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Extracellular space

Sodium Na⁺

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Phosphate

ADP

Cytoplasm

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AMWA JOURNAL MISSION STATEMENT
The AMWA Journal expresses the interests, concerns, and expertise of members. Its purpose is to inspire, motivate, inform, and educate them. The Journal furthers dialog among all members and communicates the purposes, goals, advantages, and benefits of the American Medical Writers Association as a professional organization.
To ensure the rights and welfare of research subjects are protected during the course of a clinical study, federal regulations necessitate Institutional Review Board (IRB) review of all research activities. To achieve this goal, an IRB must review all study documents. The protocol, the consent form, and, for studies conducted under Investigational New Drug (IND) regulations, the investigator’s brochure are some of the documents an IRB must review. The IRB should also review the methods and material(s) that investigators intend to use to recruit subjects. The regulations that mandate IRB review also codify study document content requirements. Unfortunately, these requirements are not well-understood among clinical study personnel. This review will address what documents are necessary for clinical study review, discuss the regulations surrounding study document content requirements. Unfortunately, these requirements are not well-understood among clinical study personnel. This review will address what documents are necessary for clinical study review, discuss the regulations surrounding study document content requirements, identify common mistakes encountered by IRB reviewers, and suggest what investigators can do to avoid those mistakes.

HISTORICAL BACKGROUND

Throughout history, failure to have meaningful regulatory oversight has led to complacency and tragedies. The Triangle Shirtwaist Factory fire\(^1\) resulted in the enactment of new laws mandating, among other things, the availability of fire extinguishers, the installation of alarm systems and automatic sprinklers, and regulation of the number of hours that women and children could work. Similar disasters in the field of human research have resulted in the enactment of bills designed to protect human subjects. In September 1937, the Elixir Sulfanilamide Incident\(^2\) hastened enactment of the 1938 United States Federal Food, Drug, and Cosmetic Act (FD&C Act, first introduced in the Senate, January 6, 1937).\(^3\) The New Drug section of this Act, requiring demonstration of drug safety, protected the nation from a potential thalidomide disaster like those seen in England and Germany in the 1960s.\(^4\) However, history repeated itself. A bill pending at that time, the Kefauver Harris Drug Amendments of 1962,\(^5\) was finally enacted, introducing a drug “proof-of-ef ficacy” requirement for the first time. Additionally, the Tuskegee Syphilis Experiment,\(^6\) conducted between 1932 and 1972 by the US Public Health Service (PHS), led to the 1979 Belmont Report\(^7\) and the establishment of the Federal Office for Human Research Protections (OHRP). Fallout from the syphilis study also led to federal laws and regulations requiring IRBs for the protection of human subjects. All IRB applications must comply with numerous regulations put in place for the purpose of protecting human subjects. A sample of these regulations is found in Figure 1.

ROLE OF THE IRB

IRBs were created as a direct result of ethical concerns regarding the preservation of autonomy (free will), beneficence (done for benefit of others), nonmaleficence (do no harm), and justice (patient rights) pertaining to research studies involving human subjects. IRBs must ensure that:

- The risks to research subjects are minimized and are reasonable in relation to anticipated benefits;
- The welfare and human rights of subjects are protected and informed consent is sought from each prospective subject or the subject’s legally authorized representative;
- Informed consent is appropriately documented;
- Adequate provisions for monitoring data collection are in place to assure the safety and physical, emotional, and mental well-being of research subjects;
- The confidentiality of data and the privacy of subjects are assured; and
- Researchers are qualified to conduct the described research on human subjects.

DEVELOPING AN IRB APPLICATION

Examples of documents the IRB should be supplied for review are outlined in federal regulations.\(^8\) These documents include:

- A study protocol,
Informed consent form(s) the investigator proposes for use in the trial,
• Subject recruitment materials (eg, advertisements),
• All written information to be provided to subjects (eg, instructions for use),
• Investigator's Brochure,
• Available safety information,
• Information about payments and compensation available to subjects, and
• Documentation evidencing investigator qualifications.

