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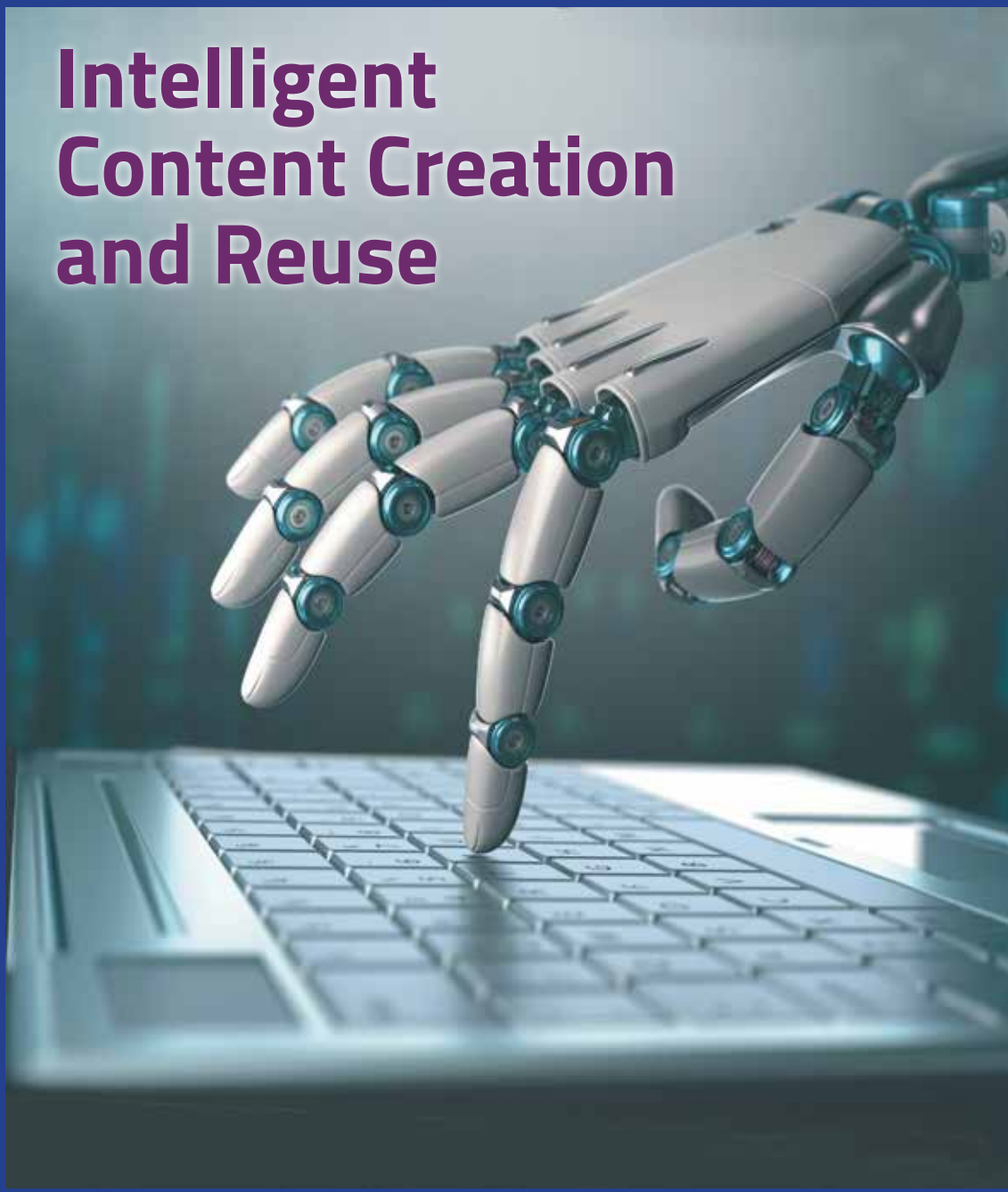
AMWA JOURNAL

ELECTRONIC EDITION

Intelligent Content Creation and Reuse



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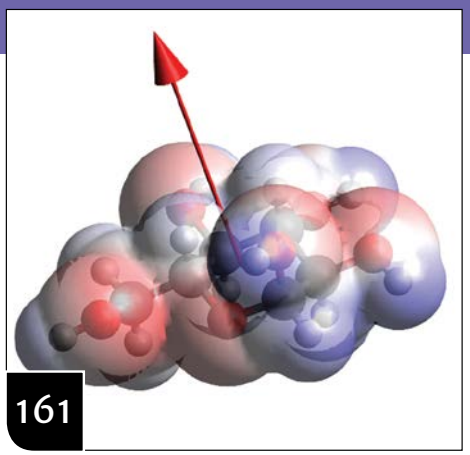

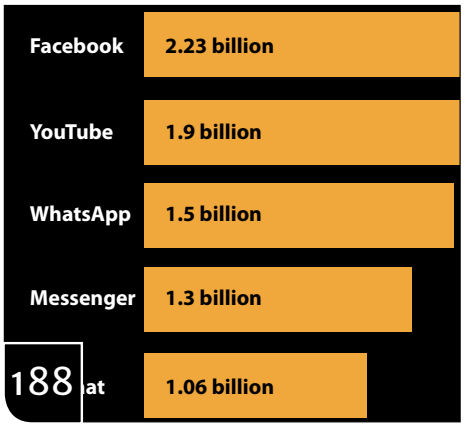

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Standardizing, Simplifying, and Scaling Medical Writing in Life Sciences: Intelligent Content Creation and Reuse

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ABSTRACT

The demand for medical writing has been steadily growing in the pharmaceutical and life sciences industries. The global health care industry has been witnessing patent expirations, rapid changes in regulatory norms, and a consistent rise in research and development spend. As a result, the need to continually adapt, create, maintain, and update medical content has intensified in the recent years.

The medical writing function accesses content/data from multiple sources, often deriving, reusing, and repurposing content to generate new documents or update existing ones. This involves scanning large volumes of data from varied, often siloed, sources to extract relevant information. The entire process is not only time-consuming and effort-intensive but also prone to iterations. While there are several technologies and models that leverage structured content authoring for ease in content extraction and generation, intelligent content solutions provide an artificial intelligence-powered approach to streamline content management and content generation-related processes.

Intelligent content solutions use modern technologies contextualized by medical expertise to harmonize content pieces and establish content relationships across documents generated in the course of a drug's life cycle. Intelligent content solutions provide auto-identification of verbatim and non-verbatim content across source and derivative documents to understand medical content reuse patterns and lineages. In combination with content management, the solution provides event-driven, workflow-based, end-to-end document management to drive efficiencies and productivity for documents across regulatory, clinical, safety, and medical domains. As a result, the entire medical writing function is further simplified, standardized, and scaled seamlessly in a robust and efficient manner, substantially reducing the time to submission of documents.

COMPLEXITIES OF MEDICAL WRITING

Medical writing is an operationally and technically complex process that involves depth of domain expertise and a wide range of stakeholders. The demand for medical writing has been steadily growing in the pharmaceutical and life sciences industries.[1] The global health care industry has been witnessing patent expirations, rapid changes in regulatory norms, and a consistent rise in research and development spend.[2] As a result, the need to continually adapt, create, maintain, and update medical content has intensified in the recent years.

Clinical or research and development (R&D) medical writing involves the development of a number of critical documents that include clinical trial protocols, investigator's brochures, clinical/non-clinical study reports, summary documents, and labeling documents. The study-related documents created during the R&D and clinical phases are further reused by medical affairs and commercial operations for commercialization and post-marketing activities. This constant generation and reuse of voluminous medical content often result in duplication of effort and other process redundancies that affect the time to document submission.[1]

This article looks at ways to simplify, standardize, and scale medical writing processes by using state-of-the-art life sciences-contextualized technologies that can improve efficiencies with high levels of accuracy, resulting in shortened time to submission as well as fewer resubmissions.

Challenges in Medical Writing

Medical writing teams handle onerous volumes of data and information that flow through study protocols, reports, investigator's brochures, and several documents generated through regulatory, clinical, safety, and marketing processes. The challenge primarily lies in handling such volumes within stringent timelines, without compromising quality and accuracy. Efficiency and productivity of the medical writing process are affected due to redundancy of content and effort, information

residing in multiple silos, and continued dependence on human expertise through the entire journey, resulting in increased time to market.

Current Solutions

The industry continues to devise ways and approaches to manage the onerous medical writing process. The traditional authoring approach is template-based and is universally accepted and adopted. However, template-based authoring is time- and labor-intensive, involving significant human efforts in writing, updating, maintaining, and reusing content. The process of managing content changes is often very challenging. To add to this, inconsistent tagging or indexing at a document level leads to considerable delay in getting the right information to the right person at the right time and results in duplicated efforts.

An improvement over template-based authoring, "structured content authoring" (SCA) classifies information in documents, extracts chunks of information identifiable as components or topics, and creates content libraries for reuse. These components are assembled into published documents based on the outline and data structure within the document. Thus, SCA has brought about a major improvement in the way content can be structured and recycled.

Next-Generation Solutions: Adopting Artificial Intelligence in Medical Writing

The intelligent way forward is to apply life sciences-contextualized artificial intelligence (AI) to auto-create, update, and reuse medical content. Such an approach is designed to simplify, standardize, and scale medical content management processes from R&D to commercialization.

Before evaluating the application of AI in medical writing, it may be useful to reflect on the use of AI in life sciences.

AI in Life Sciences

Artificial intelligence is widely being adopted across industries for its value in navigating through volumes of data and harnessing relevant information with minimal human intervention. It simulates human ways of problem-solving using algorithms based on deduction, inference, planning, commonsense reasoning, and informed search-selection processes. It also extends to recognizing patterns in language using natural language understanding algorithms and natural language processing techniques.

Artificial intelligence has found a number of important applications in the life sciences industry in accelerating drug development, transforming product commercialization, improving customer engagement, and driving differentiated patient outcomes.[3-7]

AI in Medical Writing

Intelligent content (IC) leverages life sciences-contextualized AI to auto-create, update, and reuse content across the medical writing continuum.

The methodology underlying this solution simplifies, standardizes, and scales medical content journeys from R&D all the way to commercialization and life cycle management; provides event-driven, workflow-based, end-to-end document management; and learns continuously/autonomously, managing even nuanced medical content (Figure 1).

By implementing machine learning and natural language processing techniques to structure medical content, IC seamlessly works with minimal human intervention, harmonizing content pieces, identifying and quantifying content relationships and lineages, and automating verbatim and non-verbatim content generation.[8]

Intelligent content not only reduces the time to develop content, which drives productivity, efficiency, and effectiveness, but also is modular and scalable, while remaining highly compliant.

Intelligent content autonomously extracts content from diverse sets of data that are either structured or unstructured in nature. Subsequently it processes the extracted data to understand and classify the substance and context of the content and stores the content in a dynamic semantic model along with the context information. When content needs to be reused or repurposed, IC solutions adapt the information and context of the content based on the need of diverse stakeholders in the life sciences ecosystem. The solution maintains a catalogue of information that can be easily searched using natural language queries. It also performs impact analysis to optimize change management whenever new content is made available or when existing content is modified. The underlying workflow management system integrated with IC solutions enables collaborative management of content and documents—discovery, authoring, approval, administration, and publishing.

Real-World Applications

Intelligent content solutions can be used across medical writing domains within product development and life-cycle management (Figure 2). The applicability is especially significant in areas where documents rely on other documents as sources of content. The best potential targets are those that are in the critical path of regulatory dossier submissions.

Content Mapping

Content modelling identifies chunks of unique information (components) in documents created during drug development. It maps out relationships and interdependencies across upstream-downstream documents on the basis of compo-

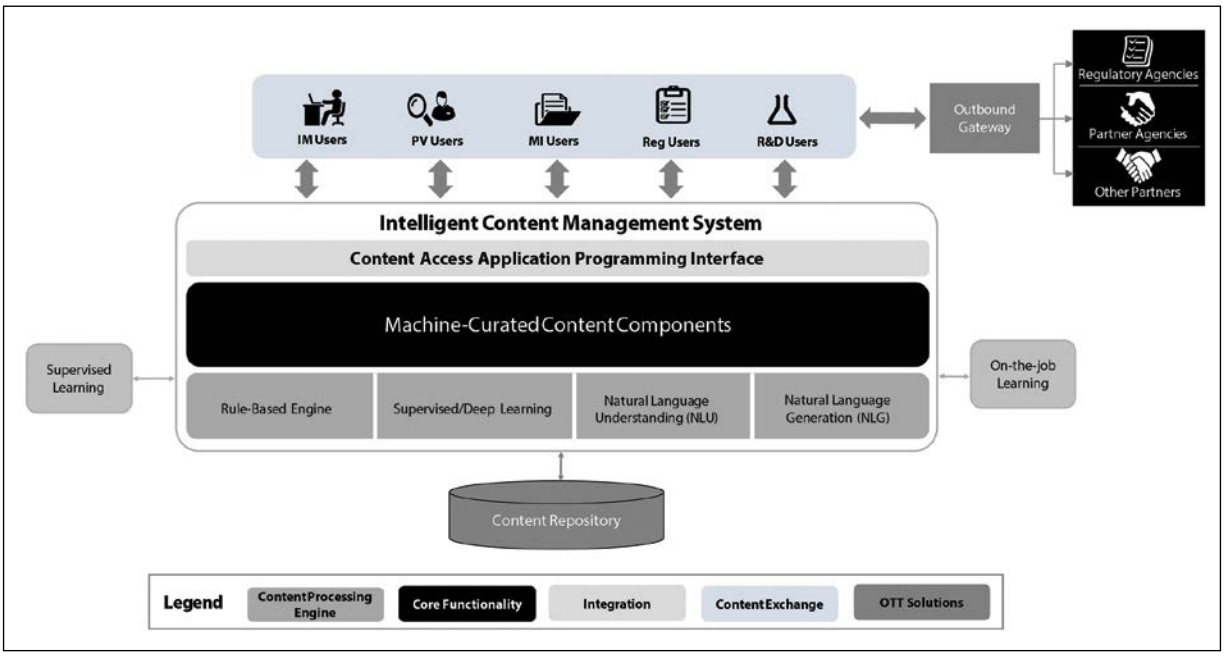

Figure 1. Components of IC solutions. IC, intelligent content; IM, information management; MI, medical information; OTT, over-the-top; PV, pharmacovigilance; R&D, research and development; Reg, regulatory.

nents and allows for visualization of content flow and usage. The model systematically and holistically determines what content or documents can be auto-generated, what content can be reused, how and where quality can be improved, and how duplications can be removed. The mapping can be customized per the documentation structure of medical writing. A key feature of this content mapping model is that updating the source documents automatically updates all documents linked to the source, greatly reducing errors and improving consistency. Generating new documents from reusable content components significantly reduces workload on medical writers and increases content consistency.

Authoring and Updating Product Labels

Intelligent content enables regulatory professionals to improve the authoring efficiency of global and local labels. Portions of labeling documents that have high reuse can be auto-authored based on the back-end relationship map that provides access to appropriate sources and content. For example, country labeling documents can be auto-authored using the summary of product characteristics or company core data sheet. Content lineage ensures that any updates to the reference label auto-triggers updates to all relevant downstream labels.

Authoring and Updating Regulatory Documents

Regulatory documents are generally in the critical path. There are interdependencies among regulatory documents that are managed by various sub-teams within the regulatory business unit. Even minor delays in individual steps or documents can cumulatively create limitations in meeting submission timelines. Intelligent content can be used to manage these interdependent documents. For example, the first draft of clinical

Medical Documents	Clinical Documents	Regulatory Documents	Safety Documents
• Auto-generating medical communication materials and AdPromo materials • Auto-generating medical information/ standard response letters • Managing medical information/standard response letter updates • Claims management and assisted medico-legal review	• Protocol designing • Protocol to data management plan • Protocol to clinical study reports • Protocol to informed consent forms • Chemistry, manufacturing, control to investigator's brochure	• CSR to clinical overview and summary documents • Investigator's brochures/clinical study reports to core labels • Core labels to global and local labels • Local labels to patient information leaflets • Managing label updates	• Auto-generating developmental safety update reports • Generation of narratives • Auto-generating risk management plans and managing updates • Developmental safety update reports/risk management plans to generating periodic benefit risk evaluation reports

Figure 2. Applications of artificial intelligence across the medical writing function in different stages along the product life cycle. CSR, clinical study report.

overview and summary documents can be auto-authored for verbatim content using clinical study reports (CSRs). Quality overall summaries can also be auto-authored using product information.[9]

Authoring Clinical Documents

Among clinical documents, IC can be used to prepare the data management plan, trial protocols, and statistical analysis plans, and to auto-author up to Section 9 of the CSR. Some of the other applications in the clinical domain include protocol designing (planning design based on prior data, literature articles, and regulatory guidance and defining patient population, endpoints, tests/procedures to align with outcome measures, including safety parameters); auto-generating patient or event-level narratives from datasets; auto-summarizing CSR efficacy and safety sections (11 & 12) from datasets; and auto-generating lay summaries for public disclosure from CSRs.

Authoring Safety Documents

Aggregate reports are closely dependent on each other, providing opportunities for content reuse. Periodic benefit-risk evaluation reports can be auto-authored using developmental safety update reports or vice versa based on the product status and using other sources like CSRs, risk management plans, and product labels. Intelligent content ensures there is consistency of information related to risk/adverse events/signal, etc, across interdependent safety documents.

Authoring and Updating Medical Information Letters

In the medical domain, IC can be used to auto-generate medical communication documents, advertising and promotional materials, and standard response letters (SRLs). Global SRLs can be used to auto-generate local SRLs. Intelligent content also enables effective and efficient management of updates based on updates in the source documents.

Journey of AI in Medical Writing

Artificial intelligence is an evolving reality that matures with usage and time. Progressed with a gradual calibrated approach, AI-powered IC solutions can bring about significant reduction in the time to content development, simultaneously driving productivity and efficiency, and creating a content environment that is modular, scalable, and highly compliant.

Implementers should be realistic about the expectations from deploying AI in medical writing. The ideal approach would be a graded implementation plan (Figure 3). Level 1 is the widely accepted manual generation of documents. Level 2 ensures that there are structures and processes in place to manually generate content in the most efficient way possible. Most medical writing teams are at these levels.

At Level 3, early automations can be put in place, guided by prudence and significant human oversight. As the journey matures, a number of content-generation processes at Level 4 can be automated across different document types. This eventually leads to Level 5 where automation extensively takes over most of the content-generation processes, with minimal expert oversight.

Automation is a progressive process that eventually helps to minimize human intervention. In general, iterative processes that require minimal critical thinking could be initially automated using AI. Multiple complex tasks could also be practically divided into smaller iterative tasks that increase the potential applications of AI.

Artificial intelligence needs to be deeply coupled with human intelligence from initiation to advanced stages. The recommended way ahead for the medical writing community is to begin the journey with content pieces that are most reused and move up the value chain, taking incremental steps to building independent autonomous mechanisms that are nuanced, compliant, and accurate.

While medical writing in its myriad complexities can be accelerated, simplified, standardized, and scaled more efficiently, it is important to be realistic about what AI can potentially do, without underestimating the power of human intelligence, and to focus on sensible automations as opposed to more broad-based generalized approaches.

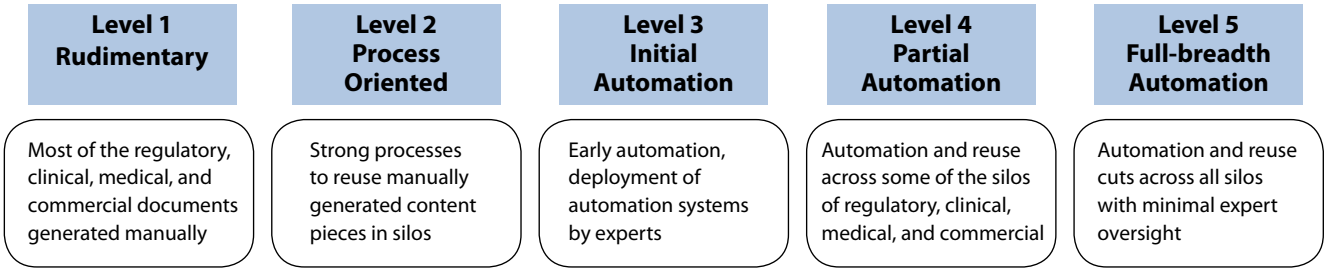

Figure 3. Evolution of artificial intelligence in medical writing.

CONCLUSION

Medical writing, over time, has evolved in expectation and complexities.

Implementation of AI is a significant way forward to drive efficiencies and effectiveness of medical content creation and reuse. When sensibly and appropriately used, AI provides improved accuracy, standardization, speed, operational excellence, and long-term competitive advantages in medical writing.

The journey of unlocking the true potential of AI in medical writing could be daunting to begin with. It is, therefore, imperative to have a long-term strategic outlook toward incorporating AI and to take measured steps in the immediate, short, and long term to successfully scale AI in the real world.

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References

1. Bernhardt SA. Improving document review practices in pharmaceutical companies. *J Bus Tech Comm.* 2003;17:439. https://cpb-us-w2.wpmucdn.com/sites.udel.edu/dist/7/419/files/2013/01/ImproveDocRevJBTC2003.pdf. Accessed July 08, 2018.
2. Total global spending on pharmaceutical research and development from 2010 to 2024 (in billion U.S. dollars). Statista website. https://www.statista.com/statistics/309466/global-r-and-d-expenditure-for-pharmaceuticals/. Published 2019. Accessed August 09, 2019.
3. Verburg F, Reiners C. Sonographic diagnosis of thyroid cancer with support of AI. *Nat Rev Endocrinol.* 2019;15(6):319-321.
4. Vidal-Alaball J, Royo Fibla D, Zapata MA, Marin-Gomez FX, Solans Fernandez O. Artificial intelligence for the detection of diabetic retinopathy in primary care: protocol for algorithm development. *JMIR Res Protoc.* 2019;8(2):e12539.
5. Ridler C. Artificial intelligence accelerates detection of neurological illness. *Nat Rev Neurol.* 2018;14(10):572.
6. Li X, Zhang S, Zhang Q, et al. Diagnosis of thyroid cancer using deep convolutional neural network models applied to sonographic images: a retrospective, multicohort, diagnostic study. *Lancet Oncol.* 2019;20(2):193-201.
7. 2018 Global life sciences outlook: innovating life sciences in the fourth industrial revolution. Deloitte website. https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-ls-outlook-2018.pdf. Published 2018. Accessed July 08, 2018.
8. Velupillai S, Suominen H, Liakata M, et al. Using clinical natural language processing for health outcomes research: overview and actionable suggestions for future advances. *J Biomed Inform.* 2018;88:11-19.
9. Hein T. Product lifecycle management for the pharmaceutical industry (an oracle white paper). Oracle website. http://www.oracle.com/us/products/applications/agile/lifecycle-mgmt-pharmaceutical-bwp-070014.pdf. Accessed July 08, 2018.

