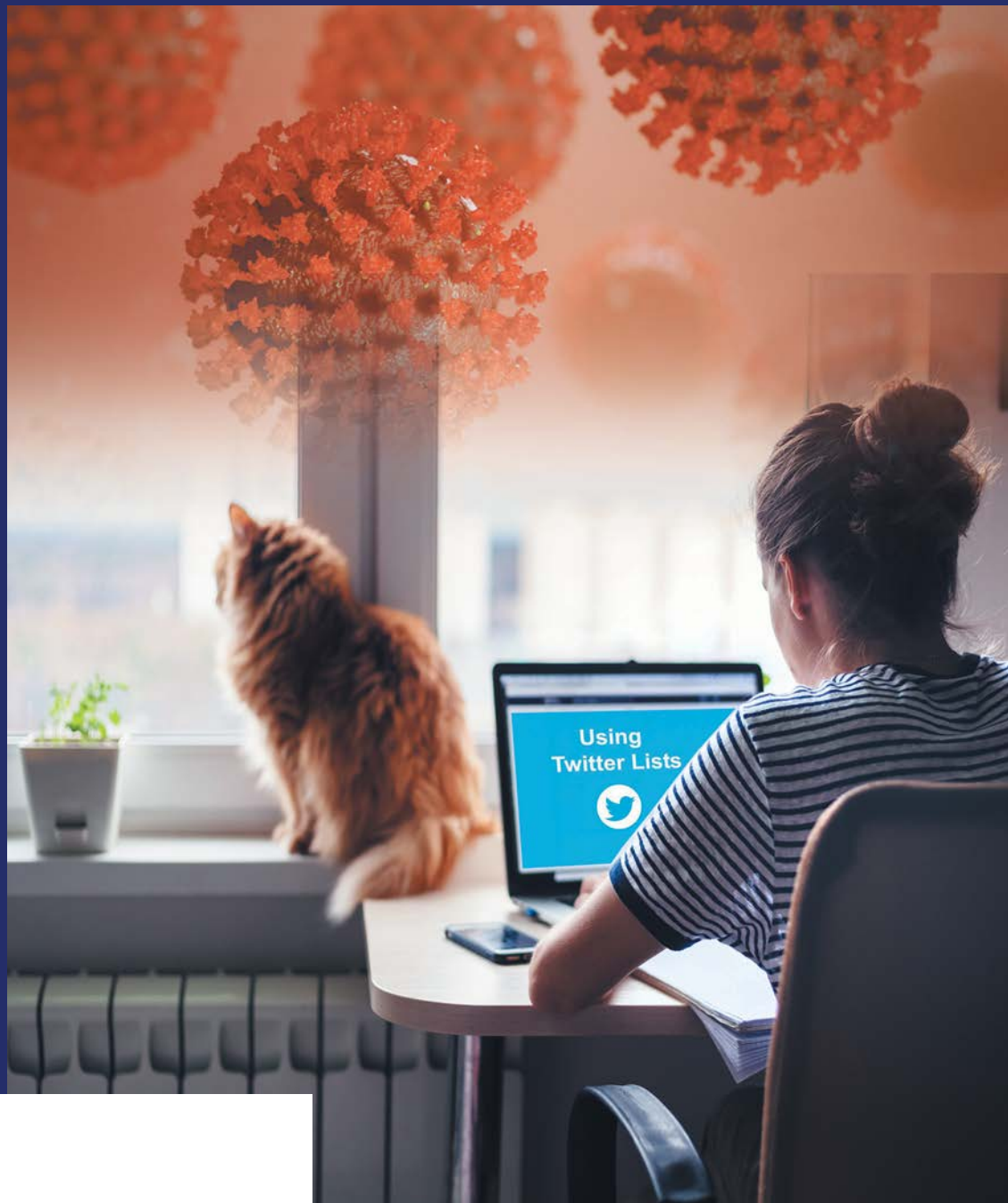
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of Style: A Guide for
Authors and Editors—
What's New in the
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SOCIAL MEDIA

How Social Media
Helped Prepare Me
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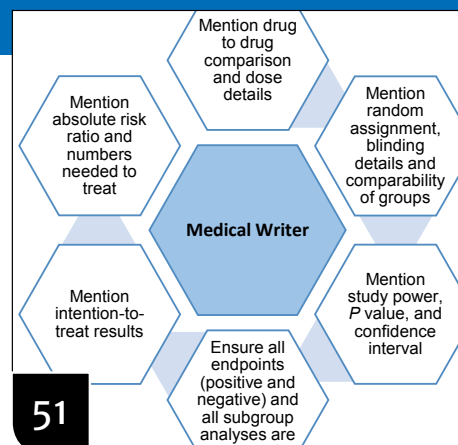
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Balancing Science and Promotion in Medical Writing

Anita Bhat, MBBS, DTCD, and Chinmayee Joshi, MBBS / Covance Scientific Services & Solutions Pvt. Ltd, Andheri (East), Mumbai, India

ABSTRACT

Medical writing is an important tool to communicate research findings in a factual and objective manner to the medical community as well as to the common man. Promotion is imperative for the pharmaceutical industry to convey important product information and encourage judicious use. However, an unhealthy tilt in the balance between promotion and science in the arena of medical writing can be a threat to patient safety. Maintaining a healthy balance between science and promotion is important and can be ensured by following best practices when reporting research findings and adhering to regulatory guidance. The medical writing fraternity is a critical touchpoint between the medical practitioners and the industry and can play an important role in maintaining this balance. This article summarizes the scope of medical writing, drawbacks of excessive promotional influence, and benefits of ethical promotion and reviews some practical solutions to ensure a healthy balance. This balance will enable the progress and dissemination of medical science in a transparent manner, allow faster and more efficient incorporation of medical advances, and contribute positively to the health and well-being of humanity.

IMPORTANCE OF MEDICAL WRITING

Medical writing is an important ally in transmitting the results of drug discovery and clinical research to the medical fraternity and the general public. This relationship is strengthened when results are communicated in a transparent, timely, and unbiased manner. A pertinent question is whether there is stealthy and steady infiltration of promotion into all elements of medical communication, tilting the balance toward an unhealthy reporting bias. This article explores the reasons for this tilt toward promotion when writing in the sciences and, more importantly, the ways to restore the balance between science and promotion.

SCOPE OF MEDICAL WRITING

Medical writing involves a spectrum of diverse documents related to drug development and regulatory approvals, medical journals, pharmaceutical medico-marketing literature, health magazines, and articles about health in the general news. Broadly, they can be divided into regulatory and medical communication documents (Table 1). Regulatory documents include well-structured documents required for regulatory approvals. Medical communication-related documents are

Table 1. Types of Medical Writing

Regulatory Writing	Medical Communication
<ul style="list-style-type: none"> • Study protocols, investigator brochures • Clinical study reports, patient narratives • Periodic safety update reports, development safety update reports, periodic benefit-risk evaluation reports, risk management plans • Common technical document modules and summary documents for regulatory submission • Toxicology reports • Product labels, summary of product characteristics, patient information leaflets • Response to regulatory queries 	<ul style="list-style-type: none"> • Publication writing: original manuscripts, review articles, systematic reviews, case reports/case series, abstracts, editorials • Conference abstracts/posters • Book chapters • Consensus statements • Guideline development/updates for different therapeutic areas • Web content on health websites for health care practitioners and patients • Continuing medical education for physicians, drug advisory board meetings, conference proceedings, slide kits developed for clinical meets • Training modules for sales representatives • Medico-marketing literature: leave-behind literature, visual aids, compact discs, drug monographs • Medical journalism: health-related newspaper articles, health magazines and white papers

more diverse, do not require structured templates, and are targeted to a broader audience that includes clinicians, patients, and the general public. Medical writers play an important role in writing these documents and shoulder the vital responsibility of ensuring the right balance of science and promotion, as more and more of the writing work is outsourced by sponsors to medical writing service providers.¹

HOW AND WHEN PROMOTION CAN CREEP IN

Drug promotion is defined by the World Health Organization (WHO) as all informational and persuasive activities by manufacturers and distributors to influence the prescription, supply, purchase, or use of medicinal drugs.² Promotion can play a dominant role in areas such as marketing literature targeted to physicians, medical journalism, slide kits, white papers, industry-sponsored meetings for key opinion leaders, and sponsored websites. However, promotion can also creep into regulated documents as well as industry-funded journal articles. Continuing medical education (CME) may be funded by commercial support, but CME activities delivered by providers accredited by the Accreditation Council for Continuing Medical Education ensure that CME content is fair, balanced, practice-based, and independent of commercial influence, with regular audits to establish compliance.^{3,4}

Medical writing can tilt toward being promotional when messages highlight the benefits of a product and underplay or even hide the risks. Manipulation of research findings by trial design, drug-dose selection, choice of comparator agents, and biased reporting (reporting of positive results and suppression of negative results) has been documented in various reports.^{5,6} The advent of unregulated medical promotion on social media applications poses yet another major challenge to ethical and scientific writing. A significant influence of promotional literature on the prescription habits of physicians has been reported.⁷

Consequences of Excessive Promotional Influence

Although the aim of medical writing is to improve health, the underlying need for promotion has the potential to harm if the approach is not balanced. Information transmitted to the medical fraternity and to patients needs to be grounded in reality, without any false claims. History is witness to the public harm inflicted when important risks associated with a drug did not reach regulatory authorities, and the medicine remained in the market.⁸ Promotional pressures are reported to cause even large and ethically inclined companies to brush aside safety risks. Siddharth Pai⁹ believes there is a veil of independent research spending in science that causes studies and their results to be biased toward the funders. He quotes 2 examples: scientific journals claiming to perform a peer review, when

they do not perform the review, and a National Institutes of Health study funded by an alcohol lobby claiming cardiovascular benefits with alcohol consumption.

Furthermore, commercial interactions between the pharmaceutical industry and the medical fraternity have the potential to dilute the responsible use of medicine. The ensuing conflict of interest can undermine the trust placed by patients.¹⁰ Richard Horton¹¹ made a chilling comment in *The Lancet*: “The case against science is straightforward: much of the scientific literature, perhaps half, may simply be untrue.” Industry sponsors a vast majority of clinical research, and a study that used a thematic approach (12 themes) found bias in every one of the themes (some examples: research question, choice of dose/comparator, trial design, reporting of study results) and concluded that this may undermine the confidence in such research.¹² However, this study did not systematically compare the incidence of bias between studies that were supported by industry and studies that were not and did not comment on the most common types of biases. Investments by industry in research and documentation of research by medical writing help deliver life-saving medicines but also have a potential to distort evidence to favor and protect the investments.

The repercussions of not reporting negative findings include losses of time and resources and the introduction of bias in meta-analysis findings, in addition to false conclusions of benefit, which bring disrepute to science and may harm patients.¹³ An example of how an evidence-based myth was created is illustrated by Dr Ioannidis¹⁴ in his 2008 article. He showed how an illusion of antidepressant effectiveness was created by the conduct of many small randomized trials with clinically nonrelevant outcomes, short follow-up, a bias in study population, and incorrect statistical-significance interpretation. Although this conclusion has been the subject of intense controversy, it was supported by a recent article that analyzed data from all published meta-analyses, including a meta-analysis of antidepressant data submitted to the US Food and Drug Administration (FDA) for drug approval, and concluded that most benefits are due to placebo response, with no clinically meaningful difference between drug treatment and placebo.¹⁵ Dr Marcia Angell,¹⁶ former Editor of *The New England Journal of Medicine (NEJM)*, opines that much of the published clinical research cannot be trusted and that even trusted physicians and guideline recommendations cannot be relied upon.

It is well recognized that financial conflicts of interest can affect the way study results and conclusions are presented.^{17,18} Pressures to publish and the commercial pull can push academicians to lend their names to papers to which they did not contribute. The percentage of industry-sponsored articles published in high-impact journals like *The Lancet*, *NEJM*, the

Journal of the American Medical Association, and *Annals of Internal Medicine* is high and varies from 67% to 75%.¹⁹ Such sponsorships have the potential to influence directly or indirectly the individuals involved in writing, editing, or publishing scientific information. An interesting article that documented attitudes and experiences of health care researchers found that guest authorship was widespread (India: 65%, 101/155). Additionally, there was a lack of awareness about conflicts of interest and how they influence research, with conflicting views on whether commercial links to companies would influence researchers.²⁰

MAINTAINING BALANCE BETWEEN SCIENCE AND PROMOTION

Adherence to Codes and Regulations

A number of codes and regulations exist to ensure that interactions between the pharmaceutical industry and health care providers (HCPs) are always oriented toward patient care and that the information provided is scientifically accurate, ethical, and fair.

Regulatory Guidance

The FDA refers to all promotional labelling and advertising materials, regardless of the format, manner, or medium by which they are presented, as promotional materials and includes (but does not limit materials to) brochures, booklets, detailing pieces, sound recordings, websites, exhibits, and print, radio, and television advertisements.²¹ The FDA primarily determines whether the claims in the promotional pieces about the risks and benefits are accurate, nonmisleading, and presented in a comparably prominent manner to enable safe use by HCPs and consumers.²² The FDA draft guidance²² for prescription drug and medical device promotion illustrates, with numerous examples, the factors relevant to disclosure of risk information to ensure compliance with the Federal Food, Drug, and Cosmetic Act. The FDA Office of Prescription Drug Promotion²³ runs a comprehensive surveillance, education, and enforcement program to ensure that the promotional information is truthful, balanced, and accurate and provides an email address and a telephone number to report misleading promotional advertising. The common violations reported include omitting or downplaying of risk, overstating the effectiveness, and misleading drug comparisons, which may lead to warning letters and civil and even criminal proceedings.²⁴

The WHO released the *Ethical Criteria for Medicinal Drug Promotion*²⁵ in 1988 to encourage rational use of drugs and prohibited use of scientific and educational activities for promotion. Implementation of these ethical criteria is not overreaching though, with promotional literature collected from an Indian hospital in 2014 satisfying only 50% of the WHO

criteria for rational drug promotion and none fulfilling all the criteria.²⁶ In 2010, the Physician Payments Sunshine Act, in the United States, enacted provisions requiring all pharmaceutical payments above \$10 or other transfers of value to physicians to be publicly disclosed. The Medical Council of India²⁷ 2016 ethical code of conduct guidelines for medical practitioners prohibit the acceptance of gifts, travel facilities, and hospitality from the industry and discourage public endorsement of a drug. The US Foreign Corrupt Practices Act and the UK Bribery Act govern the interactions between the HCPs and the industry and impose stiff penalties for contravention.^{28,29}

Industry Guidance

The International Federation of Pharma Manufacturers Association (IFPMA) was the first to introduce an international self-regulatory mechanism way back in 1981, with a code of practice for the member biopharmaceutical companies and national associations with a primary aim of self-regulation to promote ethical behavior. It has been revised 5 times since then to align it with evolving stringent regulations, and the sixth (2019) update is marked by 2 changes: a ban on gifts and promotional aids (for prescription only medicines) and a shift from a rules-based to a values-based code.³⁰ The Pharmaceutical Research and Manufacturers of America³¹ endorses the “Principles on Responsible Sharing of Truthful and Non-Misleading Information About Medicines” with HCPs and payers, with a commitment to provide science-based communication, appropriate context about data, and accurate representation of data. The European Federation of Pharmaceutical Industries and Associations³² code requires national member industry associations in the European Union to implement similar policies to govern all types of communication (traditional and digital) and was updated in 2019. The Indian pharma industry follows the Organisation of Pharmaceutical Producers of India³³ guidelines (updated in 2019) and, like IFPMA, mandates that promotional material be accurate, balanced, consistent with approved product information, updated with all relevant evidence, and complete (not misleading by omission or half-truths) to enable HCPs to form their own opinions of the therapeutic value. It also mentions that clinical trials and observational studies should have a legitimate purpose and not be a disguise for brand promotion. In addition, pharmaceutical companies should self-regulate with codes of conduct for internal compliance, sometimes broader in scope than external codes.

Publication Guidance

Guidelines like the Good Pharmacoevidence Practices³⁴ and the International Committee of Medical Journal Editors³⁵ and Committee on Publication Ethics³⁶ guidelines have

developed ethical standards for authors, editors, and peer reviewers with regard to the conduct and reporting of research in medical journals to enable accurate, unbiased, and reproducible publications. There are separate reporting guidelines for different study designs (Table 2). Following these guidelines allows authors to describe the study in enough detail to enable objective evaluation by editors, reviewers, readers, and researchers. Adherence to these guidelines is also important to ensure patient interests are not compromised. Additionally, noncompliance can invoke financial, legal, and regulatory sanctions and lead to more stringent regulations.

Role of a Medical Writer

Medical writing conveys information that can change prescribing habits of physicians and lives of patients. Good papers can persuade and inspire for the better, but if the persuasive elements lack sound scientific rationale, it can skew readers' understanding. Hence, medical writers have to maneuver the

tight rope that extends between academia and commerce with the right balance.

It is important for the writer to start with an open mind and ensure awareness of the above-mentioned ethical principles and reporting guidelines to prevent bias. A comprehensive literature search to access all relevant evidence, whether positive or negative, lays the foundation for ensuring an unbiased perspective. Building on this, the writer needs to sift through all the data and synthesize the information in a crystal-clear manner to present an accurate picture. Ensuring that technical, difficult-to-understand data are presented in very simple language is important, so as to allow accurate interpretation by the reader. Writing in an obscure and ambiguous manner can leave the reader confused about the interpretation and prevent them from making adequately informed decisions.

Medical writers work closely with academic investigators, sponsors, journal editors, and reviewers. This collaboration can place the writer in a unique position to actually practice total transparency in reporting evidence in an unpartisan manner. Academic authors would do well to follow the Chinese scholar Lu Ji, who wrote, "Writing is a struggle between presence and absence."³⁷ He urged writers to "weigh each word on a scale and use a measuring cord to make their cuts," implying the need to exercise perfect balance and judgement.

Table 2. Guidance for Medical Writers

- Conduct comprehensive literature search from validated sources.
- Simplify complex medical jargon.
- Align information with product labels and marketing authorization claims.
- Consult and refer to relevant reporting guidelines (CONSORT/PRISMA/STROBE/STARD, etc) and ethical guidelines (GPP, ICMJE, COPE).
- Present results objectively.
 - Avoid presenting statistically insignificant results in a misleading manner.
 - Present absolute rates to place relative risk in context.
- Avoid superlatives like *best*, *strongest*, *safest*, and *no side effects*—especially in the absence of strong evidence.
- Present positive and negative results factually.
- Ensure accurate portrayal of benefits and risks.
- Substantiate all claims.
- Highlight all limitations.
- Ensure medical and editorial review with quality-checking for data accuracy.
- Adhere to guidelines and regulations.
- Disclose all conflicts of interest.
- Self-regulation to ensure unbiased reporting

CONSORT, Consolidated Standards of Reporting Trials; COPE, Committee on Publication Ethics; GPP, Good Pharmacoeconomics Practices; ICMJE, International Committee of Medical Journal Editors; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses; STROBE, Strengthening the Reporting of Observational Studies in Epidemiology; STARD, Standards for Reporting Diagnostic accuracy of studies.

Use of Literature Evidence

Only validated and peer-reviewed information should be accessed to avoid information bias. Medical textbooks; texts such as *Martindale*, *US Prescribers' Digital Reference*, and *American Hospital Formulary Service*; databases like PubMed and Embase; search engines like Google Scholar; and websites such as Medscape, WebMD, and Cochrane Library offer reliable and verified information.

Data Presentation and Comparisons

The basic principle to be followed when making claims is to avoid hanging comparisons (faster, better, safer): without saying compared with what, claims like *stronger* or *more effective* should be substantiated with adequate data; exaggerated and all-embracing claims such as *the safest* and *the gold standard* should be avoided; and data should be accurately represented in figures and graphs. Examples of misrepresented graphs include combining data from different studies, suppressing zeroes to convey that drug Y is better than drug X (Figure 1), extrapolating graphs into an area with no data, omitting data that are not positive, and not labelling graph axes with parameters/units of measurement.

When it comes to presenting safety data, claims should reflect product labels and the marketing authorization that is granted. Making a comment that a product has no adverse

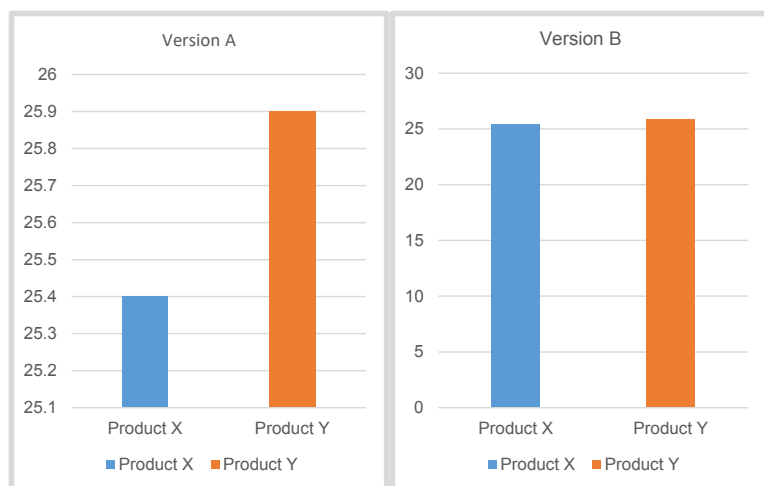


Figure 1. Misrepresentation of data by using different scales. Version A used a smaller scale than Version B, suppressed the zero, and exaggerated the difference between the 2 products.

effects or hazards can be considered an exaggerated and unsubstantiated claim.

Review Process

Every document should undergo a medical review to ascertain medical accuracy and correctness, fact checking to verify claims and data with source, and editorial review and quality checking for ensuring appropriateness in style and language. These reviews act as a bellwether to ensure that the final reader-ready document is medically and factually accurate.

For the industry, an independent medical affairs team ensures that the promotional campaign communication to clinicians is aligned with scientific data and represents no exaggerated claims. It is important for this medical affairs team to be independent of the commercial bias cascading from the higher echelons of management. In addition, industry should seek to build relationships with medical practitioners purely on the basis of sharing educational information, rather than promotional interest.

Disclosure

Registration and publication of all clinical trial results, including postmarketing safety and effectiveness information, increase transparency and avoid the publication bias imposed many a time by a quiet burial of negative results. Publication of negative results should be considered as important as publication of positive results, to increase awareness of risks as well as benefits to all stakeholders involved in improving patient outcomes. This ensures that drugs entering the patient domain remain only if they have the right benefit-risk balance, by preventing magnification of product effectiveness and underes-

timination of possible harm. A virtual firewall between people involved in research or analysis and sponsors, or developing a funding source independent of the pharmaceutical sector, can counter the commercial bias.⁷ Disclosure of all funding activities (HCP and patient groups) helps bring about a transparency in all such interactions. Although a writer may not be able to influence the creation of a firewall or enforce disclosures, being aware of such measures helps them take a more balanced approach.