PROTOCOL
It is important to remember that the Merriam-Webster dictionary definition of "protocol" does not equal the federal definition. While the dictionary definition of “a detailed plan of a scientific or medical experiment, treatment, or procedure” is indeed a required element of the federally mandated protocol, additional information is required. According to 21 CFR 56.111(a)(2), 56.115(a)(1), and 21 CFR 312.55, the study protocol must also include/address the following:
• Title of the study
• Purpose of the study (beneficence, the expected benefits obtained by doing the study)
• Sponsor of the study
• Results of previous related research (evidence-based reasoning justifying purpose and phase of study)
• Subject inclusion/exclusion criteria
• Justification for use of any vulnerable subject populations (eg, children, prisoners, pregnant women/fetus)
• Study design
• Description of procedures to be performed
• Provisions for managing adverse reactions
• The circumstances surrounding consent procedure, including the setting, subject autonomy concerns, language difficulties, and special treatment of vulnerable populations (examples above)
• The procedures for documentation of informed consent, including any procedures for obtaining assent from minors, using witnesses and translators, and document storage
• Subject compensation for participation
• Compensation available for injured research subjects
• Provisions for protection of subjects’ privacy
• Extra costs to subjects for their participation in the study
• Extra costs to third-party payers because of subjects’ participation

CONSENT FORMS
Consent forms must be appropriate to the complexity of the research and the needs of the population being studied. All potential research subjects must be able to understand the risks and benefits of the proposed research. Title 45, Part 46 states “the information that is given to the subject or representative shall be in language understandable to the subject or the representative. No informed consent whether oral or written
may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. Consent content requirements include the following:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental. Subjects must know they are not being treated with an approved product.

2. A description of any reasonably foreseeable risks or discomforts to the subject. The researcher must always protect participants from harm.

3. A description of any benefits to the subject or to others that may reasonably be expected from the research.

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. Subjects are entitled to be informed of less risky/other alternatives or if the study device has provisional approval.

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA may inspect the records.

6. For research involving more than minimal risks (i.e., greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests), an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

7. An explanation of who to contact for answers to pertinent questions about the research and research subjects’ rights, and who to contact in the event of a research-related injury to the subject. Who to contact regarding conflicts of interest and how to obtain further information regarding financial arrangements. The patient must know who is paying for the study and if the investigator has any conflicts of interest.

8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. This is preservation of the patient’s autonomy. Subjects have free will. They must not be forced to participate.

9. A statement that the particular treatment or procedure may involve risks to the subject that are currently unforeseeable.

10. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.

11. Any additional costs to the subject that may result from participation in the research.

12. The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject. Researchers must be fair to the participants, and the needs of research participants should always come before the objectives of the study.

13. A statement that significant new findings developed during the course of the research that may relate to the subject’s willingness to continue participation will be provided to the subject.

In 1999, Jesse Gelsinger died after he enrolled as a subject in a gene therapy experiment. In this study, an adenovirus vector carrying a normal gene was injected into his liver. The primary investigator had a financial conflict of interest in the development of the vector being used in the gene therapy trial. If his gene therapy vector worked correctly and was successful, he could make a lot of money by using it to treat people or selling it to other researchers. This conflict of interest may have influenced treatment decisions made by the investigator as he continued his experiments.
While the participants in your study may meet all study inclusion criteria, they are distinct individuals. While they may all be afflicted by the same condition, not every subject will have the same mental or physical capacity to make an informed decision. Because of population diversity, a proposed informed consent document should contain all federally mandated requirements AND be written at a 6th- to 8th-grade level (e.g., at a language level suitable for WebMD but not JAMA) for an adult participant. This is challenging in complex biomedical research protocols and may require more words, and ultimately a longer consent, to achieve this level of understanding among individuals in the study population. Sample language choices may be found in Table 1.

These readability requirements apply to any and all documents seen by a participant. This can include instructions for use, surveys, or advertisements. Word-processing programs such as Microsoft Word are helpful in this regard because they provide a readability score after the program finishes checking spelling and grammar (see “readability statistics”). Assent documents for children must be similarly constructed. A child may not understand the phrase “I have been informed that I may leave the study at any time without affecting my medical care and relationship with my doctor” but will understand “If you do not want to be in this study, you don’t have to. If you say you want to be in it and then change your mind, that’s OK. All you have to do is tell us. No one will be mad at you or upset with you if you don’t want to be in it.” Always keep in mind your intended audience. An Investigator’s Brochure or study protocol will be worded such that the study personnel and FDA can comprehend. However, study documents for minor children, for example, will need to be worded differently.