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http://www.acehp.org/p/cm/ld/fid=22

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February 13–16, 2020
Seattle, WA
http://meetings.aaas.org

DIA Europe 2019
March 17–19, 2020
Brussels, Belgium
https://www.diaglobal.org/en/flagship/dia-europe-2020

American Pharmacists Association Annual Meeting & Exposition
March 20–23, 2020
Washington, DC
https://aphameeting.pharmacist.com

American Copy Editors Society
April 30–May 2, 2020
Salt Lake City, UT
https://aceseditors.org/conference/2020

ISMPP Annual Meeting
April 20–22, 2020
Washington, DC
https://www.ismpp.org/annual-meeting

Health Journalism 2020
April 30–May 3, 2020
Austin, Texas
https://healthjournalism.org/calendar-details.php?id=2052

Council of Science Editors
May 2–5, 2020
Portland, OR
https://www.councilscienceeditors.org/events/upcoming-events/2020-cse-annual-meeting/

STC Technical Communication Summit
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Abbreviations: Expectations, Permutations, Revelations, Reservations, and Applications of Shortened Words and Phrases

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

ABSTRACT

Abbreviations—and their related shortenings, clippings, contractions, acronyms, backronyms, initialisms, blendings, and mnemonic devices—are far more interesting than they first appear. They are also a mixed blessing, saving writers time and effort but potentially confusing and frustrating readers. For more than 5,000 years, driven by changes in writing technologies and writing surfaces, we have always invented creative ways to write more quickly and easily. However, the gains in efficiency are often offset by reduced comprehension. Abbreviations have frustrated Roman emperors, medieval scholars, and journal editors. They have brought amusement to soldiers, confusion to enemies, and death to patients. They even have unexpected effects on the conduct and publication of clinical trials. Carefully crafted abbreviations can markedly improve communication, but unknown abbreviations can confuse and divide readers, and unintended abbreviations can have embarrassing consequences. In fact, abbreviations permeate our lives to the point that life without them is difficult to imagine. Here, I present some "revelations about abbreviations"—things you may not have known about them—and some related expectations, considerations, reservations, and applications associated with them. Although I call attention to some important aspects of abbreviations, such as capitalization and punctuation, my focus is on their history, uses, and implications. Using an abbreviation depends on how likely the primary and secondary audiences are to know what it means, how often it is used, how many other abbreviations are used, how clustered the abbreviations are, and where they appear in the document. I describe 9 common problems with abbreviations, most of which argue for using them sparingly. Finally, I summarize the most common rules and recommendations for using abbreviations in scientific publications.

EXPECTATIONS OF ABBREVIATIONS

You can't take over the world without a good acronym.
—C. S. Woolley[1]

Abbreviations are shortened words or phrases that make writing easier, the text shorter, and reading faster by reducing the need to repeat a longer word or phrase.[2-12] Abbreviations have also been used to avoid mentioning a sacred name, as magical symbols in alchemy and the occult, as language-independent marks that could be understood in multilingual societies, and to promote memory and recognition.[12]

Abbreviations mean that "maximum left arterial dimension from a right parasternal short-axis heart-base view" can be shortened to LAmax. But every time we use an abbreviation, we face the same trade-off between convenience and courtesy. That is, the more we abbreviate our writing for our own convenience, the more we risk the discourtesy of confusing readers.[7,8,13,14] Still, skillfully used, abbreviations can provide both convenience and courtesy.[10,15] Their effectiveness depends on how likely the primary and secondary audiences are to know them,[3] how often individual abbreviations are used, how many unique abbreviations are used, how close together they are, and in what part of a document they appear.

In the United States, abbreviations permeate all aspects of industry, science, and culture.[15,16] We abbreviate the names of states, scientific journals, elements on the periodic table, airports, units of measurement, Internet and email addresses, computer file extensions, months and days, directionals on street names, university names, genus names (eg, *S. aureus*), forms of address (eg, Ms), government agencies, academic degrees, military ranks, etc. As a result, the sheer volume of information about abbreviations is intimidating. The *AMA Manual of Style* has an 88-page chapter listing abbreviations on various subjects and 98 index entries on abbreviations.[5] In March 2019, Barnes & Noble listed *433 books* on abbreviations, and Google retrieved *196 million* Web hits for the term. The

online *Oxford Dictionary of Abbreviations* includes more than 100,000 abbreviations and acronyms and more than 1 million definitions,[17] and Acronym Finder contains more than 5 million acronyms and abbreviations.[18] And of course, new abbreviations are also introduced faster than they can be added to dictionaries.[16] Not surprisingly, English uses more abbreviations than any other language.[7] Curiously, however, we have created hundreds of thousands of abbreviations over the past 5,000 years only to conclude that they should be used—sparingly.

In this article, I describe some issues with abbreviations and related shortenings and review the rules and advice for using them. I do not address issues of capitalization (ED vs ed [emergency department vs edition]), punctuation (I.V. vs IV [intravenous vs Roman numeral 4]), the use of articles (*a* European Union directive vs *an* EU directive), plurals (ROSs vs ROS are [reactive oxygen species]), or possessives (HMO's vs HMOs's [health maintenance organizations, singular possessive vs plural possessive, respectively]). Instead, I focus on the history, forms, uses, and implications of abbreviations.

PERMUTATIONS OF ABBREVIATIONS

There are only 17,000 three-letter acronyms.

—Paul Bouton[19]

An **abbreviation** is a shortened word or phrase that represents the whole word or phrase[11,16,20,21] and usually consists of the most identifiable letters of the word to which it refers.[11] So, hour, minute, and second become hr, min, and sec, and professor becomes Prof.

Different shortening techniques have created several types or categories of abbreviations, such as acronyms and initialisms. Here, "abbreviation" includes all of the categories described below.

Initialisms (or alphabetisms[22] or sigla[6]) are formed from (usually) the first letter or letters of a group of words in a longer name or phrase and that are pronounced 1 letter at a time[2,5,10,11,21,23]: The National Institutes of Health becomes the NIH; amyotrophic lateral sclerosis becomes ALS (Box). Today, many Internet and texting abbreviations are initialisms (w/r/t for "with regard to"; icymi or "in case you missed it"; and @TEOTD for "at the end of the day.")

Acronyms are initialisms that are pronounced (or that are pronounceable) as words rather than as a series of letters and that are usually written in capital letters[2,4-7,11,21-24]: acquired immunodeficiency syndrome becomes AIDS; left-ventricular assist device becomes LVAD (pronounced el-vad).

Partial acronyms (or syllabic abbreviations[20]) combine the initial syllables or 2 or more words, not just the first letters. So, medicine + electronic becomes Medtronic, and MEDical Literature Analysis and Retrieval System OnLINE becomes MEDLINE.

Unfortunately, there are **second-order abbreviations**, or abbreviations that include other abbreviations: RBD is short for REM behavioral disorder, where REM is the abbreviation for random eye movement; AIMS is the APSAC International Mortality Study, where APSAC stands for anisoylated plasminogen streptokinase activator complex.[15]

Backronyms are words that are used as acronyms by assigning words to fit each letter: EQUATOR is a backronym for Enhancing the QUAlity and Transparency Of health Research. As in this example, backronyms can seem contrived if the component letters or words have to be modified too much to make them fit.

Backronyms are often used to create mnemonic devices or memory aids: the APGAR score for assessing the health of newborns, named after its developer, Virginia Apgar, is also a backronym for the assessment criteria: Appearance, Pulse, Grimace, Activity, and Respiration.[25]

Shortenings (or truncations or final clippings[10,12,23,26]) are made from the first few letters of a full word and usually consist of a single syllable[27]: influenza becomes flu; laboratory becomes lab. Many Latin terms are shortenings of this type (*exempli grata* meaning "for example" becomes "eg"; *id est*, meaning "that is" becomes "ie").[2] A less-common form of

- **The most-used initialism in the world** is "OK" (or Ok, ok, okay, or O.K.), which is believed to be a short form of "Oll Korrect," which in turn most likely came from a fad of "comical misspellings" in an 1838 satirical article about grammar published in Boston, although several other less-plausible (if more interesting) origins have been proposed.[a]
- **The longest partial acronym** appears to be "ADCOMSUBORDCOMPHIBSPAC," a 22-letter-long US Navy term for "Administrative Command, Amphibious Forces, Pacific Fleet Subordinate Command."[b]
- By far **the most interesting example of a shortening** is that associated with the second longest city name in the world (58 letters), a city in Wales—Llanfairpwllgwyngyllgogerychwyrndrobwllllantysiliogogogoch (St Mary's Church in the Hollow of the White Hazel Near to the Rapid Whirlpool of Llantysilio of the Red Cave)—which is thankfully (maybe) shortened to Llanfairpwll.[c]

[a]Read AW. The first stage in the history of "O.K." *Am Speech.* 1963;38(1):5-27. doi:10.2307/453580

[b]https://www.acronymfinder.com/Administrative-Command%2C-Amphibious-Forces%2C-Pacific-Fleet-Subordinate-Command-(US-Navy)-(ADCOMSUBORDCOMPHIBSPAC).html

[c]https://www.dictionary.com/browse/llanfairpwllgwyngyll

shortenings is apheresis or initial clippings that consist of the last few letters of a word: telephone becomes phone.[10,28]

Contractions (or suspension abbreviations[6] or elisions[12]) are shortened words that retain the first and last letters of the full word (mister becomes Mr; hypertension becomes HTN) or in which the omission of letters is indicated by an apostrophe (cannot becomes can't).[6,21]

Blendings (or portmanteaus[10,16,23]) are words formed by combining 2 separate words with different meanings to form a new, shorter term: endorphin is a blend of endogenous and morphine; genome, of gene and chromosome; vitamin, of vital and amine.[23]

Finally, **mnemonic devices**, which look like abbreviations or initialisms but are not, are sets of letters or words designed to prompt one's memory[13]: SPICED-T identifies the key elements to consider in writing titles for clinical research articles: Setting, Patients, Intervention, Comparator, Endpoint, (study) Design, and (sometimes) Time.[29]

REVELATIONS ABOUT ABBREVIATIONS

BRB, TTYL OK? Wow, I saved a ton of time with those acronyms!
—Steven Colbert[30]

The acrophonic principle (from ancient Greek: literally, "uppermost sound") is the practice of making the phonetic value of a symbol's spoken name the first letter of the name of that symbol: the letter "a" is a shortened form of its Phoenician pronunciation, "aleph," and "m" is a shortened form of "mem."[10,31] Acronyms and initialisms are created by applying this principle[31]: coronary artery bypass grafting becomes the acronym CABG (pronounced "cabbage"), and blood pressure becomes the initialism BP.

We have been shortening words and phrases for a very long time, usually because the medium of communication at the time imposed space or time or economic limits on the writing process. About 3000 BCE, ancient Egyptian scribes began abbreviating the hieroglyphic images used on murals to form a cursive script, hieratic, which was more suitable for writing on papyrus.[32] The Romans often replaced entire words with single letters or symbols ("capricious" abbreviations[12]) when carving in stone, and, in fact, most stone inscriptions had at least 1 abbreviation.[8,12] However—and this problem continues today—some abbreviations could have more than 1 meaning. Such abbreviations were used so often and led to so much confusion that Emperor Justinian passed a law regulating their use.[8] (The standard work on Latin abbreviations, compiled in 1899, consists of more than 14,000 abbreviated words.[12])

Old English, which dates to between the seventh and fifth century CE, had many abbreviations: "and" became "&" (from the Latin *et*, as in *etcetera* [and so forth]), and "the" became "ye," as in Ye Old Book Store.[2,8] Later, in medieval Europe, the price of parchment and the time needed to copy large numbers of books led to a highly abbreviated style of writing.[8] In fact, medieval manuscripts contain enough abbreviations to require a dictionary just for the abbreviations.[8]

In the modern era, the introduction in the United States of the telegraph in the 1840s led to abbreviations such as POTUS (the President of the United States).[24,33,34] However, acronyms did not come into wide use until the World Wars.[35] Early military examples include AWOL, POW, HQ, KIA, DMZ, and SNAFU, as well as MARINE (Muscles Are Required; Intelligence Not Expected), NAVY (Never Again Volunteer Yourself), and ARMY (Aren't Ready to be Marines Yet).[35] Today, the official military abbreviations are contained in the 394-page *DOD Dictionary of Military and Associated Terms* published by The Joint Chiefs of Staff.[36]

An important limitation of abbreviations was actually put to good use during World War II. To thwart censors or enemy agents, many soldiers communicated to their sweethearts with abbreviations, some of which were a bit naughty (at best), such as "N.O.R.W.I.C.H.," meaning "(k)Nickers Off Ready When I Come Home" or "C.H.I.N.A.," meaning "Come Home I'm Naked Already."[37] The very real point is that abbreviations can prevent communication as well as facilitate it.

Increasingly, clinical trials are named with acronyms: MRFIT for Multiple Risk Factor Intervention Trial.[14,38] In 2002, nearly 4,200 cardiology trials were named with acronyms,[14] and a 2015 survey identified 47 SMART trials, 40 HEART trials, and 16 HOPE trials.[38,39] Surprisingly, publications from trials named with acronyms are cited twice as often as those without,[40] and these publications tend to be accepted by higher-ranking journals. In addition, acronyms with positive connotations (SMART, ASPIRE) do better than those with negative connotations (OUCH, BEWARE).[40,41] The connotation of the acronym can actually affect patient recruitment: who would want to admit that they volunteered for the DIPSTICK study?[40]

RESERVATIONS ABOUT ABBREVIATIONS

Acronyms: Abbreviated Code Rarely Or Never Yielding Meaning
—Anonymous[42]

Abbreviations do speed writing and shorten text, may aid in recall, and can be pronounced with fewer syllables,[7] but they are now so plentiful that they often make reading difficult.[7,14] In particular, abbreviations are all too common in scientific communication, despite several problems that argue for using them carefully, if at all.

The first problem is that **abbreviations can be superfluous** when they don't reduce word count but must nevertheless be decoded by readers. The abbreviations "HD" and "OS" have the

same word count as "high-dose" and "osteosarcoma." Because the spelled-out terms are unambiguous and don't increase the word count, they needn't be abbreviated.

A second problem is that **some abbreviations cannot be easily read as words *or* as letters**. For example, LVPWT (left-ventricular posterior wall thickness, an echocardiographic measure of cardiac structure), ASCVD (arteriosclerotic cardiovascular disease), and CTEPH (chronic thromboembolic pulmonary hypertension) are too awkward to read as words or letter-by-letter and will likely be recognized as a familiar pattern of letters that are not pronounced.

A third common and serious problem is that **abbreviations are often not defined**.[14] Undefined abbreviations can obviously deprive readers of essential information, but they can also become codes that separate groups who know what they mean from groups who do not, solidifying the boundaries of both groups.[5,7,14,15,43] The heavy use of abbreviations can discourage readers in one discipline from reading articles in other disciplines.[7,14,43,44] (To readers who feel insulted by having to read the definition of an abbreviation they already know,[3] get over it!)

A fourth problem is that **readers can't find the definition of the abbreviation**.[13,14] In shorter documents, expanding the abbreviation at first mention can be sufficient. But in longer documents, or when many abbreviations are used in different parts of the text, searching the text for the definition can be frustrating, time-consuming, and unsuccessful.[4,12]

A fifth problem is that otherwise common **abbreviations can be ambiguous** (Table 1).[15] Even in the same context, some abbreviations can have several plausible meanings and so risk being misunderstood: in cardiology, TVP can mean tricuspid valve plasty, tricuspid valve prolapse, temporary transvenous pacing, or transplant vasculopathy (Table 2).[5,14,15]

A sixth problem occurs when **authors create their own abbreviations**, for example by abbreviating the names of experimental groups: PNDWH (people newly diagnosed with HIV) and PPDWH (people previously diagnosed with HIV; see problem 2 discussed earlier). A related problem is labeling experimental groups A, B, and C, rather than with descriptive terms, such as responders, nonresponders, and controls.

A seventh problem is that, even if they are familiar, **too many abbreviations in a sentence can be annoying** (a condition that has been called "abbrevobabble," a term attributed to AMWA member Sharon Naron[5,43]). Consider the sentence "The NHLBI-funded CHAART study of HEU children found that *in utero* exposure to ARVs was associated with changes in LVEF, LV contractility, and ST/PW ratio at age 2 years" and the titles "Prognostic Value of LGE-CMR in HCM"[45] and "Both NO deficiency and excess ET-1 appear to contribute to the development of PH in left HF."

Table 1. Organization Names Abbreviated as AMWA[a]

1. Advanced Media Workflow Association
2. Akina Mama wa Afrika (Swahili: Solidarity among African Women)
3. Alaskan Malamute Working Association
4. American Martial Way Association
5. American Medical Women's Association
6. American Medical Writers Association
7. American Metropolitan Water Association
8. American Museum of Western Art
9. American Muslim Women's Association
10. AMWA Development (AM Washington)
11. Archer Meek Weiler Agency
12. Army Museum of Western Australia
13. Asian Mamas Working in the Arts (seriously)
14. Association of Malaysians in Western Australia
15. Association of Metropolitan Water Authorities
16. Australian Medical Writers Association

[a] *Not counting the Arkansas Minimum Wage Act or the Average Monthly Withholding Amount.*

Table 2. Possible Meanings and Potential Misunderstandings for the Abbreviation "TD" and Its Variants

Medicine	Other Contexts
T cell-dependent	Take-down
Tabes dorsalis	Third down
Tangier disease	Target date
Tardive dyskinesia	Tax detail
Telemetry data	Technical difficulties
Temporary disability	Technical document
Terminal duct	Technology development
Test data	Temporal difference
Tetanus/diphtheria (vaccination)	Test drive
Thanatophoric dysplasia	Time delay
Therapy dog	Time difference
Thermal dose	Today
Threshold dose	Top down
Thyroid disease	Total density
Thymidylate synthase	Total distribution
Tidal breathing	Touchdown
Tissue Doppler	Tour director
Total disability	Tournament director
Toxic dose	Training and development
Toxoid	Transit district
Transaction date	Transmission & distribution
Transmitted disease	Transorganizational development
Travelers diarrhea	Treasury department
Tryptophan depletion	Trinidad & Tobago
Troland (unit of retinal illuminance)	Tropical depression (meteorology)
Tropical disease	Trust deed
Tyzzer's disease (mouse liver disease)	Turbo diesel

The letters "TD" were chosen at random. Similar tables can be created from almost any combination of 2 letters.

An eighth, all-too-common problem is **creating a name or phrase without considering how it will be abbreviated**—which it inevitably will be—and that can have embarrassing implications. Cases in point: South Lake Union Trolley,

Department of Urban and Metropolitan Planning, Department of Aging, Antonin Scalia School of Law, and Duke University Marching Band.[7]

A ninth problem occurs when **abbreviations are misunderstood**.[46-48] In a study of 643,000 medication errors, 30,000 (4.7%) were attributable to the use of abbreviations.[47] For example, IJ, "injection," was read as IV; .X mg was read as X mg (use of the leading zero, 0.X mg, is preferred); and q1d (daily) was mistaken for q.i.d. (4 times a day).[47] In the same study, 11,800 additional abbreviations were not analyzed because their meanings could not be determined.[47] In another study of 255 patient charts reviewed in 1 day in 6 Canadian hospitals, almost one-third of patients had medication orders containing abbreviations considered dangerous enough to be on a Do Not Use list.[49]

APPLICATIONS OF ABBREVIATIONS

I work with people who honestly believe that he who dies with the most acronyms wins.

—State Farm administrator[50]

The basic rules for using abbreviations are widely accepted, if not always followed. The factors to consider when using them are how likely the primary and secondary audiences are to know what they mean,[7] how often they are used, how many different abbreviations are used, how close together they are, and where they are used in the document (text, captions, titles, abstracts, etc).

There appears to be no rule requiring words or phrases to be abbreviated,[43] although several abbreviations may be used without definition: for example, DNA, RNA, HIV, CD (eg, CD4), *DSM-V*, ICD-10, EDTA, PaO2, PaCO2, SPSS, and TNM stage.[5,13]

The most common rules governing abbreviations are listed below.

When to use abbreviations

- Determine whether the publisher allows or prohibits certain abbreviations.[5,12]
- Consider using a shortening rather than an abbreviation. The abbreviation for the Joint Commission on Accreditation of Healthcare Organizations is JCHO; the shortening is the Joint Commission.
- Use abbreviations only if their meaning is clear[4,5,12] and they avoid annoying repetitions.[4]
- Use abbreviations sparingly.[5,7,12,13]
- Use only common abbreviations whose meanings are readily available in standard references.[4,6,44,51] The *APA Manual of Style*[4] recommends defining any abbreviation designated by *Merriam-Webster's Collegiate Dictionary* as "abbrev." Abbreviations without this designation may be used without definition.[4] This criterion may not be appropriate in medicine, however.
- Use abbreviations only when they appear often enough to be useful.[4,5] Many journals require that a term be used in an article at least 5 times before abbreviating it, for example. (Of course, the problem will be that perioperative 3D transesophageal echocardiography is used only 4 times in 1 paragraph and never again.)