IMPORTANCE OF CRITICAL APPRAISAL OF HCP-TARGETED PROMOTIONAL LITERATURE

Statements made by medical representatives and the promotional literature they deliver remain more focused on promotion than on physician education. Furthermore, key issues related to patient safety, like adverse reactions, contraindications, and warnings

and precautions, may be entirely skipped or skimmed over. A cross-sectional analysis of pharmaceutical advertisements in US-based biomedical journals concluded that only 18.1% adhered to FDA guidelines, that 49.4% were nonadherent with at least 1 parameter (FDA-described bias), and that 32.5% were nonadherent mainly because incomplete information.³⁸

A prospective cohort study evaluating safety information in promotional elements, with centers in the United States, Canada, and France, reported that serious adverse events were rarely mentioned, even for products with FDA black-box warnings.³⁹ A systematic analysis found a high prevalence of ethical code breaches by the pharmaceutical industry in the United Kingdom and Sweden.⁴⁰ Hence, there is a pressing need for the medical faculty to be trained to interview/interact with medical representatives and also critically appraise the evidence they are presented with, so that only evidence-based medicine is practiced.⁴¹

Medical writers can positively influence the quality of promotional literature by evaluating whether the drug being promoted is being compared with a treatment known to be inferior or is a lower dose of a competitor drug; whether the trial is adequately powered to show differences; whether all end points (positive or negative results) have been published; whether publication results are available for all centers in a multicenter trial; and whether all subgroup analyses (not only the favorable) are presented (Figure 2). These steps enable the medical fraternity to confirm the validity of the findings and enhance trust. Additionally, a continual training process for medical writers ensures that they are well versed in all technical and ethical aspects and that they create factual, objective, and balanced HCP-targeted promotional literature.

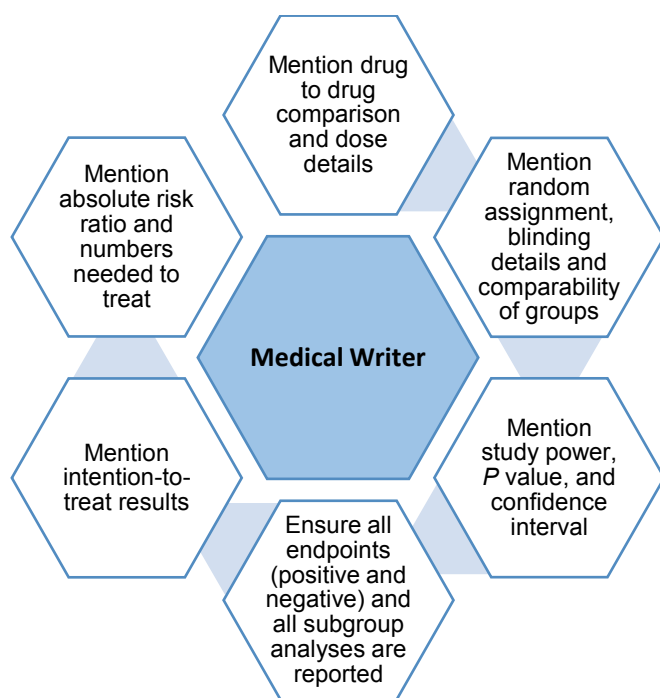


Figure 2. Critical appraisal of health care provider–targeted literature: role of medical writers.

BENEFITS OF ETHICAL PROMOTION

Ethical drug promotion contributes to enhancing the quality of health care by the rational use of medicinal drugs. It allows for an unbiased flow of accurate and evidence-based scientific information among pharmaceutical companies, HCPs, researchers, and regulatory authorities—key stakeholders in strengthening patient care. Transparent reporting of clinical trial data enables the rapid entry of life-saving drugs and devices into the market. Likewise, communicating a balanced assessment of the risks and benefits of a product allows the timely withdrawal of unsafe drugs from the market. It vests HCPs and patients with credible information related to the increasing number of treatment options and scientific advances so that they can make informed, judicious, health care decisions. Thus, rational prescribing decisions backed by objective and unprejudiced evidence empower HCPs and patients.

CONCLUSION

Balancing science and promotion in medical writing is often a challenge. The medical writing community has an obligation to shape scientific understanding in an ethical manner and contribute to the progress of medical science by authoring well-written and well-researched papers. Ensuring clarity

in content, objective interpretation of clinical results, adherence to guidelines and ethics, prompt disclosures of conflicts of interest, and not being swayed by pressures from collaborators are some of the key levers to minimize promotion and maximize science. When all key stakeholders agree with and align to the fact that transmitting objective and unbiased science is the only goal of medical writing and that only this goal serves to improve the health and well-being of humanity, a balance between science and promotion will be achieved.

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Author contact: anita.bhat@covance.com

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Outsourcing Services of Regulatory Submission Writing in the Pharmaceutical Industry

Yan Zhou, MD, MSc / Freelancer

ABSTRACT

It has been a growing trend over the last 15 years that pharmaceutical sponsors prefer to co-develop drugs in collaboration with clinical research organizations (CROs) instead of working independently. The partnership collaborations of pharmaceutical sponsors and third-party service providers have been proven with many successful industry examples. The market size and scope of CRO services are rapidly increasing along with the growth and expansion of the pharmaceutical industry. These trends are also present in China, where the CRO industry developments are eye-catching. CRO drug research and development (R&D) outsourcing services in China, including scientific writing, can be categorized by study phases, regions, and R&D function. The scientific writing services include regulatory submission writing and publication writing.

Of all the outsourcing services, the benefits and risks of regulatory submission writing are obvious. Outsourcing regulatory submission writing in China is expected to improve the professionalism of the R&D functions in pharmaceutical companies, lower R&D costs, improve R&D industry outputs and efficiency, and optimize R&D collaboration modes. The main problems and risks of outsourcing services, especially for regulatory submission writing, mainly focus on study information confidentiality, intellectual priorities, and the compatibility of the R&D teams of the pharmaceutical sponsors and CROs. The purposes of this article are to introduce the current status and developments of the CRO industry and scientific writing in China, introduce the benefits and risks of outsourcing services in regulatory writing areas, and offer the author's conclusions about the best practices for outsourcing regulatory writing services in the future.

By 2018, global outsourcing services for drug discovery were estimated to be USD \$37.1 billion.¹ The global market for clinical studies conducted by clinical research organizations (CROs) was \$23.1 billion in 2014 and was forecast to be \$35.8 billion in 2020.² In China, CRO sales were estimated to be \$80 billion in 2019, whereas the sales were merely one fifth of that much in 2011.³ More and more global and local pharmaceutical companies in China are becoming aware of the business value and scientific importance of collaborations with CROs in drug research and development (R&D) activities, thus independently conducting clinical trials in this epoch has already become impossible.

The birth of the CRO industry can be traced back to the 1970s in the United States, then expanded to Europe, Japan, and China.⁴ At the beginning of CRO business development, the outsourcing of services merely focused on simple or stylized R&D functions, such as laboratory analyses, data management, and statistical analyses; next, these services developed to include manufacturing, medical affairs, and scientific writing, etc. In China, the history of the CRO industry is less than 20 years old. Many global CRO branch offices in China and local CROs were built up in response to the needs of global and local business strategies. The CRO industry in China shows 3 main growing trends⁴: first, the CRO markets present a continuously booming growth trend along with increased R&D costs, enhanced awareness of CRO market acceptance, unexpected market risks of drug patent periods, and launches of regulatory reform policies.⁵ Second, the business models of R&D partnership collaborations and one-stop, full-package individualized R&D outsourcing services offer more business possibilities for clinical trials. Single-stage pharmaceutical R&D services cannot meet the scientific values and business needs of large pharmaceutical companies throughout the entire industry chain; therefore, in addition to quality R&D and production services, comprehensive and integrated new drug research, development, and production services in the whole R&D cycle



via establishment, cooperation, or merger and acquisition in the upstream and downstream of the industry chain are expected.¹ Third, business collaboration innovation pushes for new strategic collaboration modes between pharmaceutical sponsors and CROs. More and more pharmaceutical companies prefer to expand businesses through mergers and acquisitions in order to pursue greater profits and better business performance.

Outsourcing services in China can be categorized by R&D phases/activities, R&D functions, and regions. For instance, in the area of regulatory submissions, some pharmaceutical companies prefer to outsource the work of postmarket clinical studies, given the scientific confidentiality of early-phase clinical trials and those clinical trials with regulatory registration purposes. In most functions of drug R&D activity, written documentation cannot be avoided; therefore, third-party outsourcing services have their market needs and scientific value. Given the complexity and limitation of scientific data disclosure, scientific publications (such as complex full-text manuscripts, conference posters, etc) present more possibilities for outsourcing as compared with regulatory submission dossier documents (such as study protocols, early-phase study reports, and key regulatory submission dossier documents). On the other hand, relatively complex documents would be selected as in-house works that are allocated to internal R&D professionals within the sponsor organization for completion and would not be outsourced to a third-party CRO.

In classification by R&D function, some companies prefer merely to outsource the work of clinical operations and data management. The sponsors are responsible for the rest of the more complex and confidential R&D work (eg, statistical analyses and scientific writing). In other cases, some sponsors prefer to outsource full-spectrum R&D functional activities, merely keeping in-house project monitoring and quality control functions for the outsourced projects.

In classification by R&D regions, pharmaceutical companies prefer diverse outsourcing service strategies in the regions with imbalanced research resources. For example, some pharmaceutical companies prefer to complete full-function R&D activities with centralized in-house R&D human resources, whereas others prefer to outsource all or some parts of these R&D activities to a third-party CRO in the branch offices of other regions that have limited research resources because of a lack of competent, fully functional R&D teams or due to budget reasons.

The global market size of scientific writing has increased from \$345 million in 2003 to \$694 million 5 years later.⁶ This trend has continued, with revenue growing steadily. Of the different types of writing services, regulatory submission writing accounts for the majority of services. Although the data for the Chinese market are not available, according to a sample of 41 local CRO companies,⁷ the increase in the net profit margin of the CRO businesses in China was close to 20% from 2015 to 2018. The market need for CRO services presents a burgeoning growth trend in China. Of all the R&D expenses, the costs of CRO services accounted for 13.6% in 2008, whereas the cost percentage was two-fold that in 2017.⁸ In the R&D functions of the Chinese pharmaceutical industry, almost no scientific professionals were responsible for writing documents before 2000. As of 2019, 200 to 300 writing professionals are working in regulatory writing and publication writing in pharmaceutical companies and CROs. This trend strongly shows the business value and impacts of scientific writing in China, which are well endorsed by peers in the industry. The importance of scientific writing in China for regulatory submission activities, data disclosure of scientific publications, and other medical activities have become more and more obvious. From the career development perspectives, the scientific writing career brings increasing career self-esteem, scientific values, and economic rewards to writing professionals. This is reflected by

the existence of a burgeoning number of writing positions in the industry, positive feedback from collaborators and clinical investigators, and increased salaries of writing professionals.

In China, regulatory submissions follow the local requirements and will be compliant with the requirements of global electronic common technical documents (eCTDs) in the future. Currently, eCTD submissions are applied in most global or regional studies, but not in local studies. In 2017, China joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, and the launch of eCTD systems and guidelines has been accelerated. In 2019, the National Medical Products Administration planned to formally launch electronic systems for regulatory submissions. The requirements for document quality are expected to improve and stay consistent with global standards.

Regulatory submission writing covers the preparation of study protocols, clinical study reports, regulatory responses,

and other key regulatory submission documents. Pharmaceutical sponsors approve final versions of documents and control document quality. Exclusive of technical function areas such as pharmacokinetics, sponsors normally would direct source allocations from project key opinion leaders in medical research, maintain collaborative relationships, and take the role of being a gatekeeper for key project milestones on the critical pathways. In collaborations, CROs obtain rewards and satisfy financial interests from the outsourcing services, whereas pharmaceutical companies depend on the CROs' professional technical services to complete regulatory submissions and medical research. In outsourcing services, pharmaceutical sponsors and CROs share common interests and R&D risks. For cross-continental global pharmaceutical companies, local branch offices would benefit from contracted global partnership collaborations. As independent project sponsors, local branch offices can definitely favor their own service providers of R&D activities. The choice of collaboration

The market need for CRO services presents a burgeoning growth trend in China. Of all the R&D expenses, the costs of CRO services accounted for 13.6% in 2008, whereas the cost percentage was two fold that in 2017.⁸

mode depends on project needs (eg, business importance, levels of medical research), budgets, and the efficiency and production of projects.

The benefits of outsourcing services for medical research in China consist of reducing R&D costs, increasing R&D efficiency, optimizing R&D project team structures for pharma-

ceutical sponsors, and lowering R&D risks that push industrialization of medical research and business transfer of medical knowledge. The human resource allocations are more flexible for pharmaceutical sponsors with technical assistance from CROs in the periods with fewer study projects. Because of project complexity and task allocations, CROs and pharmaceutical companies have various team structures and responsibility allocations. In collaboration with CROs, project tasks are reallocated if the reallocations could improve work efficiency and maximize professional expertise to optimize the R&D project team structure. With professional services, the total project timeline is significantly shortened. For small or start-up biotechnology or pharmaceutical companies, study professionals with technical expertise offer professional services, and transfers of technical work to CRO services allow management teams in the sponsor companies to spend more time and effort on strategic planning of clinical development and monitoring of study outputs and quality controls. Last but not least, the burgeoning growth of professional outsourcing services brings more opportunities to regional or local medical practitioners and investigators in clinical practice to be exposed to standard practices of medical research, and offers more possibilities for them to develop themselves in global or regional collaborations.

and other key regulatory submission documents. The business modes of partnerships between the pharmaceutical sponsors and CROs have become more and more popular in drug R&D activities in China in past decades. In most cases, pharmaceutical companies prefer to contract CRO services for late-phase clinical development (such as postmarket studies including publication works) in order to use their own competent, fully fledged R&D teams for the rest of their research. The confidentiality of early-phase studies and intellectual priorities for regulatory submission, including protocols and key documents for regulatory submission dossiers, are main reasons why they prefer not to outsource their regulatory writing. For small or start-up companies, it is more common to outsource early-phase studies or studies with regulatory purposes to third-party organizations for technical assistance, given the early development stage of the companies and their limited resources for R&D activities. For regulatory submission writing projects, the responsibility is split between the pharmaceutical company and the CRO: the pharmaceutical sponsor is responsible for drafting the first version of the document synopses, and the CRO is responsible for developing the synopses into full-text documents, coordinating review cycles, incorporating review comments into the intermediate versions of documents, and producing final versions of docu-

On the other side of this double-edged sword, especially for regulatory submission work, the risks of outsourcing services would follow along with the benefits. First of all, as described above, the confidentiality and intellectual priorities would be the main worries for sponsors; therefore, the performance of internal or external audits is recommended at certain intervals. Second, the validity of reducing R&D costs and improving R&D efficiency needs to be proven in real-world practice. The work efficiency for service providers of outsourcing services and the team compatibility with third-party organizations should be tested with caution. Highly competent outsourcing service teams cause these assumptions, but the competency levels are diverse in global and local CROs in China; thus, it is more difficult to screen qualified medical research outsourcing teams, maintain the team competencies of high performers, and lower turn-over rates within teams. All of these are challenges brought by outsourcing services. In addition, we have to meet the language challenges of global and regional studies, local systems of the study sites, and laboratory tests. Therefore, before collaborations, well-rounded assessments of the systems (including training systems), standard practice procedures, the qualifications of medical research staff, and previous project service experiences are of importance for the success of project collaborations.

Regarding business modes of outsourcing services, sponsors may prefer full-package outsourcing services from manufacturing to late-phase clinical development with a whole-package discount. They can also be offered “buffet services” and choose one or several specific functional outsourcing services. In the future, collaboration modes will be more individualized, and tailored outsourcing services with multiple options will be the new trend. In the pharmaceutical industry, because of the differences in business sizes, product portfolio needs, and budget costs, pharmaceutical companies have various outsourcing expectations. For example, in regulatory submission writing, some sponsors could prefer outsourcing service packages for registration studies plus postmarket observational studies/real-world studies, whereas some sponsors might prefer registration studies plus regulatory responses, or registration studies plus clinical submission dossier documents according to actual regulatory purposes and policy requirements. In collaborations, sponsors and CROs have more room to negotiate the collaboration modes and contents. The procurement prices of outsourcing services are not the only factor for considering competency of outsourcing service providers. Collaboration flexibility, system reliability, employment stability of medical research professionals, and feasibility of strategic developments are new success factors for project collaborations between third-party CROs and pharmaceutical sponsors. Along with the development and

progress of the CRO industry, specialty services have become strong competencies for collaborations with pharmaceutical sponsors. For instance, the strength of one company might be laboratory services, whereas another company could offer consulting services of business analyses and product pipelines in addition to services of medical research. Thus, large-sized and comprehensive outsourcing companies (ie, one-size-fits-all outsourcing services) may not meet customer expectations for pharmaceutical companies in the future. Instead, individualized specialty services would be more welcomed by pharmaceutical customers in China with diverse R&D needs.

To summarize, pharmaceutical sponsors and CROs in China will continue to collaborate and proceed further hand-in-hand on the fast track of industry progress and development of medical research in the industry. In regulatory submission activities, collaboration modes are still controversial and need to be discussed. Outsourcing scientific writing as a new collaboration mode will bring more business and scientific value to the CRO industry, and CRO companies will become indispensable assistants to pharmaceutical sponsors in standardizing medical research.

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Author contact: zhouyan311@hotmail.com

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ICMJE Proposes a New Author Disclosure Form for Work Submitted to Medical Journals

Andrea Blotta, PhD / Freelance Medical Writer, Boston, MA

The *perception* of a potential conflict of interest is as relevant as an *actual* conflict of interest in judging the validity of scientific research. This understanding is at the heart of a new author disclosure form proposed by the International Committee of Medical Journal Editors (ICMJE) for work submitted to medical journals, published in an editorial in the *Annals of Internal Medicine* and simultaneously in other ICMJE journals in January 2020.¹ This new disclosure form will be adopted by all members of ICMJE, previously known as the Vancouver Group (Table). Many other nonmember journals report that they follow the ICMJE's Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals.² Therefore, the new author disclosure form proposed by the ICMJE will likely be incorporated by a large number of journals.

Table. Members of the International Committee of Medical Journal Editors (ICMJE)

Journal	Headquarters
<i>Annals of Internal Medicine</i>	United States
<i>British Medical Journal</i>	United Kingdom
<i>Bulletin of the World Health Organization</i>	Switzerland
<i>Deutsches Ärzteblatt</i>	Germany
<i>Ethiopian Journal of Health Sciences</i>	Ethiopia
<i>Journal of the American Medical Association</i>	United States
<i>Journal of Korean Medical Science</i>	Korea
<i>New England Journal of Medicine</i>	United States
<i>New Zealand Medical Journal</i>	New Zealand
<i>The Lancet</i>	United Kingdom
<i>Revista Médica de Chile</i>	Chile
<i>Ugeskrift for Læger</i>	Denmark
<i>World Association of Medical Editors</i>	India

A potential conflict of interest exists when professional judgment regarding a primary interest might be influenced by a secondary interest. For instance, judging the validity of research or its benefit to patients may be influenced by potential financial gain for the researchers. A potential conflict of interest exists when relationships and activities have the potential to result in biased judgment.³ Public trust in the scientific process and the credibility of published articles relies on how accurately authors disclose relationships and activities directly or indirectly associated with a work, and many other stakeholders depend on these disclosures to inform their assessments. Transparency, consistency, and completeness of disclosures are critical for editors, peer reviewers, clinicians, patients, educators, policymakers, and the general public to make decisions and build trust.¹

In the 1980s, biomedical journals began adding conflict-of-interest requirements to their instructions to authors as a natural reaction to having a noticeable commercialization of biomedical sciences in the American press, as well as to the US Congress holding hearings on federal research funds and their relationship to conflicts of interest.^{4,5} However, at that time, the mechanisms of collecting and reporting authors' relationships and activities potentially relevant to a published work were not uniform. Accordingly, 10 years ago, the ICMJE adopted the ICMJE Form for the Disclosure of Potential Conflicts of Interest to create uniformity in how journals collect and report potential conflicts of interest, thus preventing confusion and controversy.¹

Although this uniform disclosure form has helped the scientific community and other stakeholders become aware of potential conflicts of interest in publications, modifying their assessments and views accordingly, issues have remained. One of the most important refers to how opinions vary over which relationships and activities should be reported. One may decide not to report a relationship because of differences in opinion regarding relevance, definitions, or simple oversight. Others may interpret the listing of a potential conflict of inter-

est as an indication of problematic influence. Another issue is that the software supporting the current disclosure form makes its use difficult or impossible for an increasing number of authors.¹

Having these perceptions in mind, the ICMJE has now proposed a new disclosure form to address these issues. The first measure was to eliminate words that may associate activities and relationships with problematic influences or malpractice. For this purpose, the previous title "... for the Disclosure of Potential Conflicts of Interest" was changed to "The ICMJE Disclosure Form." Also, authors will no longer be asked to decide what could be perceived as a potential conflict of interest. Instead, they will disclose all of their activities and relationships, and the readers will then decide whether these activities and relationships should influence their assessment of the work.

To avoid omissions, the proposed form includes a checklist of activities and relationships for authors to complete.¹ These activities and relationships will be listed in a table, and the authors will check *yes* or *no* for each one, adding comments when appropriate. Examples of relationships on the new form are the following: grants or contracts from any public, private, for-profit or not-for-profit entity; royalties or licenses; consulting fees; and payment or honoraria for lectures, presentations, speaker bureaus, manuscript writing, or educational events, among others. The draft of the proposed disclosure form can be accessed on the ICMJE website.⁶

Furthermore, the ICMJE has proposed to accept disclosures from Web-based repositories, such as Convey (<https://www.aamc.org/services/convey>), which will enable authors to keep an inventory of their activities and relationships and create electronic disclosures specifically tailored for entities such as the ICMJE, without the need to repeatedly create a new disclosure form for numerous occasions. The ICMJE will accept disclosures from repositories that meet the following criteria: collection and reporting of relationships and activities according to ICMJE requirements; absence of fees to enter, store, or export data; provision of disclosure to journals electronically, as well as another option for journals without a digital interface; and compliance with the General Data Protection Regulation.

The ICMJE planned to receive comments and suggestions for the new author disclosure form until April 30, 2020, before finalizing and adopting the new version. According to comments sent by researchers, pharmaceutical companies, and readers of medical journals,⁷ there is certainly room for improvement. Clarification of terms, such as *topically related* and *directly related*, and use of plain language are recurrent suggestions. The wording of the proposed disclosure form has been perceived as a barrier to achieving transparency.

Additionally, the use of subgroups to report forms of support may be needed, as disclosure of writing support, for instance, may be easily overlooked when presented in the same group of receipt of materials.

Another important critique to consider is that the use of the same disclosure form in different publications goes against the instructions of the form, which says that activities or relationships to be disclosed should be in the time frame of initial conception and planning of the work to the moment of publication. Therefore, each disclosure form should be tailored to each submission, according to comments written to the ICMJE. It remains to be seen if these comments will be taken into consideration to improve the new disclosure form.

Overall, the proposed changes to the disclosure form are likely to be beneficial in terms of increasing transparency and helping authors list all relevant relationships and activities. Improved transparency will help stakeholders better assess the published research and shape their opinions on the credibility of statements.