Table 1. Consent Language Examples

<table>
<thead>
<tr>
<th>NOT:</th>
<th>BUT:</th>
</tr>
</thead>
<tbody>
<tr>
<td>“You will be randomized into one of the study groups described below.”</td>
<td>“You will be ‘randomized’ into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of [#] study groups. Neither you nor your doctor can choose the group you will be in. You will have an [equal/one in three/etc.] chance of being placed in any group.”</td>
</tr>
<tr>
<td>“Study data will be published in the medical literature.”</td>
<td>“If new information about the study device/drug becomes available during the study, the investigator or staff will tell you about the new information and will discuss with you whether you want to continue in the study. Remember that participation in this study is entirely voluntary and you are free to stop participating in the study at any time without giving a reason.”</td>
</tr>
<tr>
<td>“2 mL of your blood will be drawn to test hemoglobin levels.”</td>
<td>“2 mL (or about 2 teaspoons) of your blood will be drawn to test hemoglobin levels. Hemoglobin is a protein in your red blood cells that carries oxygen and carbon dioxide through your body. If a hemoglobin test reveals that your hemoglobin level is lower than normal, it means you have a low red blood cell count (anemia). Symptoms of anemia, like fatigue, happen because organs aren’t getting enough oxygen to function properly.”</td>
</tr>
</tbody>
</table>

YOUR INTENDED AUDIENCE—THE IRB REVIEWER

It is federally mandated that all constituted IRB committees include a nonscientific lay person as a member. As such, writers should make no assumptions about the knowledge base of the potential IRB member reviewers. Study documents must consistently provide information sufficient to justify the conduct and/or continuation of the research proposal using language that is accessible to all members of the IRB. Details are important to enable IRB reviewers to make the determination of overall risk to the subject. Conversely, too much detail can be unnecessary. For example, the protocol must disclose that blood will be drawn for the study, the numbers of subject visits planned, and any planned compensation for study subjects. Commonly omitted details might include the volume of peripheral blood being drawn, the length of subject visits, and the lack of a prorated compensation plan for partially completed research procedures.

A study protocol must have research justification and plans in sufficient detail, thereby providing the IRB reviewers with adequate information to make a risk-benefit assessment on the research, as well as a final determination of the approvability of the project. A lack of specificity and gaps in the information supplied via the IRB submission process will prompt the IRB to pose a multitude of questions to the investigator until the picture of the research proposal is complete enough to make necessary patient risk determinations. Therefore, having a well-written IRB application, according to accepted guidelines, makes the work of the IRB easier, expedites the review process, and helps to ensure that research is being conducted professionally and according to ethical standards.

In the United States, IRB review is necessary before human research can commence. Retrospective IRB review is not per-
mitted. An IRB may approve, disapprove, or require modifications to research protocols. It may also suspend or terminate its approval of ongoing or previously approved research. IRB approval can take anywhere from weeks to months, depending on how often the IRB committee meets, workload, staffing, and the types and complexities of the research being evaluated. Nevertheless, an IRB is not a roadblock to completion of your clinical study—in addition to safeguarding patients, an effective IRB review will decrease the risk of suspension or disruption of your research during an investigation or inspection. This in turn reduces the likelihood of damaging investigator reputations and their ability to obtain future funding. An effective IRB assure that researchers are compliant with federal and state regulations, thereby keeping an institution and its research moving forward. The IRB helps researchers by looking for risks in a research proposal that the investigator may have overlooked or underemphasized, thereby protecting the researcher, the institution, and all potential research subjects.

In conclusion, it is smart practice to engage an IRB early in the research process as they can be a valuable research resource. The formula for IRB submission success is straightforward:

- **Simplify**: Use simplified language that is easy to understand.
- **Justify**: Provide science-based rationale for the study, the design, and the risk to subjects.
- **Protect**: Make sure the protocol clearly describes the many ways the protection of subjects is provided throughout the research experience. Investigators should never downplay patient risk in applications so that the proposed research appears safer than it actually is.

- **Be complete**: Provide complete, detailed information in all areas of the required documents.
- **Be consistent**: Achieve consistency of the information provided in each section and across study-related documents.

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**References**

Up and Down or Side by Side: Structuring Comparisons in Data Tables

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

ABSTRACT

Introduction: In tables reporting data for independent and dependent variables, a common dilemma is whether to name the independent variable (eg, treatment and control groups) in the column headings, where data are compared between groups horizontally, or in the row headings, where they are compared vertically.

Methods: I investigated the visual aspects of horizontal and vertical scanning, searched for studies on how tabular information is processed, and reviewed dozens of books on scientific and medical writing published since 1900 to determine whether and how they addressed this dilemma.