When to define abbreviations

- Define abbreviations in parentheses at first mention, unless they are so common that, in context, a definition is unnecessary (eg, DNA, HIV).[4,5,12-14] However, when in doubt, define them.
- When defining an abbreviation, put the most common or recognizable element first: continuous positive airway pressure (CPAP); NSAID (nonsteroidal anti-inflammatory drug).[3]
- Once defined, use the abbreviation throughout the rest of the text,[4] except to begin a sentence or in figures or tables, where they should be defined again in captions and titles so readers will not have to consult the text for their definitions. However, I think a case can be made for (1) spelling out the full term occasionally after it has been defined (for example, in the conclusions of a scientific article) and (2) redefining the term at the beginning of long reports or long sections in a text, such as in each chapter of a book.[4]
- For documents that are long or have several abbreviations, include a list of abbreviations at the beginning of a document, if the format of the document allows.[5]

When not to use abbreviations

- Don't use or define abbreviations in titles and headings unless they are so well known that their meanings are unambiguous in context without being defined.[4,5,7] (Wonderfully, the American Chemical Society's *ACS Style Guide* advises writers to "avoid abbreviations in the title of a paper." But, apparently, not in book titles.[7])
- Don't use an abbreviation as the only term in a heading.[5]
- Don't ever create abbreviations unique to a specific document.[5,12,14] (I suppose the exception would be proposing that a field of science adopt a new term or nomenclature.)
- Don't begin a sentence with an abbreviation,[4,5] although this rule is not practical in many life-science topics.[5]

CONCLUSIONS

The decision to use abbreviations is easy in documents that use no more than, say, 5 common ones that represent long terms and that are used often. In reality, the skillful use of abbreviations requires judgment, which should be informed by a knowledge of their strengths and weaknesses. Much depends

on the assumptions you make about the primary and secondary audiences, the number and location of terms that can be abbreviated, and how often they might be used. The best advice? Put courtesy before convenience.

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References

1. Woolley CS. GoodReads. https://www.goodreads.com/quotes/6934137-you-can-t-take-over-the-world-without-a-good-acronym. Accessed May 3, 2019.
2. Grammarly blog. https://www.grammarly.com/blog/abbreviations/. Accessed May 3, 2019.
3. Jordan MP. Using acronyms in technical writing. *Technostyle*. 1999;15:54-60.
4. *Publication Manual of the American Psychological Association Style Manual, 6th edition*. Washington, DC: American Psychological Association; 2009.
5. Iverson C, Christiansen S, Flanagin A, et al. *AMA Manual of Style, 10th edition*. New York, NY: Oxford University Press; 2007.
6. Council of Science Editors. *Scientific Style and Format: The CSE Manual for Authors, Editors, and Publishers, 8th edition*. Chicago: University of Chicago Press; 2014.
7. Hales AH, Williams KD, Rector J. Alienating the audience: how abbreviations hamper scientific communication. Association for Psychological Science website. https://www.psychologicalscience.org/observer/alienating-the-audience-how-abbreviations-hamper-scientific-communication. Published 2017. Accessed May 3, 2019.
8. Wiles K. The history of abbreviation. The History Vault website. https://www.thehistoryvault.co.uk/the-history-of-abbreviation/. Published 2017. Accessed May 3, 2019.
9. Abbreviations or shortenings in modern English tendentions of their development. https://lib.rosdiplom.ru/library/prosmotr.aspx?id=495656. Accessed May 3, 2019.
10. Melenciuc D, Zbant L, Constantinescu O. Peculiarities of acronyms and shortenings. Lingvistică și Literatură. ISSN 1811-2668. http://www.diacronia.ro/ro/indexing/details/A17843/pdf. Accessed May 3, 2019.
11. Anonymous. Abbreviations and acronyms. Goodwill Community Foundation. https://edu.gcfglobal.org/en/grammar/abbreviations-and-acronyms/1/. Published 2019. Accessed May 3, 2019.
12. Honkapohja A. Manuscript abbreviations in Latin and English: history, typologies and how to tackle them in encoding. *Studies in Variation, Contacts and Change in English Volume 14 – Principles and Practices for the Digital Editing and Annotation of Diachronic Data*. http://www.helsinki.fi/varieng/series/volumes/14/. Published 2013. Accessed May 3, 2019.
13. Bloom DA. Acronyms, abbreviations and initialisms. *BJU Internat*. 2000; 86:1-6.
14. Minimize abbreviations. Plain language.gov website. https://plainlanguage.gov/guidelines/words/minimize-abbreviations/. Accessed May 3, 2019.
15. Fred HL. Acronymesis: the exploding misuse of acronyms. *Tex Heart J*. 2003;30(4):255-7.
16. Kuzmina OD, Fominykh AD, Abrosimova NA. Problems of the English abbreviations in medical translation. *Procedia Social Behav Sci*. 2015; 199:548-554.
17. *Oxford Dictionary of Abbreviations*. http://www.oxfordreference.com/view/10.1093/acref/9780199698295.001.0001/acref-9780199698295. Accessed May 3, 2019.
18. Acronym Finder. https://www.acronymfinder.com. Accessed May 3, 2019.
19. Paul Bouton Quotes. https://www.azquotes.com/author/58714-Paul_Boutin. Accessed May 3, 2019.
20. Hlukhovs'ka NA. Abbreviations and shortenings in modern English Language. https://revolution.allbest.ru/languages/00973986_0.html. Accessed May 3, 2019.
21. What does "shortening" mean? Is it different from "abbreviation?" English Language & Usage. https://english.stackexchange.com/questions/12910/what-does-shortening-mean-is-it-different-from-abbreviation. Accessed May 3, 2019.
22. English Language and Linguistic Online. http://www.ello.uos.de/field.php/Morphology/Initialism. Accessed May 3, 2019.
23. Graening L. All about abbreviations. Daily Writing Tips. https://www.dailywritingtips.com/all-about-abbreviations/. Published 2010. Accessed May 3, 2019.
24. Zimmer B. Acronym. *The New York Times Magazine*. December 16, 2010.
25. Oxford Dictionary. 11 acronyms that are actually 'backronyms.' https://blog.oxforddictionaries.com/2015/11/18/backronym-list/. Accessed May 3, 2019.
26. Jamet D. A morphophonological approach to clipping in English: can the study of clipping be formalized? *Lexis*. https://journals.openedition.org/lexis/884. Published 2009. Accessed May 3, 2019.
27. New words in English. Teaching English. British Council. https://www.teachingenglish.org.uk/article/new-words-english. Accessed May 3, 2019.
28. Clipping and word formation. One Hour Translation website. https://www.onehourtranslation.com/translation/blog/clipping-and-word-formation. May 1, 2019.
29. Lang T. *How to Write, Publish, and Present in the Health Sciences: A Guide for Clinicians and Laboratory Researchers*. Philadelphia, PA: American College of Physicians; 2010.
30. Steven Colbert. https://www.goodreads.com/quotes/233225-brb-ttyl-ok-wow-i-saved-a-ton-of-time. Accessed May 3, 2019.
31. Acrophony. World Wide Words: Investigating the English language across the globe website. http://www.worldwidewords.org/weirdwords/ww-acr2.htm. Accessed October 1, 2018.
32. Roberson JA. A very brief introduction to Hieratic. http://www.egyptologyforum.org/bbs/Stableford/Roberson,%20A_Very_Brief_Introduction_to_Hieratic.pdf. Accessed May 3, 2019.
33. Onion R. "U Tr?": A glossary of abbreviations used by early-20th-century telegraph operators. *Slate*. https://slate.com/human-interest/2015/05/history-of-telegraph-operators-abbreviations-used-by-telegraphers.html. Published May 11, 2015. Accessed May 3, 2019.
34. Collister L. LOL in the age of the telegraph. The Conversation website. http://theconversation.com/lol-in-the-age-of-the-telegraph-42578. Published September 1, 2015. Accessed May 3, 2019.
35. Joyner J. A history of acronyms: Robert Lane Greene investigates the rise of acronyms, initialisms, and other informal shortenings of speech. *Outside the Beltway*. https://www.outsidethebeltway.com/a-history-of-acronyms/. Published October 1, 2010. Accessed May 3, 2019.
36. Office of the Chairman of the Joint Chiefs of Staff. *DOD Dictionary of Military and Associated Terms*. Washington, DC: The Joint Staff; 2019. https://www.jcs.mil/Portals/36/Documents/Doctrine/pubs/dictionary.pdf. Accessed May 3, 2019.
37. Sheppard A. 11 Sexting acronyms from the 1930s. http://mentalfloss.com/article/53690/11-sexting-acronyms-1930s. Accessed May 3, 2019.
38. Labos C. The alphabet soup of clinical trial acronyms. ACRONYM: an Albeit Cool but Really Obtuse Naming strategY for Medical studies. https://www.medscape.com/viewarticle/857543. Accessed May 3, 2019.
39. Cheng TO, Julian D. Acronyms of cardiologic trials–2002. *Int J Cardiol*. 2003;91:261-351.
40. Goldfarb NM. Study nicknames. *J Res Best Prac*. 2016;12(2):1-4.
41. Pottegård A, Haastrup MB, Stage TB. SearCh for humourIstic and Extravagant acroNyms and Thoroughly Inappropriate names For Important Clinical trials (SCIENTIFIC): qualitative and quantitative systematic study. *BMJ*. 2014;349:g7092. doi: 10.1136/bmj.g7092. Accessed May 3, 2019.

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Plan S Is Coming: What You Need to Know

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Since it was first announced in September 2018, an open access (OA) initiative called Plan S has caused quite a stir in the scientific publishing industry. Plan S is expected to go into effect on January 1, 2021, and will mandate that all scholarly articles stemming from research funded by cOAlition S—a group of private and public funders that have adopted Plan S—be made freely available online immediately on publication.[1]

Plan S also includes provisions related to article copyright and licensing, transparency of publishing costs and fees, and acceptable business models for scientific publishing.[1] If implemented as written, Plan S will eliminate journals' revenues from article reprints and permissions and effectively ban cOAlition S–funded researchers from publishing in traditional subscription journals and hybrid journals (subscription journals that allow authors to make articles freely available to the public for a fee).

cOAlition S

Plan S is coordinated by Science Europe and is supported by the European Commission and the European Research Council. As of August 2019, cOAlition S comprised 16 public funders and 2 charitable foundations that have committed to implementing the principles of Plan S. Most of these funders are in Europe (Table).[2]

United States federal funders have not adopted Plan S yet and seem unlikely to do so in the near future. In a recent interview, Kelvin Droegemeier, Director of the White House Office of Science and Technology Policy, said, "One of the things this government will not do is to tell researchers where they have to publish their papers. That is absolutely up to the scholar who's doing the publication."[3] In December 2018, Chinese funders expressed strong support for Plan S, but it is not clear whether they will adopt all of its principles.[4]

Compliance With Plan S[1]

cOAlition S recognizes that a range of business models can be used to comply with the immediate OA requirements of Plan S.

Table. cOAlition S Public Funders and Charitable Foundations

Public Funder	Country
Der Wissenschaftsfonds	Austria
Academy of Finland	Finland
Agence Nationale de la Recherche	France
Science Foundation Ireland	Ireland
Istituto Nazionale di Fisica Nucleare	Italy
Luxembourg National Research Fund	Luxembourg
Netherlands Organisation for Scientific Research National Funder	Netherlands
The Research Council of Norway	Norway
National Science Centre Poland	Poland
Slovenian Research Agency	Slovenia
Swedish Research Council for Health, Working Life and Welfare	Sweden
FORMAS	Sweden
UK Research and Innovation	United Kingdom
National Science and Technology Council	Zambia
The Higher Council for Science and Technology	Jordan
Vinnova, Sweden's Innovation Agency	Sweden
Charitable Foundation	**Country**
Wellcome	United Kingdom
Bill & Melinda Gates Foundation	United States

An obvious option is the gold OA model, in which authors pay a publication fee (also known as article processing charge, or APC) to make the work freely available online. The hybrid publishing model is not categorically banned by Plan S, but cOAlition S members will not allow researchers to use grant money to pay for publication fees in these journals. Fees to publish in all other compliant journals (ie, OA venues or subscription journals under limited-time transformative agreements to flip to full OA) will be covered by funders.

Plan S calls for full transparency and monitoring of publishing fees and costs. Under the plan, journal publishers will be required to disclose the costs of their internal publishing functions: triage, peer review, editorial work, copyediting, art and layout, etc. cOAlition S plans to establish a monitoring system to maintain transparency of costs and fees. If "unreasonable prices" are observed, funders may decide to standardize and cap the reimbursement for publication fees.

Plan S requires the copyright of the work to remain with the authors or their institutions. The plan also mandates the use of Creative Commons Attribution CC BY 4.0 license unless an exception has been granted by funders. Under this license, articles can be shared and adapted for any purpose, including commercial use, provided proper attribution is given to the authors.

cOAlition S is working with the Directory of Open Access Journals (DOAJ), the Directory of Open Access Repositories (OpenDOAR4), and other partners to help identify journals, publishing platforms, repositories, and transformative agreements that fulfill the plan's requirements.

Reactions to Plan S

Plan S was met with strong reactions, both positive and negative, from many stakeholders, including commercial publishers, nonprofit scientific societies, and researchers. The initiative was called radical and disruptive by opponents, whereas advocates saw it as a necessary push to accelerate immediate free public access to scientific knowledge.

As expected, commercial publishers of subscription journals were alarmed by the proposed plan. They predicted that, if implemented, Plan S would undermine their business model and disrupt the entire scientific publishing system.[5] Several commercial publishers, including Springer Nature and Wiley, expressed their commitment to OA publishing but urged support for hybrid journals.[6] In contrast, gold OA publishers, such as PLOS, welcomed the plan and reminded researchers that their journals are already compliant with Plan S.[7]

Nonprofit scientific societies, including the American Association for the Advancement of Science (AAAS), warned they could be hit especially hard by the plan to the point of being forced to shut down journals and slash services.[8] Society journals tend to publish hybrid titles. By eliminating the hybrid publishing model and mandating the CC BY license, Plan S effectively eliminates all sources of revenues for most society journals.[9]

How do researchers feel about Plan S? Many have expressed strong support for eliminating paywalls. For example, more than 1,900 academics signed an open letter voicing support for OA mandates from funders (although the letter does not specifically reference Plan S).[10] This letter acknowledges that OA mandates may limit publishing options in the short term, but it asserts that these mandates will ultimately lead to a system that "optimizes what we really care about: maximizing the reach of our scholarship and its value to the research community and public."

On the other hand, more than 600 researchers signed a different letter voicing concerns over the potential negative unintended consequences of Plan S.[11] This letter describes Plan S as "a serious violation of academic freedom" because it bans publishing in subscription journals, including many highly reputable journals such as *Nature*, *Science*, and *Cell*. It also criticizes the plan's heavy reliance on the gold OA model as it is frequently associated with very expensive publication fees (up to thousands of dollars). The letter also points out that Plan S may harm international collaborations if funders in other parts of the world do not adopt similar policies.

In an editorial in the *Journal of the American College of Cardiology: Basic to Translational Science*,[12] Douglas L Mann, MD, Editor-in-Chief, argued that Plan S may increase the costs of publishing for researchers because if funding agencies decide to withdraw their commitment to pay (because of a financial crisis, for example), publication fees will ultimately shift to the researchers themselves. He also pointed out that if a cap on publication fees is imposed, OA journals will need to publish more and more articles to remain financially viable. This incentive to increase volume poses a serious risk to the scientific literature because if financial gain is placed above rigorous scientific review, the quality and originality of the published articles will suffer.

Of note, cOAlition S has pledged to ignore the prestige of journals (eg, journal impact factor) when making funding decisions. This principle was added to address the criticism that it would be difficult for researchers to adopt Plan S if funding agencies continue to value publishing in highly selective, prestigious journals, many of which have paywalls.[13] It remains unclear, however, what alternative metrics will be used to evaluate the merit of publications.

Conclusion

Plan S is a bold move that aims to ensure that no research is locked behind paywalls. So far, only 18 funders, most of them

in Europe, have committed to implement the plan. However, other funders might follow suit. The adoption of Plan S as currently written could transform scholarly publishing practices worldwide and is expected to have tremendous effects on commercial scientific publishers and nonprofit societies. Medical writers and editors who work in those sectors should be aware of the rules of Plan S and prepare for its potential effect on their work.

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References

1. cOAlition S. Accelerating the transition to full and immediate open access to scientific publications. https://www.coalition-s.org/wp-content/uploads/PlanS_Principles_and_Implementation_310519.pdf. Accessed August 5, 2019.
2. Plan S. Funders that have endorsed Plan S and are jointly working on its implementation. https://www.coalition-s.org/funders. Accessed August 5, 2019.
3. American Institute of Physics. An interview with OSTP Director Kelvin Droegemeier. https://www.aip.org/fyi/2019/interview-ostp-director-kelvin-droegemeier. Published April 30, 2019. Accessed August 5, 2019.
4. Schiermeier Q. China backs bold plan to tear down journal paywalls. *Nature News*. https://www.nature.com/articles/d41586-018-07659-5. Published December 5, 2018. Accessed August 5, 2019.
5. Else H. Radical open-access plan could spell end to journal subscriptions. *Nature*. 2018;561(7721):17-18.
6. McKenzie L. Who's afraid of Plan S? Inside higher ed. https://www.insidehighered.com/news/2019/02/19/publishers-express-concern-about-unintended-consequences-plan-s. Published Februray 19, 2019. Accessed August 5, 2019.
7. Vilhelmsson A. PLOS welcomes the revised Plan S guidelines. *PLOS Blogs*. https://blogs.plos.org/thestudentblog/2019/06/01/plos-welcomes-the-revised-plan-s-guidelines. Published June 1, 2019. Accessed July 30, 2019.
8. Brainard J. Scientific societies worry Plan S will make them shutter journals, slash services. *Science News*. https://www.sciencemag.org/news/2019/01/scientific-societies-worry-plan-s-will-make-them-shutter-journals-slash-services. Published January 23, 2019. Accessed August 5, 2019.
9. Clarke M. Plan S: Impact on society publishers. The Scholarly Kitchen. https://scholarlykitchen.sspnet.org/2018/12/05/plan-s-impact-on-society-publishers. Published Dec 5, 2018. Accessed August 5, 2019.
10. Open letter in support of funder open publishing mandates. http://michaeleisen.org/petition/index.php. Accessed August 5, 2019.
11. Reaction of researchers to Plan S. https://zenodo.org/record/1484544#.XSjV8nspDb0. Published November 12, 2018. Accessed August 5, 2019.
12. Mann DL. What are the off-target effects of Plan "S" for translational investigators? *JACC Basic Transl Sci*. 2019;4(1):132-133.
13. Else H. Ambitious open-access Plan S delayed to let research community adapt. *Nature News*. https://www.nature.com/articles/d41586-019-01717-2. Published May 30, 2019. Accessed August 5, 2019.

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Abbreviations *continued from page 157*

42. Anonymous. Quora. What's a good acronym for acronym? https://www.quora.com/Whats-a-good-acronym-for-acronym. Accessed May 3, 2019.
43. Brumback RA. ABRV (or abbrevobabble revisited). *J Child Neurol*. 2009;24(12):1477-79.
44. Shilo L, Shilo G. Analysis of abbreviations used by residents in admission notes and discharge summaries. *QJM*. 2018;111(3):179-183. doi: 10.1093/qjmed/hcx241.
45. Weng Z, Yao J, Chan RH. Prognostic value of LGE-CMR in HCM: A meta-analysis. *JACC Cardiovasc Imaging*. 2016;9(12):1392-1402. doi: 10.1016/j.jcmg.2016.02.031.
46. Rodwin B. Why you should think twice about using medical abbreviations. *Clin Correlat*. https://www.clinicalcorrelations.org/2013/07/31/why-you-should-think-twice-about-using-medical-abbreviations/. Published July 31, 2013.
47. Brunetti L, Santell JP, Hicks RW. The impact of abbreviations on patient safety. *Jt Comm J Qual Patient Safe*. 2007;33(9):576-583.
48. Tariq RA, Sharma S. *Inappropriate Medical Abbreviations*. StatPearls [Internet]. Treasure Island, FL: StatPearls Publishing; 2019. https://www.ncbi.nlm.nih.gov/books/NBK519006/. Accessed May 3, 2019.
49. Cheung S, Hoi S, Fernandes O, et al. Audit on the use of dangerous abbreviations, symbols, and dose designations in paper compared to electronic medication orders: a multicenter study. *Ann Pharmacother*. 2018;52(4):332-337.
50. Wylie communications. Quotes on acronyms. https://www.wyliecomm.com/writing-tips/concise-writing-tips/quotes-on-acronyms/. Accessed May 3, 2019.
51. Mack C. How to write a good scientific paper: acronyms. *J. Micro/Nanolith MEMS MOEMS*. 2012;11(4):1-2. http://nanolithography.spiedigitallibrary.org/. Accessed May 3, 2019.

Transport of Substances in the Body: Uptake of Sugars

Laurie Endicott Thomas, MA, ELS / Author and freelance medical writer, Madison, NJ

ABSTRACT

The digestion of carbohydrates yields simple sugars, such as glucose, galactose, and fructose. These water-soluble compounds dissolve easily in water and thus are easily transported in the blood. But as they cannot dissolve in oil, they cannot enter or leave a cell except through some sort of transporter. Fourteen facilitative hexose transporters (GLUT1 through GLUT14) and 2 sodium/glucose-linked co-transporters (SGLT1 and SGLT2) have been identified in humans. Only one of them (GLUT4) is associated with insulin receptors. The facilitative transporters allow sugar molecules to diffuse passively across cell membranes until the sugar concentration is the same on both sides. In contrast, the SGLTs are powered by a sodium gradient that is created by sodium pumps, which in turn are powered by ATP. Part 1 of a 2-part series, this article explains how sugars are absorbed from the intestine and carried to the liver, which absorbs practically all of the fructose and galactose and much of the glucose before the blood rejoins the systemic circulation. It also describes the tissue distribution of various sugar transporters. Part 2 will explain how the liver and pancreas normally work together to maintain glucose homeostasis. Under the control of pancreatic hormones, the liver can either store or produce glucose on an as-needed basis. This system helps to explain why low-carbohydrate diets and low-glycemic-load diets have had disappointing results in promoting weight loss and controlling blood sugar, as well as why low-fat, high-carbohydrate diets have been associated with lower diabetes mortality on a population level. Part 2 will also describe some other disorders that can result from problems in sugar transport within the body.