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Author contact: caricilli@gmail.com

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The *AMA Manual of Style: A Guide for Authors and Editors*—What’s New in the 11th Edition

Kelly Schrank, MA, ELS¹; Stacy L. Christiansen, MA^{2a}; and Annette Flanagin, RN, MA, FAAN^{3a}

¹Freelance Medical Editor and Owner, Bookworm Editing Services, LLC, Canastota, NY; ²Managing Editor, *Journal of the American Medical Association (JAMA)*, The JAMA Network, Chicago, IL; ³Executive Managing Editor; Vice President, Editorial Operations, JAMA and The JAMA Network, Chicago, IL

^aAMA *Manual of Style* Committee Member

Development of the much-anticipated 11th edition of the *AMA Manual of Style* has been an ongoing process for 4 years. Most of the chapters have been thoroughly revised and updated, with the 10-person committee going through a continuous process of updating, revising, and peer reviewing and then finally completing the final revisions (Box 1).

In the “Style and Substance: The *AMA Manual of Style*, 11th Edition” session at the 2019 Medical Writing & Communication Conference, Stacy Christiansen showed photos of older versions of the *AMA Manual of Style* and described how it has gone from a 68-page, in-house document used by *JAMA* and specialty journal staff in 1962 to a 1,067-page published book used by authors and editors in the 10th edition in 2007 and an online version that followed in 2009. The new edition is upwards of 1,200 pages. Herein we identify some of the changes to be found in the 11th edition.

Box 1

10 committee members
23 chapters revised
4 years of iterations

ABBREVIATIONS

Many new abbreviations have been added to the new edition. A few examples include

ACEI	angiotensin-converting enzyme inhibitor
ACL	anterior cruciate ligament
GWAS	genome-wide association study
LGBTQAI	lesbian, gay, bisexual, transgender, queer (or questioning), asexual (or allied), intersex
MERS	Middle East respiratory syndrome
OD	opioid use disorder
SNV	single-nucleotide variant

Abbreviations no longer needing expansion in manuscripts include CI, CME, HIV, OMIM, PMID, SD, SE, and SEM. Abbreviations removed from the list include CD and PDA.

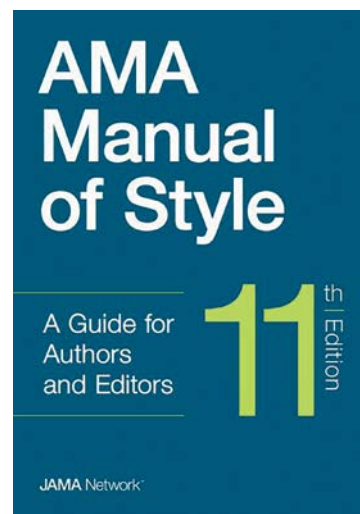
Byline abbreviations are being scaled back in the new edition: only academic degrees (eg, medical doctor [MD], doctor of philosophy [PhD]), licenses (eg, registered nurse [RN]), and credentials (eg, editor in the life sciences [ELS]) should be listed after author names in the bylines. Fellowships, honorary degrees, or awards should not be included.

AUTHORSHIP RESPONSIBILITIES

The roles of contributors, authors (bylined and nonbylined), group authors, and nonauthor collaborators are further described and defined in the new edition. There are more examples of how to mention shared authorship and co-corresponding authors in the Acknowledgments section; how to handle changes in authorship; and how to acknowledge support, assistance, and contributions from those who are not authors. There are many more examples of the different contributors who may need to be acknowledged, as well as an example of an Acknowledgment section, with all of the possible elements provided.

CONFLICTS OF INTEREST

The new edition provides more information about conflicts of interest (COI) for authors, peer reviewers, and editors; what the COI statements should say; and what to do about undisclosed COI.



EDITORIAL RESPONSIBILITIES

Because “Corrections are important to the integrity of the published literature,” more information has been added about managing errors and corrections. An editorial in *JAMA* (Box 2) was published to explain the available approaches for managing a range of types of errors and to get feedback from others.

In the past, there were only 2 kinds of errors:

- *minor errors* (inconsequential errors), which are corrected online without a correction notice, and
- *substantive errors*, which require a correction notice and a corrected article that is reciprocally linked to the original article.

Box 2

Christiansen S, Flanagin A. Correcting the medical literature: “to err is human, to correct divine.” *JAMA*. 2017;318(9):804–805. doi:10.1001/jama.2017.11833

A new type of error is a *pervasive error*, which is a serious but inadvertent error that affects many data reported in an article. For example, a pervasive error could result from a coding problem during data collection or a miscalculation that caused extensive inaccuracies throughout an article that needs to be corrected in the abstract, text, tables, figures, and/or supplementary material.

There are 3 paths to take when there is a pervasive error:

- Letter of Explanation and Correction: used when there are no major changes and none of the conclusions or interpretations are affected and there are no statistically significant changes in the results
- Retraction: used when there are substantial changes and the results, interpretations, and conclusions change and the science is no longer valid
- Retraction and Replacement (NEW OPTION): used when there are substantial changes, and the direction or significance of the results, interpretations, and conclusions changes but the science is still valid

Retraction and Replacement is a new option that allows an article with inadvertent but pervasive errors to be replaced with a corrected version and a complete explanation from the authors published as a linked letter, eliminating the stigma associated with a “do not use” retraction. Studies have found that 21% of retractions were not due to misconduct, so this allows the literature to be corrected and the science to continue to benefit the community. With Retraction and Replacement, a notice is added to the corrected article indicating that the original article was replaced, and portable document format (PDF) copies of the original article with errors highlighted and the corrected article with corrections highlighted are published in an online supplement.

GRAMMAR

In keeping with other style resources, such as *The Chicago Manual of Style* and the *AP Stylebook*, the *AMA Manual of Style* will now allow the use of the singular *they* in a few instances: when rewriting the sentence as plural is awkward, when patient identification is a concern, or when referring to a patient or population that does not identify with a binary sex distinction of female or male. Although the preference is still to recast or rewrite sentences in a plural form, it is now more acceptable for those stated uses.

The section on how to use the indefinite articles *a* and *an* was revamped extensively to help writers, especially those for whom English is a second language, figure out how to identify the correct indefinite article. For example, whether to use *a* or *an* is difficult before a word starting with the letter *h*: it could be *a histogram* but *an hour*. The lists in this section have been expanded.

Advice for how to use proper grammar to discuss scientific content in social media includes the following

- Use proper capitalization.
- Use basic punctuation.
- Use easily recognized symbols (&, ≥, =) and contractions.

Other changes to “web words” and “e words” include removing the hyphen from *email* and lowercasing *internet* and *website* to align with current usage. Other *e*-compounds, such as *e-cigarettes* and *e-book*, continue to use the hyphen. Other “web words” have been combined, such as *webcam*, *webpage*, and *webcast*.

INTELLECTUAL PROPERTY

The intellectual property chapter has been expanded and now covers many new and evolving topics, such as public access, open access, preprints, data sharing, and predatory publishing; updates on copyright and publication licenses for many types of content, including digital content, social media, and other material; and updates on trademarks, including protecting websites and domain names.

NOMENCLATURE

The nomenclature chapter is one of the largest, with 18 sub-chapters. The Genetics subsection has been thoroughly revised and vetted. Use of the gene symbol is recommended, rather than any aliases or nicknames. It may be necessary to dual-report for genes with aliases that are well-entrenched: for example, “*ERBB2* (previously *HER2/neu*).”

The Human Genome Variation Society now recommends the terms *sequence variant*, *sequence variation*, *alteration*, or *allelic variant* rather than the terms *mutation* and *polymorphism*. For example, single-nucleotide polymorphism (SNP)

should be replaced by single-nucleotide variation (SNV). During this transition, it may be necessary to dual-report: “SNV (previously SNP).”

NUMBERS

The 11th edition recommends changes for spacing in temperature measurements: there should now be a full space between the number and the degree symbol, and the degree symbol and F or C no longer need to be repeated in a range when a hyphen is used. This is in keeping with International System of Units (SI) recommendations.

Examples:

The temperature was 37.5 °C (not 37.5°C)

The temperature range was 99–101 °F (not 99°F–101°F)

Exceptions are degree symbols for angles and latitude and longitude.

PROTECTING THE RIGHTS OF PATIENTS AND RESEARCH PARTICIPANTS IN PUBLICATIONS

The new edition provides updated and new information about the rights of research participants; the ethical review and approval of research, regulations, and policies that exempt low-risk research from ethical review; and requirements for informed consent. Examples of when more information is needed are given, to provide more transparency and to comply with the US federal regulation known as the “Common Rule,” which was revised in 2017 and formally implemented in 2019.

More discussion of patients’ right to privacy in publication is provided in the new edition. If a patient or family member can recognize themselves or the patient in a scientific or clinical report, then it is not private enough. If permission from identifiable patients cannot be obtained, then information needs to be de-identified. For example, removal of specific information, such as sex and age, is acceptable if not clinically necessary, but such data should not be altered (eg, changing from female to male).

PUNCTUATION

The new edition has expanded the list of nonhyphenated words and provided more insight into when to not use hyphens. For example, do not hyphenate modifiers in which a letter or number is the second element, such as *type 1 diabetes* or *phase 2 study*. Similarly, avoid hyphens in combinations of words that are commonly read as a unit, such as *amino acid levels*, *bone marrow biopsy*, *deep venous thrombosis*, and *open access journal*.

REFERENCES

New Types of References

There were many additions to keep up with social media and new technologies:

- Facebook: JAMA Facebook page. Accessed November 2, 2019. <https://www.facebook.com/JAMAJournal/>
- Twitter: @AMAManual. The 11th edition: more examples of references in scientific publications, including newer sources such as trial registries, data repositories, preprints, and social media. Posted November 1, 2019. Accessed November 2, 2019. <https://twitter.com/AMAManual/status/1190283198544203776>
- Apps: JN Listen. *Version 1.0.15. American Medical Association*. Updated March 1, 2019.
- Blog: Orellana J. Resources for references. *AMA Style Insider blog*. Posted October 25, 2019. Accessed November 2, 2019. <https://amastyleinsider.com/2019/10/25/resources-for-references/>
- Podcasts: Bauchner H. Editor’s audio summary. *JAMA*. Posted October 22, 2019. Accessed October 31, 2019. <https://edhub.ama-assn.org/jn-learning/audio-player/17356045>

Other additions included manuscripts stored in institutional repositories and preprints:

- Manuscripts in Institutional Repositories: Tseng V. Effect of noise reduction methods in the ICU on sleep quality. UC Irvine. Published June 8, 2016. Accessed August 17, 2016. <http://escholarship.org/uc/item/190551hq>
- Preprints: Bloss CS, Wineinger NE, Peters M, et al. A prospective randomized trial examining health care utilization in individuals using multiple smartphone-enabled biosensors. *bioRxiv*. Preprint posted online October 28, 2015. doi:10.1101/029983

One thing to note about the preprints is that the descriptor is not in brackets, as similar types of references would have been in the past. This means changes to references that are letters and published online:

- Gross R, Neria Y. Posttraumatic stress among survivors of bioterrorism. Letter. *JAMA*. 2004;292(5):566.
- Cannon CP, Braunwald E, McCabe CH, et al. Pravastatin or atorvastatin evaluation and infection therapy—Thrombolysis in Myocardial Infarction 22 Investigators. Comparison of intensive and moderate lipid lowering with statins after acute coronary syndromes. *N Engl J Med*. doi:10.1056/NEJMoa040583

Many more examples were provided for data in data repositories:

- Data Repository: HUGO Gene Nomenclature Committee (HGNC). Human Gene Nomenclature database search engine. Accessed March 14, 2018. <http://www.genenames.org>
- Data Set in a Data Repository: Francuzik W. Data from: Skin microbiome in atopic dermatitis: 16S gene sequence data. *figshare*. 2016. doi:10.6084/m9.figshare.4028943
- Data in a Data Repository and Original Publication: Cutter AD, Gray JC. Data from: Ephemeral ecological speciation and the latitudinal biodiversity gradient. *Evolution*. 2016;70(10): 2171-2185. Dryad Digital Repository. Deposited August 17, 2016. doi:10.5061/dryad.734v9

Examples are now provided for common trial registries, such as ClinicalTrials.gov (United States), anzctr.org.au (Australia and New Zealand), isrctn.com (United Kingdom), trialregister.nl (the Netherlands), umin.ac.jp/ct (Japan), and EU Clinical Trials Register/EudraCT (Europe).

- Clinical Trial Database: Evaluation of phage therapy for the treatment of Escherichia coli and Pseudomonas aeruginosa wound infections in burned patients (PHAGOBURN). ClinicalTrials.gov identifier: NCT02116010. Updated July 23, 2015. Accessed October 13, 2019. <https://www.clinicaltrials.gov/ct2/show/NCT02116010>

Changes to Existing Types of References

Because it's not able to be tagged correctly in extensible markup language (XML), the death dagger (†) is no longer used in the bylines of the article when the author (or one of the authors) is deceased. If it's necessary to note that the author died in the interim, this can be noted in the Acknowledgments at the end of the article.

Example: Additional Information: Coauthor John Doe, MD, died January 30, 2018.

In keeping with the change to not include the location of drug manufacturers, the location of publishers is no longer needed for book references. This is supported by the fact that many publishers have more than 1 location, the correct location can be difficult to determine, and it is unnecessary when trying to retrieve references.

To assist readers in accessing online references, the new edition recommends that digital object identifiers (DOIs) and uniform resource locators (URLs) be moved to the end of the reference that contains them and that no period follow them.

Leaving off the terminal period should allow people to more easily copy and paste the DOI address and have the link work. Dates of access and publication go before the link.

Examples:

- Harman S, Verghese A. Protecting the sanctity of the patient-physician relationship. *JAMA*. Published online October 29, 2019. doi:10.1001/jama.2019.17965
- Centers for Disease Control and Prevention. Million Hearts: meaningful progress 2012-2016. Published May 2017. Accessed August 9, 2019. <https://millionhearts.hhs.gov/files/MH-meaningful-progress.pdf>

New Reference Format for the *AMA Manual of Style*

Christiansen S, Iverson C, Flanagan A, et al. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020.

STUDY DESIGNS AND STATISTICS

In the new edition, 20 types of study designs are described, and reporting guidelines are identified and listed, so that editors can help writers understand the different types. Links to each type of reporting guideline are provided in the online edition.

The discussion of *multivariable* and *multivariate* has been updated in the online version to explain the difference in more detail and to specify that the terms are not synonymous (the last print edition incorrectly stated that these terms were synonymous).

The Statistics Glossary has been thoroughly revised and updated, including 21 types of bias. Additional types of study designs and other statistical terms have also been added, such as

- Cluster randomization
- Mendelian randomization
- Mediation analysis
- Difference-in-difference analysis
- Forest plots
- I^2 statistic
- Equivalence
- Noninferiority

Additional guidance has been provided on *P* values, including discussion of the preference for presentation of effect size (odds ratio [OR], hazard ratio [HR]), and estimates of error (95% CI) and avoiding the presentation of *P* values alone.

TABLES AND FIGURES

To aid in readability, the new edition recommends that text in table cells be left aligned. The previous format of aligning by singles digit was sometimes hard to read, leaving a river running through the data. Capitalization in column headings has

also been changed from capitalizing the first letter of every major word (initial cap style) to sentence case because those headings are difficult to read in initial cap style and because it was sometimes difficult to know what to capitalize.

The new edition also includes many updated and new examples of figures (and ways to display data), such as spaghetti plots, genetic heat maps, and clinical images, and all are displayed in full color. The AMA Style Committee recommends against the use of pie charts because they are often uninformative or misleading; the new edition provides an example of how to recast a complicated pie chart into a divided bar chart that better displays the data. For Kaplan-Meier curves, the new edition requires the numbers at risk for each measurement point to be displayed below the figure. Network and heat maps are

being used with more frequency, and examples are provided in the “new” edition.

USAGE

The 11th edition contains entries on the use of socioeconomic terms. Describing people with their socioeconomic status, such as *the poor* or *the unemployed*, is not recommended. Using *third-world* or *developing* to describe a country or region also is not recommended. New terms, such as *low-income* or *limited-income* for individuals or *resource-limited* for a country have been added and are described in more detail in the new section.

In keeping with patient-first language, new terminology and recommendations for how to discuss addiction have been added. For instance, the 11th edition recommends not using

Table. Summary of Notable Changes

Before	After
Include fellowships from the UK and Canada, honorary degrees, or awards after author names in the byline	Only include academic degrees (MD, PhD), licenses (RN), and certifications (ELS) after author names in the byline Fellowships, honorary degrees, or awards should not be included.
Expand and define <i>CME</i> , <i>HIV</i> , <i>OMIM</i> , and <i>PMID</i>	Do NOT expand and define <i>CME</i> , <i>HIV</i> , <i>OMIM</i> , and <i>PMID</i>
Do NOT use singular <i>they</i>	Use singular <i>they</i> in specific situations
Use <i>e-mail</i>	Use email
Use <i>Internet</i>	Use internet
Use <i>Website</i> , <i>Webcam</i> , <i>Webpage</i> , <i>Webcast</i>	Use <i>website</i> , <i>webcam</i> , <i>webpage</i> , <i>webcast</i>
Use gene aliases	Use the gene symbol Double report if the alias is well-known
Use <i>mutation</i> and <i>polymorphism</i>	Use <i>sequence variant</i> , <i>sequence variation</i> , <i>alteration</i> , or <i>allelic variant</i>
Expand and define <i>CI</i> on first use	Do NOT expand and define <i>CI</i>
No space between the number and the degree symbol Repeat the degree symbol and F or C in a range when a hyphen is used.	Add a full space between the number and the degree symbol Do NOT repeat the degree symbol and F or C in a range when a hyphen is used
Put a dagger (†) next to a name in an article byline, which is connected to a footnote to indicate a deceased author	Put a note in the Acknowledgments to indicate a deceased author
Include publisher location	Do NOT include publisher location
Include DOIs and URLs before Published and Accessed dates	Include DOIs and URLs at the end of the reference, with no terminal period
<i>Multivariable</i> and <i>multivariate</i> are synonymous	<i>Multivariable</i> and <i>multivariate</i> are NOT synonymous
Center text in columns and column heads Capitalize text in column heads using initial caps	Left align text in columns and column heads Capitalize text in column heads using sentence case

DOI, digital object identifier; ELS, editor in the life sciences; MD, medical doctor; PhD, doctor of philosophy; RN, registered nurse; UK, United Kingdom; URL, uniform resource locator.

the terms *alcoholic*, *addict*, or *user*. Recommended phrasing includes “he abuses alcohol” or “people with opiate addiction.” The Correct and Preferred Usage list has other new additions, such as

- Nauseous, nauseated
- Elicit, illicit, solicit
- Alternative, alternate

ADDITIONAL CHANGES

Out

- Indexing chapter
- Pie charts

In/New

- Extensive updating/revision of every chapter
- Enhanced linking down to the fifth level of subheadings
- Combined Design, Typography, and Editing chapters
- Example of an Acknowledgment section, with all of the possible elements provided
- Additions to types of bias
- Figures for survival curve, dot plot, individual-value plot, forest plot, funnel plot, hybrid graph, network map, and multipart figure
- Figures are in full color

New “How to”

- How to credit authors, contributors, and collaborators
- How to provide sufficient information on COI for authors, peer reviewers, editors
- How to handle different types of corrections
- How to use indefinite articles
- How to use social media to discuss scientific content
- How to protect the rights of research participants
- How to protect patients’ right to privacy in publication
- How to differentiate and understand reporting guidelines
- How to use *P* values, presentation of effect size (OR, HR), and estimates of error (95% CI)
- How to use hyphens (when they are/are not needed)
- How to use socioeconomic terms
- How to discuss addiction, including terms and recommendations

KEEPING UP WITH UPDATES

All changes are published on the Updates page: <http://www.amamanualofstyle.com/page/updates>

Updates were recently made to the online version to add COVID-19 and SARS-CoV-2 to the section on virus nomenclature.

The Twitter account is active, with updates and questions being answered on a daily basis: @AMAManual.

AMA Style Insider Blog has regular posts: <http://amastyleinsider.com/>

Quizzes are being revised, and they are being released in packages.

The *AMA Manual of Style* Committee has created an introductory [video](#), and they plan to have monthly podcasts.

As a benefit of membership, AMWA members get a 20% discount on the print and online editions.

The new edition was published in February 2020.

Note: Slides from the session are available here: <https://www.amwa.org/page/2019sessions>. Many examples included herein are from the *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Copyright 2020 American Medical Association.

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Author contacts: kelly@headbookworm.com,
annette.flanagin@jamanetwork.org, and
stacy.christiansen@jamanetwork.org

Lifting the Veil on Compensation for Employed Medical Communicators

Roshawn Watson, PharmD, PhD, BCPS / Associate Director, Clinical Scientist; Clinical Development Execution, Vertex Pharmaceuticals, Boston, MA

Let's be honest: salary is one of the most uncomfortable, loaded topics in today's workplace. It is highly personal, deliberately shrouded in secrecy, and sometimes even contentious. Public disclosure is frequently deemed uncouth, meaning that your salary is typically kept between you and your employer. This creates a concentration of salary information exclusively held by employers, who know not only your salary but those of all your colleagues and who presumably have human resources departments dedicated to studying fair and competitive compensation trends. Asymmetric salary information does not necessarily benefit employed medical writers. If you do not know what you are worth in the marketplace, it is easy for you to undervalue your knowledge, services, and experience, perhaps falling victim to systemic biases in compensation or even subtle manipulation to keep your salary depressed. The opposite could also be true: you can literally price yourself out of the market (or at least a job) if your desired or actual salary does not reflect the current market sentiment. Consider Google employee [Erica Joy Baker](#)¹ who started a [spreadsheet](#) that detailed salary and compensation data for approximately 5% of employees at Google a few years ago.² As more of her colleagues participated, it led to some very pointed questions directed to management, with some of her colleagues even demanding "equitable pay" on the basis of the shared data. Information is power. One benefit of the *AMWA 2019 Medical Communication Compensation Report* is that you do not have to create a stealth spreadsheet for this valuable data. It provides access to a treasure trove of self-reported salary data from medical communicators—data that would typically be reserved for industry insiders—that will hopefully be directly beneficial as you progress through your career. This article will mainly focus on some key observations from the full report related to the salaries of medical communicators employed full time at companies of all sizes, locations (mostly in the United States [US]), and sectors. The main topics discussed are (1) what types of companies pay medical commu-

nicators the most, (2) what types of medical communicators get paid the most, (3) how salary growth for medical communicators compared with growth in other industries, (4) which employer types had the greatest salary growth over the last few years, (5) the impact of having advanced terminal degrees on medical communicator salary, (6) how salaries of medical communicators in the US compared with those of ex-US respondents, and (7) whether gender bias was detected in salaries. This article is not an exhaustive review of all of the survey findings, so do feel free to purchase a copy of the [full report](#)³ if you want to do a deeper dive. You may also review the previously published [Executive Summary](#)⁴ for the main highlights.

The *AMWA 2019 Medical Communication Compensation Report* indicates that full-time-employed medical communicators (N = 845) experienced considerable salary growth since the published 2015 survey results (N = 732), in general (no direct comparison can be made because the 2 samples were different). Overall, the mean salaries for employed medical communicators increased by 20.2%, nearly 3 times the rate of inflation between 2014 and 2018,^{5,6} possibly suggesting increased purchasing power for medical communicators over this time period.⁷⁻¹² Salary growth outpacing inflation was not surprising, given that medical communication is a complex, integral, and highly desirable skill set. However, the magnitude of salary growth relative to inflation was indeed notable. Additionally, the mean salary increase was higher than the approximately 14.7% that salaries increased across all industries during that same period,⁷⁻¹² possibly suggesting heightened demand for medical communicators. Three standout employers with respect to salary growth were the government, medical device companies, and pharmaceutical companies, in which salaries for medical communicators increased during this period by 55.7%, 29.0%, and 28.7%, respectively. Salary increases for these 3 employers appeared considerably higher than those reported for other employers. Workers in these 3 sectors also comprised 28.4% of all employee respondents to the 2019

survey, so they appear to be driving a considerable portion of the salary increases during this period. It was also notable that that medical communicator salaries at biotechnology companies increased by 12.3%, representing lower salary growth than the average increase for medical communicators (20.2%) and appearing nominally lower than the expected salary growth across all industries (14.7%) during that period. Nonetheless, even with the lower growth rate in biotechnology companies, their employees were the second highest paid among all employed medical communicators in the 2019 survey. Perhaps the lower growth rate was just a correction due to supply and demand or was a result of medical communicators working for biotechnology companies starting out ahead from 2015. They were, notably, the highest paid according to the 2015 results. One additional observation is that there was a nominal increase in the proportion of full-time-employed medical communicators in supervisory positions who responded to the 2019 compared with the 2015 survey, which could possibly explain some of the salary growth as well (37.4% vs 31.6%, respectively).

Although the 2015 AMWA salary survey for employed medical communicators did not break down salaries by writer type (ie, regulatory writing, scientific communications), such data were included in the 2019 results and indicated that regulatory writers were the highest earners. AMWA member data show that we have grown our membership in regulatory writing in the past 5 years and that those members are more experienced, thereby likely earning more than entry-level writers and potentially artificially elevating reported salaries for this writer type overall. Employed regulatory writers (N = 347) made a median of \$112,000 compared with the overall median (N = 845) of \$97,000 and earned a mean (standard deviation) salary of \$124,877 (\$54,162) that is considerably larger than the overall mean of \$108,444 (\$48,131); $P < .001$. It would not be surprising if the gap is further increased in future surveys as more regulatory writers participate in the survey. That is because a disproportionate number of regulatory writers work for biotechnology and pharmaceutical companies, 2 employer types known for providing higher base salaries, larger bonuses, and equity as long-term incentives. Even other medical communicators employed directly by pharmaceutical and biotechnology

companies would still draw smaller compensation in comparison with regulatory writers, as these benefits (bonuses and long-term incentives) are often determined as a percentage of one's base salary.

Although a primary remit of the salary survey is to paint a very broad portrait of the financials of being medical communicators, one thing that may be useful in the future would be to see the data broken down more granularly for regions known to be particularly affected by unique economic trends. For example, a considerable portion (28.4%) of participants work for pharmaceutical (N = 164) and biotechnology (N = 70)

companies. Certain areas have a concentration of these companies. Limited supply and abundant demand sometimes drive up salaries for medical communicators residing in these hubs. As such, the economics of working as medical communicators in these areas can meaning-



AMWA 2019
Medical Communication
Compensation Report
A comprehensive guide to compensation for
professional medical writers and editors

It provides access to a treasure trove of self-reported salary data from medical communicators—data that would typically be reserved for industry insiders—that will hopefully be directly beneficial as you progress through your career.

fully differ from the regional and overall averages. Reporting such data is helpful because it enables those who reside in such areas to better benchmark their compensation to locally matched peers; it uncovers niche markets, thereby making them more broadly accessible, helps identify locoregional disparities, and places the overall and regional salary data in finer context. Although 845 full-time-employed respondents represent a sizable sample cohort and made for an informative survey, most locations did not have a large enough respondent pool to support a granular interrogation. This is why census areas were chosen for regional considerations. Perhaps there will be more participants in the next survey to inform these granular analyses, or maybe apparent hubs with considerable medical communicator bases (ie, Boston, San Diego, and San Francisco) will be chosen for deeper dives. Similarly, although it is helpful to see that the 2019 data set included the percentile breakdown, minimums and maximums or even box plots or scatter plots would be immensely helpful, allowing readers place these data into even finer context. Requests for additional granularity are par for the course when the readers are scientifically literate.

One curious finding in the 2019 salary survey was that the analysis of income by highest degree earned suggested salary differences among medical communicators who held terminal degrees. Terminal degrees are the highest degrees one can

obtain in a given discipline, such as medical doctor (MD), doctor of pharmacy (PharmD), doctor of optometry (OD), doctor of medicine in dentistry (DMD), and doctor of philosophy (PhD). The salaries for those with MDs and PharmDs and other terminal degrees (excluding PhDs) were increased compared with those with PhDs (\$127,251 vs \$110,768, respectively). I originally was unclear on whether this suggested that MDs/PharmDs made more because (1) employers were intrinsically willing to pay more for their medical communication services because of higher perceived value; (2) these degree holders had higher seniority as medical communicators, thereby commanding higher salaries; or (3) these individuals were full-time employees as health care providers and part-time medical communicators, suggesting that their higher income was the result of income supplementation rather than differences in employer behavior. However, it turned out that years of experience was a significant covariate. When adjusted for years of experience, there was no difference in the salaries between non-PhD terminal degree holders and PhD medical communicators, which is the best possible scenario when comparing individuals performing the same job responsibilities.

Another observation is that the survey included and aggregated the results from both US and ex-US medical communicators, which presents some contextual challenges in interpreting these data. Certainly, given the fact that we are in a global marketplace, and some of us work for multinational companies, looking at the ex-US (N = 65) medical communicator market is certainly not surprising. However, even across the US (N = 835), regional differences in salary require context for interpretation, including differences in cost of living, ease of changing jobs, and distance of the job from one's family. For example, the cost of housing can be considerably higher in some coastal regions, where higher-salary jobs may be more abundant compared with the Midwest. Analyzing geographical salary differences across countries can be even more opaque and challenging, considering potential differences in currency conversions, repatriation of money (if applicable), tax systems, socialized benefits, overall economies, local market forces, and cost-of-living differences that can be quite profound. For example, I have seen US-based companies outsource medical writing and editing activities to the Philippines and India for fractions of the costs of resourcing the same services state-side. Thus, the sizable absolute decline in the average salary for those working outside the US (\$77,927 [\$33,685]) compared with the average salary in the US (\$110,568 [\$48,280]) should be taken with a grain of salt and may not be too informative absent the aforementioned context. Given the small relative percentage of ex-US respondents (7.2%), their influence on the overall results was not thought to meaningfully confound the overall data.

My final observation regarding the 2019 survey data was that a \$13,000 difference in the mean salaries of male and female medical communicators was apparent: \$119,236 (\$55,950) compared with \$106,210 (\$46,080), respectively. Gender-based pay disparity is a known issue across several industries. Thus, these data, on the surface, seemed to follow the all-too-familiar trope of wage suppression for women performing the same job and who have similar job experience as their male counterparts. Often-cited reasons for the disparity include everything from outright discrimination to systemic and/or unconscious biases and lack of female representation in senior positions. To partly address this problem, [California passed a law in 2018](#)¹³ mandating that public companies headquartered in California have at least 1 woman on their boards of directors by 2019. What is even more notable about women making less among AMWA survey respondents particularly is that a whopping 83.4% of respondents were women, meaning that if ever there was an opportunity and expectation for there to be gender pay parity, it would hopefully be seen with medical communicators. Fortunately, the observed gender salary difference was actually attributable to differences in highest degree achieved and years of experience. Male respondents in this sample were more likely to have more terminal degrees and have longer tenures. After correcting for these variables, there was not a difference in men's and women's salaries.

In conclusion, the *AMWA 2019 Medical Communication Compensation Report* provides a rare glimpse into the livelihoods of fellow medical communicators and the overall compensation trends since 2015. Interestingly, we now know that mid-February 2020 marked the end of the longest bull market in history, with over 10 years of growth (and over 400% returns in the stock market since March 9, 2009¹⁴). Surely, one would expect that a material portion of the growth seen in medical communicator salaries over the last few years stemmed from growth in an overall, thriving economy. Since then, the stock market quickly entered bear territory (over 30% declines¹⁵ as of March 23, 2020), and a considerable contraction of the gross domestic product is currently predicted for multiple consecutive quarters in 2020 (ie, recession). Many companies have pressed pause on new hires, announced layoffs and furloughs en masse, enacted broad pay cuts,¹⁶ and commandeered bonuses.¹⁷ Many businesses and governments are struggling to continue their existence.^{18,19} The unprecedented edict to shelter in place is expected to drain trillions from the US economy alone, as coronavirus disease 2019 has already resulted in nearly 200,000 deaths globally (as of the time of this writing) and has brought the world to a halt. In the US, 22 million filed for unemployment over a 4-week period ending on April 11,²⁰ representing the most precipitous decline in employment since the Labor Department began tracking these

data in 1967. Interestingly, in subsequent weeks, unemployment continued to rise despite the US stock market recovering some significant ground.²¹⁻²² This begs several questions, such as “How many of the newly unemployed were medical communicators?” “Will the current job crisis stimulate new interest in the medical communications profession?” and “Will overall compensation stagnate or decline for medical communicators fortunate enough to maintain employment?” Although there are certainly more pressing and important concerns than compensation trends during these trying times, the long-term impact on medical communicator compensation and overall livelihood cannot be known. However, it is unequivocally business as unusual. Given these macroeconomic considerations, the next compensation survey may be one of the most compelling reads yet.

Author's note: External data referenced in this manuscript are not included within the AMWA 2019 Medical Communication Compensation Report.

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

Author contact: shawn@roshaunwatson.com

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Strategies to Advance Your Medical Writing Career Part II: Identifying Opportunities and Developing Skills

By **Yanni Wang, PhD,¹** and **Lindsey Summers, MBA²** / ¹Principal Medical Writer, International Biomedical Communications, Frederick, MD; ²Director, Pharmaceutical Consulting Division, Green Key Resources, Denver, CO

Medical writing is a diverse profession, and different career paths exist. Which path should you choose? What will it take for you to reach the next level in your career? In the first article of this series, Lindsey Summers, MBA, shared insights on how to identify and effectively work with a recruiter.¹ In this second article, she describes common career paths in medical writing, shares tips for identifying opportunities in and beyond medical writing, and highlights skills needed to advance your career in the ever-changing medical writing landscape.



Ms Summers is Director, Pharmaceutical Consulting Division, at Green Key Resources, Denver, Colorado. She is a seasoned third-party recruiter specializing in helping companies hire medical writers and has been providing guidance on career advancement in medical communications to medical writers for more than a decade. She has led workshops on career paths in medical communications and frequently offers advice through LinkedIn and the American Medical Writers Association (AMWA) Engage Forum.

Journal (Wang): *What are the common career paths in medical writing? And what are the skills needed to thrive in these career paths?*

Summers: Medical writing and communication is a diverse field that contains many specialty areas, including

- Regulatory/clinical medical writing,
- Medical and scientific publications,
- Promotional medical writing, and
- Educational medical writing for health care providers, patients, and the general public.

All of these specialty areas require excellent writing and communication skills, but each has its own set of unique requirements beyond writing competency. AMWA's website provides rich information on the differences between different types of medical writing. For those who are new to medical writing or who wish to explore different options, learn about the career path you are interested in as much as you can before making a decision. AMWA's "Ultimate Guide to Becoming A Medical Writer" is a great starting point for new writers.²

Journal : *In the first article of this series, you shared tips and strategies for entering the medical writing profession. What are the most common opportunities for those who have gained years of medical writing experience?*

Summers: That's a hard question. When navigating your career, it's important to realize that advancement can mean all sorts of things, and neither I nor anyone else can tell you what drives you—only you can. Advancement could mean being the lead on a project, program, or client engagement. An increase in responsibility could mean working remotely, moving to another office, or managing people. Remember, your next big opportunity may or may not be within your current company. Constantly maintaining your professional network will not only expose you to many opportunities that you may be able find on your own but also provide you with opportunities to brainstorm with others about career paths you may not have already considered.

Journal: *What are the most common high-level positions in medical writing, and what are the basic requirements?*

Summers: It depends on what you actually mean by high-level. The most common position that I fill is a role titled

Senior/Principal Medical Writer. This type of role typically requires 7 to 15 years of medical writing experience with a bachelor's degree at a bare minimum and a preference for a degree in the sciences. The ideal candidate will hold an advanced degree (an MS or, most often, a PhD). Usually a research background before working in writing is highly preferred because the ability to analyze and translate data into written messages is an absolute must. A candidate's capability to analyze and translate data into a written summary is often tested prior to an offer being extended.

Journal: *What are the opportunities for experienced medical writers who do not wish to take on management responsibilities?*

Summers: Opportunities for experienced medical writers who do not wish to take on management responsibilities include

- Becoming a technical lead or a lead medical writer within your company,
- Starting your own freelance medical writing and consulting business (regulations are changing, however, so make sure you investigate tax obligations and payment terms before committing to this), and
- Exploring opportunities in related fields, including government, universities, clinical science, medical affairs, medical communication agencies, public health, and basic science if you have worked in applied sciences or vice versa.

Journal: *For experienced medical writers, are there career opportunities beyond medical writing?*

Summers: Yes, there are career and job opportunities beyond medical writing. Many experienced medical writers have acquired a wide range of transferable skills, including verbal and written communication, time and project management, and the capability of working/leading in cross-functional environments. These skills can be easily transferred to many related fields, including but not limited to

- Scientific, medical, or regulatory affairs in pharmaceutical and biotech companies and
- Public relations and medical communications departments in research institutions, hospitals, and government agencies.

However, plan your next career move strategically. Know what you want, what you are good at, and what you enjoy doing. Talk to those in the field you wish to enter or at the career level you wish to reach, and then decide if the field or position is truly what you want to pursue. If so, find out what it takes to get there and develop the skills required accordingly.

Journal: *How can experienced medical writers identify opportunities within and outside their company?*

Summers: You will want to develop a short list of companies, including the type of company and the ideal role that you are interested in, so that you have a clear idea about what you want for your next step. It's also a good idea to have a mentor or mentors with whom you have developed a professional relationship over the course of your career. However, don't wait until you are looking for a job to get their perspectives on what your next step should look like. You should be constantly growing and developing.

In addition, 1 of the most important things you can do is actively nurturing your network. You don't want to wait until you need to make a career move to start approaching people with whom you may have not spoken in 10 years. A good rule of thumb is scheduling regular times to touch base with at least someone in your network once a week or month. It could be a quick email to say hello or a phone call to arrange a lunch.

I also highly recommend engaging with recruiters who are in your area of specialty, even if you are not considering a career move. That way, when you are ready, you will have experts who not only may have an opportunity for you but also are more receptive to you.

Journal: *What skills should medical writers be developing/refining to remain employable and thrive in the era of artificial intelligence (AI) and machine learning?*

Summers: People in many professions are concerned about AI and machine learning, as explained in a recent Forbes article.³ Relax—it's been shown time and time again that it will take many years for AI to catch up to the point that the technology can think like the human mind. Instead of being afraid, think of these technologies as simply helping us. Thirty years ago, you would go to the library and look through the card catalog; today, we use online databases. This does not mean that the databases don't need to be updated and that resources don't need to be verified by a human. There will still be work; it will just be different from how we might view it today. It's important to be open to change and to different ways of doing things, but the basics won't go away.

Currently these AI/machine-learning technologies are mainly used to help with aggregating data from multiple places, which might help your clients reduce the time it takes to conduct research on a topic and create cost-saving measures. However, there are some areas you might want to avoid, and these areas often involve tasks that can be easily replicated over and over again.

Journal: Are there certain therapeutic areas/technologies that might become obsolete in the future?

Summers: It is important to consider areas in which you are thinking about working in the future. Take hepatitis C as an example; in the last few years, we have seen a cure for hepatitis C. As a result, not only do individuals who work in this field need to reinvent themselves, but a few companies need to completely reinvent themselves as well.

Another example of evolving technology that affects many of the roles I recruit is database management. For example, many companies are switching their database management system from Excel or SharePoint to Veeva and the like.

Journal: How important are emotional intelligence skills for a medical writer's professional success?

Summers: Medical writers are often in a position where they have to influence without authority. In many cases, medical writers need to work with cross-functionality across the globe and deal with different personalities and cultures. Having emotional intelligence and being empathetic to others while being judicious in the writing process not only is important to the medical writer's own successes but also affects others.

Journal: What are the top trends in medical writing that you have observed in recent years? And how should medical writers be prepared?

Summers: I have noticed 2 trends:

1. Many medical writers prefer working remotely.

The number 1 thing experienced or new medical writers care about seems to be the opportunity to work remotely, which is also the number 1 thing companies tend to address right away. Many people assume that because medical writers work in front of computers all day, they should be able to and have the flexibility to work remotely. Most companies I have worked with allow some remote flexibility, but not all. If you're a manager who works remotely, don't assume everyone who applies wants to work remotely; conversely, if you are a candidate, don't assume you can work remotely.

A company may not allow working remotely, even if you are stellar, because the arrangement could change team dynamics and create favoritism if remote working is not allowed for everyone. The bottom line is knowing your personal tolerance for working remotely and sticking to it.

2. Many writers want to be independent.

If you have been following AMWA's Engage Forum, you most likely have seen a number of posts about legislation in cer-

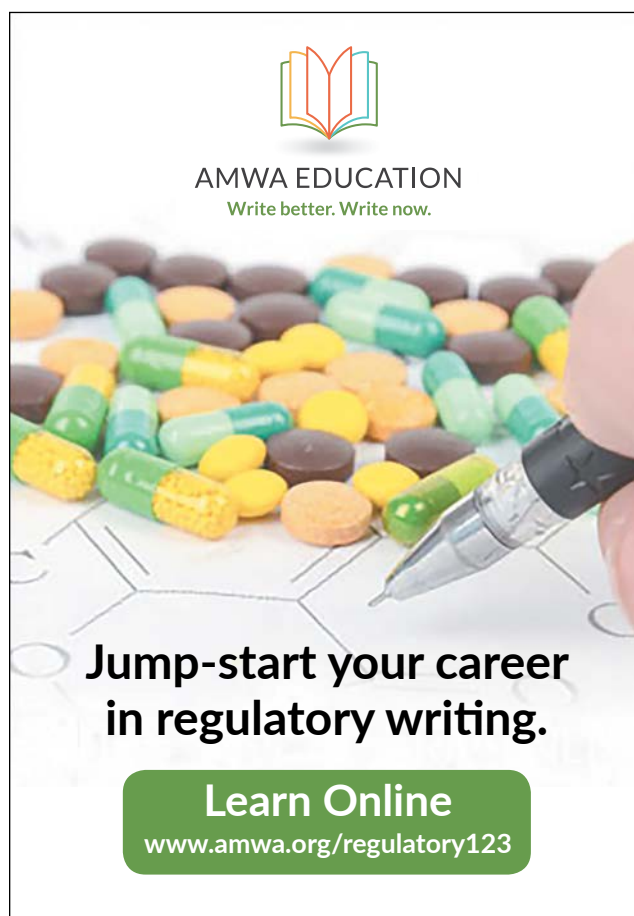
tain states that affects freelancers. Many companies are not willing to take the risk of potentially misclassifying freelancers, no matter where the freelancers live. It's incredibly important to periodically seek tax and legal advice from professionals with tax or legal expertise throughout your freelance career to protect not only your business but yourself personally.


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

Author contacts: Yanni Wang: dr.yanni.wang@gmail.com; Lindsey Summers: lsommers@greenkeyllc.com

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Guiding Ethical Interactions with Health Care Professionals: Follow the Codes

Julie Ravo / Clinical Technical Writer, North Haledon, NJ

Conflicts of interest may compromise or appear to compromise professional judgment in the conduct or reporting of research, as well as in the marketing of health care products. The impact of these can be damaging to the integrity of the health care field. In 2018, the medical director of a leading cancer research center in the United States failed to disclose financial ties and involvement with pharmaceutical companies related to appearances at medical conferences.¹ A pharmaceutical company recently was ordered to pay \$3.5 million to resolve allegations that it employed illegal kickbacks and lavish gifts to influence physicians to prescribe their dermatology drugs.²

A conflict of interest may also result from a simple exchange of merchandise, such as offering tickets to a clinician who shares an interest in baseball. Although this may not be viewed as harmful as that of the aforementioned scenarios, it nonetheless could be perceived as an influence for future product purchases.

The appropriate marketing of pharmaceuticals and medical devices can help to ensure access to vital products, which may enhance the quality of life for patients. The collaboration of pharmaceutical and medical technology manufacturers with health care professionals is critical to achieving this. However, these interactions should not be perceived as inappropriate or self-serving in nature or result in compromise of the integrity of both parties.

Professional guidelines provide a practical and ethical framework for decision-making and instill a sense of responsibility and accountability. The pharmaceutical and medical technology industries have developed applicable codes or guidelines to direct interactions with health care professionals to manage potential conflicts of interest, encourage high ethical standards in the conduct of business and clinical research, and best serve the interests of patients.³ These codes were adopted by The Pharmaceutical Research

and Manufacturers of America (PhRMA), which represents pharmaceutical and biotechnology companies, and by the Advanced Medical Technology Association (AdvaMed), which fulfills a similar role for the medical device industry.

The PhRMA Code became effective in 2002, the original AdvaMed Code was created in 1993, and revisions to both Codes have been issued in later years. The PhRMA Code encourages compliance with the guidelines, but compliance is voluntary. Conversely, AdvaMed requires its member companies to abide by the Code. In several states (ie, California, Connecticut, Nevada), compliance with the Code's guidelines is mandatory. The unique distinction for the development of the AdvaMed Code is that medical devices differ from drugs as a result of the more "hands-on" relationship between the device and the health care professional.⁴ Nonetheless, many of the components of the AdvaMed Code parallel those of the PhRMA Code (Table).

This review, although not inclusive, presents some of the key messages from comparable sections of each Code, as well as those that may be most relevant for the American Medical Writers Association community.

Consulting Arrangements

Consulting arrangements allow companies to obtain information from medical experts on the industry market, products, therapeutic areas, and patient needs; this information is often used to ensure that the products developed and marketed meet the needs of patients.

Selection or retention of health care professionals as consultants should be made on the basis of defined criteria (ie, expertise and reputation, or knowledge and experience regarding a particular therapeutic area). Continuous efforts should be made to ensure that consultant arrangements are neither inducements nor rewards for prescribing or recommending a particular medicine or course of treatment.

Table. Guidelines for Compliance for Interactions With Health Care Professionals for Each Code

PhRMA	AdvaMed
<i>Informational presentations by pharmaceutical company representatives and accompanying meals</i>	<i>Consulting arrangements with US health care professionals</i>
<i>Prohibition on entertainment and recreation</i>	<i>Prohibition on gifts, entertainment, and recreation</i>
<i>Pharmaceutical company support for continuing medical education</i>	<i>Company-conducted training & educational programs</i>
<i>Pharmaceutical company support for third-party educational or professional meetings</i>	<i>Company-conducted business meetings</i>
<i>Consultants</i>	<i>Business courtesies for health care professionals (travel, lodging, meals, educational items)</i>
<i>Speaker programs and speaker training meetings</i>	<i>Supporting third-party educational grants, research grants, charitable donations, and commercial sponsorships</i>
<i>Educational items and prohibition of noneducational and practice-related items</i>	<i>Demonstration, evaluation, and consignment products</i>
Health care professionals who are members of committees that set formularies or develop clinical practice guidelines	Providing health economics & reimbursement information
Scholarships and educational funds	Added as of January 2020
Prescriber data	Jointly conducted education & marketing programs
Independence and decision-making	Communicating for the safe & effective use of medical technology
Training and conduct of company representatives	Representatives providing technical support in the clinical setting

Content in italics denotes similar sections.