Glucose is the simple sugar that green plants produce during photosynthesis, which makes it one of the most important fuels in nature. Glucose is also the main sugar in our blood, and it is the primary fuel for many of our body's cells, including red blood cells and brain cells. Blood glucose levels are a Goldilocks problem: too low (hypoglycemia) is bad, but so is too high (hyperglycemia). You need to have the blood glucose level that is just right, or at least within a healthy range (euglycemia). To understand how glucose levels are maintained in this just-right range, you need to understand how glucose enters and leaves the bloodstream. This article will focus on how glucose and other sugars are absorbed from the food. Part 2 will describe how the body regulates glucose levels.

"CARBS" IN FOOD

Some foods, such as grapes, are rich in glucose. Other foods contain other carbohydrates (sugars and starches) that are converted into glucose during digestion. For example, the digestion of sucrose (table sugar) yields a 50:50 mix of glucose and fructose. (By comparison, high-fructose corn syrup is a 55:45 mixture of fructose and glucose.) Much of the fructose from the diet is converted to glucose in the liver. In contrast, the digestion of starches yields pure glucose. For this reason, a high-carbohydrate meal can deliver a large load of glucose to the body. The glycemic index is a measure of how quickly a food can deliver glucose to the bloodstream after it is digested[1] (see Glycemic Index and Glycemic Load sidebar).

SOME BACKGROUND INFORMATION

To understand glucose transport, start by reviewing the concepts in my series "How Cells Communicate" (*AMWA J*, 2017, vol 32, nos 2, 3, and 4). This series explains how intercellular signaling pathways help to maintain homeostasis. The first article also points out that the liver was the first organ known to have an endocrine function: it sometimes secretes glucose into the bloodstream. Also, look at the first installment of this series: "Transport of Substances Within the Body" (*AMWA J*, 2018, vol 33, no 3). It explains the paradox of transport: water-soluble substances can be easily transported in the blood but cannot easily pass through cell membranes to enter or leave

a cell. In contrast, fat-soluble substances can dissolve in the cell membrane and can thus pass easily through the cell membrane to enter or leave a cell, but they are hard to carry in the bloodstream. The body uses proteins to solve these transportation problems. Some proteins transport fat-soluble substances in the blood, whereas others carry water-soluble substances across cell membranes.

GLUCOSE MOLECULES

Glucose is a hexose (a 6-carbon sugar), as are galactose and fructose. All of the hexoses have the same chemical formula ($C_6H_{12}O_6$). However, their H and OH groups are arranged differently, which gives each hexose slightly different chemical properties, which is why they are all handled differently by the body.

The hexoses are polar molecules: although their overall electrical charge is neutral, their electrical charge is distributed in a lopsided manner over their outer surface (Figure 1). As a result, a hexose molecule has some areas that are positively charged (positive poles) and some that are negatively charged (negative poles). Because of this polarity, hexoses crystallize well: the positively charged areas of one glucose molecule are attracted to the negatively charged areas of other glucose molecules, so the molecules can pack together in an orderly crystalline structure.

Like other strongly polar molecules, glucose is highly soluble in water. Because water molecules are strongly polar, glucose molecules are more highly attracted to water molecules than they are to each other. Thus, glucose crystals readily dissolve in water, at least until the solution is saturated. For this reason, glucose dissolves easily in the watery fraction (plasma) of blood. Thus, glucose is easily transported in the bloodstream. Fat-soluble molecules and small polar molecules can easily cross the cell membrane to enter or leave a cell. In contrast, the cell membrane presents an impermeable barrier to large polar molecules (eg, sugar molecules) and to electrically charged particles (ie, ions; see Why Cell Membranes Are Semipermeable sidebar).

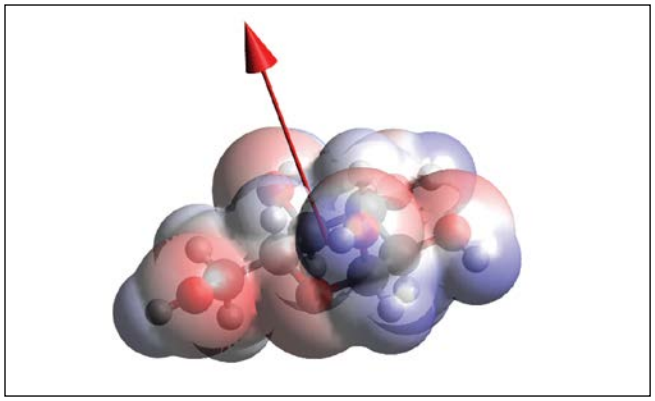

Figure 1. Glucose is a polar molecule. A glucose molecule has an equal number of protons and electrons, so its overall electrical charge is neutral. However, its electrical charge is distributed unevenly over its surface. Because oxygen atoms are so strongly electronegative, they tend to pull the electrons in a covalent bond toward themselves. As a result, there is an area of negative charge (shown in red) near each oxygen atom and an area of positive charge (shown in blue) near the hydrogen atoms that are bound to oxygen atoms. Because these positive and negative areas are distributed in a lopsided way, the molecule has a net dipole moment, as shown by the red arrow.

Glycemic Index and Glycemic Load

The glycemic index is a measure of how fast a food can deliver glucose to the bloodstream.[1] It is measured by the area under the blood glucose concentration curve that results when people eat a prescribed amount of a carbohydrate-containing food after a 12-hour fast. This result is then divided by the results of feeding the same people a reference food (either white bread or a glucose solution). The glycemic index is used only for foods that contain carbohydrate. Foods that are digested slowly (beans and whole grains) have a low glycemic index. Processed foods (white flour or white rice or corn syrup) have a high glycemic index. The glycemic load is calculated by multiplying the glycemic index by the total amount of carbohydrates in the food. Carrots and potatoes have a high glycemic index. However, a serving of carrots has a low carbohydrate content. Thus, carrots have a low glycemic load, whereas white potatoes have a high glycemic load. Although low-glycemic-index diets have become popular, they do not seem to be an effective way to lose weight or control blood sugar.[20]

Why Cell Membranes Are Semipermeable

Ions and polar molecules dissolve well in a polar solvent like water. However, they do not dissolve well in nonpolar solvents, such as oil. That is why sugar does not dissolve in gasoline! Water is a polar molecule. However, water molecules are small enough to slip through the double layer of phospholipid molecules that makes up a cell membrane. Sugar molecules are too large to do that. Ions cannot do it because of their electrical charge. For this reason, cell membranes are semipermeable. Water can seep through the cell membrane, but sugars and salts cannot. To cross the cell membrane to enter or leave a cell, a sugar molecule or an ion must pass through a gap created by a protein called a transporter. (For an introduction to transporters, see Transport of Substances Within the Body, *AMWA J*, 2018, vol 3 no 3).

HEXOSE TRANSPORTERS

There are 2 families of hexose-transporter proteins in humans (Table 1):

- There are 14 different facilitative hexose transporters, called GLUTs.[2] Facilitative transporters allow passive transport of a particular kind of substance: they allow that substance to

Table 1. Some Important Hexose Transporter Proteins

Transporter Protein	Substances Transported	Tissue Distribution
Facilitative transporters[a]		
GLUT1	Glucose[5]	All cells, but especially red blood cells and the blood-brain barrier[5]
GLUT2	Glucose, galactose, and glucosamine[6,7]	Liver, intestine, kidney, and pancreatic islet beta cells, as well as in the central nervous system in neurons, astrocytes, and tanycytes[7]
GLUT3	Glucose[8]	Nerves, brain cells, embryos, white blood cells, some carcinoma cell lines[8]
GLUT4	Glucose[9]	Heart and muscle cells and fat cells[9]
GLUT5	Fructose[10]	Intestine, testis, kidneys, skeletal muscle, fat tissue, and brain[10]
Symporters[b]		
SGLT1	Glucose or galactose and sodium[11]	Enterocytes, kidneys, parotid glands, submandibular glands, and the heart[11,12]
SGLT2	Glucose and sodium[13]	Kidney[13]

[a] *There are 14 GLUTS encoded by the human genome.*[14]

[b] *The human genome contains 11 different members of the sodium/glucose co-transporter family. Some members of the family are multifunctional membrane transporters whose functions are still poorly understood.*[15]

flow "downhill" in relation to a concentration or voltage gradient.

- There are at least 2 different sodium-dependent hexose transporters, called sodium-glucose linked transporters (SGLTs).[3] The SGLTs are symporters: they carry 2 substances in the same direction at the same time, the co-transport being powered by an electrochemical gradient for 1 of the substances.

The various hexose transporters play different roles in the system by which the body manages glucose transport and controls blood glucose levels. Surprisingly, only 1 of these glucose transporters (GLUT4) is associated with insulin receptors. To understand how these different transporters work, you need to know something about how glucose normally passes through the body.

DIGESTION OF CARBOHYDRATES

Some of the carbohydrates in our food are in the form of simple sugars (monosaccharides), such as glucose or fructose. Others are in the form of complex sugars (disaccharides and polysaccharides), such as lactose, sucrose (table sugar), and starch. The di- and polysaccharides must be broken down by enzymes into monosaccharides before they can be absorbed from the intestine. Some of these enzymes are found in saliva or in the secretions of the pancreas, whereas others are found anchored on the surface of the enterocytes (the absorptive cells that line the small intestine).[4]

Glucose Uptake From the Small Intestine

The lining of the small intestine consists of a single layer of enterocytes held together with tight junctions. Thus, any sugar that is absorbed must pass through the bodies of these cells as opposed to passing between them. A system of 3 transporters is involved in the absorption of glucose from the intestine: a sodium pump, the SGLT1 sodium-dependent hexose transporter, and the GLUT2 glucose transporter (Figure 2 and Table 1).

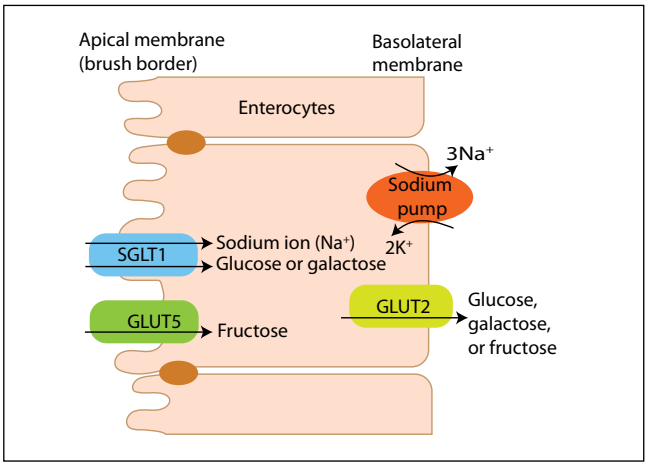

Figure 2. Glucose uptake from the small intestine. The sodium pumps (Na^+/K^+/ATPase antiporters) on the basolateral side of the enterocytes (cells that line the small intestine) use energy from ATP to pump 3 sodium ions (Na^+) out of the cell and 2 potassium ions (K^+) into the cell. Both movements are "uphill" against a concentration gradient. The resulting electrochemical gradient powers the sodium–dependent hexose transporters (SGLT1) to pull a sodium ion and a sugar molecule (galactose or glucose) from the intestinal contents into the enterocyte. Because the glucose content is higher in the enterocyte than in the bloodstream, the glucose can flow out passively through the GLUT2 transporters. In contrast, fructose can diffuse passively into the enterocyte through GLUT5 transporters on the enterocyte's apical surface. If not consumed by the enterocyte, the fructose molecule can flow out of the enterocyte through GLUT2 transporters on the enterocyte's basolateral surface.

Sodium Pump—The sodium pumps (Na^+/K^+/ATPase) on enterocytes are antiporters, which means that they transport 2 substances at the same time but in opposite directions. These antiporters use cellular energy that they obtain from adenosine triphosphate (ATP) to expel 3 sodium ions (Na^+) from the enterocyte while pulling 2 potassium ions (K^+) into the enterocyte—both against their concentration gradient.[16] Because of the action of these sodium pumps on the enterocyte's basolateral membrane (the side of the cell facing the bloodstream), the sodium concentration is lower within the enterocyte than in the intestinal lumen (the interior space of the intestine). This intracellular sodium deficit thus provides the power for the co-transport of sodium ions and glucose molecules into the enterocyte.

SGLT1—The enterocyte's apical membrane (the side that faces the food in the intestinal lumen) has sodium-dependent hexose transporters (SGLT1) that allow sodium and glucose (or galactose) to enter the enterocyte.[11] When the SGLT1 protein binds to a sodium ion, it changes shape to create a pocket that can hold a glucose or galactose molecule. When the sugar molecule enters that pocket, the transporter undergoes another change in shape, which carries the sodium ion and the sugar molecule across the cell membrane, so that they are now facing the inside of the cell. The sodium ion can then be released inside the cell. The release of the sodium ion triggers the release of the sugar molecule. After the sodium and sugar are released, the SGLT1 protein then flips back to its original shape, and the cycle can repeat.

GLUT2—The transport of glucose into the enterocyte allows the enterocyte to have a higher glucose concentration than is found in the bloodstream. As a result, glucose can passively diffuse out of the enterocyte into the bloodstream, through GLUT2 transporters on the basolateral surface of the enterocyte.[11]

Fructose Uptake From the Small Intestine

Fructose enters the enterocyte through GLUT5 transporters on the apical membrane. The enterocytes convert much of this fructose to glucose or other substances. If the enterocytes are taking in more fructose than they can metabolize, the excess fructose can pass into the bloodstream through the GLUT2 transporters on the basolateral side of the enterocyte. This transport of fructose is passive because the fructose concentration is higher in the intestine than in the bloodstream.[10]

The uptake of fructose from food is limited by the number of GLUT5 transporters on the enterocytes.[17] Some people have a relatively small number of GLUT5 transporters, either for genetic reasons or because of damage to the lining of the intestine. Thus, these individuals have a limited ability to absorb fructose. If they eat a lot of fructose (either from fruit or from table sugar or high-fructose corn syrup), they may suffer from fructose malabsorption, which produces symptoms (bloating, flatulence, and watery diarrhea) similar to those of lactose intolerance. Fructose malabsorption is not the same thing as hereditary fructose intolerance, which is due to the lack of an enzyme needed for the metabolism of fructose in the liver.[18]

Uptake of Sugars by the Liver

The blood that absorbs nutrients from the gastrointestinal tract is carried by the hepatic portal vein to the liver. In the liver, the glucose and fructose can flow through GLUT2 transporters into liver cells.[19] The liver cells can then convert those glucose and fructose molecules into other biologically important substances. Glucose can be converted into a starch called glycogen. Most of the incoming fructose is converted to glucose, much of which is then used to make glycogen. About a quarter of the fructose is converted to lactate, which can be used as fuel by various cells throughout the body. A small fraction of the fructose is also converted to fat (triglyceride), most of which is released into the bloodstream. As the liver converts the glucose and fructose into these other substances, glucose and fructose can continue to flow passively into the liver cells through the GLUT2 transporters, until the glucose and fructose levels are the same on both sides of the cell membrane.

Through this process, the liver takes up nearly all of the fructose and much of the glucose that comes to it via the hepatic portal vein. Yet when a person is fasting, the liver can release glucose to make it available to the rest of the body. The liver can raise or lower blood sugar levels on an as-needed basis because its actions are controlled by hormones from the pancreas. Insulin, which is produced by the beta cells in the pancreas, encourages the liver to convert glucose to a starch called glycogen. Because this causes the glucose concentration in the intracellular fluid in liver cells to decrease, more glucose can passively diffuse into the liver cells through the GLUT2 transporters. In contrast, glucagon, which is produced by the alpha cells of the pancreas, stimulates the liver cells to convert glycogen back to glucose and to make glucose out of noncarbohydrates. These processes cause the glucose level within the liver cell to increase so that the glucose can then flow passively out of the liver cell through the GLUT2 transporters.

Uptake of Sugar by Other Cells

Table 1 provides an overview of the tissue distribution of the various hexose transporters. Many people believe that insulin is needed in order for glucose to enter cells. But if that were true, then people with a severe insulin deficiency (ie, untreated type 1 diabetes mellitus) would not be able to absorb glucose from their food. In reality, only 1 of the glucose transporters is

affected by insulin signaling: the GLUT4 transporter found on adipose, heart, and muscle cells. Part 2 of this presentation will go into more detail about the hormonal control of blood sugar.

CONCLUSION

Before the carbohydrates in our food can be absorbed, they must be broken down into simple sugars, such as glucose, fructose, and galactose. Because those molecules are highly polar, they cannot dissolve in the oily membrane that surrounds each cell. The mucosal cells that line the intestine are held together with tight junctions. Thus, to be absorbed, sugars must pass through (as opposed to between) the bodies of these cells.

To pass through the intestinal mucosa, the sugars must pass through transporters on mucosal cells' cell membranes. Once sugars pass through this mucosal barrier, they can diffuse into the blood that is flowing through the small blood vessels in the intestine. This blood then flows to the liver, which usually absorbs much of the glucose and practically all of the fructose and galactose. Thus, the liver plays an important role in keeping blood sugar from rising too high after a meal. The liver also keeps blood sugar from dropping too low when the person is fasting or eating a low-carbohydrate diet. The liver can perform this regulatory role because of signals from the pancreas and other endocrine glands, as will be discussed in more detail in Part 2.

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References

1. Brouns F, Bjorck I, Frayn KN, et al. Glycaemic index methodology. *Nutr Res Rev.* 2005;18(1):145-171.
2. Thorens B, Mueckler M. Glucose transporters in the 21st century. *Am J Physiol Endocrinol Metab.* 2010;298(2):E141-E145.
3. Harada N, Inagaki N. Role of sodium-glucose transporters in glucose uptake of the intestine and kidney. *J Diabetes Investig.* 2012;3(4):352-353.
4. Smith ME, Morton DG. Digestion and absorption. In: Smith ME, Morton DG, eds. *The Digestive System.* New York, NY: Churchill Livingstone; 2010.
5. Uldry M, Thorens B. The SLC2 family of facilitated hexose and polyol transporters. *Pflugers Arch.* 2004;447(5):480-489.
6. Uldry M, Ibberson M, Hosokawa M, Thorens B. GLUT2 is a high affinity glucosamine transporter. *FEBS Lett.* 2002;524(1-3):199-203.
7. Thorens B. GLUT2, glucose sensing and glucose homeostasis. *Diabetologia.* 2015;58(2):221-232.
8. Simpson IA, Dwyer D, Malide D, Moley KH, Travis A, Vannucci SJ. The facilitative glucose transporter GLUT3: 20 years of distinction. *Am J Physiol Endocrinol Metab.* 2008;295(2):E242-E253.
9. Huang S, Czech MP. The GLUT4 glucose transporter. *Cell Metab.* 2007; 5(4):237-252.
10. Douard V, Ferraris RP. Regulation of the fructose transporter GLUT5 in health and disease. *Am J Physiol Endocrinol Metab.* 2008;295(2):E227-E237.
11. Röder PV, Geillinger KE, Zietek TS, Thorens B, Koepsell H, Daniel H. The role of SGLT1 and GLUT2 in intestinal glucose transport and sensing. *PLoS One.* 2014;9(2):e89977.
12. Sabino-Silva R, Mori RC, David-Silva A, Okamoto MM, Freitas HS, Machado UF. The Na(+)/glucose cotransporters: from genes to therapy. *Braz J Med Biol Res.* 2010;43(11):1019-1026.
13. Ferrannini E. Sodium-glucose co-transporters and their inhibition: clinical physiology. *Cell Metab.* 2017;26(1):27-38.
14. Mueckler M, Thorens B. The SLC2 (GLUT) family of membrane transporters. *Mol Aspects Med.* 2013;34(2-3):121-138.
15. Wright EM, Turk E. The sodium/glucose cotransport family SLC5. *Pflugers Arch.* 2004;447(5):510-518.
16. Thorsen K, Drengstig T, Ruoff P. Transepithelial glucose transport and Na+/K+ homeostasis in enterocytes: an integrative model. *Am J Physiol Cell Physiol.* 2014;307(4):C320-C337.
17. Douard V, Ferraris RP. The role of fructose transporters in diseases linked to excessive fructose intake. *J Physiol.* 2013;591(2):401-414.
18. Ali M, Rellos P, Cox TM. Hereditary fructose intolerance. *J Med Genet.* 1998;35(5):353-365.
19. Karim S, Adams DH, Lalor PF. Hepatic expression and cellular distribution of the glucose transporter family. *World J Gastroenterol.* 2012;18(46):6771-6781.
20. Franz MJ. The argument against glycemic index: what are the other options? *Nestle Nutr Workshop Ser Clin Perform Programme.* 2006; 11:57-72.

Update:

AMWA 2019 Medical Communication Compensation Survey

As the leading professional association for medical communicators, AMWA has conducted periodic compensation surveys to benchmark salaries and income for employed and freelance medical writers and editors for the past 30 years. Survey results are one of the most valued resources for AMWA members, and access to the results is highly desired within the medical writing community.

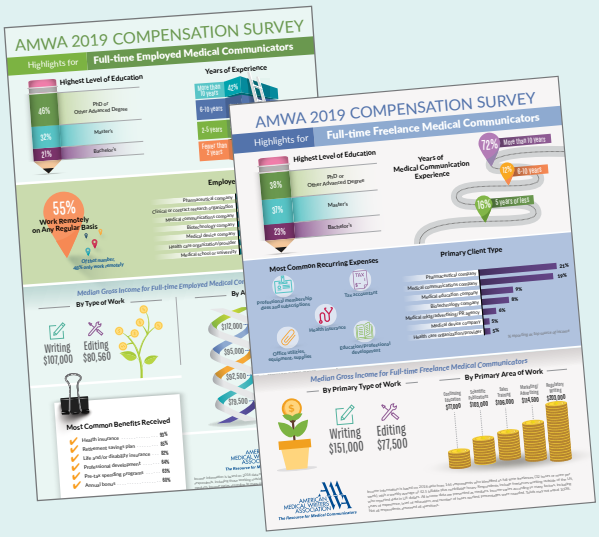
In previous years, AMWA relied solely on volunteers to develop the questions, solicit respondents, analyze the data, and summarize the results. For the 2019 survey, AMWA engaged a research firm, Association Research, Inc (ARI), to conduct the survey, manage the data analysis, and prepare a comprehensive report. This partnership enabled AMWA to publish the initial survey results in a timely manner (see the Executive Summary in the previous issue of the *AMWA Journal*) and provide access to more resources based on the results than ever before. Members can now explore the income data using an interactive, online compensation calculator that provides the mean, median, and quartiles within various fields of interest, including years of experience, highest degree, and professional work setting. Additional resources are in development for AMWA members, including a series of *AMWA Journal* articles with additional analyses of and insights into the survey results.