Reasonable compensation for consulting services (eg, reimbursement for travel, lodging, and meal expenses incurred during services) should be offered on the basis of fair market value.

Health care professionals often enter into clinical study agreements to provide clinical research services. These services must perform a legitimate research purpose and should include a written agreement of services, as well as fair compensation for the services.

Company-Conducted Training or Educational Programs

It is the responsibility of pharmaceutical and medical device companies to train and educate health care professionals on the product or device, including product features, service offerings, and potential adverse events. Professionals who are to be trained must have proper qualifications and expertise to prescribe the drug or to utilize the device. In addition, the setting for these training sessions must facilitate the effective transmission of product information (eg, the health care professional's office, a conference venue). Hands-on technical

training should be held at training facilities, medical institutions, laboratories, or other facilities. The training staff from the company should have the proper qualifications and expertise to conduct such training. This may include qualified field sales employees who have the technical expertise necessary to perform the training.

Companies may provide attendees with modest meals and refreshments in conjunction with these programs. However, meals and refreshments should be secondary to the training and/or educational purpose of the meeting.

Third-Party Educational Grants, Research Grants, Charitable Donations, and Commercial Sponsorships

Third-party scientific and educational conferences or professional meetings can contribute to the improvement of patient care, and, therefore, financial support from companies is appropriate.

Support for these meetings may be provided through

- A grant to the conference sponsor to reduce conference costs,

- An educational grant that reduces the costs of the educational component of the meeting,
- A grant to a training institution, or
- A commercial sponsorship that allows attendance by medical students, residents, fellows, and other professionals who will be trained on the product.

Charitable donations may be made by the company to support patient education or indigent care or to sponsor events, provided the profits from the event are intended for charitable purposes.

Prohibition on Gifts, Entertainment, and Recreation

Companies should not provide or pay for any entertainment or recreational event or activity for any health care professional who is not an employee of the company. These activities include provision of theater or concert tickets, sporting events or equipment, or vacations, regardless of (1) their value, (2) whether the health care professional is engaged as a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose. Companies also may not provide health care professionals with gifts such as alcohol, flowers, chocolates, holiday gifts, or cash or cash equivalents.

Educational Items and Prohibition of Noneducational and Practice-Related Items

There are occasions in which a company may provide items to health care professionals that benefit patients or serve in an educational function. However, any such item should have a fair market value of less than \$100 (not including medical textbooks or anatomical models for educational purposes, as these likely exceed that amount). Additionally, the items cannot be used for noneducational or non-patient-related purposes, nor can they be used by the health care professional's family, friends, or office staff. These include noneducational branded items (eg, pens, notepads, or any such item with the company name or logo). However, it may be appropriate to provide product samples for patient use.

Evaluation and Demonstration Products

Providing products to health care professionals at no charge for evaluation or demonstration purposes can benefit patients in many ways. These benefits include improving patient care, facilitating the safe and effective use of products, improving patient awareness, and educating health care professionals regarding the use of products.

Under certain circumstances, reasonable quantities of products may be provided to health care professionals at no

charge for evaluation and demonstration purposes. These products may include those for single use (eg, consumable or disposable products) and multiple use (sometimes referred to as "capital equipment"). This enables health care professionals to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future. Company products provided for evaluation are typically expected to be used in patient care.

2020 Updates to the AdvaMed Code

To keep pace with the evolving needs of the industry, 3 new sections have been added to the AdvaMed Code, which became effective on January 1, 2020. These sections provide guidance on jointly conducted education and marketing programs, the communication of off-label claims, and the presence of company personnel in clinical settings.

It is important to note that the PhRMA and AdvaMed Codes should not replace any laws, regulations, or codes that contain stricter requirements.

Conclusion

The collaboration between companies and health care professionals offers a rewarding partnership for the advancement of medical science and technology. Complying with preestablished codes of conduct can help maintain transparency and avoid the potential conflicts of interest that may jeopardize this collaboration.

The content has been adapted from the AdvaMed and PhRMA Codes of Ethics as provided on their respective websites. For additional details on each Code, please visit www.advamed.org or www.phrma.org.

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Brian Bass



Lori De Milto



Ruwaida Vakil

Q Why is confidence important in succeeding as a freelancer? How did you build your confidence?

A Being a freelance businessperson also means you are a sales and marketing person, unless you hire someone else to do that for you. You are selling yourself, your services, your business, and your capabilities. If you don't project confidence in yourself, why would anyone else feel confident to give you work? **Experience** is what gives confidence: we must be very clear about our hands-on experience when we pursue projects. *Never, never lie to a prospective client about your experience*; never say, "I can do that" if you really have never done that before. This will not inspire confidence in the client.

Today, I would not hire anyone who came to me and said s/he could do it but had never done it before; I would consider it cocky and dishonest. [I've done this twice in years past (one writing, one desktop publishing)—it cost me thousands of dollars to fix their errors.] So be sure you really do know how to do something before trying to get someone to pay you to do it.

Especially in the pharmaceutical/biotechnology industry, you should not try to sell yourself just based on a degree in science and the fact that you may have written a paper or a thesis: the industry is complex, and you need to understand it deeply and have experience with the process of drug development, clinical research, FDA regulations, etc.

Fake confidence is awful; leave it alone. You gain confidence through experience and if you don't have experience in medical writing, it's better not to try to freelance. Rather, try to acquire appropriate experience via a full-time job at a trainee level. Maybe at an ad agency, hospital, managed-care company, or contract research organization? Better yet, try to find work, either full-time or freelance, in a field you truly do know.

— Cathryn D. Evans

Confidence is important to success in any endeavor. When you exude confidence (not arrogance), you make it easy for others to have confidence in you. This makes for a smooth, professional working relationship. When a client calls a freelancer with an assignment, they expect that assignment to

be delivered on time, on target, and on budget. If you make it hard for the client to have confidence in your ability to deliver to that level of expectation, they won't take a chance on hiring you.

How do you build your confidence? It's much like building your client base; it takes experience! But, of course, just like it's hard to get experience without the work, it's hard to get the work that will give you opportunities to gain that experience when you don't have the confidence. So, you need to build at least a base of confidence yourself, first.

When I started out as a freelance medical writer, I built my confidence around the narrow range of experience I had. Then I used that confidence as a proxy for the confidence I lacked. I extrapolated to potential clients how my (perhaps unrelated) experience applied to what they were asking me to do. Although I lacked the confidence of having done it, I was confident that I could figure out how to do it. Of course, then I had to be very careful about not crossing the fine line between what I realistically could and couldn't do.

Little by little, project by project, my confidence in myself increased—and with it, my clients' confidence in me increased. Once confidence starts building on itself, it's unstoppable.

— Brian Bass

Confidence helps you attract great clients and build a stable, successful, freelance medical writing and/or editing business. If you believe in yourself and your ability to succeed, clients will too. You'll be able to build trust and make a great first impression. Trust is crucial, because clients want to work with freelancers whom they trust, or whom someone they know trusts. Also, confidence helps you meet the inevitable challenges of freelancing head on and take the risks that lead to great opportunities.

It's very common to lack confidence, especially if you're a newer freelancer. You probably have a lot more going for you than you think you do—and little or no reason to lack confidence. I've seen this over and over again in the freelancers I've met.

Build your confidence by knowing that you are good enough to succeed and then by doing great work for every client on every project. As you work with more satisfied clients and complete more projects, your confidence will grow.

As for me, I was too naive to lack confidence when I started freelancing. I had been working as a writer for about 12 years and found that I could easily learn about medicine. I taught myself how to market my business and, by doing a lot of marketing in the first year or so, I was able to build a stable, successful, freelance medical writing business.

— Lori De Milto

Q Why is in-person networking still important in the digital age?

A Nothing will ever beat in-person networking for meeting people and starting to build trusting relationships. Trust is crucial in attracting new clients on your own and getting referrals from colleagues to new clients. The annual AMWA Medical Writing & Communication Conference and other conferences and meetings of professional associations are the best way to network in person. You can make lots of key contacts, including with other freelancers, in a few days and deepen relationships with current key contacts.

Having a strong network of other freelancers helps you get more referrals—the easiest way to build your freelance business. Most of my referrals come from freelance friends whom I met at AMWA conferences.

While in-person networking is stressful for most freelancers (including me when I was starting out), you can learn how to be comfortable, and even enjoy, networking. If you approach networking as getting to know people instead of trying to “sell yourself,” it’s much easier. Also, remember that everyone is there to network, most people are nice (especially in AMWA), and other people are shy or scared too. Like any skill, the more you practice networking, the better—and more comfortable—you’ll get.

It is possible to build trusting relationships with people through social networking platforms such as LinkedIn and AMWA Engage. But it’s a lot easier to do this if you’ve met the person at least once. Social networking is a great way to stay in touch with the people you meet in person and build trusting relationships with them.

— Lori De Milto

Social networking will continue to be a strong part of networking in the digital age. However, there is nothing that can substitute for human interaction. In-person interactions allow for nonverbal communication and understanding that simply cannot be translated virtually. Meeting clients in person allows them to put a face to an email and can solidify relationships. Therefore, I strongly feel that although digital networking will

continue to emerge as the primary source for networking in the foreseeable future, in-person networking will still outweigh the benefits of virtual networking.

— Ruwaida Vakil



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Trends and Opportunities for Medical Communicators

The Evaluation of Efficacy, or How Do We Know Whether a Treatment Works? Part 1

Thomas M. Schindler¹ and Helen Bridge² / ¹Medical Writing Europe, Boehringer Ingelheim Pharma, Biberach a.d. Riss, Germany; ²Medical Communications, AstraZeneca, Cambridge, United Kingdom

Imagine the following situation. Over the course of a few weeks, patches of skin on your elbows and knees have become red and flaky, and the patches are itching so badly that you're having difficulty sleeping. You're really busy at work, and it's difficult to find time to see a dermatologist, so you do an internet search. You discover a condition called psoriasis, which is characterized by patches of red, dry, itchy, and scaly skin. You've never heard the term before, but you have a look at various health sites and learn that psoriasis occurs when skin cells are replaced more quickly than usual and is thought to be caused by overactivity of the immune system. The websites mention a number of home remedies. One of these is an oatmeal bath, which can apparently help relieve the itching. You decide to try this out. It feels rather strange, and getting all the soggy oatmeal out of the bath afterward is a bit of a chore, but you immediately notice that your elbows and knees feel less itchy, and over the next few days, the abnormal patches of skin seem to shrink and look less red and scaly. "It worked," you think to yourself.

Most people would probably draw this conclusion. However, evaluating the efficacy of treatments (ie, how well they work) is actually not as straightforward as we might think. In this hypothetical example, you used a treatment and then noticed an improvement in your symptoms. It is human nature to infer cause and effect from sequences of events in time, in this case to assume that the treatment caused the improvement in your skin. Although it is possible that this is the case and an oatmeal bath really is an effective treatment for psoriasis—assuming your self-diagnosis is accurate—there are several other possible explanations for the improvement. For example, it is quite possible that your skin would have improved anyway and this had nothing to do with the oatmeal bath. Many conditions, including psoriasis, have a natural course that involves flare-ups followed by

periods when the symptoms are less severe. A second possibility is that other changes in your lifestyle, such as a reduction in stress or a different diet, caused the improvement.

Scientific Evidence for Efficacy

Now let's take a different perspective. Imagine you are a regulator at the US Food and Drug Administration (FDA), and your job is to decide whether new drugs can be approved for marketing. You need to examine all the available evidence pertaining to the effects of a drug to determine whether it works sufficiently well and reliably to recommend its use in patients. Clearly, 1 patient's subjective impression that a drug (or an oatmeal bath!) has worked for her, although important, is not robust enough evidence to justify approval for potentially millions of patients. Regulators need to be convinced that the new drug works well in a large and representative group of people with the disease. They further require that the evidence provided is free from any systematic error (ie, bias).

The strongest evidence is derived from large, double-blind, randomized controlled clinical trials. These trials provide a very controlled setting and limit the potential for bias. Trials have to be designed in such a way as to allow firm conclusions about whether a drug is able to induce improvements in a group of patients with a given disease. Such trials have a number of features:

- **Controlled:** The study must include a treatment arm that represents a control. This can be either placebo or another drug, a so-called active comparator. The 2 groups must undergo the same procedures; the only difference is the treatment they receive.
- **Parallel-group:** The group receiving the test drug and the control group must be treated at the same time, within a single study protocol (ie, under the same conditions), to make them truly comparable.

- **Randomization:** All patients need to have the same chance of being assigned to the test treatment group and the same chance of being assigned to the control group. This avoids systematic bias in how patients are allocated to treatment groups. Randomization should ensure that the treatment groups are comparable at baseline in all important characteristics, whether these are explicitly assessed or not. This provides the basis for us to conclude that any improvement observed in 1 group in comparison with the other is due to the treatment and not to disease fluctuation or chance.
- **Double-blind:** Neither the patient nor the investigator must know which treatment the patient is receiving. This prevents bias in the way the measurements are taken and clinical symptoms are interpreted.

Efficacy and Disease

It is only meaningful to talk about the efficacy of a drug in relation to the disease it is intended to treat (sidebar). Diseases are, however, often complex, with multiple symptoms and physiological manifestations. Before we can determine efficacy, we need to identify a feature of a disease that is highly relevant for the patient's health and can therefore represent the disease burden. The feature we select needs to change with disease severity. It must be measurable, and the measurement should be fairly simple and robust. Measuring the severity of a disease must not be significantly influenced by who is taking the measurement or where that person is located. Repeated measurements taken shortly after an initial one should yield very similar results (ie, the feature needs to have some stability and must not fluctuate within a short time).

For many diseases, the regulatory authorities and appropriate medical societies have agreed on the features that best represent the disease and can therefore be used for determining whether a treatment is efficacious. In some cases, the feature chosen allows us to measure the disease only indirectly (eg, via a blood biomarker that varies in concentration proportionally to variations in disease severity). A well-known example of this kind of “surrogate” marker is the use of glycosylated hemoglobin (HbA1c) for evaluating the efficacy of treatments for diabetes. A high level of HbA1c (ie, 8% of hemoglobin or above) is a key physiological consequence of diabetes and in itself constitutes neither the disease in all its complexity nor a symptom that is troublesome to patients (Figure). However, HbA1c is straightforward to determine from a blood sample and, unlike blood glucose (which fluctuates considerably over the course of the day), is a reliable marker for the average amount of glucose in the blood over the previous 8 to 12 weeks. Furthermore, the concentration of HbA1c correlates with the frequency of serious consequences of diabetes, such as stroke, heart attack, retinopathy, and nephropathy. The efficacy of a

medicine to treat diabetes can therefore be assessed by its ability to lower the concentration of HbA1c. This is quicker and much less costly than measuring clinical outcomes of diabetes, such as strokes or heart attacks, diabetic eye disease, or diabetic kidney disease.

In some diseases, there is no agreed biomarker that can serve as a surrogate for disease severity, and clinical outcomes are the preferred measure for evaluating treatments. In cancer, for example, the gold standard is to measure the length of time patients remain alive after being randomly assigned to a particular treatment (overall survival). Measurements of the size of the tumor lesions over time are also generally used (eg, progression-free survival). In psoriasis, it is the clinical symptoms

Defining Disease

The concept of efficacy is only meaningful in the context of a specific disease or condition. Modern drug development relies on the “biomedical model” of disease. The idea is that diseases come about because 1 or more molecules become dysfunctional. This causes the molecular machinery to behave in an abnormal way and leads to disease. Within the biomedical model, it is assumed that the malfunction can be fixed using the right molecular tool (ie, a medicine) that stops or corrects the malfunction and brings it back to normal (ie, to a healthy state). The quest to develop efficacious treatments therefore depends on understanding the disease biochemically. When it is known how a disease comes about on the molecular level, an appropriate molecular tool can be developed.

This model is not the only possible way of understanding the causes of disease. Holistic approaches to disease focus on the whole person—body, mind, and spirit—and the importance of balance. Some cultures believe that disease is the result of forces such as spirits, imbalances of *yin* and *yang*, or a blocked flow of *qi*. In these belief systems, the interventions sought as a remedy for a disease are very different. The rectifying measures often try to address imbalances and to restore harmony within the individual and with the environment.

Even the question of what constitutes a disease is not straightforward and is the subject of intense philosophical debate. It is easy to find historical examples in which a particular state has been regarded as a disease on the basis of societal beliefs that are not grounded in biomedical science. Not so long ago, medical textbooks described homosexuality as a (mental) illness. Because of cultural change, some diagnoses, such as hysteria or drapetomania (a 19th-century “disease” attributed to slaves with a tendency to run away from their masters) have their fashion and then disappear. Even today, some diagnoses—such as female sexual arousal disorder or attention-deficit hyperactivity disorder—raise questions as to where the boundary is between “normal” and what is seen as a dysfunction that qualifies as an illness.

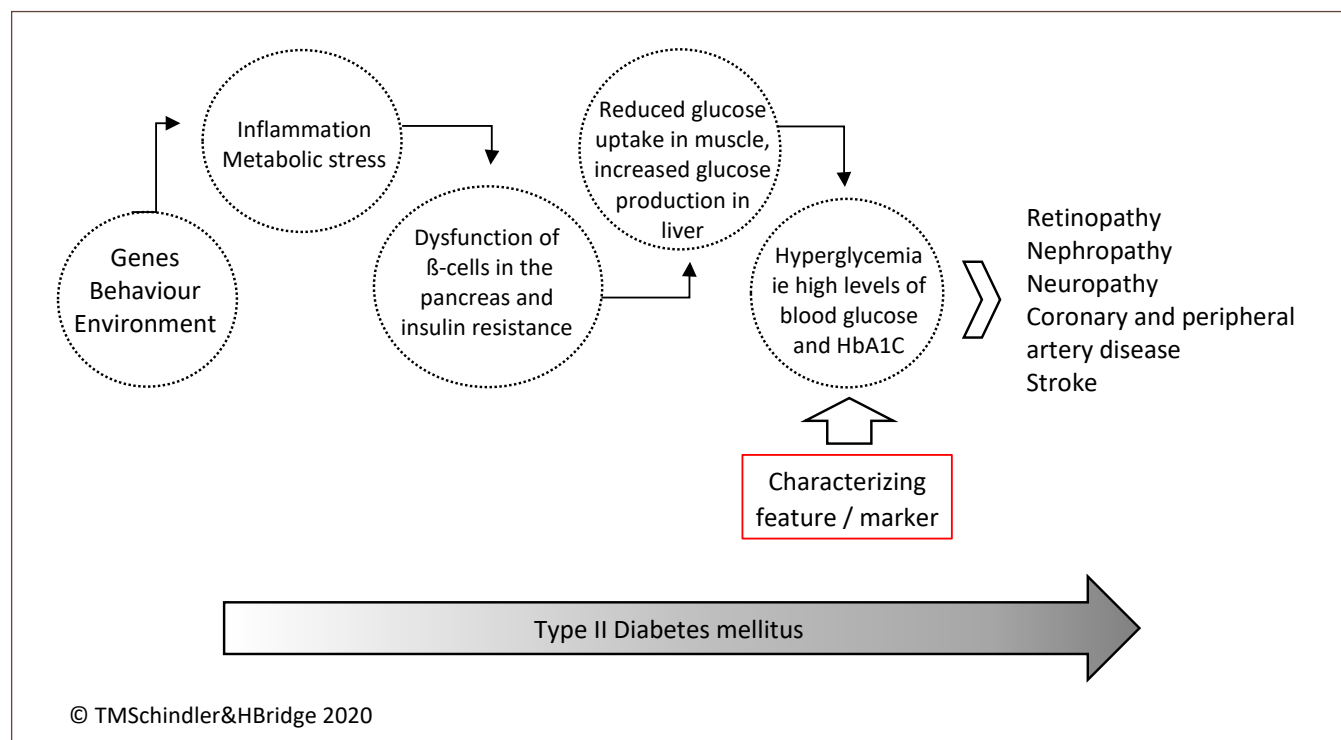


Figure. Disease map for diabetes: the relationship between disease and measured characteristic.

that are measured, and an instrument called the Psoriasis Area Severity Index (PASI) has been developed for this purpose. PASI is a detailed questionnaire that physicians complete on examining a patient. Their answers enable the calculation of a single numerical measure of the average redness, thickness, and scaliness of the lesions, weighted by the area of disease involvement (the lower the score, the less severe the psoriasis).

Endpoints for Efficacy Evaluation

Once we have chosen the features that we want to measure, we need to “package” them as endpoints. An endpoint is a variable whose value captures the benefit we hope to see with a treatment, as defined in a trial objective. Endpoints are usually derived by a calculation based on the variables measured (Table). They need to be precisely defined and often capture a change between 2 specified time points, usually the start and the end of the treatment period. Any variable measured on a numerical scale—such as HbA1c or PASI—can be analyzed either in terms of the average change over time or in terms of the proportions of patients achieving a “response,” such as an improvement in PASI of at least 75% or an HbA1c value below 7%; this is known as a “responder analysis.”

To provide a comprehensive picture of the efficacy of a treatment, clinical trials generally use a number of efficacy endpoints. Regulators require that these endpoints are pre-specified in the clinical trial protocol and statistical analysis

plan. This prevents retrospective cherry-picking of results that look positive but are in fact simply the result of random variation or the natural course of the disease.

The Challenge of Variability

To get clear results for the chosen endpoints, the patient population in a randomized clinical trial needs to be clearly defined. Patients are checked (the technical term is screened) for compliance with the eligibility (ie, inclusion and exclusion) criteria specified in the trial protocol. The more heterogeneous a trial population is (ie, the more variation there is), the harder it is to demonstrate an overall treatment effect. In heterogeneous groups, it will be difficult to detect a difference between treatments against the background noise of all the variation due to other factors. It is therefore important to control the amount of variability in a clinical trial population to ensure a valid test of the treatment (called *internal validity*).

However, human beings vary in myriad ways, so it is not helpful to test a drug in an extremely narrow group of patients if there is a broader population in need of the treatment. The results of a clinical trial need to be applicable to a target population in the real world (called *external validity*). Trial eligibility criteria therefore attempt to strike a balance between the need for a reasonably homogeneous trial population and the requirement that the population is broadly representative of the target population likely to receive the drug once approved.

Table. From Disease to Endpoints

Term	Definition	Example 1: HbA1c	Example 2: PASI
Disease	Medical entity considered abnormal	Diabetes	Psoriasis
Sign, Symptom, or Disease Characteristic	Measurable feature representing an important disease aspect	HbA1c—reflecting average blood sugar concentrations over the past 8 to 12 weeks	Redness, thickness, and scaliness of the skin (captured by PASI questionnaire)
Measurement	Process of determining and recording the value of a variable that represents a disease characteristic	Recording of HbA1c (%) in blood sample	Recording of answers to PASI questionnaire
Variables and Endpoints	<p><u>Variable:</u> A measurable attribute, phenomenon or event, with a value expected to vary over time and between subjects. A variable may be either directly measured or derived from measured variables.</p> <p><u>Endpoint:</u> Variable that pertains to an objective of a trial (shown in bold)</p>	<p>Directly measured/recorded:</p> <ul style="list-style-type: none"> • HbA1c at baseline • HbA1c at week 26 <p>Derived:</p> <ul style="list-style-type: none"> • Change in HbA1c from baseline to week 26 (patient level) • Responder (HbA1c <7%) at week 26 (patient level) • Mean change in HbA1c from baseline to week 26 (treatment-group level) • Response rate (HbA1c < 7%) at week 26 (treatment-group level) 	<p>Directly measured/recorded:</p> <ul style="list-style-type: none"> • PASI score at baseline • PASI score at week 16 <p>Derived:</p> <ul style="list-style-type: none"> • Change in PASI score from baseline to week 16 (patient level) • Responder (PASI 75) at week 16 (patient level) • Mean change in PASI score from baseline to week 16 (treatment-group level) • PASI 75 rate at week 16 (treatment-group level)

HbA1c, glycosylated hemoglobin; PASI, Psoriasis Area Severity Index; PASI 75, measure indicating a 75% or greater reduction in PASI scores from baseline. Definitions are based on those given in Hamilton S, Bernstein AB, Blakey G, et al; Budapest Working Group. Critical review of the TransCelerate Template for clinical study reports (CSRs) and publication of Version 2 of the CORE Reference (Clarity and Openness in Reporting: E3-based) Terminology Table. *Res Integr Peer Rev.* 2019;4:16. doi:10.1186/s41073-019-0075-5

Because of the many biological differences among people, it is normal to see a variety of responses to a given treatment, even in a relatively homogeneous group of patients with the same disease. Treatment effects are not fully predictable: some people may experience a big improvement, whereas others may notice no difference or even a worsening of disease symptoms. This is why it is important to analyze treatment effects on a group level. We need to aggregate data from all the patients and carry out statistical tests to determine whether there is a true difference in the average outcomes for patients randomly assigned to different treatments. Regulators require the results of these tests to be statistically significant (ie, to show that there is a reasonable probability that the difference observed between treatment groups has been caused by the treatments and is not the result of chance).

Statistical Significance Compared With Clinical Meaningfulness

Assuming a statistically significant difference between the test group and the control group is achieved, regulators will also be very interested in the size of the treatment effect. A *P* value

does not tell us anything about the magnitude of the difference between the groups. When comparing very large groups, even very small effect sizes become statistically significant. It is therefore essential always to report the treatment effect (ie, the difference between groups), together with its confidence interval, and not just the *P* value.

Regulators need to assess whether the benefit provided by a new treatment is clinically meaningful. Determining the minimum size of a treatment effect that is clinically meaningful, known as the *minimally clinically important difference* (MCID), is a medical decision, not a statistical one. For many efficacy endpoints, there is a consensus in the medical community regarding the MCID; this typically can be found in guidelines produced by the regulatory authorities and medical societies. In type 2 diabetes, for example, a reduction of HbA1c by 0.3% is considered clinically meaningful. In psoriasis, however, there is no such clear consensus, and improvements in PASI of both at least 50% and at least 75% have been considered clinically meaningful.

To reach a conclusion on whether a drug can be approved, regulators evaluate the benefits demonstrated in clinical

trials (ie, the treatment effect demonstrated for the main efficacy endpoints) in relation to the risks of using the drug. (We describe clinical trial safety reporting in “For Safety’s Sake”: *AMWA J.* 2018;33[2]:68-72 [part 1] and 2019;34[1]:32-37 [part 2]). In brief, all drugs have adverse effects, some of which may be experienced by a large proportion of patients, whereas others may be very rare but serious. In some disease settings (eg, a terminal cancer), patients may be willing to tolerate severe adverse effects if the drug offers a significant extension of life or even a cure. The key question is whether the benefits of the drug outweigh the risks for most patients (ie, whether the benefit-risk ratio is positive).

Beyond Efficacy: Effectiveness

Randomized controlled trials are a valuable source of evidence for the benefits and risks of treatments, but they do have limitations. As we have seen, these trials are conducted under tightly controlled conditions—a clearly defined patient population that receives the treatments under close observation—that may differ substantially from the conditions under which patients will receive the treatment in clinical practice. Evidence of *efficacy* (ie, that a drug works under ideal, controlled conditions) is not a guarantee of *effectiveness* under real-world conditions. Part 2 of this paper will examine why a drug that shows evidence of efficacy in clinical trials may not show similar effectiveness in the real-world setting. Because so-called *real-world evidence* is becoming more important in the approval of drugs, as reflected in a recent FDA initiative, medical writers are increasingly required to write documents based on real-world data.

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Author contacts: Thomas.Schindler@boehringer-ingenelheim.com; Helen.Bridge@astrazeneca.com

RESOURCES

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Freedom to Write: New Tools for Streamlining Document Development From Start to Finish

Elizabeth Clarke, PhD, MPH, MS,¹ and Krithi Bindal, MS, PhD, MBA² / ¹Regulatory Medical Writer, Aroga Biosciences, San Diego, CA; ²President and Principal, Aroga Biosciences, San Diego, CA

Medical writing is a dynamic and evolving field, and writers need to keep up with changing regulatory submission guidelines, style/formatting conventions, and pharmaceutical company mergers and acquisitions. These ongoing shifts impact document content, structure, and style. Now, more than ever, streamlining document development is critical for success. Fortunately, today, medical writers have an expanding array of tools to help address these challenges through the use of artificial intelligence (AI) and automation, integrated Microsoft (MS) Word toolbars, cloud-based options, and more. This article presents new tools and programs that are emerging as solutions for boosting accuracy and efficiency during document development.

Automating aspects of document creation and quality control (QC) review can save time and allow medical writers to focus on the science and how the data are described and interpreted. These tools can automate a wide range of tasks, including

- creating standard text and tables,
- running QC on abbreviation lists and hyperlinks,
- managing references,
- enhancing document collaboration, and
- anonymizing sensitive information.

A summary of the resources reviewed in this article may be found in the Table on page 88.

Document Editing

Document editing can present a major time sink for medical writers and involves repetitive, error-prone tasks. Software solutions are emerging that dramatically cut down time spent on these tasks.

Med-Brighter, *Pearce Clinical*, <https://pearceclinical.com/>
This product is a brand-new MS Word add-in for regulatory

medical writers that automates many of the most tedious and time-consuming aspects of creating documents.¹

- Med-Brighter applies QC algorithms to catch and correct common mistakes made with abbreviations; hyperlinks; bookmarks; tables, figures, and listings (TFL); and more.
- It creates and maintains lists of abbreviations, hyperlinks, section references and headings, and bookmarks, as well as cross references and table captions.
- It automatically generates correctly formatted end-of-text and in-text tables directly from TFL files.
- Pearce Clinical claims the software can reduce the time medical writers spend working on abbreviations by up to 70%.
- Although the current Med-Brighter toolbar is customized for regulatory medical writers, in the future, Pearce Clinical plans to apply similar algorithms to help other medical writers automate work on a wider range of technical documents.

PerfectIt, *Intelligent Editing*, <https://intelligentediting.com/>
This software is another MS Word add-in program for all medical writers that boosts accuracy and efficiency before, during, and after document creation.²

- PerfectIt operates on the basis of consistency checks, allowing the user to enforce style rules, locate undefined abbreviations, customize in-house styles, and more.
- It uses the Word sidebar in tandem with the document as an interface to accept or reject suggested changes, which provides context so the user can quickly decide whether the change needs to be made.

DocQC, *GenInvo*, <https://www.geninvo.com/>

This program offers a suite of authoring tools for regulatory medical writers, including DocQC, which automates QC checks and document/data anonymization, respectively.³

Table. Selected Automation Tools for Medical Writers

Category	Tool	Fee	Company	Capabilities
Document Editing	Med-Brighter	Yes	Pearce Clinical	<ul style="list-style-type: none"> QC: abbreviations, hyperlinks, bookmarks, and TFL Creates and maintains tables and captions, LoA, hyperlinks, section references, headings and bookmarks, and cross references
	PerfectIt	Yes	Intelligent Editing	<ul style="list-style-type: none"> Customizes and enforces style rules, locates undefined abbreviations Uses MS Word sidebar as an interface to accept or reject suggested changes
	DocQC	Yes	GenInvo	<ul style="list-style-type: none"> Real-time or batched checks within document and from source documents Includes data sets, TFL, patient safety narratives, CSRs, risk-management plans, and publications
Authoring	DocXtools	Yes	Litera Microsystems	<ul style="list-style-type: none"> Ensures style and formatting compliance Inspects for PDF generation Organizes/modifies all abbreviations Fixes deviations from best practices Automated ToC, appendix, cross-reference, figure, and table generation
	Sage Submissions	Yes	Sage Submissions	<ul style="list-style-type: none"> MS Word–based templates Enforces the global eCTD submission standard and supports FDA CDRH and GHTEF STED presubmissions and submissions
	StartingPoint	Yes	Accenture	<ul style="list-style-type: none"> “Author” MS Word–integrated toolbar automates compliance with ICH and regional structure and formatting requirements >450 eCTD and >100 medical-device templates
	Regulatory Document Templates	No	TransCelerate BioPharma	<ul style="list-style-type: none"> Suite of authoring templates: CPT, CSR, and CSAP Streamlines the clinical development process across stakeholder groups
	NLG Tools	Yes	Yseop	<ul style="list-style-type: none"> NLG solutions For CSR, PSN, and PV
Document Collaboration	SmartDocs	Yes	36Software	<ul style="list-style-type: none"> Cloud-based, integrates with MS Word and SharePoint Share content across documents and authors, create and centralize documents from existing content, and centralize documents Content maps, customizable document wizards, smart searching across documents and users, usage tracking, bulk publishing, etc
	Cloud Collaboration	No fee up to 10 GB storage	Box	<ul style="list-style-type: none"> Cloud-based Safely share content within and outside of the organization and across any device Comment and assign tasks directly within files Seamless, automated workflows Integrates with >1,400 apps
	Vault-RIM RIM Suite	Yes	Veeva	<ul style="list-style-type: none"> Cloud-based Workflow includes submission-document management, product-registration management, health-authority correspondence and commitments, and submission archiving
	PleaseReview	Yes	Ideagen	<ul style="list-style-type: none"> Cloud-based, secure for internal and external collaboration Coauthoring and redaction capabilities, life-cycle document reviews, comments, changes, and discussions for all stages of the document
Data Anonymization	Shadow	Yes	GenInvo	<ul style="list-style-type: none"> Automates data and document anonymization Risk-analysis tools, assessment of data utility after de-ID, generates redaction proposals and anonymization plans and reports Stores and applies de-ID strategies in metadata repository at multiple workflow levels, generates performance metrics, etc
	ClinGenuity Redaction Management Service	Yes	Synchrogenix	<ul style="list-style-type: none"> AI-enabled NLP solution for automatically identifying and redacting sensitive information Access to expert consulting on regulatory policy and guidance
Reference Management	EndNote	Yes	Clarivate Analytics	<ul style="list-style-type: none"> Integrates with MS Word
	Mendeley Cite	Yes	Elsevier	<ul style="list-style-type: none"> Customizable formatting, reference organization/storage, and search tools

AI, artificial intelligence; CDRH, Center for Devices and Radiological Health; CPT, Common Protocol Template; CSAP, Common Statistical Analysis Plan; CSR, clinical study report; eCTD, electronic Common Technical Document; FDA, US Food and Drug Administration; GHTEF, Global Harmonization Task Force; ICH, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; ID, identification; LoA, list of abbreviations; MS, Microsoft; NLG, natural language generation; NLP, natural language processing; PDF, portable document format; PSN, patient safety narrative; PV, pharmacovigilance; QC, quality control; RIM, Regulatory Information Management; STED, summary technical documentation; TFL, tables, figures and listings; ToC, table of contents.

- DocQC conducts checks on source information within the document and in other documents (eg, data sets, TFL, patient safety narratives, clinical study reports [CSRs], risk-management plans, publications) in real-time or via batch/scheduled execution options.
- It generates QC reports detailing failed checks and performance-metrics reports to track document quality and processing.

Authoring

Medical writers can also benefit from document templates and other tools that enforce standardized style and content.

DocXtools, *Litera Microsystems*, <https://www.litera.com/products/life-sciences/docxtools-for-life-sciences/>

This software package accelerates regulatory document drafting and review by automatically enforcing customizable standards for content, style, and format.⁴

- DocXtools automates document QC review, style, and formatting compliance; ensures approved symbol usage; inspects for portable document format (PDF) generation; and organizes/modifies all abbreviations in 1 place.
- It identifies and quickly fixes deviations from best practices and finds and fixes phrases that should be avoided.
- It offers drafting tools and automated tables of contents, appendices, cross references, figures, and tables.

Sage Submissions, <http://www.sagesubmissions.com/>

This product offers MS Word–based templates that enforce the global electronic Common Technical Document (eCTD) submission standard for regulatory medical writers.⁵

- The templates also support all of the US Food and Drug Administration Center for Devices and Radiological Health and Global Harmonization Task Force’s Summary Technical Documentation presubmissions and submissions in electronic copy format and enable compliance with global agency guidance and specifications for PDF files.

StartingPoint, *Accenture*, <https://www.accenture.com/us-en/services/life-sciences/startingpoint-submission-authoring-suite>

This program is a submission authoring suite that integrates into MS Word via an “Author” toolbar for the purpose of speeding up document creation for regulatory medical writers.⁶

- StartingPoint automatically ensures documents are compliant with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and regional structure and formatting requirements.
- It offers more than 450 eCTDs and more than 100 medical-device templates.

- The design is eCTD-specific, with predefined heading styles, fonts, margins, and table formats, and offers preset validation and compliance, including advanced document validation, Physician Labeling Rule functionality, and reference management.

TransCelerate BioPharma, Inc.

<https://transceleratebiopharmainc.com/>

TransCelerate offers a suite of authoring templates for regulatory writers, including the Common Protocol Template (CPT), Common CSR, and Common Statistical Analysis Plan (SAP).⁷

- The CPT initiative streamlines the clinical development process across stakeholder groups, including clinical trial sponsors, regulators, institutional review boards, and ethics committees.
- Medical writers work within a MS Word ready-to-use CPT for all phases and therapeutic areas, which enhances document structure and content for easier input, review, implementation, and extraction.
- The Common CSR template integrates guidelines from key sources, including the ICH E3 guidance⁸ and *CORE Reference*⁹ for headings, content, and data, as well as sponsor-specific standards for appendices and TFL.
- The common SAP enables writers to create and seamlessly integrate with the CPT and focuses on information for reporting and disclosure while addressing the ICH E9 draft guidelines on estimands.¹⁰

Another approach to streamlining document writing is the application of natural language generation (NLG) software. Using AI, NLG tools automate the conversion of complex data sets into written narratives with speed and accuracy. Thus, NLG can be useful for generating text that does not require analysis or scientific interpretation.

Yseop, <https://www.yseop.com/solutions/pharmaceuticals>

This program is an AI-powered NLG application that automates regulatory report writing.¹¹

- The tool offers NLG solutions for CSRs, patient safety narratives, and pharmacovigilance.
- The NLG tool frees up medical writing teams to focus on more writing that requires scientific knowledge/interpretation and strategizing.

Document Collaboration

An increasing array of tools are available to enhance document collaboration and coauthoring.

SmartDocs, *36Software*, <http://www.thirtysix.net/smartdocs/features/medical>

This cloud-based software integrates with MS Word and enables medical writers of all specialties to share content across documents and authors, create documents from existing content, and centralize documents using MS SharePoint.¹²

SmartDocs features document content maps, customizable document wizards, smart searching across documents and users, usage tracking, bulk publishing, and more.

Box, <https://www.box.com/home>

This platform helps all types of medical writing teams organize and create content via the cloud.¹³

- Users can safely share content with individuals in and outside of the organization and across any device (eg, desktop, mobile, browser).
- Box enables writers to comment and assign tasks directly within files, quickly shares content with external collaborators, and create seamless, automated workflows.
- The software integrates with more than 1,400 apps, including Office 365, G Suite, Slack, and more.

Vault-RIM, *Veeva*, <https://www.veeva.com/products/vault-RIM/>

Veeva recently launched Regulatory Information Management (RIM) Suite, another cloud-based collaboration tool for regulatory medical writers.¹⁴

- Vault-RIM unifies multiple regulatory processes and operations. Submission document management, product registration management, health authority correspondence and commitments, and submission archiving are all built into the workflow.
- This suite helps writers by streamlining stakeholder communication, disseminating the impact of new regulatory guidelines and requests, and improving data quality.

PleaseReview, *Ideagen*, <https://www.ideagen.com/products/pleasereview>

Ideagen offers a suite of cloud-based collaboration tools, including PleaseReview, document management software for all medical writers that features review, coauthoring, and redaction capabilities for all stages of the document life cycle.¹⁵

- Collaborating with both internal and external colleagues is equally secure.
- The software enables document reviews, comments, changes, and discussions documented in one place and recorded in a comprehensive reconciliation report.

Data Anonymization

Since 2015, pharmaceutical companies intending to market therapeutics in Europe have had to comply with European Medicines Agency Policy 70, which requires that clinical

reports contained in Marketing Authorization Applications be made publicly available for the purposes of transparency and disclosure. Adherence to these rules requires careful data and document de-identification (de-ID), which can require considerable effort. In response, several companies have come up with solutions to automate this process.

Shadow, *GenInvo*, <https://www.geninvo.com/shadow/>

This software automates data and document de-ID and anonymization in regulatory writing workflows.¹⁶

- Shadow features risk-analysis tools (eg, determines risk for re-identification), assessment of data utility after de-ID, and generation of redaction proposals and anonymization plans and reports.
- This software stores and applies de-ID strategies in a meta-data repository at multiple workflow levels and provides interactive rule application and testing, before and after views, and performance metrics to evaluate the precision/efficiency of strategy application and effectiveness of the de-ID teams.

ClinGenuity Redaction Management Service, *Synchrogenix*, <https://www.synchrogenix.com/wp-content/uploads/2018/07/Redaction-Anonymization.pdf>

Synchrogenix offers is an AI-enabled technology solution for automatically identifying and redacting sensitive information.¹⁷

- Natural language processing and natural language recognition are used to accurately identify and call out sensitive information in lengthy documents.
- Users can also benefit from access to expert consulting on regulatory policy and guidance, anonymization methodologies, reports, and agency support.

Reference Management

Finally, for reference management, a plethora of solutions are available. Leading the pack are **EndNote** (*Clarivate Analytics*, <https://endnote.com/>) and **Mendeley Cite** (*Elsevier*, <https://www.mendeley.com/reference-management/mendeley-cite>), both of which integrate with MS Word and feature customizable formatting, reference organization/storage, and search tools.

Summary

The last decade has seen immense strides in the development of automation tools for medical writers, and we look forward to the growth of additional solutions in the next decade. This software can save medical writers huge amounts of time while boosting accuracy in our work. Programs like Med-Brighter eliminate the headaches involved in document accuracy and compliance, programs such as StartingPoint ensure template compliance and validation, SmartDocs and other collaboration software streamline teamwork, reference solutions such as

EndNote take care of citations, and data anonymization tools speed up data anonymization.

Tedious, repetitive activities that are subject to error and do not require scientific knowledge or interpretation are finally being automated. These tools promote job satisfaction by freeing up medical writers to do what we do best: write.

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Author contact: eclarke@arogabio.com

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How Social Media Helped Prepare Me for Life in the Time of Corona

Larry Lynam, DSc, RM, SM / Principal, The Lynam Group, LLC, Coral Springs, FL

As I write this article from our Tucson home, like most of you, I'm sheltering in place from the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Not content with merely sheltering, we raised our virus game level—I'm actually in quarantine because of a coronavirus disease 2019 (COVID-19) exposure. Fortunately, no sign of infection ... just doing my part in preventing possible spread—just in case.

Luckily, I'm sitting in a comfortably stocked and prepared home, and our house I commute from in Florida is also stocked and prepared—largely thanks to my social media network. In December 2019, ominous tweets detailing an unusual pneumonia striking citizens in Wuhan, China, began appearing in my Twitter feed. By January, many thought a significant epidemic was building. I didn't know when it would arrive here—and it sounded like it could be serious—but thanks to my Twitter feed, I was not caught off-guard. Insider knowledge was not my reason for creating a Science Twitter “posse”; I thought it might benefit my freelance business. Nevertheless, thanks to this network, I was prewarned, informed, and able to prepare for this nightmare. Once again, incorporating social media into my business strategy created an advantage—only this time it was one I never before imagined I would need.

Shifting From Corporate Science to Accidental Social Media Science Communication

My degrees are in microbiology and immunology, and most of my corporate career was spent in commercial biopharmaceutical vaccine and immunological products programs. Throughout my career, I have been involved in nearly every aspect of bringing a biological product to market. In 2009, I left the corporate world and started my freelance business specializing in areas I am passionate about: training and development. I began by concentrating in an area that has always fascinated me: infectious diseases.

This timing was perfect for setting up my freelance business. The H1N1 influenza (commonly called “swine flu”) pandemic was just beginning, and concern was rising. When designing and teaching microbiology classes, I usually incorporated stories of the Great Influenza Epidemic of 1918 into my courses. Quickly, calls and messages from former students and colleagues began pouring in as the epidemic grew. I prepared a small “refresher and explainer” around influenza—what we knew, as well as what was new.

I emailed it to friends and colleagues, and they in turn emailed it to their friends and families. Suddenly, not unlike a virus working its way across the country, my email somehow landed on a television producer's desk, landing me an unusual project. I was contracted as a script consultant for his television series episode about surviving an influenza epidemic. My role was keeping their science accurate, and that evolved into an on-camera role with me serving as a “talking-head scientist.” This was a unique experience and provided me with a great icebreaker I still use: “I'm not just a microbiologist in real life; I also play one on TV.”

Later that year, I met a colleague from my corporate days for a networking coffee, and as I described this adventure, she rolled her eyes in disbelief that I was so behind the social media curve and uttered a phrase that changed my world: “We have got to get you a Twitter handle, *now*.” I left that Boca Raton Starbucks as “@scopedbylarry,” and my journey with incorporating science into social media began.

Turning Twitter Into a Business Tool: It Didn't Happen Overnight

I wasn't sure where this was headed, but I waded into Twitter by following and developing a few online relationships with fellow scientists, journalists, and even an assortment of individuals, simply because they were interesting and quirky and provided my Twitter feed with additional color and character.

I often describe my Twitter feed as a virtual cocktail party, but it probably has more of an old-school salon evening vibe. Followers pop in, and I serve as host; people come to chat, watch, listen, learn, or contribute on a variety of issues and topics. My role, albeit virtual, mirrors a real-life party-host role. I try to maintain an atmosphere in which my guests enjoy themselves, learn something on a topic of interest they

dropped in for, and, as a result, leave something beneficial behind for others. Occasionally, like in a real-life party, a guest may cross a line. Usually other guests will “help steer the ship back,” but, if necessary, I will escort an offending guest out using the mute or block feature, depending on the severity of the offense. I strive to maintain an atmosphere that encourages guests to stay, return frequently, and contribute more.

Host Your Social Media Just Like You Would Host a Party

- Host Behavior is essential—this is your party and a good party host attends to their guests needs.
- Your menu sets your style—if you promote and serve what your guests like and expect, they are more likely to show up.
- Keep serving your guests more—they will keep your timeline loaded and refreshed with good content, and they will keep coming back more frequently.
- Continually mingle with your followers—make your guests feel welcome and introduce them around; people stay and return where they feel welcome and appreciated.
- Watch and monitor—make certain the conversations are productive and meaningful, and if they need to be steered back on track, step in, but tread lightly; resist being overly controlling.
- Control the atmosphere—create an atmosphere in which people realize you provide content they benefit from, making it more likely they in turn will contribute content that benefits you.