AMWA is publishing a complete report with more than 200 pages of results, including detailed statistical tables and expanded content. The *AMWA 2019 Medical Communication Compensation Report* will provide detailed, up-to-date information about the salaries, benefits, and incomes of those working in the medical communication industry. Companies that employ medical communicators can make use of these data to ensure their compensation packages remain competitive. Employed medical communicators can continue to rely on these survey results when negotiating compensation, and freelance medical communicators now have relevant benchmarks to help them determine project fees and hourly rates. This unique report is intended to be sold to the wider community of employers and companies in the field of medical communication; it will also be available at a discount to members.

AMWA is grateful for the time and expertise shared by our valuable members who served on the 2019 Salary Survey Task Force. Under the thoughtful leadership of Joanne Rosenberg, MS, ELS, as Chair, the committee included Clifton Chunn, Erik MacLaren, PhD, Thomas Schindler, PhD, and Laura Sheppard, MBA, MA. Kathy Spiegel, PhD, MWC®, served as the Board liaison, and Shari Rager, MS, CAE, provided project management support as the staff liaison. The task force worked with ARI to ensure the survey and subsequent analyses captured all of the nuances associated with medical communicators who work in a wide variety of settings. With their careful attention to detail, these volunteers have enabled AMWA to deliver detailed information of value to full-time, part-time, employed, and freelance medical communicators and the companies that hire them. As a group, these AMWA volunteers put forth an enormous amount of effort, and we thank them.

Individually, the task force members continue to support the analysis and distribution of the survey results. Joanne Rosenberg and Cliff Chunn developed the table of select results published here, which provides greater insights into the facts and figures presented in the infographics. Laura Sheppard and Joanne Rosenberg presented an education session about the survey results at the AMWA 2019 Medical Writing & Communication Conference. Additional articles planned for publication in the *AMWA Journal* in 2020 are in development, including one with a deeper analysis and trends regarding data on employed writers by Thomas Schindler, and an article on topics unique to the freelance data by Erik MacLaren.

Have you seen the infographics highlighting the AMWA 2019 Medical Communication Compensation Survey results for freelance and employed medical communicators?



Access your member benefits and download the infographics today.

www.amwa.org/Member_Benefits

Select Results of the
AMWA 2019 Medical Communication Compensation Survey

The AMWA 2019 Medical Communication Compensation Survey asked medical communication professionals to report compensation information from 2018. Some high-level results are presented below for full-time employed medical communicators and full-time freelance medical communicators. An executive summary of the results is available in the fall 2019 issue of the *AMWA Journal*.

All income data are reported in US dollars. Note that because of the variability and distributions of responses to many of the questions, medians rather than means are used to present the income data.

Full-time Employed Medical Communicators		
Respondent Characteristics (N=903)		
Characteristic	**n**	**Percent**
Gender (N=896)		
Female	734	81.9
Male	162	18.1
Region of work (N=900)		
United States	835	92.8
Outside United States	65	7.2
Highest level of education (N=902)		
Bachelor's	191	21.2
Master's	288	31.9
PhD	357	39.6
Other advanced degree	53	5.9
Other	13	1.4
Holds AMWA Essential Skills Certificate (N=898)	**197**	**21.9**
Years of medical communicator experience (N=901)		
<2	63	7.0
2-5	277	30.7
6-10	187	20.8
>10	374	41.5
Employer type (N=898)		
Pharmaceutical company	179	19.9
Clinical or contract research organization	126	14.0
Medical communications company	125	13.9
Other[a]	85	9.5
Biotechnology company	76	8.5
Medical device company	67	7.5
Healthcare organization or provider	66	7.3
Medical school or university	58	6.5
Medical education company	36	4.0
Healthcare professionals' organization or society	31	3.5
Medical marketing, advertising, or public relations agency	22	2.4
Government agency	16	1.8
Full-service provider/staffing company	11	1.2
Work remotely on any regular basis[b] (N=900)	**492**	**54.7**

Full-time Employed Medical Communicators Respondent Characteristics (N=903) *continued*		
Characteristic	**n**	**Percent**
Benefits received[c] (N=872)		
Health insurance	807	92.5
Retirement savings plan with matching contributions	738	84.6
Life and/or disability insurance	713	81.8
Professional development	558	64.0
Pre-tax spending programs	552	63.3
Annual cash bonus	520	59.6
Tuition reimbursement	281	32.2
Pension plan	213	24.4
Annual stock options or grants	203	23.3
Certification or license fees	167	19.2
Stock options or grants as sign-on incentive	106	12.2
Profit-sharing	83	9.5
Other	32	3.7
None	12	1.4

Not all respondents answered all questions.
a: includes respondents that selected "other" (n=69) as well as categories with <10 respondents
b: of those who reported their percentage of remote work (n=493), 47.9% work remotely 100% of the time
c: respondents selected all that applied

Full-time Employed Medical Communicators Gross Income Before Taxes in 2018 (in US Dollars)				
Characteristic	**Number of Respondents**	**First Quartile (25%)**	**Median (midpoint)**	**Third Quartile (75%)**
All	**845**	**76,000**	**97,000**	**130,000**
Type of work				
Writing	557	81,500	107,000	138,000
Editing	210	64,875	80,560	100,000
Quality Control	24	72,000	82,000	116,000
Research	20	73,250	103,500	148,750
Other	34	89,000	135,500	170,000
Main area of work[a]				
Regulatory writing	347	86,000	112,000	150,000
Scientific publications	212	75,000	92,500	125,000
Medical research/grants	60	62,250	79,500	92,250
Marketing/advertising	54	75,000	95,000	112,813
Continuing education	35	67,000	85,243	122,000
Educational materials for lay audiences	33	66,500	79,000	93,000
Medical news	10	73,728	79,500	103,500

Income information is based on 2018 data reported by full-time employed respondents, including those working outside the United States. Categories with fewer than 10 respondents are not shown.
a: area identified by respondents as "other" is not shown (n=77).

Full-time Freelance Medical Communicators		
Respondent Characteristics (n=179)		
Characteristic	n	Percent[a]
Gender (N=174)		
Female	146	83.9
Male	28	16.1
Highest level of education (N=178)		
Bachelor's	40	22.5
Master's	66	37.1
PhD	46	25.8
Other advanced degree (includes MD, PharmD, DVM, JD, and others)	22	12.4
Other	4	2.2
Holds AMWA Essential Skills Certificate (N=176)	**37**	**21.0**
Years of medical communicator experience (N=179)		
≤5	29	16.2
6-10	22	12.3
>10	128	71.5
Years of medical communicator experience before solely freelancing (N=177)		
0	55	31.1
<1	5	2.8
>1 – 2	13	7.3
>2 - <5	23	13.0
>5 - <10	27	15.3
≥ 10	54	30.5
Client type providing highest percentage of individual's income[b] (N=177)		
Pharmaceutical company	37	20.9
Medical communications company	34	19.2
Other[c]	28	15.8
Medical education company	15	8.5
Biotechnology company	14	7.9
Medical marketing, advertising, or public relations agency	10	5.6
Medical device company	8	4.5
Healthcare organization or provider	8	4.5
Medical book publisher	7	4.0
Healthcare professionals' association or society	6	3.4
Medical school or university	5	2.8
Clinical or contract research organization	5	2.8
Recurring operating expenses (N=174)[d]		
Professional member dues and subscriptions	163	93.7
Tax accountant	122	70.1
Office utilities	109	62.6
Education and professional development	105	60.3
Health insurance	85	48.9
Unreimbursed business travel	59	33.9
Errors and omissions or general liability insurance	54	31.0
Marketing	47	27.0

Full-time Freelance Medical Communicators Respondent Characteristics (n=179) *continued*		
Characteristic	**n**	**Percent[a]**
Recurring operating expenses (N=174)[d] *(continued)*		
Office space	44	25.3
Life insurance	41	23.6
Licensing fees	41	23.6
Information technology support	40	23.0
Lawyer or legal advisor	34	19.5
Disability insurance	31	17.8
Other	15	8.6
Administrative assistance	13	7.5
Contribute to retirement account (N=173)		**69.4**

a: not all respondents answered all questions. For each item in this table, the denominator was the number of respondents answering the question.
b: only shows types selected by ≥ 2% of respondents
c: includes respondents that selected "other" (n=15) as well as categories with <5 respondents
d: respondents selected all that applied

Gross Income or Revenue Before Taxes and Expenses in 2018 (in US Dollars)				
Characteristic	**Number of Respondents**	**First Quartile (25%)**	**Median (midpoint)**	**Third Quartile (75%)**
All	**164**	**71,071**	**114,500**	**218,750**
Primary type of work				
Writing	114	89,250	151,000	236,250
Editing	36	53,225	77,500	109,000
Other (includes research and quality control)	14	63,750	102,052	172,399
Area in which individual earned greatest percentage of income[a]				
Regulatory writing	42	143,000	203,000	250,125
Scientific publications	24	85,500	103,000	201,250
Continuing education	19	56,000	77,000	160,000
Marketing/advertising	16	95,500	114,500	212,500
Other	16	67,500	106,300	211,250
Sales training (pharmaceutical and biotechnology industries)	15	81,000	106,000	305,000
Medical research/grants	10	26,907	73,500	138,500

Income information based on respondents who identified as full-time freelances (32 hours or more per week), with a weekly average of 42.5 billable plus nonbillable hours. (Not all respondents answered all questions.) Respondents include freelances working outside of the US. Categories with fewer than 10 respondents are not shown.
a: categories with <10 respondents are not shown

Hourly Rates for Full-Time Freelances in 2018 (US Dollars) by Type of Work				
Type of Work	**n**	**First Quartile (25%)**	**Median (midpoint)**	**Third Quartile (75%)**
Writing	160	90.00	110.00	140.00
Editing	120	60.00	85.00	123.75
Quality control or technical quality control	86	63.75	100.00	136.25

Note that hourly rates varied by years of experience, years of freelance experience, type of client, level of work, and other factors.

Accentuate the Appositives!

Laurie Endicott Thomas, MA, ELS / Author and freelance medical writer, Madison, NJ

To appose things means to place them next to each other. Apposition is a grammatical construction in which 2 elements, usually noun phrases, are placed next to each other so that one provides some sort of information about the other. One of those elements will generally fit into the grammatical structure of the sentence, while the other, which is called the appositive, provides some sort of supplementary information.

Here are some examples of appositives. Note that the appositive can appear at the beginning, the middle, or the end of a sentence.

- The oldest and most commonly used antibiotic, penicillin is still effective against strep throat.
- Julius Caesar, the first Roman Emperor, had been a famous general.
- Glucose is a hexose, a 6-carbon sugar.

When you are thinking of using an appositive in a sentence, ask yourself the following questions:

- Does this appositive add important information, or can I omit it?
- Do I need to set it off with commas, or perhaps with parentheses or dashes?
- Should I turn it into a relative clause instead of an appositive?

Restrictive or Nonrestrictive?

A *restrictive* appositive provides some sort of limit or restriction on who or what is meant by the word or phrase in apposition. In contrast, a *nonrestrictive* appositive could be deleted without changing the meaning of the phrase in apposition.

- Alexander Fleming discovered the antibiotic penicillin (restrictive)
- Alexander Fleming discovered the first antibiotic, penicillin (nonrestrictive)

In the first example, the appositive *penicillin* is restrictive. It specifies which antibiotic is meant. If that restrictive appositive were deleted, the meaning of the sentence would change. In the second example, the appositive *penicillin* is nonrestrictive. The adjective "first" has already restricted the concept of antibiotic so that only penicillin could be meant.

Note that the same appositive could be restrictive in one situation and nonrestrictive in another:

- Bella's brother Joseph is a nurse. (Restrictive: Bella has two or more brothers, but we are only talking about Joseph, the nurse.)
- Bella's brother, Joseph, is a nurse. (Nonrestrictive: Bella has only one brother, the nurse named Joseph.)

Nonrestrictive appositives are parenthetical. A parenthesis is a word, clause, or sentence that is added as an explanation or afterthought in a passage that is grammatically correct without it. Parenthetical elements should be set off from the sentence with commas, parentheses, or dashes.

- Lyme disease is caused by a spirochete, *Borrelia burgdorferi*.
- The smallpox virus (an orthopoxvirus) is a double-stranded DNA virus.
- Nobody—absolutely no one—can be allowed in the hospital nursery without identification.

Necessary or Unnecessary?

A restrictive appositive provides some sort of essential identifying information without which the meaning of the sentence would be altered. In contrast, nonrestrictive appositives provide less important information. Thus, a careful writer would think carefully about whether the nonrestrictive appositive needs to be included in the sentence.

- This infection can be treated with penicillin, a cheap generic antibiotic.

Why would you need to say that penicillin is a cheap generic antibiotic? The question of whether to leave that appositive in the sentence is a matter of judgment. If the cost of the drug is important to the overall point that you are making, you would leave it in. Otherwise, you might be tempted to take it out.

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Medical Device Labeling: A Universe of Confusion

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ABSTRACT

Medical devices are instruments used specifically for medical purposes. They encompass nearly every medical product that does not achieve its intended purpose through chemical action or by being metabolized by the body, ie, the difference between a medical device and an everyday device is its intended use.

Medical devices range from simple, low-risk products like bedpans, to complex, high-risk implantable apparatuses that sustain life. They include mobile applications, software programs, smartphone accessories, and combination drug-device products—to complicate matters further, the scope of products and technologies within the device realm grows with every passing day!

Consequently, the universe of medical device labeling is tumultuous, necessitating order and restraint. However, this statement is not as simple as it seems. Although constraints seem rational and unavoidable, these regulations have limitations as they are not tailored to specific device indications but rather to the vague and varying notion of intended use.

While in the world of drugs and biologics, governing bodies exist that monitor and enforce labeling laws; understandably, authorities have not established such decisive conventions in the realm of medical devices. Ergo, when it comes to the methodology of labels and labeling, drugs and medical devices have few similarities.

Because medical device labeling is a universe of confusion—even for its governing authorities—we seek to familiarize readers, who may be inexperienced with medical device labeling, with the basics of device labeling regulations, the importance of intended use, and the essentials of medical device advertising, promotion, and misbranding.

Medical devices span all physician specialties, touch every conceivable anatomical part, and are applied to nearly every medical procedure. They range from the simplest surgical staples to the most complex electronic implants that stimulate the heart. Medical devices also transverse the gamut of technological and biotechnological innovation to include software as medical devices (SaMDs) and combination device products, with devices as the primary mode of action. In short, medical devices encompass almost every medical product that does not achieve its intended purpose through chemical action or by being metabolized by the body.[1-4]

While strict and rigorous naming and labeling conventions govern drugs and biologics, such clear-cut governing conventions do not exist in the medical device arena. Consequently, regarding labeling methodologies, drugs and medical devices have few similarities.

The United States Food and Drug Administration (FDA) has an extensive scope of regulatory authority, and the list of traditionally recognized product categories that fall under the agency's regulatory jurisdiction is exhaustive. In addition, the FDA has responsibilities closely related to those of several other government agencies—and those agencies have functions closely related to those of the FDA. For example, even though the FDA has regulatory jurisdiction over tobacco products, the Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB) regulates alcohol and tobacco production, importation, wholesale distribution, labeling, and advertising.[5] While the FDA regulates *medical* devices, the Consumer Product Safety Commission (CPSC) works to ensure the safety of *everyday* devices such as toys, cribs, power tools, cigarette lighters, household chemicals, and other products that pose a fire, electrical, chemical, or mechanical hazard. The FDA under the Federal Food, Drug and Cosmetic Act (FDCA) regulates the *labeling*

of medical devices; however, to regulate *advertising*, the FDA partners with the Federal Trade Commission (FTC), a federal agency that protects consumers by stopping unfair, deceptive, or fraudulent practices in the marketplace, while also promoting competition. It's little wonder that determining which of the appropriate regulatory agencies to contact is confusing and frustrating for both consumers and companies alike![5,6]

Thus, regulating not only the extensive range of medical devices but also their labels, labeling, naming, and promotion is complicated and dynamic—and even the FDA has a hard time keeping up with, let alone addressing, the new issues that arise every day in this universe of confusion.[7]

LABEL VERSUS LABELING

Labels and labeling are two very different concepts. However, for simplicity's sake: if it's *on the device* (ie, attached to the unit, box, case, package, or wrapper), it is a label; *everything else* is considered labeling, including the Instructions for Use, promotion, and advertising.[8]

Advertising and Promotion

Medical device advertising and promotion are different from drug advertising and promotion, most noticeably because of the absence of decisive regulation.[9] Other key differences include the product life cycle and frequency of product modifications, the nature of the manufacturers' interactions with health care providers, the need for product training, and the applicable reimbursement methodologies.[10]

According to an appellate court decision, "*Most, if not all advertising, is labeling. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.*"[11]

Apart from that court ruling, there is minimal FDA guidance for device advertising. By contrast, the FDA has extensive and detailed regulation for the requirements and prohibitions of drug advertising (21 CFR Part 202).[11-13] For example, FDA regulations require that drug advertising include a fair balance between the benefits and risks of the drug, the specific language, and the print size. The regulations also explicitly prohibit unsubstantiated efficacy, comparability, and superiority claims.[11,12]

The promotional guidance documents for medical devices, on the other hand, are limited and far less explicit than 21 CFR Part 202, and the proactive requirements that apply to drugs do not necessarily apply to the reactive reality of device advertising, marketing, and promotion (Table). For example, if a drug company proposed a product name to the FDA like "ViraCalm," the *drug* name would be disallowed without acceptable clinical data, supporting the inference of viral inactivation. Yet, without any regulatory restraint, the FDA cleared ViraCalm, "the world's first non-invasive, zero side-effects treatment *device* for genital herpes"[14]—even though no such indication or supporting data exist. (Actually, the ViraCalm device had obtained FDA clearance for the "symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain.")[15]

So, if devices do not have the same promotional restraints/requirements as pharmaceuticals, and, for example, there are no black box warnings or full disclosures of potential side

Table. An Illustrative Comparison Between Pharmaceutical and Medical Device Labeling Requirements

Labeling Requirement	For Drugs	For Medical Devices
US Food and Drug Administration (FDA) Naming Authorities	Office of Prescription Drug Promotion (OPDP) and Division of Medication Error Prevention and Analysis (DMEPA)	None
Name Changing	Disallowed	Allowed; FDA Federal Unified Registration and Listing System (FURLS) website
Label	National Drug Code (NDC), Address, and Contact Information	Address and Contact Information
Indications for Use	On Label	Optional; Statement of Intended Use within the Instructions for Use may be required, depending on risk level (Class I, II, III or unclassified)
Intended Use	On Label	
Selection for Use Testing	Required	Optional
Warnings, Precautions, and Contraindications	Required	Optional, depending on risk level

This list is not all–inclusive and is subject to change and interpretation.

effects, then how do medical device companies advertise their higher-risk products? They use "yellow zone" terms to describe or imply clinical benefits, based on device classification (or risk)—yet another key difference between drugs and medical devices. For example, if Device X, a Class II phototherapy device that kills certain acne-causing bacteria on the skin, is described as a *cure for acne*, that would be considered "red zone," as the statement is inaccurate and deceptive—and a breach of labeling regulation. An improved description or "yellow zone" term would be, *treat*, eg, Device X is used to *treat* acne. However, a "green zone" term, which is the ideal standard for device promotion, would be a term such as *manage*: Device X may be used to *manage* mild to moderate acne. That sentence is accurate and truthful and unlikely to cause harm.

The FDA regulates the advertising and promotion of devices by reviewing the labeling and other publicly available information by any means and from any source. FDA compliance reviewers read journal articles, periodicals, and product Web pages, and surf the Internet to learn how companies are describing their devices and how consumers are using them. Reviewers also attend tradeshows and conferences to hear how company representatives and spokespeople are explaining, describing, or promoting the intended use of their devices, including tradeshow giveaways and promotions. Moreover, an FDA agent will—at any time and without warning—visit a company's facilities for inspection.[7,16]

Any agency must prioritize to manage time more effectively, and the FDA is no exception. Therefore, the agency uses risk analysis principles to evaluate product classifications and determine enforcement priorities. The riskier the product, the more attention it gleans, and the tighter its enforcement environment.[17] When it comes to product promotion, the FDA collaborates with the consumer protection arm of the FTC to monitor the advertising and marketing of medical devices, irrespective of classification. However, the advertising and promotion of experimental or investigational devices, or approved products that are marketed for off-label use—which the FDA views as misbranding—is strictly prohibited.

Because advertising is considered *accompanying material*, the FDA regards any bias reflected toward a product as advertising or promotion, and thus, as labeling. For this reason, depending on the device classification or risk, the advertising will become the subject of scrutiny not only for the FDA but also the FTC.

Thus, unsurprisingly, in 2012, the Center for Devices and Radiological Health (CDRH) submitted an enforcement letter to NeuroMed Devices, Inc, for making claims outside their product, ViraCalm's, cleared use. According to the Warning Letter, the CDRH had previously asked, and NeuroMed had agreed, to revise the name of ViraCalm so as to remove any implied reference to the treatment of herpes. Additionally, the CDRH had asked NeuroMed to remove all references to the treatment of genital herpes from the device's indications for use. The CDRH concluded that the claims on NeuroMed's website rendered the ViraCalm device misbranded and adulterated.[15]

> While strict and rigorous naming and labeling conventions govern drugs and biologics, such clear-cut governing conventions do not exist in the medical device arena.

The Internet and Social Media

Social media plays an essential role in the marketing and promotion of products. Engaging social media pages give companies credibility and provide a way for consumers and health care professionals to learn about new devices, treatment options, and innovative procedures.