When hosting, give it your best effort, but also keep in mind:

Even when you do your best to set the stage for an enjoyable and rewarding time for all, not everyone is going to enjoy the style of party you are offering. When this happens, just let them go—in the end, they will be happier and so will you and your other guests.

Figure 1. Suggestions for successful Twitter engagement.

Focusing Twitter for Success

For me, the rewards have outweighed any problems. To increase the rewards, I organize key people I follow into topical lists. This helps me isolate conversations and themes of interest and usefulness. A Twitter stream rushes by so rapidly that the timeline is often compared to “drinking from a fire hose.” Grouping related people into specific lists increases the likelihood that I will see content that is of value to me.

Early on, while exchanging useful information with my Twitter follows, valuable relationships developed. These have been beneficial in enhancing client projects as well as expanding my portfolio. The more contacts I make, the more gaps I fill, and the more my knowledge in multiple areas grows.

In 2011, at the Interscience Conference on Antimicrobial Agents and Chemotherapy, I discovered “live conference tweeting,” and this opened another valuable social media chapter.

There were only a few fellow science tweeters in attendance, but this established another layer of relationship building that made social media an even more valuable tool in my freelance business.

Whenever I explore a new therapeutic or clinical area, I reach out to my established network of virtual colleagues around the globe to begin filling knowledge gaps. My networking game, which was already fairly strong, developed new muscle, thanks to my social media connections.

Along Came Ebola

The Ebola outbreak in West Africa definitively established the value of this Twitter network for my business. As Ebola spread that year, panic and misinformation around it spread even faster. By creating a list of Twitter follows who were providing accurate and timely news and facts, I was able to focus on cur-

My Formula That Makes Twitter Useful for Me

Create lists to follow

Lists bring order to the chaos that flows into your timeline. They can make your time here more productive.

Using lists improves your social media experience by increasing the likelihood you will see the tweets with information you need and want: the ones satisfying your curiosity, adding to your knowledge base, or even possibly introducing you to new opportunities.

Don't just be a spectator

Make it a habit to regularly share new content and to retweet content that you know will be of interest or benefit to the people who follow you.

Actively participating in your own social media experience will bring you additional rewards and satisfaction, as it satisfies your curiosity while fueling your creativity and strengthening your communication skills.

Be a generous tweeter

It will be both liberating and rewarding if you strive to make social media an area where you contribute to others' knowledge even as you increase your own.

Strive to practice humility when you share and express gratitude when others share useful knowledge with you. It will make your experience more rewarding in a multitude of ways.

Figure 2. Suggestions for making Twitter more useful.

rent and pertinent information and distinguish it from misinformation. This became my first “incident-targeted” Twitter list, and I continue to create new ones as situations arise.

I compiled my Ebola list with another Twitter pal, infectious disease physician Dr Judy Stone (also known as @drjudystone on Twitter). We started with mutual contacts who covered Ebola; we evaluated, selected, and added contacts these key follows recommended. Soon we were providing updated guid-

ance on personal protective equipment used for health care providers and in public health initiatives, as well as enhancing our own online blogs and posts with useful Ebola information and perspectives. As a result, we were being sought out as reliable sources for dependable information.

This led to yet another surreal moment; while leaving our 2014 AMWA Annual Conference in Memphis, I shared a flight to Atlanta with our keynote speaker, health care policy expert



Med/Sci Writer peeps
Larry Lynam @scopedbylarry
90 Members 0 Subscribers

Corona outbreak list
Larry Lynam @scopedbylarry
24 Members 0 Subscribers

I designate my lists as “private.” This does not permit others to subscribe to them, but it saves me from the drama that can result when people don’t wish to be included on public lists or when they receive notifications that they have been added or removed from a list.

Making Social Media Time More Productive With Lists

- Organize key follows into a series of lists based on topics or interests that they tweet that interest you.
 - Make your lists “private” so that people do not become concerned as you add or delete members that increase the value and efficiency of your topic-specific lists.
 - Add, delete, or transfer list members as you realize the usefulness of contributions they provide you on a subject.
- Create additional lists as you see the need arise to help increase needed information flow on a specific topic.
- Spend less time scrolling your Twitter feed and more time scrolling tweets in your more focused lists— this practice increases the likelihood of seeing information that is of interest or use to you.

Med/Sci
Larry Lynam @scopedbylarry

Med/Sci Writer peeps
Larry Lynam @scopedbylarry

Microbiology
Larry Lynam @scopedbylarry

News with a twist
Larry Lynam @scopedbylarry

Figure 3. Suggestions for creating and using Twitter lists more effectively.

Rosemary Gibson. As Rosemary and I were waiting for connecting flights in the Delta Airlines Sky Club, chatting casually about health care policy changes, my cell phone suddenly seemed to come alive on the glass-top table between us. It began intensely vibrating, ringing, and flashing message after message on the screen. For a moment, I just stared at it—the first diagnosed case of Ebola in the United States had just been announced. Suddenly every information source was being tapped into—including me. A Twitter follower who was a reporter from the Center for Infectious Disease Research and Policy was texting me for an introduction to my sources, and a BBC World News Service reporter who had discovered my tweets was calling to ask if I was available for an interview on her show—which was live and on the air at that very moment. So much for my opportunity to continue the fascinating discussion with our brilliant keynote speaker!

The Sentinel Chicken Approach

Since then, my Science Twitter lists have helped me prepare and stay on top of several infectious disease outbreaks. I call my process “the sentinel chicken approach.” Public health scientists place small flocks of chickens in areas prone to harboring mosquitoes capable of carrying viruses that cause human diseases, including dengue, viral encephalitis, and Zika. Periodically, blood samples are drawn from these sentinel chickens and screened for evidence of these viruses. This epidemiological “listening” alerts scientists when a human disease is emerging in a community and permits mitigation strategies against mosquito populations to be quickly launched and prevent disease.

Likewise, my Science Twitter follows from around the world signal me toward approaching trends. This enables me to research, prepare, and be better informed—if or when a need or an opportunity should arise. This method served me well when dengue, chikungunya, and, more recently, Zika virus invaded our lives in Florida. I was prepared and able to quickly provide my clients and colleagues with information they needed. In each instance, my Twitter network had me up to speed much faster than in the pre-social media world.

As my long-time microbiology colleague and Twitter pal Hilary Lappin-Scott (also known as @lappinScott), retired Vice-Chancellor of Swansea University, once pointed out, “If only Twitter had been around when we began our academic careers, we might have leveled so many silos.” That sums up what social media and Twitter in particular have done for me and my business; they have removed obstacles and provided access to people and materials that have allowed me to prepare and stay ahead of the information curve, benefiting my clients, my business, and now my own personal safety.

Twitter: My Early Warning System in the Age of Corona

This is why I credit my Science Twitter for my advanced preparation for the SARS-CoV-2 pandemic. Those December tweets signaling a pneumonia outbreak in the Wuhan markets immediately captured my attention. In early January 2020, even as many of our leaders in the United States began to downplay the threat, my Twitter feed continued showing that the virus was no longer confined to China. These events triggered my Ebola memories, and I immediately created my Twitter “outbreak list.”

I added key public health entities and professionals leading the effort, including scientists providing newly acquired information and explanations about the virus and pathophysiology, epidemiologists providing analysis of newly emerging data, and journalists reliably covering the various aspects and angles of the outbreak and its effects on our society.

From the beginning of this outbreak, political maneuvering and economic concerns were trampling scientific knowledge as well as public health concerns and actions. My global Twitter science community helped me more accurately frame discussions with emerging facts and data and filter out the political spin and deflection. My Twitter early warning system had me prepared, had me ready to work, and helped serve as a reliable information source for my colleagues, clients, friends, and family.

Because this SARS-CoV-2 COVID-19 outbreak involves a previously unknown virus, it is producing many unique challenges. As additional data emerge and are analyzed, many practices must be revisited and shifted as needed, when supported by newly validated data. My social media network connections are proving invaluable for keeping information current. This permits me to more quickly prepare updates when speed and accuracy are most needed. It also enables me to keep anecdotal observations and misused data properly framed, especially when there are attempts to influence practices and policy changes with it. These added benefits essentially guarantee continued inclusion of social media in my networking game.

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Author contact: *l.lynam@thelynamgroup.com*

Predatory Publishing – What Medical Communicators Need to Know

Andrea Bucceri,¹ Peter Hornung,² and Thomas M. Schindler³ / ¹Dove Medical Press Limited, London, United Kingdom; ²Norddeutscher Rundfunk, Ressort Investigation, Hamburg, Germany; ³Boehringer Ingelheim Pharma, Medical Writing Europe, Germany

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www.emwa.org*

Abstract

The rise of “predatory journals”, also known as pseudo-scientific journals, poses a risk to the integrity of science and therefore medical communicators need to know about their practices. Upon receipt of a publication fee, predatory journals publish manuscripts regardless of their scientific merit, very often without any peer review, and without providing editorial services. To maximise profit, such journals disregard all aspects of scientific integrity and foster the dissemination of bad and bogus science, lobby materials, and conspiracy theories. Publishing in predatory journals can have dire consequences for authors, their careers, and the reputation of their institutions. Medical communicators can help authors avoid falling prey to predatory publishers.

The Problem of Predatory Journals

You may already have heard about “predatory journals”, also known as pseudo-scientific journals whose sole purpose it is to siphon off money from authors. These journals use the open access (OA) model to publish just about anything as long as the authors pay the required fee. The deal is: you pay the money, we publish without looking at the article too closely (if at all). The author gets a publication to add to the curriculum vitae and the publisher gets the money. Unlike genuine scientific journals, predatory journals shortcut the peer-review process entirely or substitute it for a superficial pseudo-review.

Medical communicators may be aware of predatory journals but may have thought of them as a peripheral phenomenon. This perception needs to change.

The number of predatory journals has risen dramatically in recent years and so has the number of articles published in them. Data from the Northern German Broadcasting

Network suggest that, globally, some 400,000 scientists from all fields have published in such journals.¹ One company, OMICS, accused of platforming predatory and low-quality journals, prides itself on publishing over 700 journals generating tens of thousands of articles per year.^{2,3} The problem has become so big that the US Federal Trade Commission has recently obtained a ruling of \$50 million against OMICS for deceptive business practices.^{4,5}

Predatory publishers harm science and society as a whole. By publishing bad science and by making it available, they undermine trust in science and scientific progress. Their activities allow bogus work to be quoted and entered into the literature. Bad science as a starting point may lead other scientific investigations astray. Predatory journals take away money from taxpayers or grant-giving charities that was made available as part of research grants. Even worse, when uninformed patients in desperate situations get hold of unfounded, bogus research, they may turn to ineffective and harmful treatments.

The practices of predatory publishers undermine the credibility of science. This will directly affect medical communicators because they are part of the scientific endeavour. Medical communicators make science accessible. If sources are fouled with bogus science, the texts, documents, and summaries based on them will also be bogus and the work of medical communicators will be devalued.

Open Access Publishing and How the Problem Came About

OA publishing makes articles freely accessible online upon publication. Contrary to subscription-based publishers, whose published articles are only accessible after payment of a fee or via a subscription, OA publishers cover their publishing costs by charging authors a publication fee upon acceptance of a manuscript.⁶ Since it began in the early 2000s, OA

publishing has grown to become a well-established publication model, and currently, many funding agencies and international organisations require that the data derived from the research they fund be published in an OA journal.⁷⁻¹⁰

The success of OA publishing in science and medicine has opened the door for a new type of fraud that exploits the need of authors to publish their results for career advancement and to obtain funding. These fraudulent publishers are now widely known as “predatory publishers” because of their aggressive and damaging tactics.¹¹ To maximise profit, they want to attract and publish as many manuscripts as possible. Articles are published without the usual standards and processes that genuine publishers adhere to.¹⁰⁻¹² Predatory publishing is therefore best defined as the exploitation of the OA-publishing system for the sole purpose of making a profit, while neglecting key aspects of scientific rigour and publication ethics.

The number of predatory journals is rising.¹³ Their fraudulent activities are fuelled by the need of researchers to publish results to advance their careers and increase their chances to obtain funding.^{11,14} In some countries, professional advancement in science and medicine is directly linked to the publication record through a point system.¹⁵ Many universities and research institutions require that PhD students publish their work in a journal—regardless of its quality—before awarding a degree.

To mislead authors, some predatory journals carry names that are similar or even identical to well-known established journals. This is a form of hijacking because these journals aim to divert submissions intended for genuine scientific journals. By misleading authors, they seek to get hold of scientifically sound content that they can then use to obscure the nature of their business.^{16,17}

The increasing number of predatory journals has led to an increase in the number of articles published in these journals and, in turn, possibly even the citation of their articles in policy documents and medical guidelines. Because most predatory journals do not perform a proper peer review, they serve as a venue for badly conducted science. It is therefore not surprising that conspiracy theorists, such as anti-vaxxers and climate change deniers, use these outlets to publish.^{18,19} Some predatory publishers do perform a pseudo peer-review process, after which they accept manuscripts regardless of the recommendations of the peer reviewers.^{20,21}

Although the traditional peer-review system has its flaws, it remains the best way to evaluate scientific content. It has served its purpose quite well since its systematic implementation in the 1970s. One possible way forward is implementing “open peer review”. This ensures full transparency to the reader as both the names and affiliations of the reviewers and their comments are available online.²²

The Dangers of Using Predatory Journals for Authors and Their Institutions

The opportunity to publish anything in predatory journals is tempting for some researchers who want to publish irrelevant or inconclusive results for the sake of career advancement.¹³ However, this carries some long-term risks and authors should be aware of them (Table 1).

Publications in predatory journals harm science and medicine. Without the scrutiny of a proper peer review, it is not possible to distinguish between good, mediocre, and bad science. Good science published in a predatory journal becomes contaminated and devalued. It loses its credibility because of the context in which it is placed. Question arise: Was the article published in a predatory journal because it did not meet the standards of a genuine journal? Was the authors’ priority not scientific integrity but speed of publication?

Table 1. Potential Consequences of Publishing in Predatory Journals for Individual Researchers

Researchers’ work appears in questionable environment. Their work is made available next to mediocre, bad, or even fake science articles.
The researcher’s name and affiliations may be used for advertising by the predatory publisher without their knowledge or consent.
The researcher’s name is permanently linked with the predatory publisher and its website, which may have negative consequences for their academic career.
There is no assurance of permanent archiving, traceability, or accessibility of the article.
Papers are not included in reputable databases because some databases actively remove references to articles published in predatory journals.
Researchers cannot prevent their articles from being re-used by predatory publishers to enhance their database or for advertising.
Researchers may have to pay additional fees, particularly if they request withdrawal of the manuscript.
Public and third-party funds are wasted, resulting in potential liability.
Enforcing rights may be difficult because predatory publishers hide their location to avoid legal action. Even when their location is known, most predatory publishers fall under other jurisdictions than the authors’, complicating legal action.

Researchers who have submitted their work accidentally to a predatory journal may want to withdraw it upon realisation. This, however, is often not possible or only permitted after paying an additional fee. Scholars who publish their research in a predatory journal waste the time, effort, and money spent conducting it. Public money or third-party funds are wasted and are no longer available for genuine research. If scientists are aware of the predatory nature of a journal and nevertheless publish their work there, they may even be liable to prosecution. They are liable for using funds on dubious journals and by incurring expenses for travelling to scientifically pointless conferences offered by some predatory publishers. Research appearing in journals without scientific value ultimately becomes worthless to the authors and to the scientific community.

Authors cannot rely in any way on predatory publishers. Predatory journals are dishonest in regard to peer review, they hide the true costs, and they do not abide by rules and agreements. Authors who have submitted a manuscript to a predatory journal but want to withdraw it later will often not succeed because the journal may want to upgrade its reputation by keeping it. Authors who are denied withdrawing their work have essentially lost the opportunity to publish in a genuine journal because this would constitute a second publication of the same content.

It is important for authors that their research is permanently available to the scientific community. With predatory publishers, however, permanent archiving and accessibility are not ensured. Should a dubious publisher go out of business, the articles published by them may no longer be available. In addition, there have been cases where articles were simply republished under different author names and with slightly different titles without consent of the initial authors. Predatory publishers do this to enlarge their article database.

Those who publish their good research in predatory journals are unintentionally upgrading the bad and false science also published there. Predatory publishers use the names of well-known scientists for their marketing purposes. By doing this, they appear genuine, which allows them to obscure their business model. When using predatory journals, serious scientists bring themselves down to the level of researchers of dubious reputation, wannabe scientists, conspiracy theorists, and lobbyists. For example, climate change sceptics are publishing papers rejected by serious journals in predatory journals.¹⁹ Unethical companies publish pseudo-studies in predatory journals to use the apparently genuine scientific reference to market their ineffective and potentially dangerous treatments. Anti-vaxxers spread their theses (“Vaccinations cause autism!”) in predatory journals.

Researchers risk their reputations and careers, as well as the reputation of their institutes when they publish in

predatory journals, even when they do not realise what they were doing. Researchers who did not know about the predatory nature of a journal expose their ignorance and naivety. If they consciously use predatory journals, they might be accused of deliberate deception. Researchers should not count on the possibility that their publications in predatory journals will disappear from the internet at some point. Throughout their career, they will have the stigma of having used such an outlet; even years later, references to articles published in predatory journals can be found by commonly used search engines. Should the growth of predatory journals continue unabated, science may become viewed with suspicion. If the public, politicians, and the media can no longer tell good from bad science, its impact on society will be lost. This loss of trust in science may negatively influence funding decisions and the availability of an adequate research infrastructure.

How to Avoid Predatory Journals

Although there is no golden rule for identifying a predatory journal, there are certain common characteristics.¹⁰⁻¹² One can avoid falling prey to predatory publishers by checking some free online checklists such as the Think. Check. Submit checklist²³ and the Centre for Journalology at The Ottawa Hospital checklist.²⁴

Critical items are summarised in Table 2. Taken individually, the items listed do not necessarily prove that a journal is predatory. However, if several items do not apply, the likelihood of dealing with a predatory journal is high.

Because fraudulent publishers tend not to invest in website design or English language proofreading, their websites and emails often contain spelling mistakes, poor grammar, and poor design elements, such as low-resolution logos or images or overlapping text.

Names of editorial board members of predatory journals are sometimes entirely made up. They may also use names of genuine healthcare professionals without their knowledge or consent. Therefore, if the identity of the editorial board members cannot be verified, this may indicate the predatory nature of a journal.

Few genuine science publishers do not yet use a recognised submission system such as ScholarOne. Therefore, if a journal asks authors to send their manuscript simply to an email address, the alarm bells should start ringing.

Faking impact factors and indexing features is very common among predatory journals. Because of this, it is advisable to check their claims in the Journal Citation Report²⁶ and PubMed Central.

Lack of commitment to digitally archiving the published articles in a safe repository is also common among predatory publishers. A reputable journal will likely participate in a

Table 2. Checklist for Identifying Predatory Journals

Item	Details
Overall	Look at the totality of the evidence; failure in complying with one item does not necessarily indicate a predatory journal.
Membership in a reputable publishing association	Absence of membership in reputable open access association such as the Open Access Scholarly Publishers Association (https://oaspa.org/), World Association of Medical Editors (http://www.wame.org), Committee on Publication Ethics (https://publicationethics.org/), and Directory of Open Access Journals (https://doaj.org/) is a sign of likely being a predatory journal.
Website design and use of English language	Spelling and grammar mistakes or poor web design are indicative of predatory journals.
Transparency about fees	Not clearly showing fees on the journal website is a sign of a likely predatory journal.
Editorial Board Members	Not being able to verify the identity the Editorial Board members with the information provided by the journal is a sign of a likely predatory journal.
Editorial office contact details	Not being able to verify a publisher's location, phone numbers, or email address is a sign of a predatory journal.
Scientific quality of articles	If the articles published by the journal are not well written, if you have not heard about the other authors that publish in the journal, and if you have never heard of the institutions mentioned, this could indicate a predatory journal.
Submission process	Providing only an email address as a method of submitting manuscripts is a sign of a likely predatory journal, as opposed to using a recognised submission system such as ScholarOne.
Digital Archiving	Not participating in a recognised digital archiving system, such as CLOCKSS (https://clockss.org/), is a sign of likely being a predatory journal.
Indexing	Not being included in a recognised index, such as PubMed Central is a sign of likely being a predatory journal (http://www.ncbi.nlm.nih.gov/nlmcatalog?term=journalspmc).
Journal Impact Factor	Not being able to verify that a claimed Impact Factor can be found in the Journal Citation Report website (https://clarivate.com/products/journal-citation-reports/) ²⁶ is a sign of likely being a predatory journal.
Adherence to ethical standards	Absence of policies dealing with the disclosure of conflicts of interest and absence of statements on copyright, intellectual property, or publishing licences are indicative of a predatory journal.

recognised digital archiving system, such as CLOCKSS (<https://clockss.org/>).

Finally, being a member of an international OA organisation such as the Open Access Scholarly Publishers Association (<https://oaspa.org/>) or the Committee on Publication Ethics (<https://publicationethics.org/>) is a good sign that the journal is not predatory because the associations carefully scrutinise journals before admitting them as members.²⁵

Conclusion

Medical communicators need to know about all aspects of predatory publishing because it not only undermines the credibility of science but may also have serious consequences for

authors, their careers, and their institutions. Medical communicators are often asked to support selecting an appropriate journal; therefore they are in a key position to help authors avoid falling prey to predatory publishers.

Disclaimers: The opinions expressed in this article are the author's own and not necessarily shared by their employers or EMWA.

Conflicts of interest: The authors declare no conflicts of interest.

Author contact: Thomas.schindler@boehringer-ingenheim.com

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Author Information

Andrea Bucci, PhD, has spent over 10 years in scientific research in Italy, The Netherlands, and Switzerland, where he earned a PhD in Molecular Genetics at the ETH Zurich. After a postdoc, he moved to Open Access Scientific Publishing. For a few years, he worked in medical communications for pharmaceutical companies before becoming Publication Development Manager at Dove Medical Press (now part of Taylor & Francis Group, an Informa Business).

Peter Hornung, MA, studied political science and history in Vienna and Regensburg, as well as journalism in Mainz. He worked as an editor, presenter and reporter at the Hessischer Rundfunk (radio), before becoming a correspondent and bureau chief of ARD German Broadcasting in Prague, Czech Republic. He is currently an editor and investigative reporter at Norddeutscher Rundfunk and a research lecturer at the Academy for Journalism in Hamburg.

Thomas M. Schindler, PhD, studied biology and linguistics in Germany and the UK, then obtained a PhD in molecular physiology and continued with postdoctoral training in the UK. Thereafter he went into publishing and became a popular science editor. He turned to medical writing and has now gained some 23 years of experience in both medical affairs and regulatory medical writing. He is currently the head of the Innovation Medical Writing Group at Boehringer Ingelheim Pharma.

FROM THE PRESIDENT

Responding to the Challenge**Ann Winter-Vann, PhD** / 2019–2020 AMWA President

In a normal year, the President's Column in the Summer issue would be focused on the priorities, goals, and new initiatives for the American Medical Writers Association (AMWA). This year, as you may have guessed, the coronavirus disease 2019 (COVID-19) pandemic has prompted us to rethink our priorities in light of changes to our members' needs, their ability to participate, and potential financial constraints. Our staff and our many volunteers are still hard at work, but we are in the process of pivoting as global circumstances change. Although the pandemic and its economic repercussions will certainly affect AMWA, I'm grateful that we are in a sound financial position to weather the storm.

Our April Board of Directors meeting provided an excellent opportunity to hold strategic discussions about the challenges and risks for AMWA in these uncertain times, as well as opportunities to shift our resources to better support our members' changing needs. As I write this column, stay-at-home orders are in place across the country. Although I am hopeful that those restrictions will be eased as summer approaches, we recognize that some members will not be comfortable participating in face-to-face educational activities; as such, we anticipate an increase in the demand for online educational opportunities. We also anticipate that changes in the pharmaceutical and health care industries will increase both the number of people exploring a career in medical communication and the number of current medical writers who choose to establish themselves as freelancers.

Supporting Our Members

AMWA cares deeply about its members. We understand that many of you may be struggling financially right now, even as your need for education and networking may be greater than ever. I'm pleased to share that the Board of Directors approved a hardship policy to allow for a dues reduction for our loyal professional members who find themselves in significant need. If it is time to renew your membership and you have extenuating circumstances that would make it difficult to afford your professional dues, please contact us at membership@amwa.org for more information on our hardship policy.

To better meet your needs and understand your unique challenges, AMWA has surveyed our members about their work situation, educational needs, and ability and willingness

to travel. My thanks to all who took the time to participate. Your input is essential in helping us understand the ongoing changes in your professional circumstances and educational needs.

Maintaining a Connection

Historically, our chapters have provided a unique opportunity for members to connect for networking events and local conferences or other educational sessions. Several chapter conferences were postponed or cancelled because of the COVID-19 pandemic and stay-at-home orders, and numerous smaller chapter events have been put on hold. However, our chapter leaders have really risen to this challenge. I have been pleased to see many chapters hosting webinars, online book clubs, or virtual meet-ups; the AMWA Southwest Chapter was even able to present its chapter conference in an online format. Please look for upcoming events on chapter websites, in e-newsletters, or mentioned on Engage; they offer a wonderful platform to stay in touch with or meet new local colleagues.

The Engage platform also allows you to create or maintain that connection with other medical communicators. Our membership community is extraordinarily supportive, and members are always willing to share their expertise. Don't hesitate to reach out on Engage if you have a question or simply want to connect with others in your field.

Educational Opportunities

Online education is a high priority for AMWA in the midst of the COVID-19 pandemic. As we work to increase our online content, I am pleased to highlight the many educational opportunities that AMWA already offers in a virtual format. The entire Essential Skills program is available in the form of digital self-study workbooks, which means that you can complete the Essential Skills Certificate remotely, working at your own pace. If you are ready for more advanced or specialized training, AMWA has interactive online programs available individually or as topic-specific packages. If you are interested in exploring a new area of focus within medical communication, this is an excellent way to start. I hope you've already taken advantage of AMWA's live webinars, which are available to members for \$20 in 2020. AMWA also offers a library of recorded webinars that are available to watch any time; a different recorded webinar is available to members for free

each month. If you are looking for a quick tutorial, be sure to check out AMWA's Pocket Trainings, available free for members. Finally, you may want to consider whether this would be a good time to register and prepare for the Medical Writing Certification examination to bolster your credentials as an established medical writer.

The AMWA Education Department has been working hard over the last few years to create new workshops. Seven new workshops were presented at the 2019 conference in San Diego, where they received rave reviews. Several new workshops are currently being developed, including workshops on mentoring, visual communication, and the foundations and art of medical writing. Please stay tuned: AMWA is exploring new ways to deliver workshops online as interactive, instructor-led classes.

As I write this column, we know that the 2020 Medical Writing & Communication Conference will be quite different from our typical conference. Although I do not yet know what format the conference will take, I do know that AMWA staff and

volunteers are hard at work to ensure that the 2020 conference is a safe and meaningful experience. I also know that we have an excellent lineup of sessions this year. Please check our website for the program and the latest updates on the conference. Registration should be opening mid-summer. Even if we cannot meet face to face, I hope that you will attend the conference and help us celebrate AMWA's 80th anniversary.

Finally, a word of thanks to all of our members who have been working hard over the last many months. As the COVID-19 pandemic has developed, I have been impressed by the quality of the medical communication that I have read and the pace at which new clinical trials are being rolled out. I know that our members are working behind the scenes to write public-facing health and medical communications or draft protocols, protocol amendments, and informed-consent documents that keep medical research moving forward under challenging circumstances. I am proud of the work that our members have done—and continue to do—to support the health and well-being of all.

American Medical Writers Association Annual Financial Report, 2018–2019

Julie L. Phelan, MD, MBA / 2018–2019 AMWA Treasurer

It has been a pleasure serving as Treasurer for the American Medical Writers Association (AMWA) over the past year, and I am pleased to provide this financial report for the 2018 to 2019 fiscal year, which ended June 30, 2019.

AMWA began and ended the fiscal year in a strong financial position and continued to invest in new initiatives and to expand valuable and timely education, resources, and member benefits.

Financial Performance

AMWA's net income for the 2018 to 2019 fiscal year was \$270,152 against a budgeted net income of \$84,900.

Revenues

AMWA's program revenue for the 2018 to 2019 fiscal year was \$1,883,493. Membership, annual conference, and education and certificate program income continue to be AMWA's major sources of revenue, providing 89% of income for the year. Net investment income accounted for \$74,377, representing 3% of total revenue (Figure 1).

Expenses

AMWA provides valuable programs, products, and services to members and the medical writing community. Total program

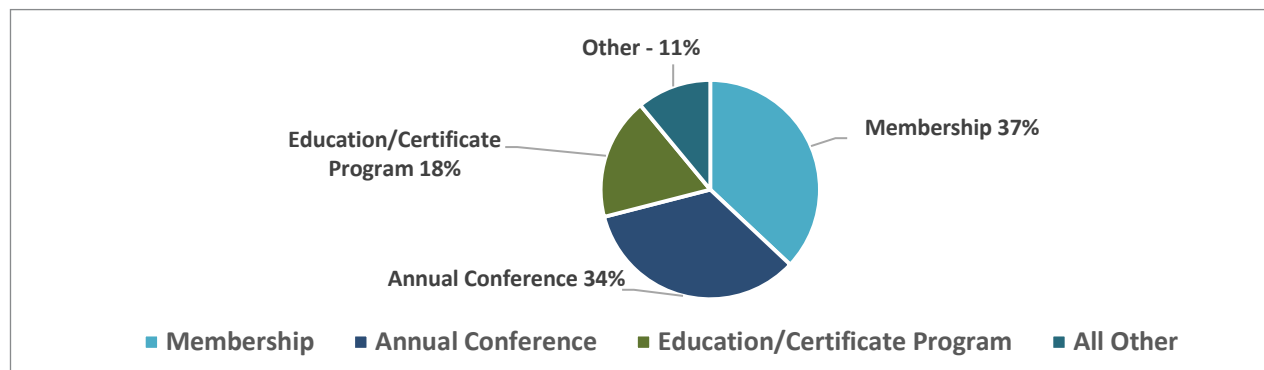


Figure 1. Sources of program revenue for the fiscal year ending June 30, 2019.

expenses for the 2018 to 2019 fiscal year were \$1,687,718, with 28% of the expenses going to fund membership services and to produce the annual conference. Further, 9% of expenses fund the Essential Skills Certificate program, and 5% of expenses support the Online Education program (Figure 2).

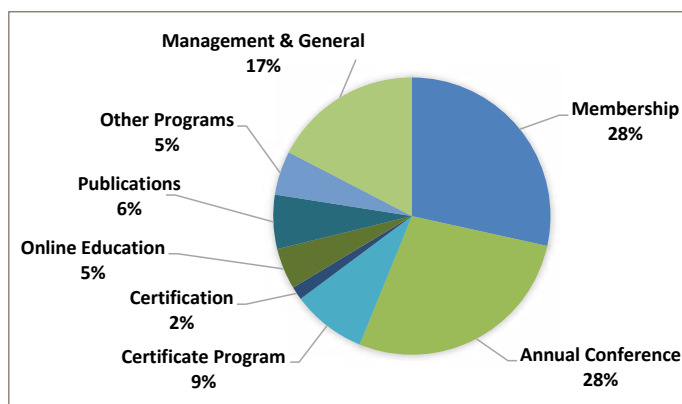


Figure 2. Sources of program expenses for the fiscal year ending June 30, 2019.

Reserves

Reserves are the accumulation of funds over time that enable the 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 \$1,966,700 for the fiscal year from July 1, 2019, to June 30, 2020, the target for AMWA's reserves ranges from \$1 million to \$2 million. AMWA's unrestricted short- and long-term investment reserve level of \$1,708,600 on June 30, 2019, was within the targeted range.

AMWA's restricted Endowment and McGovern funds totaled \$193,498 and \$158,885, respectively, as of June 30, 2019.

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 \$3,052,662 as of June 30, 2019, and the organization's liabilities totaled \$902,219.

Conclusion

Abercrombie and Associates, AMWA's independent auditors, expressed an unqualified opinion regarding their audit of the financial statements for the fiscal year ending June 30, 2019. The audit report is available to AMWA members on request. 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 contin-

ues to be in a strong financial position as it continues important educational and resource initiatives into the next fiscal year.

Acknowledgment

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

Author contact: Julie@biomedisysinc.com

Dear approved MWC applicants and certified medical writers,

Please note the following important changes regarding eligibility and recertification periods.

The eligibility period once an MWC applicant's application has been approved was 1 year. However, we have now changed eligibility to 2 years. Thus, those 2019 and 2020 successful applicants have been notified that they now have 2 years to take the MWC exam rather than 1 year. This is the new policy moving forward. The exam is currently offered at testing centers all around the world in June and December, which provides 4 testing opportunities.

MWC certification lasts 5 years, at which time recertification is required, either through continuing education communicated through a recertification application process at the end of the person's 5th year or retesting.

The recertification application deadline has been updated. MWCs must submit their recertification application by the due date of September 1st of their 5th year. If an application submitted by September 1st is found not to qualify for recertification, the applicant will be notified, and they will have through December 31st to gain additional credits and resubmit their recertification application. Those who do not have enough continuing education credits noted in their application by December 31st would have to retest to recertify. If a certificant knows they either wish to or will have to retest to continue their certification, they should schedule to retest in June during their 5th year to avoid having a break in their certification status.

Due to COVID-19 and associated cancellation of education opportunities, MWC recertification candidates for the year 2015 will now have one year added to their recertification window. Thus, instead of submitting their recertification application in 2020, those individuals in their 5th year of certification will now submit their recertification applications in 2021; or, they could retest.

We will update this language in our process documents.

Sincerely,

On behalf of the MWC Commission
David B. Clemow, PhD, MWC

AMWA's Second Medical Writing Executives Forum: Redefining Talent Acquisition, Development, and Engagement—Ideas to Action

Cynthia L. Kryder, MS, MWC / 2018–2019 AMWA President

Abstract

The 2019 American Medical Writers Association (AMWA) Medical Writing Executives Forum gave executives of medical writing departments at some of the world's top biopharma companies the opportunity to discuss shared concerns with their peers and propose solutions. In this collaborative environment, leaders identified their top challenges in the regulatory writing setting and provided insight into how AMWA can provide resources to address these challenges.

Introduction

The American Medical Writers Association (AMWA) hosted the second annual Medical Writing Executives Forum on November 6, 2019, in San Diego, California. This forum brought together medical writing executives from some of the world's top health-science, pharmaceutical, and biotechnology companies, as well as several companies that provide regulatory medical writing and consulting services, to generate new and innovative solutions to common challenges they all experience. The theme of the 2019 forum was “Redefining Talent Acquisition, Development, and Engagement—Ideas to Action.”

This annual, invitation-only event supports AMWA's strategic priority to build ongoing relationships with executives and medical communicators in the biopharma industry and to develop resources to support them. Joan Affleck, MBA, ELS, Executive Director and Head of Medical Writing at Merck & Co, chaired the forum. Cynthia L. Kryder, MS, MWC, 2018-2019 AMWA President; Ann Winter-Vann, PhD, 2019-2020 AMWA President; Gail Flores, PhD, 2019-2020 AMWA President-Elect; and Kathy Spiegel, PhD, MWC, 2018-2019 Immediate Past President, also participated.

Common Concerns Among Medical Writing Executives

The 2019 forum was a working rather than didactic event. Attendees were assigned to small groups where they engaged in ideation exercises and brainstormed innovative solutions to their mutual concerns. Jennifer Whitcomb of The Trillium Group facilitated the activities.

Prior to the event, invitees were asked to identify high-priority problems that were affecting their medical writing teams

and for which they sought solutions. Their responses were analyzed and grouped into 4 key areas, which served as the main topics of the small-group discussions (Figure).



Figure. Forum discussion topics.

Effective Practices for Attracting and Retaining Talented Medical Writers

Managers identified several approaches that worked well with regard to attracting and retaining talent. Giving medical writers flexibility, autonomy, and adequate work-life balance was vital. Moreover, providing diverse writing opportunities, such as enabling medical writers to work on varied document types and in different therapeutic areas, can keep them interested and engaged. Offering leadership opportunities as well as lateral moves within the corporate structure also aids in retention.

Three challenges were top of mind with regard to talent acquisition and retention:

- Training
- Remote work
- Evaluating medical writers' qualifications when hiring

There was overall consensus that training for medical writers should be a top priority. Well-trained medical writers

are highly valued by managers and are valuable assets to the teams with whom they work. Attendees discussed the importance of and the challenges associated with ensuring new medical writers are adequately trained not only during the immediate post-hire period but throughout their employment. Training often can be piecemeal without a unified approach. Given AMWA's expertise in delivering education, this was seen as an area where AMWA could help.

Participants agreed that adequate support is a key factor in preventing employee burnout; however, it can be difficult to provide ongoing support, especially in light of constant mergers and acquisitions taking place in the biopharma industry.

Remote work was seen as a challenge from the perspective of employee engagement. Although many employees consider being able to work remotely a benefit, it can be difficult to keep remote workers engaged in the company and corporate structure when they interact with colleagues and managers virtually from a distance. Concerns about how to engage and train remote medical writers and integrate them into teams emerged as a theme across every discussion group and topic.

With regard to evaluating candidates' qualifications during the hiring process, managers voiced several concerns (Table). Managers pointed out that even when highly qualified candidates join the team, some quickly decide they do not want to be a medical writer and resign unexpectedly, leaving staffing gaps that negatively affect project timelines.

Table. Difficulties Managers Encounter During the Hiring Process

Finding candidates with all the desired skills
Identifying candidates who fit the organization/culture
Identifying the candidate's potential during the interview
Lack of racial, ethnic, and socioeconomic diversity among candidates
Perceived lack of respect for the profession drives away excellent candidates

Training, Career/Leadership Development, and Engagement of Medical Writers

The top challenges in this area were

- Mentoring
 - Peer-to-peer mentoring
 - Sabbaticals/cross-company internships
 - Apprenticeships
- Raising the profile of medical writers
- Remote workers' training and engagement

Photo: EPNAC.com



Cynthia L. Kryder, Ann Winter-Vann, and Joan Affleck at the 2019 Medical Writing Executives Forum in San Diego, CA.

Forum attendees agreed that mentoring was a missing piece in the training of many junior medical writers that should be addressed. Mentoring can be delivered in several ways: peer to peer, through sabbaticals and cross-company internships, or through apprenticeships. Some companies are already mentoring and doing it well, whereas others lack the resources to establish structured mentoring programs. Advanced-career employees need to be trained to mentor, especially those who were not mentored themselves. A proposed solution to the absence of mentoring programs was to bring in outside experts to train junior writers.

The need to raise the profile of medical writers was linked to the value discussion. Managers noted the importance of countering the misperception that medical writers are merely scribes. Involving medical writers earlier in the document-development process and giving them a seat at the table with regard to decision-making will help to dismiss that inaccurate perception and prove their value. This tactic was seen as especially important for remote workers.

New or Emerging Technologies That Affect the Medical Writing Field

With regard to new and emerging technologies, the primary concerns were

- Training, implementation, and adoption
- Breadth of tools
- How AMWA could help

Managers agreed that successful use of any new technology depends on structured training for all users, including freelancers and contract employees, with periodic follow-up after training to ensure proper implementation. Ageism—the inaccurate perception that older medical writers may not be willing or able to adopt new technologies—was discussed as a potential problem to combat. This is especially relevant given the composition of the current workforce, with multiple generations working together.

Attendees acknowledged that the sheer number of technologies available to medical writing teams can be paralyzing, making it difficult to choose which tools are best to meet each organization's needs. Categorizing technologies into 2 types—

connectivity tools and productivity tools—was suggested as one way to simplify the evaluation and decision-making process. This group offered suggestions for how AMWA could assist:

- Establish an ad hoc task force to evaluate new technologies that are affecting the industry and produce a report summarizing these tools and their uses.
- Offer a technology sandbox as a feature at every annual conference, where people could have hands-on experience with new tech tools.
- Develop educational resources to teach medical writers how to build business cases for new technologies.

Quantifying the Value of Medical Writing

The need to quantify the value of medical writing emerged as a theme across topic areas. There was overall consensus that to meet future workplace expectations in an increasingly competitive job market, medical writing teams need hard evidence to demonstrate the value they bring to the table. Attendees noted the challenges in identifying value markers, given the many settings in which medical communicators work and the variety of documents produced. Nevertheless, this presents an opportunity for the profession to begin collecting data and analyzing metrics that will prove our value.

An interesting dichotomy emerged among forum attendees with regard to their personal perceptions about feeling valued and recognized for the work they do. Regulatory writers who were employees of biopharmaceutical companies felt extremely valued and recognized by their employers. In contrast, writers in other departments within those same companies, and those who worked in other settings (such as consulting firms or contract research organizations), did not share that perception.

From Ideas to Action

When all attendees considered the topics that were identified by each subgroup, the medical writing executives identified 3 concerns as the most important to address immediately:

- Training
- Mentoring
- Value

AMWA will focus on those opportunities that support its mission and align with its overall goals and priorities; 23 of the participants in the 2019 Medical Writing Executives Forum volunteered to assist AMWA in this effort.

With regard to training

- The AMWA Regulatory Writing Advisory Committee, chaired by Dr Kathy Spiegel, will provide guidance on the educational content needed to prepare medical communicators for success as regulatory writers at all career levels. This committee will

2019 AMWA Medical Writing Executives Forum Activity sheets.



Photos: EPNAC.com



Forum attendees enjoying San Diego weather.

- Assess AMWA's education on regulatory writing topics to identify gaps and opportunities.
- Recommend topics and subject matter experts for new educational resources.
- In 2019, the ad hoc Workforce Training Committee created a list of recommended training topics for regulatory writers and proposed a curriculum roadmap to guide employees through the training. This publication will be published and disseminated in 2020.

To address the issue of mentoring, Lori L. Alexander, AMWA Education Director, is exploring ideas for new educational resources. Currently, a mentoring workshop is in development and will be offered at the Medical Writing & Communication Conference in Baltimore, Maryland, in October 2020. The workshop also will be available to companies for onsite training.

On the topic of quantifying the value of medical writing, the AMWA Medical Writing Executives Council, chaired by Joan Affleck and comprising several department heads and directors who attended the 2019 Medical Writing Executives Forum, will work on this issue over the next year.

The best way to understand what training and resources regulatory medical writers need is to ask the people who hire them. The annual Medical Writing Executives Forum offers the ideal setting for AMWA to engage employers and learn how to design education to meet the needs of their employees. Armed with this information, AMWA can confidently create resources that will enable medical communicators to flourish in their careers and meet future workplace demands in the biopharma industry.

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

Author contact: clkwriter@comcast.net

Exciting News. #AMWA2020 is Going Virtual!

Since the beginning of the COVID-19 pandemic, AMWA leadership and staff have been monitoring the conditions and evaluating several possible scenarios for the 2020 AMWA Medical Writing & Communication Conference. The health and safety of all conference participants and AMWA staff have always been our top priority. Given the continuing uncertainty and the clear feedback we received from AMWA members who completed the recent member survey, the AMWA Board of Directors has voted to transform the 2020 Medical Writing & Communication Conference from an in-person experience to a virtual event.

AMWA conferences are known for their warm and welcoming environment and excellent educational offerings. Although the

format of this year's conference will be different, we will provide you with an engaging program and a robust schedule of sessions for you to enjoy. Volunteers and staff have committed a great deal of time and energy to developing the program for the 2020 Medical Writing & Communication Conference, and we will work with presenters to create a special experience for the AMWA community.

Online delivery of educational content is not new to AMWA, and we are committed to offering the best virtual experience for attendees. As soon as we have more information about how, where, and when the virtual conference will take place, we'll let you know.

We hope you'll join us for this historic event!



Mary Elizabeth Williams, 2020 Alvarez Award Recipient

Elise Eller, 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.*

I am thrilled to announce that our 2020 Alvarez Award recipient is **Mary Elizabeth Williams**, author of *A Series of Catastrophes & Miracles: A True Story of Love, Science, and Cancer* and passionate advocate for bridging the communication gaps among patients, doctors, and researchers. Her writing and advocacy reach thousands of people and highlight the importance of the many forms of medical communication.

As I write this *AMWA Journal* article in April, we are facing uncertain times because of the COVID-19 pandemic. We have entered a new world, and we don't know what the world will look like once we get through this pandemic or even when we'll get through it. Ms Williams can tell us a bit about facing uncertainty and new worlds. Ms Williams, a writer for publications such as *Salon* and *The New York Times*, was confronted with a stage 4 recurrence of melanoma in 2011. She chronicled her journey with stage 4 cancer in *Salon* and other publications, culminating in her 2016 book, *A Series of Catastrophes & Miracles: A True Story of Love, Science, and Cancer*. I highly recommend this book. Ms Williams describes what it means to be a patient with cancer with humor, generosity, and love. She participated in a phase 1 clinical trial of Bristol Myers Squibb's investigational PD-1 inhibitor nivolumab (now approved by the US Food and Drug Administration and marketed as Opdivo®) in combination with Bristol Myers Squibb's CTLA-4 inhibitor ipilimumab (Yervoy®). Ms Williams credits this regimen with saving her life.

Since then, Ms Williams has spent considerable time writing and speaking publicly about cancer, clinical trials, immunotherapy, grief, and the mental health challenges of living with illness. In doing so, she reveals the personal side of living with cancer and participating in a clinical trial. Her story is one of resilience, and it is her hope that her story is part of the conversation to make the health care experience better for all of us. No matter what types of medical writing we do, it is a reminder that underlying our work are the people who step forward to participate in clinical trials.

We are honored to host Ms Williams this year and to hear her story.



Mary Elizabeth Williams is an author and a journalist. She has written for *The New York Times*, *Los Angeles Times*, *The Guardian*, *Time*, *Salon*, and numerous other publications. In 2011, after a melanoma recurrence at stage 4, she became one of the first patients in the world to enroll in a groundbreaking immunotherapy clinical trial at Memorial Sloan Kettering Cancer Center. Twelve weeks later, she showed no evidence of disease, and she has been cancer-free ever since. She chronicled her experience and the science behind it in the National Geographic memoir, *A Series of Catastrophes & Miracles: A True Story of Love, Science, and Cancer* and continues to work with the cancer and clinical trial community. She is pursuing certification in the Narrative Medicine Program at Columbia University.



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