The facts speak for themselves:

- 80% of individuals go to the Internet and social media in search of information about their health[18]
- 88% of physicians use the Internet and social media to research pharmaceuticals, biotech products, and medical devices[19]
- 42% of those looking for health information also search for health-related customer reviews[19]

Social media is a far cry from the types of marketing or communication channels we have seen in the past. Interactions take place in the public space and in real time, and consumers seek guidance and expect feedback—instantly. Patients coping with disabilities or chronic conditions, and those who have recently been diagnosed, for example, are some of the most engaged users of social media.[19]

Despite the power of these marketing tools and the effect they have on brand perception—and sales—it is crucial that medical device marketers also know that there are risks to using these platforms for product promotion. According to the FDA, companies are responsible for the accuracy of all their

branded online content,[20] but what that means in real-life can be confusing. For example, the FDA sent a Warning Letter to a company that "liked" a Facebook comment regarding the off-label use of a medical product they were promoting. This seemingly innocuous act was enough to get that firm in hot water with the FDA.

Per the FTC, many rules that apply to other forms of advertising also apply to the Internet and social media, including third party product endorsements and testimonials (such as that "like" on Facebook).[6] However, what if an independent third party, not under a firm's control or influence, shared erroneous or misleading information about a product, regardless of permission or even validity? Bloggers and other such third parties are rarely medical or health care professionals, and although they generate interest in a product, they can also misinform consumers, or affect their behavior or decisions about the product.

The FDA guidance on correcting independent third-party misinformation about prescription drugs and medical devices states that if an unaffiliated third party shared inaccurate, unreliable, or off-label information about an FDA-approved or cleared product, a firm may choose to provide appropriate truthful and non-misleading corrective information or a reputable source from which to obtain the correct information (such as the firm's contact information for their Medical Affairs Department).[20] Accordingly, "appropriate corrective information" should be

- Relevant and responsive to the misinformation
- Limited and tailored to the misinformation
- Non-promotional in nature, tone, and presentation
- Accurate
- Consistent with the FDA-required labeling for the product
- Supported by sufficient evidence, including substantiated evidence, when appropriate
- Posted in conjunction with the misinformation in the same area or forum (if posted directly to the forum by the company) or reference the misinformation and be intended to be posted in conjunction with the misinformation (if provided to the forum operator or author)
- Transparent, disclosing that the person providing the corrective information is affiliated with the company that manufactures, packs, or distributes the product

In short, to avoid enforcement action by the FDA and FTC, or both, when promoting or marketing devices or other medical products on the Internet and social media, companies must be ethical, socially responsible, and honest.[21]

INTENDED USE

The concept of *intended use*, under the FDCA, has long served as a fundamental tenet of the FDA's regulatory system. The concept is used to determine whether a product meets the definition of a drug, a device, or another regulated product, and thus, whether or not that product may be regulated by the FDA.

What Are Your Intentions?

One of the most critical questions in FDA law pertains to the Statement of Intended Use: what evidence should be considered when defining the intended use of a drug or device?[22] Both device regulation, 21 CFR Part 801.4,[23] and its counterpart drug regulation, 21 CFR Part 201.128,[24] define the concept of *intended use* so broadly, it poses interpretive challenges. For example, the regulation defines intended use as the "objective intent" of the manufacturer as expressed through their promotional activity. However, the regulation then suggests that other evidence, such as how the product is *actually* used by physicians and consumers, can also determine intended use. With rare exceptions (eg, cases with unusual facts[25]), the courts have historically determined intended use by referencing the claims that manufacturers make to promote their products.

Leading You Down the Wrong Path

According to Section 502 of the FDCA, misbranding occurs when advertising or promotion (including labeling and naming) is false or misleading in any way.[26] Misbranding also applies if a label does not contain required information, like the generic name of the product in a typeface that is at least half the size of the trade name; an abbreviated Statement of Intended Use; a description of the components of the device; and the device warnings, contraindications, side effects, and cautionary statements.[27]

A medical device name is also considered its label. However, medical device naming is discretionary—not to mention, complicated. With no foundational metrics; wide, unclear boundaries; and gargantuan product range, the naming of medical devices is a matter of CDRH review-panel subjectivity—and inference of proper (or improper) promotion of implied claims.[7]

For example, names like TumorBuster and NeuroCure are medical device names that, unsurprisingly, did not receive CDRH approval. Among the many issues raised, the most evident was that these names suggest intended use: to cure, mitigate, or treat a diseased or damaged state—irrespective of claim validity.

However, it defies regulation to apply naming conventions to medical devices merely in an attempt to reign in this

universe of discovery within the life sciences. The rate of innovation and the breadth of discovery within device technology, much less the vocabulary being generated to describe them, surpass the ability of regulators to establish a naming methodology for these devices, software systems, and combination-device products. Nonetheless, a name is a label and, thus, also can be false, misleading, or even threatening to the public health.[28] (Remember ViraCalm?)

Another subject of concern for the FDA is the concept of off-label use. The FDA approves or clears products for the specific intended use they describe in their labeling. If the evidence demonstrates that a company's actual intended use is different from the use for which it was approved or cleared (ie, off-label), the product is deemed misbranded—which can lead to civil or criminal penalties.

> It is crucial that medical device marketers also know that there are risks to using [social media] platforms for product promotion.

A note about website links: companies that provide hyperlinks to sites that promote the off-label use of their devices (eg, by referencing unevaluated clinical benefits or unsubstantiated claims on other sites) are misleading their customers, and therefore in breach of device labeling regulations—which again can lead to disciplinary action from the FDA or FTC (or both).

In short, a drug or device company may not make statements that are incorrect or create a false impression—intentionally or unintentionally. This rule applies to the advertising, the packaging, and all the product information a firm publishes—including in the media or online (such as testimonials on websites or social media pages). It makes no difference whether a sponsor intended to mislead; if an advertisement, promotion, quote, statement, or any other representation creates a misleading impression, it is a breach of labeling regulations.[7,29]

Don't Get Your Terms in a Tangle

We often hear the term *IFU* used when referring to *Indications* or *Instructions for Use*, and sometimes even, *Intended for Use*. However, these IFUs have significant differences—and are *not* interchangeable.

Instructions for Use

This IFU constitutes any approach a manufacturer might take to convey the information about how to use their device safely and effectively. The Instructions for Use can include any or a combination of any of the following:

- Directions on the back of a Tyvek pouch
- Printing on the shaft of an instrument
- Printed material housed within the box or packaging
- Quick-start guide
- Instruction or training video

Indications for Use

This IFU, which is also commonly used in pharmaceuticals, refers to the reasons or situations in which a device should be used.

Intended for Use

Sometimes, people refer to a product's intended use as an IFU (Intended for Use), perhaps because the Statement of Intended Use is required to be located at the front of the Instructions for Use, Operators Manual, or User Manual. However, as we have established, the Statement of Intended Use is not an IFU; it is a regulatory tenet. The intended use statement is for what the label—and the FDA—say the device is used.

CONCLUSION

Historically, medical device regulations have trailed drug regulations—and labeling is no exception. Hopefully, however, such successful drug labeling regulations as full disclaimers, public advertising disclosures of probable side effects, and conditions of use will apply in the future to devices as well. As such—and as the authors have sought to illustrate—the greatest challenge for medical devices today is the massive range of products and scope of technologies that require regulation.

While the FDA seeks to better regulate this universe of confusion, they must also stay current not only with the innovative (yet inexhaustible) device technologies that seem to emerge on a daily basis but also with their ever-evolving terminologies. It remains to be seen, however, if this feat is indeed possible.

Because of the elementary nature of this article, other essential labeling topics, such as symbols, electronic and over-the-counter product labeling, and toxins, are beyond its scope. Furthermore, areas of particular interest to the FDA, like investigational devices, the re-use of single-use devices (SUDs), and the International Medical Device Regulators Forum (IMDRF), formally the Global Harmonization Task Force (GHTF), are topics the authors hope to address in future articles.

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References

1. Bergsland J, Elle O, Fosse E. Barriers to medical device innovation. *Med Devices*. 2014;7:205-209.
2. CDC. Classify your medical device. https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device. Accessed July 18, 2019.
3. Jarow JP, Baxley JH. Medical devices: US medical device regulation. *Urol Oncol Semin Orig Investig*. 2015;33(3):128-132.
4. Kruger K. The medical device sector. In: Burns LR,ed. *The Business of Healthcare Innovation*. Cambridge, UK: Cambridge University Press; 2005:271-321.
5. FDA. What does FDA regulate? About FDA. https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate. Accessed 29 August, 2019.
6. Federal Trade Commission. About the FTC. https://www.ftc.gov/about-ftc/what-we-do. Accessed August 29, 2019.
7. Basile EM, Armentrout E, Reeves KN. Medical device labeling and advertising: An overview. *Food Drug Law J*. 1999;54(4):519-533.
8. Pietzsch JB, Aquino LM, Yock PG, Paté-Cornell ME, Linehan JH. Review of U.S. medical device regulation. *J Med Device*. 2007;1(4):283.
9. Kupchyk AL. FDA regulation of medical device advertising and promotion. *Corporate Compliance Insights*. https://www.corporatecomplianceinsights.com/fda-regulation-of-medical-device-advertising-and-promotion/. Accessed December 6, 2019.
10. Sullivan T. FDA: The differences with pharmaceutical and device promotion standards. *Policy and Medicine*. https://www.policymed.com/2013/11/fda-the-differences-with-pharmaceutical-and-device-promotion-standards.html. Accessed August 29, 2019.
11. Gellad ZF, Lyles KW. Direct-to-consumer advertising of pharmaceuticals. *Am J Med*. 2007;120(6):475-480.
12. Baylor-Henry M, Drezin NA. Regulation of prescription drug promotion: Direct-to-consumer advertising. *Clin Ther*. 1998;20(suppl C):C86-C95.
13. Frosch DL, Grande D, Tarn DM, Kravitz RL. A decade of controversy: Balancing policy with evidence in the regulation of prescription drug advertising. *Am J Public Health*. 2010;100(1):24-32.
14. Silverstone LM. Vira Calm Treatment for genital herpes neuro med devices. LinkedIn Slide Share.
15. Covington & Burlington. Advisory | Food & Drug: Summary of FDA advertising and promotion enforcement activities. https://www.lexology.com/library/detail.aspx?g=61f81b20-fc82-49f2-971f-984c42dcd194. Accessed December 10, 2019.
16. Collier R. Medical journal or marketing device? *CMAJ*. 2009 Sep 1:181(5):E83-E84.
17. Mansour M. The basics of advertising and marketing medical devices. *JDSupra*. https://www.jdsupra.com/legalnews/the-basics-of-advertising-and-marketing-57547/. Accessed August 28, 2019.
18. Limaya N, Saraogi A. How social media is transforming pharma and healthcare. *Appl Clin Trials*. 2018;27(2).
19. Warden C. 30 Facts & statistics on social media and healthcare. *ReferralMD*. https://getreferralmd.com/2017/01/30-facts-statistics-on-social-media-and-healthcare/. Accessed August 28, 2019.
20. FDA. Guidance For Industry: Internet/social media platforms: Correcting independent third-party misinformation about prescription drugs and medical devices. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/internetsocial-media-platforms-correcting-independent-third-party-misinformation-about-prescription/. Accessed August 28, 2019.
21. Post J. Medical product promotion in the age of social media. Inside medical devices: Updates on developments for medical devices. *Covington*. https://www.insidemedicaldevices.com/2013/02/medical-product-promotion-in-the-age-of-social-media/. Accessed September 3, 2019.
22. Danzis S. FDA Proposes amending the definition of "Intended Use." FDA device regulation. https://www.insidemedicaldevices.com/2015/09/fda-proposes-amending-the-definition-of-intended-use/. Published 2015. Accessed June 8, 2019.
23. FDA. Meaning of Intended Uses. USA; 2018. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=801.4. Accessed July 24, 2019.
24. FDA. Meaning of "Intended Uses." USA; 2018. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=201.128. Accessed July 24, 2019.
25. *FDA v. Brown & Williamson Tobacco Corp*. 529 U.S. 1(2000).
26. FDA. Labeling Requirements - Misbranding. General Device Labeling Requirements. https://www.fda.gov/medical-devices/general-device-labeling-requirements/labeling-requirements-misbranding. Accessed July 24, 2019.
27. FDA. Product name placement, size, and prominence in promotional labeling and advertisements: Guidance for industry. 2017. https://www.fda.gov/media/87202/download. Accessed August 29, 2019.
28. FDA. Guidance for industry: Presenting risk information in prescription drug and medical device promotion. 2009. https://www.fda.gov/media/76269/download. Accessed July 24, 2019.
29. Fries RC. *Handbook of Medical Device Design*. Boca Raton, FL: CRC Press; 2018.

Building an Ethical Culture: The Role of the Human Resource Professional

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The culture of an organization creates a framework for ethical standards, which is based on the values embedded in the organization's DNA. The values are often expressed in the organization's code of ethics and through relationships between management and their employees. The most important factors in an ethical culture are trust and integrity. Employees must trust that the organization will treat them fairly, evaluate them based on the quality of their performance and not on any conscious or unconscious biases, provide equal pay for equal work, and develop a system to report misconduct without fear of retribution.

Sex, age, and/or racial discrimination; sexual harassment; health and safety issues; and compliance with federal and state regulations comprise the ethical issues faced by both small and large organizations. It is in this aspect that the organization's human resources function plays a key role. While human resources specialists recruit, screen, and interview potential employees, they are often responsible for planning, directing, and ensuring compliance with ethical standards, including any code of ethics violations. Activities include promoting core ethical values, strengthening ethical leadership, building trust into human resource policies, and modeling ethical behavior. Human resource professionals work to promote fair and impartial practices throughout the organization and should communicate acceptable and unacceptable behaviors to ensure conformity with the code of ethics. This sends a message that ethical behaviors will be rewarded and that unacceptable behaviors will not be tolerated.[1]

Although many companies rely on the human resources department to promote an ethical culture, many organizations have a separate ethics department that includes an Ethics and Compliance Officer.

Regardless of how these activities are managed, human resource professionals are often responsible for enforcing an ethical culture and a culture of compliance. This includes designing and implementing policies and processes that support good governance and fair practices.[2]

Ethics and Talent Management

Human resource professionals are often the initial company contact for potential candidates and new hires. Any perceived disreputable practices can hinder a company's opportunity to obtain and retain talent. Qualified job seekers are not likely to apply for a position if they feel that a company condones unethical practices, and current employees may not continue their employment under the same circumstances.

The Use of Social Media

Social media and social networking activities could affect workplace culture. As such, potential employers may check the social media presence of a candidate. Because social networking activities are an important aspect of life, employers often use social media to get a sense of the character of a recruit through their online activities. In today's social media–driven culture, candidates should expect that potential employers may monitor their activity during the hiring process.

According to a survey by CareerBuilder, 70% of employers use social networking sites to research job candidates during the hiring process. Of those that conduct social media research, 57% have found content that caused them not to hire candidates. When researching candidates, employers often look for[3]

- information that supports their qualifications for the job (58%);
- the professional online persona of the candidate (50%);
- information others have posted about the candidate (34%);
- reasons not to hire the candidate (22%).

The survey reports that 40% of those who were not hired as a result of personal social media activities engaged in provocative or inappropriate photographs, videos, or other negative behavior. This was followed by posting information about drinking or drug use (36%) and discriminatory comments related to race, sex, religion, etc (31%). Other activities included criminal behavior (30%), lying about qualifications (27%), disparaging a previous company or fellow employee (25%), and sharing confidential information from previous employers (20%).[3]

A Pew Research Center survey asked workers why they use social media on the job. The main reason was to take a mental break from work (34%), followed by connecting with friends and family at work (27%). Other reasons are work related: to obtain information that is required to do their job (20%); to build or strengthen personal relationships with coworkers (17%); and to obtain answers to job-related questions (12%).[4] It has been reported that employees spend between 1 and 3 hours a day surfing the web for personal use during the workday. Employees shop, bank, visit sporting sites, chat on Facebook, tweet on Twitter, and post photos on Instagram. However, monitoring an employee's time on social media can signal distrust and may have negative implications for the culture of an organization.[5] Nevertheless, it may be necessary for employers to make sure that their employees do not post any offensive comments about other employees, customers, or others with whom the organization has a relationship, particularly if it creates privacy issues. The key to having an effective social media policy is balance. In today's social-media-driven world, it is difficult to expect that employees will not engage in some online activities during the workday.

Bullying and Other Misconduct in the Workplace

Workplace bullying is a persistent pattern of mistreatment from others in the workplace that causes either physical or emotional harm. This includes unprofessional emails to colleagues that create a hostile environment. Unfortunately, the rise of social media has contributed to this behavior. A 2014 survey on workplace bullying found that 6.5 million workers said they were affected by bullying in the workplace. Sixty-one percent of respondents said their employer failed to react to abusive conduct.[6] Additionally, posting provocative photos or surfing pornographic sites can have detrimental effects on the employee and employer, including a negative work environment, charges of sexual harassment, and potential lawsuits.

The State of Ethics & Compliance in the Workplace, published by the Ethics and Compliance Initiative (ECI), presented results from a survey in which employees were asked about misconduct at their place of employment.[7] Survey results indicated that 47% of employees observed misconduct in the workplace and that 67% of these employees reported that the wrongdoing consisted of multiple incidents or was part of an ongoing pattern. The most frequently observed misconduct includes

- Lying to employees and external stakeholders (26%)
- Abusive behavior (21%)
- Internet abuse (16%)
- Conflicts of interest (15%) (eg, purchase of materials from a family member rather than the lowest bid)
- Health violations (15%) (eg, unsafe working conditions)

Improving the Ethical Culture

The State of Ethics & Compliance in the Workplace[7] also provides a series of recommendations for improving ethical culture in the workplace:

- Promote a statement of values throughout the organization and set ethical standards to guide employee actions.
- Include ethics and compliance in performance goals.
- Regularly survey employee attitudes about pressures to disregard ethics.
- Assess the ethical culture in the company and provide support in any weak areas.
- Reinforce cultural norms on the unacceptability of performance without integrity.
- Ensure that company ethics and compliance programs are of high quality.

While unethical behavior should be discouraged, it is important that proper behavior be rewarded to establish an ethical culture. One way is to transition from periodic formal performance evaluations to routine and ongoing feedback from supervisors to employees. An informal appraisal system provides instant feedback so employees know where they stand and how they can improve their performance without waiting for the annual review. This can also help to build trust in the performance evaluation system.[8]

Conclusion

The challenges in today's workplace of building an ethical culture are more pronounced than ever. Human resource professionals, in partnership with management, should not only lead by example to create a culture of mutual respect but also motivate colleagues to do the same. The organization will be stronger as a result.

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References

1. Corporate culture: the center of strong ethics and compliance. *The Wall Street Journal*. January 19, 2018. https://deloitte.wsj.com/cfo/2018/01/19/corporate-culture-the-center-of-strong-ethics-and-compliance/. Accessed August 5, 2019.

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Brian Bass


Melissa L. Bogen


Lori De Milto


Gail Flores

Q What advice do you have for new freelances?

A For the new freelance with less than 1 year of freelancing experience:

- Don't let the fear of failure hold you back from making mistakes. If you can't make mistakes, you can't make anything.
- Learn from every mistake you make, and don't make it again.
- Being a great medical writer will get you in the door, but being a great freelance medical writer will get you back in the door again.

For the new freelance who is also new to medical writing:

- Knowing how to write doesn't make you a great writer any more than knowing how to think makes you a great brain surgeon. Take every basic writing workshop you can find, no matter how much you think you know.
- Knowing how to write doesn't make you a good business person any more than being a good business person makes you a good writer. Successful freelances need to be good at both.
- See my response (above) for 3 more important tips!

— Brian Bass

Before I started my business, I consulted with 2 business advisors, 1 in New York (American Women's Economic Development, which offered free advice for women starting a business) and 1 in Palo Alto (paid). Additionally, I took the Small Business Association's SCORE workshop (free) on starting a new business. I recommend anyone planning to start a business take a SCORE workshop—and consider paying a professional consultant in the future, as necessary.

What I wish I had been told but was not (or perhaps did not listen well enough) was how critical it is to set up your own 401K or other retirement plans immediately, from Day 1. Always take a percentage of all income and put it aside for retirement (the amount and investment medium at your own discretion). I was advised quite clearly to put aside money as a cushion to draw upon during lean times—and indeed I did this, much to my advantage. But I did not put quite enough away for a robust retirement.

So… all you newly self-employed medical writers heed this advice: start saving now, regardless of your age, today!

— Cathryn Evans

If you want more success and less stress, do the hard work early. Many freelances start out thinking that clients will just somehow find them. I call this magical thinking, because it just doesn't happen. We attract clients by doing the right things: developing a marketing infrastructure that's focused on the needs of clients and then actively marketing to them. This is work.

Your LinkedIn profile, AMWA Freelance Directory listing, and website are key parts of your marketing infrastructure. They all need to clearly explain what you do and how what you do benefits your clients.

But having a great marketing infrastructure isn't enough. If you want clients who give you work you enjoy and pay you well, instead of taking whatever work comes along, you need to find them and then market to them. Developing prospect lists and then crafting a customized email to each client is an effective way to attract clients.

You also have to network actively through professional associations. This will help you get clients (mostly through referrals) and meet other freelances who can provide advice and support (this is really important when you're starting out and aren't sure what's normal and what's not).

Once you're established, if you do great work for your clients and build a strong network, more clients will find you (through referrals). But you need to build your business before this happens.

— Lori De Milto

Some advice for a new freelance:

- Treat your work as a freelance *business* from the very beginning. Like every new business, you need to invest in the tools you will need for success. This includes hardware (eg, a reliable computer, cell phone, printer, scanner, and even a second monitor if possible); software (eg, the most recent version of Microsoft Office, Adobe Professional [to annotate PDFs], and an accounting program); subscriptions (journal or textbook sites, a medical dictionary, social media scheduling); and the things that show your clients and potential clients that you are a professional (a logo,

business cards, a Web domain, and even business incorporation). Join organizations, attend local functions, and travel to conferences. This upfront investment in your business will pay off in the future.
- Track the time it takes to do every single task, so that you'll be able to estimate fair project fees now and in the future. This includes writing, research, email, phone calls, and travel. I use an online time tracker that I can also access on my phone when I'm working without WiFi or am away from my computer.

— Gail Flores

New freelance editors (<1 year):
One of the biggest questions for freelances just starting out is what to charge. Many people don't like to talk about money, so finding out what others charge can be challenging. Begin researching rates by checking AMWA's 2019 Medical Communication Compensation Survey results (https://www.amwa.org/page/Salary_Survey). The 2019 Survey results noted mean hourly rates of $113/hr for writers and $93/hr for editors, which is higher than the rates from the 2015 survey.

If you wish somebody, anybody, would just give you some idea of the going rate for various editorial tasks, then you could look at the editorial rates chart published by the Editorial Freelancers Association (https://www.the-efa.org/rates/). The big caveat is that the EFA rate chart is on the low side (consider them beginning rates) and should be considered only as a rough guideline because the posted ranges apply to all sorts of industries. The medical communications industry commands higher rates, perhaps 60% or more than what's listed in the EFA's chart. For example, the EFA chart lists $60 to $70/hr (80¢ to 95¢/word) as the range for medical writing.

Part of what to charge comes from knowing your expenses and having a business mindset. Read this book from cover to cover: "*What to Charge: Pricing Strategies for Freelancers and Consultants*," by Laurie Lewis (https://www.amazon.com/What-Charge-Strategies-Freelancers-Consultants/dp/143276764X). Without telling you specifically what to charge, Laurie reveals the factors that go into deriving a rate for yourself, so you can apply them to your specific situation.

— Melissa Bogen

Q What advice do you have for midcareer freelances?

A For the midcareer freelance with 3 to 5 years of freelancing experience:
- Self-confidence is key to growing your business. Let clients pay you to gain experience in new therapeutic areas.
- On the other hand, know when to say "no" to a project that's too far beyond your current knowledge and ability.
- Trust your gut. It's better to have turned down a client or a project you should have taken than to take on a client or project you should have turned down.

— Brian Bass

Be careful how you quote a fixed-fee project. Be sure you have a clearly written, ironclad contract, one that has been approved by your attorney. Do not trust a prospective new client unless s/he has been referred by someone you know, or unless you have researched him/her and the company well. The most important thing is that your description of the project and the *precise terms of the contract are described in detail*. Nothing ambiguous. Contracts should specify not only what a price includes, but what it does NOT include. Especially with fixed-fee quotes, a client can suddenly come up with all sorts of extra "scope creep" activities that you failed to clarify in the contract.

Here is another one: Be very careful about providing a full project proposal until you have a signed contract—or unless the client agrees to *pay you for your time designing and writing a project proposal*. Copyright any proposals you create, which you can turn over to the client once you have been awarded the project. In many cases, once you have written a very good project proposal, essentially you have given the prospective client the benefit of your creative process/work, as well as a step-by-step method of executing it and all the important cost increments along the way. Many unethical people will obtain multiple bids/proposals from different consultants, then choose the cream from each one and execute the project in-house or with a vendor who agrees to implement *your* ideas at a lower cost.

— Cathryn Evans

It's time to start thinking strategically about your business. When you're starting out, you're so busy launching your business, getting your first clients, and then doing great work for them that it's difficult to see the big picture. But once you've been freelancing for a few years, take some time to think about where you are and where you want your business to be.

I didn't do a strategic business review for many years, until I lost a few big clients. When I looked at the type of work I had been doing, I realized that much of it wasn't what I liked best. So, I refocused my marketing and started going after—and attracting—much more of my preferred work. I should have started thinking strategically much earlier.

After your initial strategic business review, do a year-end review to continually evaluate your work, your clients, and other aspects of your business.

— Lori De Milto

Some advice for a midcareer freelance:

- Consult past and current AMWA Medical Communication Compensation Surveys to ensure that you are charging enough. Don't be afraid to demand a market rate! When freelances work at low rates, it doesn't just hurt them—it hurts all of us.
- Charge project fees! If you estimate properly, this will ensure higher income. Proper estimation comes from your own time tracking data and conversations with other writers. If you don't know what to charge for a document, you should ask other writers how long it takes them to write such a document, not how much they charge for it.
- Create a document with a list of lessons learned and things you've promised yourself you will always do (eg, request payment within 30 days, not work on weekends) or not do (eg, take on additional work from a client who doesn't pay on time or is just difficult, or not follow your gut instinct about a project or client). We experienced freelances often advise on how to work, yet go back to our offices and do some of the things we advise against, perhaps because we're going through a slow period or otherwise feel generous. Refer to the document often to remind yourself of the rules you need to follow to ensure a successful business.
- Create a mantra, and stick to it! Mine is: *To do work that I enjoy for clients who pay well and treat me well.* I refer to this whenever I consider new projects.

— Gail Flores

At midcareer, freelance editors may be wondering how to increase productivity and gain more clients. You can increase productivity by keeping abreast of tech trends and ensuring your software and hardware are up to date. Never scrimp on your business. Always spend the money to have the best printer, software, etc that you can afford. Because as freelances we almost always work remotely, our reputation rests partly on our virtual presence in a company. Make sure, for example, that you have the full professional version of Adobe Acrobat to match what your clients use, or, if you're opting for a less-expensive program that's a "reasonable facsimile" of Acrobat, you know exactly how that PDF program interacts with Acrobat files. You don't want your clients to be dismayed at your output because the functionality doesn't match the software they use.

For gaining more clients, you should have a well-developed LinkedIn profile and a network of colleagues gained from volunteering in AMWA and word of mouth who may refer you for work.

Looking for techniques to develop your business? Check out Lori De Milto's website, The Mighty Marketer (http://www.themightymarketer.com/author/lori/) and read her practical and inspirational blogs on finding high-paying clients.

— Melissa Bogen

Q What advice do you have for freelances who are nearing retirement?

A For the late-career freelance approaching retirement:

- There's no reason to stop if you don't want to. Slowing down is an option.
- There's no reason to keep going if you don't want to. Just make sure you have a plan to stay mentally stimulated, intellectually challenged, and physically engaged.
- You had a commitment to build the career you wanted. Don't be afraid to build the future you want as well.

For the late-career medical writer thinking about retiring to freelance:

- Leverage your contacts including the company you work for now. They know what you can do and represent the path of least resistance to getting started.
- Be prepared to be busier and work harder than before you retired.
- If you plan to juggle both retirement and freelancing, let me know how that works out!

— Brian Bass

It is essential to stay current with the various ways of doing business today, to be more careful about contracts and terms of payment, and to consider carefully whether and when to accept or reject projects from some of the unethical people who seem to have emerged in this business over the last 10+ years or so. And again, it is important to try to put away at least 20% of gross earnings when/if you can!

— Cathryn Evans

If you're close to retirement, like I am, you should be thinking about whether you're doing the type of work you really want to be doing and you should have a retirement plan. I'm 59 now

and while I don't plan to retire until my 70s, I am thinking about what I want my future to look like.

I'm focusing now on the type of work I like best: content marketing mostly for hospitals/health systems, health care marketing agencies, and disease-focused associations. I still do other types of work for a few long-term clients but I'm not actively pursuing other types of work. If your current work isn't optimal, this is the time to start making changes. Now that you've got a lot of experience, it will be easier for you to do this.

In developing a retirement plan, freelances don't have to choose between working full-time or not working at all. We can work part-time in "retirement" to stay busy and make some extra money. That's what I'm planning to do. I'd like to taper off my work from about 50 hours a week to eventually about 10 to 20 hours a week. And I'm only going to do work I really enjoy for low- or no-stress clients (I always only work with clients who pay me well).

The other big part of a retirement plan is investing enough money to live well. I'm not a financial expert so all I'm going to say is that if you haven't been investing enough, start putting away as much as you can in a SEP (Simplified Employee Pension) plan or other retirement plan for self-employed people.

— Lori De Milto

Hey, I'm not there yet! I'm going to work until lunchtime before my funeral!

Realistically, though, long-time freelances need to appraise how they can remain relevant in our field. Continuing education—brushing up on tech skills—remains a priority. Don't let your reluctance to learn something new lead clients to look elsewhere for needed skills.

Need a refresher on statistics? Take a course at an AMWA chapter meeting or the annual conference.

Have multiple clients asked if you can create, fix, or edit an EndNote library? Buy AMWA's online learning course, "Harness the Power of EndNote: Manage Your Library's Data," by Stephen Palmer (http://amwa.mycrowdwisdom.com/diweb/catalog/item/id/816322). If you need to buy the EndNote program, use your AMWA member 20% discount (https://www.amwa.org/page/Partner_Discounts).

Lastly, as a late-career freelance who is *not* approaching retirement soon, I advocate that every freelance should have an emergency fund, especially if you do not have short-term disability insurance. This fund can be an online savings account, which often has a higher annual percentage rate for interest than a regular bank. Look at Discover (https://www.discover.com/) or Capital One (https://www.capitalone.com/bank/), both of which my accountant uses and recommends. I've set up a certain amount of money to be diverted automatically and regularly from my checking to my savings account.

— Melissa Bogen

Appositives *continued from page 171*

Choppy or Smooth?

An apposition is an example of a hyperbaton—a figure of speech in which a phrase is made discontinuous by the insertion of other words. The term *hyperbaton* came from Greek words meaning "stepping over." In other words, the appositive can be a stumbling block that your reader has to step over. So, if you want your prose to flow smoothly, you will be cautious about using appositives. Omit the unnecessary ones and consider converting the necessary ones to relative clauses by adding a relative pronoun and a linking verb:

- 😑 Glucose, another hexose, is an important energy substrate.
- ☺ Glucose, which is another hexose, is an important energy substrate.

By using a relative clause instead of an appositive, you can avoid the garden-path effect. A garden path sentence is a sentence that is unambiguous but that initially leads the reader into a false interpretation. The garden-path effect is annoying because the reader must go back to the beginning of the sentence and reparse it. Appositives can create a garden-path effect because the reader may not be sure initially that the appositive is an appositive, as opposed to being the second item in a list. Another way to avoid the garden-path effect is to set a nonrestrictive appositive off with parentheses or dashes. Thus, you make it clear that the element is parenthetical as opposed to being just the next item in a list.

Laurie Endicott Thomas is the author of five books, including Not Trivial: How Studying the Traditional Liberal Arts Can Set You Free *(www.nottrivialbook.com)*

Traditional Versus Self-Publishing: What's Best for Your Book?

Barbara Goodheart, BA, ELS[1] **and Clyde Goodheart, MD, MBA, MS**[2] / [1]President, Barbara Goodheart, Inc, Fort Lauderdale, FL; [2]President, Clyptek, Inc, Fort Lauderdale, FL

Is there a book kicking around in your head? Maybe something in the medical field, or a novel, or a relative's memoir? Many of our fellow AMWA members have written and are selling books. What are *you* waiting for?

Networking

A few months ago, we brought our Kindle with one of our published e-books, *Blood Glucose Levels and Diabetes Control* (Figure 1), and a draft copy of our latest print creation, *Life's Code: How DNA says who we are* (Figure 2), to show-and-tell at an AMWA Chapter gathering in South Florida. After the initial *oohs* and *aahs* upon seeing the books, one of the first questions was, "Did you seek an agent and traditional publisher or go the self-publishing route?" Thus, a most interesting conversation about book publishing options ensued.

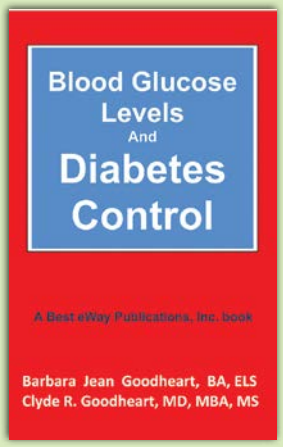

Figure 1. Cover for Diabetes Series, Book 1, Second Edition (print edition)

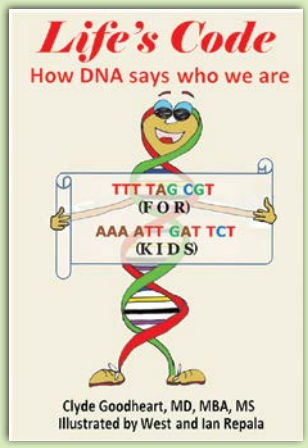

Figure 2. Cover for *Life's Code* (print edition)

So, You Want to Publish a Book?

We understand that the idea of publishing a book can be intimidating. The traditional route can be frustrating: being bogged down, querying agents and publishers, drafting a lengthy book proposal, writing sample chapters, revising, and waiting, rewriting, and waiting again. And often in vain. However, the thought of self-publishing can be just as frightening. We know because we've been there. As a writing team, we have self-published both print and electronic books through Amazon. Before that, we each published our own books the traditional way, through publishers.

Having experience with both options, our bias is toward self-publishing—and it seems we are not alone. Fellow AMWA member Helen Osborne shares our sentiment. When her traditional publisher was bought out, Helen self-published—and she's pleased with the results. "Best of all," she says, "I have full control of the decisions ahead."

Who Knew?

Self-publishing predates Amazon by centuries. In fact, in 1685, Martin Lister, MD, enlisted his 2 daughters as illustrators and self-published a heavily engraved 4-volume work on mollusks and shells, thus keeping control and sidestepping "the expensive commercial route," according to the journal *Science*.[1]

Consider This

Things to consider before deciding whether you want to go the traditional publishing route or self-publish include market research, time, royalties, sales and marketing, and control, to name a few.

Before you start writing, you need to do some initial market research to find what's selling in your category.

Amazon updates their titles' sales ranking every hour. We use KDSpy to help us with that task. KDSpy, which you can buy on the Internet, shows the rankings for any category and creates a table that includes the monthly unit and dollar sales. It also indicates keywords in titles. Choose some best-seller keywords for maximum exposure.

When time is of the essence, self-publishing gives you the option to publish electronically. As timeliness is vital, especially in the medical field, writing an e-book and uploading it within several months is a win. And if news breaks, demanding a revision, a quick edit is all it takes to give you a new edition in just a few days.

> The traditional route can be frustrating: being bogged down, querying agents and publishers, drafting a lengthy book proposal, writing sample chapters, revising, and waiting, rewriting, and waiting again.

Traditional publishing, on the other hand, doesn't allow for any of this. Traditional publishing typically means wait times of more than a year before publication[2]—and that's *after* you've written and revised your book. There's undoubtedly no pathway for a quick edit and "repub" should new information come to light. Also, many large publishers are closed to "unagented" work, according to the Science Fiction & Fantasy Writers of America. The few exceptions are likely to encounter a wait of anywhere from 1 to 6 months[2] before they even see the publisher. We're too type A for that!

For example, in June 2018, Clyde had an idea for a children's book. Seven months later, he uploaded the prefinal print version, titled *Life's Code*, distributed proof copies for beta and advance reviews, and planned the upload for sale several weeks later. That's a little over 8 months from concept to market. If he'd wanted an agent or traditional publisher, we'd probably still be looking!

Money, Marketing, and Control

When it comes to royalties, self-publishing wins again. With Amazon, your royalty is approximately 70%[3] on e-books (figured on the difference between the sales price and the few cents Amazon charges for download). With printed books, Amazon subtracts the printing cost (quoted in advance) from the sales price (set by the author), so the author receives approximately 60% of the difference.[3]

The Nonfiction Authors Association estimates that for a book selling at $20, traditional publishers pay about $1.25 per book in royalties.[4] Contrarily, selling your self-published book at a retail store could fetch you $5 to $10 per book, while selling it online could get you as much as $16! Remember that traditional publishers make money by spending money on the bigwigs. With rare exceptions, other authors don't get significant advances or generous contracts. Some traditional publishers offer up to 15% of the net profit, called *publisher's net*. Others provide the mysterious *percentage of publisher's net*, a term that seems to mean "what's left in the company's budget after bookstore promos and discounts, and wining-and-dining the Grishams."[5]

Another thing to consider is that Amazon doesn't charge for uploading print or e-books. All books are printed on demand. So, no boxes of books in your garage! (But remember, it is essential to buy a proof copy to proofread before you hit the "Publish" button.)

A traditional publisher might offer some marketing hints or spring for a signing or two at a local book store, but unless you're a VIP, marketing is in your hands. Don't be fooled by the "marketing benefits" claims of traditional publishers. You're better off hiring a professional or doing it yourself.

Finally, if you expect control, remember that traditional publishers typically take full control of a book, designing the cover and interior, selecting fonts, and formatting content. Self-publishers who demand control of their work may need to pay a designer or do it themselves. We're not artists, and we created the covers for all our books.

Notwithstanding, when formatting or converting an e-book to print, some writers feel that the Amazon templates result in *look-alikes*. For this reason, we chose to format our books using Word. Word allows you to put the title of the book and the page number on each page as a header, insert images, and set the page (trim) size before you start writing. Then save it as a PDF with embedded fonts (for e-books, save as Web Page filtered), upload to Amazon, and you're done.

If you self-publish, you have complete control. You set the sales price, and you can choose to hire out any part of the process, or you can choose to do it all yourself, but be sure

to have a second pair of eyes review it, such as a professional editor. It's up to you!

Cover Design

A book cover needs to be eye-catching, especially on Amazon, and the title and any key details need to be readable (think thumbnails!). For e-books, Amazon needs only the front cover; for print books, they need both the front and back. Some authors use FIVERR.com to design covers, but for *Life's Code*, we used our great grandkids, who did the cover and all the illustrations—and the results were delightful (Figure 2)!

For the print version of our first diabetes book, we chose a large font and bright colors to make it stand out (Figure 1). For print books, we used the Amazon cover template, customizing it for each book. We entered the trim size and number of pages, which sets the spine width, then downloaded the template. Using Photoshop, we pasted the images for the front and back cover into the template, saved it as a PDF, and we were done. The book is ready to be uploaded.

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References

1. Newman C. Illustrating nature. *Science*. 2019;363(6425):353.
2. Brewer RL, ed. *Writer's Market 2019: The Most Trusted Guide to Getting Published*. 98th ed. Cincinnati, OH: Writers Digest Books; 2018.
3. Amazon, Inc. Royalty options. Kindle Direct Publishing website. https://kdp.amazon.com/en_US/help/topic/G200644210 /. Accessed May 20, 2019.
4. Chandler S. 12 reasons why self-publishing kicks butt over traditional publishing. Nonfiction Authors Association website. https://nonfictionauthorsassociation.com/12-reasons-why-self-publishing-kicks-butt-over-traditional-publishing/. Accessed May 20, 2019.
5. Field A. How do publishers pay authors? The Bindery website. Updated May 30, 2018. https://www.thebinderyagency.com/blog/howdopublisherspayauthors. Accessed May 20, 2019.

HELPFUL SITES

The Amazon website provides step-by-step instructions on self-publishing:
https://kdp.amazon.com/en_US/help/topic/G202187740.
Specific detailed instructions from KDP:
https://kdp.amazon.com/en_US/help/topic/G200645680?fbclid=IwAR2MA-U3VLVgFa7WqqpImdjYi9lxnd0liH0W7-DOJiEK2GXL2HYf6bQNVEA.

The Amazon website lists, but does not endorse, service companies for almost everything:
https://kdp.amazon.com/en_US/help/topic/G201723120

Amazon also lists many how-to books, with some free e-books:
https://www.amazon.com/s?k=books+on+self+publishing+with+amazon&ref=nb_sb_noss_2.

The Nonfiction Authors Association offers a handy *Self-Publishing Checklist*:
https://nonfiction.lpages.co/self-publishing-super-simple-checklist/.

AMWA member Helen Osborne offers her take on self-publishing:
BMI35: *How to Go from Traditional to Self-Published: Practical Ways to Communicate Your Message*:
www.bookmarketingmentors.com/traditional-to-self-published.

Everyday Ethics *continued from page 179*

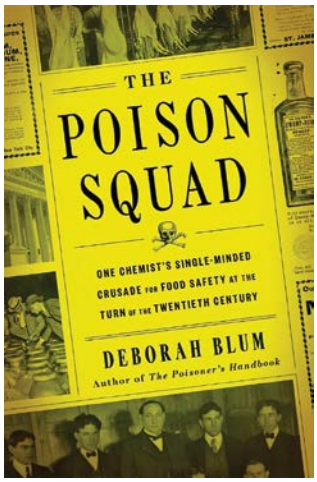
2. Stanton P. Building an ethical culture: the role of human resource practitioners. https://www.ibac.vic.gov.au/publications-and-resources/ibac-insights/edition-3/building-an-ethical-culture. Accessed August 4, 2019.
3. More than half of employers have found content on social media that caused them not to hire a candidate, according to recent CareerBuilder survey [press release]. Chicago, IL: CareerBuilder; 2018. http://press.careerbuilder.com/2018-08-09-More-Than-Half-of-Employers-Have-Found-Content-on-Social-Media-That-Caused-Them-NOT-to-Hire-a-Candidate-According-to-Recent-CareerBuilder-Survey. Accessed August 4, 2019.
4. Lampe C, Ellison NB. Social media and the workplace. Pew Research Center website. https://www.pewinternet.org/2016/06/22/social-media-and-the-workplace/. Accessed August 4, 2019.
5. Heathfield SM. Surfing the Web at work: what are an employer's alternatives to monitoring employees online? The Balance Careers website. https://www.thebalancecareers.com/surfing-the-web-at-work-1919261. Updated June 25, 2019. Accessed August 4, 2019.
6. Wright AD. What HR can do about cyberbullying in the workplace. SHRM website. https://www.shrm.org/resourcesandtools/hr-topics/technology/pages/what-hr-can-do-about-cyberbullying-in-the-workplace.aspx. Published May 13, 2016. Accessed October 4, 2019
7. Ethics and compliance initiative. The state of ethics & compliance in the workplace. https://43wli92bfqd835mbif2ms9qz-wpengine.netdna-ssl.com/wp-content/uploads/2018/05/GBES2018-Final.pdf. Published March 2018. Accessed August 5, 2019.
8. Kokemuller N. What can serve in the place of a performance appraisal? *Houston Chronicle*. https://smallbusiness.chron.com/can-serve-place-performance-appraisal-15491.html. Accessed October 4, 2019

MEDIA REVIEW

The Poison Squad: One Chemist's Single-Minded Crusade for Food Safety at the End of the Twentieth Century

Deborah Blum

New York: Penguin Press, 2018. 330 pp. Hardcover. $28.00



You probably haven't heard of Dr Harvey Washington Wiley, but without him, we wouldn't have the US Food and Drug Administration. *The Poison Squad*, as the book's subtitle suggests, tells the story of this indefatigable chemist whose quest to keep adulterated food and dishonest labeling out of the American food supply made him a household name at the time. His biggest achievement, the passage of the Pure Food and Drug Act in 1906, was often called "Wiley's Law" in tribute to his unrelenting work in the then-new field of food safety.

There is much in Ms Blum's recounting—political deals and companies obsessed with profits at the expense of workers and consumers—that sounds all too familiar today. Yet while reading this lively book, occasionally I had to remind myself how pioneering Wiley had been. For example, in 1890, when he was chief of the Bureau of Chemistry in the US Department of Agriculture, Wiley hired Alex Wedderburn, a journalist, to write brochures explaining to consumers (usually housewives) how to read labels when food shopping, what false advertising meant, and the importance of safety in the food supply—"Honest food," as Wiley put it. This may have been the first time a federal employee sought to communicate directly to the members of the public, to educate them about how they could protect their health.

Wiley eventually became a national celebrity through his monthly column for the magazine *Good Housekeeping*. In his column, he explained the basics of food chemistry, clearly and without condescension, to an overwhelming female audience. He knew that women concerned about their families' health were eager for this information, and he understood the power of mobilizing women's concerns (taking a leaf from the women's suffrage movement, whose leaders were his allies).

The book takes its title from Wiley's audacious idea to test the effects of consuming borax, a common food preservative, in a controlled clinical trial. Twelve brave young men—primarily low-paid federal employees (and bachelors) for whom free meals were a motivation—were recruited for the 6-week experiment, conducted under strictly controlled conditions in the basement of the US Department of Agriculture building. Participants ate all their meals there, and their seating was arranged so that they did or did not receive borax-laced meals (without them knowing which was which). Participants had to keep food diaries, pledge not to eat anything outside the test kitchen, be examined by physicians every 2 weeks, and bring in "every particle of their excreta," in Wiley's words, for testing. Remarkably, participants dropped out after several weeks not because of the onerous routine, but because of multiple side effects. A repeated experiment testing the equally common preservative benzoate yielded even more alarming results. These studies became part of the evidence that finally propelled passage of the Pure Food and Drug Act, despite determined lobbying from food and beverage makers.

Blum knows how to tell an engaging, and sometimes revolting, story. Yet she avoids the easy way out of demonizing food manufacturers and grocers, some of whom seemed genuinely unaware of adulterations in what they sold and some who felt forced to put various additives in their products to make profits in the face of rising costs.

If you enjoy American history, are a food buff, or have studied nutrition or chemistry, you will enjoy this book. The extensive quotations from key players bring the narrative to life, and the footnotes and bibliography showing the author's extensive use of archival materials is a gold mine for anyone doing research in this area.

Reviewer: *Karen Potvin Klein, MA, ELS, GPC, MWC®*

Karen Potvin Klein is the owner of Clarus Editorial Services, a biomedical grant consulting and manuscript editing company in Winston-Salem, NC.

SOCIAL MEDIA

Social Marketing and Social Media: Friends with Benefits

Claudia Parvanta, PhD / Professor, College of Public Health, University of South Florida, Tampa, FL; Co-Director, WHO Collaborating Center for Social Marketing and Social Change

For decades, when telling someone I did "social marketing," responses ranged from "I hate telemarketers" to "Is that like communism?" or, most often, "What is that?" Now, 1 out of 5 students who sign up for our introductory graduate class in social marketing are surprised to find out we're not teaching them how to use HootSuite. ("You give credit for Instagram?") This is a slight exaggeration, but the point is that while social marketing and social media share an important adjective, they are more like the western United States and Route 66 than an apple and an orange.

Let's Begin With Social Marketing

Lefebvre and Flora defined it in 1988 as "[t]he design, implementation, and control of programs aimed at increasing the acceptability of a social idea, [or] practice, [or product] in one or more groups of target adopters. The process actively involves the target population who voluntarily exchange their time and attention for help in meeting their needs as they perceive them."[1,2,a] Nancy Lee has called it simply "Behavior change for good." This is consistent with the International Social Marketing Association consensus definition, which also emphasizes behavior. To be doing social marketing requires a focus on specific groups of people, (ie, one size does not fit all) and seeking to understand the social, environmental, and cultural factors that lead to health problems and potential solutions. If it sounds like health education or health promotion, they are close cousins. But social marketing started evolving away from them as early as the 1950s.

In 1952, psychologist G. D. Wiebe published an article in *The Public Opinion Quarterly*[3] with the intriguing title of "Merchandising commodities and citizenship on television." He referenced Kate Smith's 1943 war bonds campaign, carried out over CBS television and radio networks. According to Wiebe, it had all the important merchandizing mechanisms in place to succeed. Among these were the "force of motivation" (buying the bonds was a direct aid to the fighting men), the minimization on several levels of both physical and psychosocial distance (it was Kate Smith on the TV or radio in your living room; you used your phone), and the process of purchasing the bonds was made very easy (you called a dedicated phone line). Personal sacrifice of money was accounted for in the messaging and, if you got a busy signal when you called, you interpreted it as "everyone is doing it—I'm on the bandwagon." There is more to this groundbreaking article, but it foreshadowed a revolution in using the strategies and tactics of commercial marketing to promote ideas, services, and products that were for the common good.

By the late 1960s, leading advertising and public relations executives began realizing that rather than doing socially beneficial work on the side and pro bono, this work could stand on its own. Richard Manoff founded the first social marketing agency in 1967. Bill Novelli and partners established Porter Novelli in 1973. From there, companies popped up around the "beltway" in Washington, DC, and up the Amtrak corridor to Boston, serving the needs of clients such as the US Agency for International Development, the National Heart, Lung, and Blood Institute, the National Cancer Institute, and, later, the Centers for Disease Control and Prevention as well as not-for-profits such as the Diabetes Foundation and American Heart Association. The issues overseas were chiefly safe and effective family planning, clean water, immunization, combatting hunger and malnutrition, preventing human immunodeficiency virus, increasing education opportunities for girls, and so on. Domestically, the focus was on knowing your blood pressure,

[a]Quoted, with added words in brackets, in Parvanta C. Behavior change communication; Theories, models, and practice strategies. In: Parvanta C, Nelson D, Harner R. *Public Health Communication. Critical Tools and Strategies.* Burlington, MA: Jones and Bartlett Learning; 2018.

not smoking, accepting neighborhood facilities for persons with cognitive impairment, preventing and treating diabetes, and, eventually, human immunodeficiency virus prevention. The challenges were enormous. Watching the success of Coke, Pepsi, and, at the time, the tobacco industry in building enormous profits brought the likes of anthropologists, epidemiologists, and academicians in communication and marketing to band together under social marketing's umbrella to emulate their methods but not their need to return profits to stockholders.

In 2002, academic social marketer Alan Andreasen laid out 6 criteria considered "benchmarks" for social marketing.[4] These were modified by French, Blair-Stevens, McVey, and Merritt[5] and eventually became canon for organizations such as the National Social Marketing Center of the United Kingdom, the European Social Marketing Association (ESMA), and International Social Marketing Association (see Box 1). Perhaps the most essential criteria are the concepts of audience segmentation, or "one size does not fit all," and that research is necessary to design effective strategies that will appeal to different groups. The benchmarks are processes used to create and promote a "product," which has 4 attributes summarized as "the 4 Ps." The Ps stand for the product's *p*ositioning, which is a combination of its attributes and benefits, its *p*rice or cost, its *p*lacement, and how it is *p*romoted.

We can demonstrate how the 4 Ps work in imagining a public health campaign against teenage vaping:

- The product's positioning: Vaping encompasses both a tangible product and a behavior. Both the device itself and the liquids are tangible products to which a teen might attach some value. A recent study suggests that the JUUL and similar vape pens appealed to a segment of teens who viewed them like smartphones, and hence, cool to own and be seen using. The behavior of vaping has a social value depending on the teen's peer group. Is it necessary to come up with an alternative tangible product? Hookah smoking still goes on. So, both the tangible product and the behavior of vaping need to be researched to develop a successful counter-marketing strategy.
- The price: Taxing tobacco products is shown to have significantly reduced teen smoking over the past 10 years, so raising the tangible cost is 1 component in this equation of "price." Selling vaping pens and liquids to anyone under the age of 21 is on the table in some states (at the time of this writing), which would further increase the risk, and hence, cost of doing the behavior in public. But the rest of the price calculation requires balancing how a teen's peer group views the behavior and what kind of "rewards" the teen feels by either vaping or not in this peer group. This psychological cost is what social marketers tend to work with, leaving the policy change to government regulatory bodies.
- The place: Like price, place has a tangible component. Just as it is illegal to smoke indoors, laws concerning vaping are beginning to emerge. But to what extent will this drive vaping into spaces that teens feel are "safe to vape" or make it more "cool"? Place in social marketing also refers to where communications about vaping would most effectively be seen by teens—which leads to the promotional strategy.
- The promotion: To de-market vaping, we need to come up with offerings that a teenager would value more than how he or she perceives the benefits of vaping, even if it becomes illegal to vape. As Bill Smith, a contemporary leader in the field of social marketing, famously said, you must make the alternative (to a harmful behavior) "fun, easy, and popular." And there are multiple ways to do this, by making the harmful practice more costly (in terms of money or social perception); making the alternative easier; creating a social norm among teens for not vaping; finding a way to make not vaping fun (ie, alternative uses of time); and finding the right promotional strategy, including what to communicate, across what channels, and using what media, to reach your intended audience or user group.

So, This Brings Us to Social Media

Others in this journal have written about the frontiers being opened by social media, including, as of today, about 21 top sites to consider. See Box 2 for a rundown of monthly active users. An important research tool a social marketer might use is customer journey mapping to understand where our intended users "go" (physically in space, online, cognitively) while they are in the process of deciding what to do. We would

Box 1

Benchmark Criteria for Social Marketing

The following criteria are used to determine if an effort uses accepted social marketing principles or not. According to Dr Susan Kirby, Associate Editor for *Social Marketing Quarterly*, the journal refers to these criteria when reviewing manuscripts for publication:

1. Clear focus on behavior, with specific behavior goals.
2. Uses consumer and/or market research
3. Is theory-based & informed
4. Is insight driven
5. Uses exchange concept
6. Uses a competition concept
7. Uses a segmentation approach
8. Integrates a mix of methods (or Marketing Mix – 4 P's and beyond)

then select social or traditional media channels that are best suited to these parameters. If, for example, we are trying to promote something that is important for an older generation, such as colon cancer screening, we might use Facebook because—as everyone knows—it is your mother's (grandmother's) social media site. But we might also use TV, radio, outdoor, and YouTube. If we are trying to reach teens, we would select different social media platforms where they tend to hang out.

There are some very effective strategies using social media, particularly relying on its interactive format and user-generated content. Some innovators in this space include Rescue Agency, which developed the concept of "Peer Crowds" to describe their groupings of teenagers and young adults into audience segments. Borrowing labels from music, anti-smoking messages for "hip-hop" teens feature urban music and dancing; "alternative" kids have messaging around the harm that tobacco companies do testing products on animals; and "country" teens are shown how much money they can save for their hunting and fishing gear if they don't spend it on "dip" or cigarettes. Branding campaigns (eg, Fresh Empire for hip-hop; Down and Dirty for country), creating live events, and using social media are combined to bring specific content to different teen peer crowds.

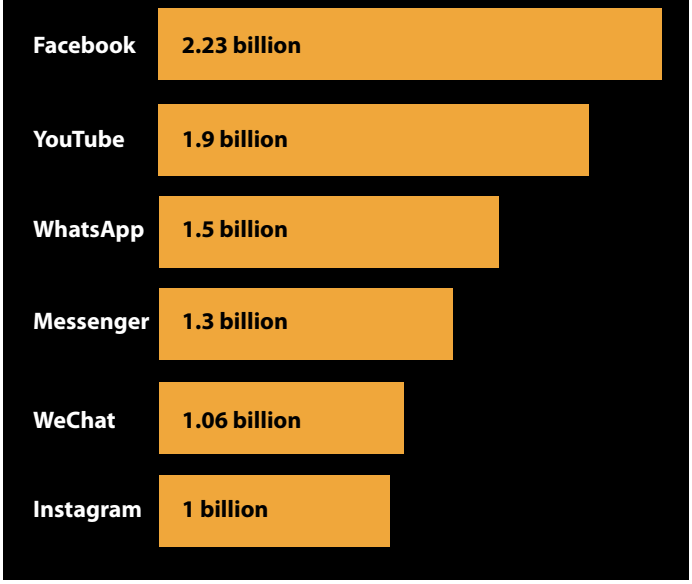
How Can Medical Writers Use Social Marketing and Social Media Together?

There are several ways medical writers might engage in social marketing, with or without social media:

- Identify potential clients and work with them: Public sector, nonprofit, and academic organizations are developing socially focused campaigns. These always involve creation of "copy" to be used in print, video, websites, and social media posts, let alone grant proposals and peer-reviewed publications. Your skills are needed! The Centers for Disease Control and Prevention, the National Cancer Institute, and the US Food and Drug Administration tend to fund most of the social marketing efforts in the United States, and the US Agency for International Development sponsors most of the international work. It makes sense to contact larger companies with which they contract or include yourself on small business opportunities. Both are available through https://beta.sam.gov/.
- Once working on a project, use social marketing to segment audiences and tailor content using secondary research, where available, or suggest ways to gather new insights.
- Beyond specific campaigns, public sector companies and nonprofits need to tell their success stories to funders, policymakers, and the public at large. These, too, need to be shared across different platforms to reach intended audiences.

Box 2

Social Media Platforms Ranked in Terms of Monthly Active Users



After that, Tumblr, Twitter, Reddit, LinkedIn, Viber, Snapchat, Pinterest, and some more popular overseas have a few million active users.
Source: https://buffer.com/state-of-social-2019. Accessed September 29, 2019.

Learn More

The University of South Florida will hold the 26th University of South Florida Social Marketing Conference in Clearwater Beach in June 2020, with *Social Marketing Quarterly* (the field's primary journal) as our publication partner. The University of South Florida offers online graduate course work in social marketing year-round. The Social Marketing Association of North America and its counterparts in Europe, Australia, Latin America, and globally are going strong. You have so much to give as a medical writer, and we hope to see you get involved.

Author declaration and disclosures: *The author is a professor in the College of Public Health at the University of South Florida and lead author/editor of several textbooks on health communication. She receives a small royalty on the sale of the textbooks from Jones and Bartlett Learning.*

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References

1. Lefebve RC, Flora JA. Social marketing and public health intervention. *Health Educ Qtly.* 1988;15(4):299-315.
2. Parvanta, CF. 2018, Behavior change communication: theories, models, and practice strategies. In: Parvanta CF, Nelson DE, Harner RN. *Public Health Communication: Critical Tools and Strategies.* Burlington, MA: Jones and Bartlett Learning; 2018:177-222.
3. Wiebe GD. Merchandising commodities and citizenship on television. *Public Opinion Quarterly.* 1951-1952;15(4):679-691. Available at: https://www.jstor.org/stable/2745955
4. Andreasen AR. Marketing social marketing in the social change marketplace. *Journal of Public Policy and Marketing* [Online]. 2002;21(1): 3-13. Available at: https://doi.org/10.1509%2Fjppm.21.1.3.17602
5. French J, Blair-Stevens C, McVey D, Merritt R. *Social Marketing and Public Health: Theory and Practice.* Oxford, United Kingdom: Oxford University Press; 2009.

FROM THE PRESIDENT

Inaugural Address

Ann Winter-Vann, PhD / 2019–2020 AMWA President

It's both an honor and a pleasure to take the gavel as the new president of AMWA. With the perspective of an amateur ballroom dancer, I have to admit it's a bit intimidating to step onto the dance floor as AMWA president. As I follow in the footsteps of so many exceptional leaders, I am grateful that so much of the choreography has already been mapped out. I also appreciate the fact that I am not alone on the ballroom floor; I'm supported by an outstanding cast of volunteers on the Board and in committees. And, as with my dance routines, I have the pleasure of working with an outstanding professional staff, whose support and training help me look good.

Getting started in medical writing was not as straightforward as getting started with dance. I couldn't just walk into my neighborhood studio, pay for a package of lessons, and dive right in. To become a medical writer, I needed a lot more. I needed the writing skills that I had developed over a lifetime of education; I needed the scientific knowledge that I had gained in college and in graduate school; and I needed a whole host of what I now know are soft skills: skills like collaborating with others, managing projects, and politely stalking people who were otherwise too busy to help. I needed a mentor who would teach me the nuts and bolts of regulatory writing—and I needed luck to land that first job.

I consider myself fortunate that all of those pieces came together; I was in the right place at the right time and happened to have the right foundational skills. I know many established medical writers have similar stories about landing in this career, either by accident or by luck—but that's not a great career strategy. Even with the advent of excellent academic programs in medical writing, new writers still face the impossible situation of trying to find a job when they have no experience, but they can't get that experience without a job.

I had the pleasure of moderating the inaugural Executives Forum, a gathering of directors of medical writing that AMWA hosted during the 2018 Annual Conference. I found it fascinating that this group of executives—leaders in the field of regulatory writing—expressed frustration with the flip side of this exact same problem. They struggled to bring in and train entry-level writers. As a result, they tended to hire only writers with experience, but everyone at the forum recognized that to be an unsustainable solution. To paraphrase Joan Affleck, Executive Director of Medical Writing at Merck and Co and leader of the Executives Forum, "We are all fishing from the same small pond. What we really need to do is grow that pond."

Following that meeting, AMWA worked in cooperation with a smaller group of medical writing executives to create a Medical Writing Training Outline, which is essentially a road map for companies to follow as they hire and train entry-level writers. This plan outlines not only the educational content and documents that entry-level writers need to learn, it also outlines the training and support that experienced writers need in order to successfully mentor these new writers. As a result, we now have an outline of educational content for both new and experienced regulatory writers in the corporate setting. AMWA's new Education Director is hard at work identifying which educational content we have—and what we still need to develop—to support this initiative. Stay tuned: you will see this training plan and the new programming rollout over the next couple of years. Of course, the new programming will be available to all members, in the form of webinars, workshops, and conference sessions, making it easier for anyone who is interested in improving their skills in regulatory writing, mentoring, project management, and soft skills.

This year's forum focused on problem solving in the areas of attracting and retaining writers; training, developing, and

engaging writers; new and emerging technologies that affect the medical writing field; and quantifying the value of medical writing. After a half-day session of brainstorming and discussion, we left the meeting with fresh ideas on how to support medical writers at all levels of experience. Again this year, I was struck by the collaborative nature of the meeting. Rather than viewing each other as competitors, these medical writing executives shared their challenges and frustrations. They also volunteered to work with AMWA to find solutions to address these common concerns and to come up with tangible ways that AMWA can further support writers. I will be excited to see the new initiatives that develop as the result of these conversations.

AMWA's staff have been extremely busy this year. I hope you noticed the new workshops that were offered in San Diego; these were all taught by new faculty. We are making an effort to train new workshop leaders, so if you are an expert on any aspect of medical communications (or any of the other skills that medical communicators need in order to be successful), I would encourage you to reach out to AMWA headquarters. We would love to have your help in developing or teaching new workshops.

Another exciting initiative over the past year has been the development of AMWA's new content strategy plan. This document was data driven, with the goal of matching AMWA's educational offerings with our members' needs. It covers all aspects of medical communications, and it will guide the development of new member resources, new educational content, conference content, and *AMWA Journal* content. Our goal is for the content strategy plan to be a living document, updated periodically as the medical communications landscape changes and as we get more information on our members and their educational needs. I encourage you to update your member profile if you haven't lately. The more we know about your work, your needs, and your professional goals, the better AMWA will be at providing you with the resources you need.

One of the early products of this content strategy plan is a new member resource library, which was released in October. This website is a one-stop shop for finding the online resources you need to stay up to date with changes in the field. The website includes PDFs available for download as well as relevant links to guidances and external resources on a host of topics related to medical communications. Once again, I ask for your help: if you notice any links that no longer connect or recommend another resource be added to the list, please let us know! We are stronger with your support.

You will also see the content strategy in play in the 2020 Medical Writing and Communication Conference as we return to the East Coast and AMWA's home state of Maryland. We're excited about the conference location in Baltimore's Inner Harbor area and hope that you will join us as we celebrate AMWA's 80th birthday.

Speaking of celebrations, I would like to congratulate our members from the Pacific Southwest. The Board of Directors recently voted to approve their chapter status, and we are thrilled to have them back. I'm particularly excited that the 2019 conference was in their own back yard so that we had the opportunity celebrate in person.

As the first bars of music begin on what promises to be a productive and exciting year for AMWA, I don't know if I'm stepping into a raucous samba, a crazy whirlwind of a Viennese waltz, or a slow and deliberate tango. I have to admit, I'm hoping for a smooth, elegant foxtrot. Whatever the coming year resembles, with the support of the staff, Board of Directors, and our many volunteers, I'm confident that we will be successful as we strive for new and better ways to support our members.

Front row, l to r: *Katrina Burton, BS, Secretary; Julie Phelan, MD, MBA, Treasurer; Gail Flores, PhD, President-Elect*
Top row, l to r: *Cyndy Kryder, MS, MWC®, Immediate Past President; Ann Winter-Vann, PhD, President*
Photo credit: EPNAC.com

The future is full of challenges and opportunities for medical communicators.

AMWA's Vision

Creating clear communications that lead to better health and well-being.

What's your vision for creating clear communications in the future? Do you have expertise that will lead to better understanding of these trend-setting topics?

- Artificial intelligence
- Clinical trial registration and results posting
- Collecting and using metrics
- Crisis communications
- Data visualization
- Effect of digital advancements on scientific publishing
- Emerging social media platforms
- Patient decision aids
- Patient involvement (in research, peer review, or CME)
- Plain language summaries of publications
- Publication metrics
- Regulatory writers' role in inspection readiness
- Structured authoring
- Transparency and data-sharing statement requirements

SAVE THE DATE!

Share your vision and help medical communicators prepare for the future.

Look for the Call for Proposals in early 2020

2020 AMWA

Medical Writing & Communication Conference

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