Results: We are physiologically more inclined to scan (and thus to compare) horizontally than vertically. In vertical comparisons, all numbers in each cell can easily be compared up and down rows, without visual interruption. In horizontal comparisons, numbers being compared are farther apart and can be separated by other elements in the cells. However, research and expert opinion differ on the preferred arrangement, indicating that the difference is likely not important. Of 109 books reviewed, 21 specifically recommended vertical comparisons, 11 used examples involving vertical comparisons, and 8 had examples of both arrangements or considered each arrangement appropriate. Only 13 specifically recommended horizontal comparisons, and 56 did not address the issue.

Conclusion: The difference between arrangements does not appear to affect the utility of a table, although readers may intuitively prefer side-by-side comparisons. Fitting a table to the dimensions of a page is often more important than arranging the direction of the comparisons.

INTRODUCTION

A common decision when making a table is how to arrange the data to help readers compare them as easily as possible. In tables reporting independent and dependent variables, the question is whether the groups (the independent variable: eg, treatment and control) should be named in the column headings or in the row (stub) headings. When the groups are named in the row headings, the data will be compared vertically, up and down rows in the same column (Figure 1). When the groups are named in the column headings, the data will be compared horizontally, in the same row and across columns (Figure 2). Because many people favor one arrangement over another, and because reasonable arguments support each one, I sought to determine whether there were compelling reasons to choose one arrangement over the other.

The Arguments for Vertical Comparisons

The ease of comparing one number to another in a table is affected by how far apart the numbers are (closer is better) and presumably by how many visual elements separate the values (fewer is better). By these criteria, numbers should be more easily compared vertically (Figure 1) than horizontally (Figure 2). In vertical comparisons, the mean values are as close as they can sensibly be, and the space between them is not interrupted. Vertical comparisons allow all numbers in each cell to be compared directly up and down rows, without visual interruption (Figure 1). Indeed, an easier comparison is difficult to imagine. This arrangement is familiar because we see numbers this way when performing arithmetic operations. In contrast, in horizontal comparisons, mean values are farther apart and are often separated by other numbers in the same or neighboring cells (Figure 2).

Vertical comparisons can sometimes use space more efficiently (Figure 3). The width of a page is fixed, creating a trade-off between the number and the width of columns. Placing group labels and sample sizes in the column headings often...
### Table. Surgical Simulation Scores for 35 Colorectal Surgeons, by Level of Experience.
Scores range from zero (poor) to 100 (excellent).

<table>
<thead>
<tr>
<th>Surgical task</th>
<th>Residents (n = 12)</th>
<th>Fellows (n = 8)</th>
<th>Staff (n = 15)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cutting</td>
<td>75 (59 to 84)</td>
<td>85 (80 to 94)</td>
<td>91 (75 to 99)</td>
<td>0.03</td>
</tr>
<tr>
<td>Suturing</td>
<td>63 (57 to 85)</td>
<td>87 (78 to 99)</td>
<td>92 (69 to 94)</td>
<td>0.04</td>
</tr>
<tr>
<td>Ablating</td>
<td>80 (66 to 93)</td>
<td>88 (77 to 93)</td>
<td>93 (88 to 99)</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Figure 1. Vertical comparisons require the independent variables (test groups) to be named in the row headings.

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<td>80 (66 to 93)</td>
<td>88 (77 to 93)</td>
<td>93 (88 to 99)</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Figure 2. Horizontal comparisons require the independent variables (test groups) to be named in the column headings.

### A
Table. Survival after hospital discharge.

<table>
<thead>
<tr>
<th>Group</th>
<th>Survival, median (IQR), months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Placebo, n = 47</td>
<td>X (0.XX – XX)</td>
</tr>
<tr>
<td>Usual care, n = 52</td>
<td>X (0.XX – XX)</td>
</tr>
<tr>
<td>Active drug, n = 49</td>
<td>X (0.XX – XX)</td>
</tr>
<tr>
<td>Men, n = 71</td>
<td>X (0.XX – XX)</td>
</tr>
<tr>
<td>Women, n = 77</td>
<td>X (0.XX – XX)</td>
</tr>
</tbody>
</table>

### B
Table. Survival after hospital discharge. Data are medians and interquartile ranges.

<table>
<thead>
<tr>
<th>Survival, months</th>
<th>Treatment group, median (IQR)</th>
<th>Sex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo, n = 47</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usual care, n = 52</td>
<td></td>
<td></td>
</tr>
<tr>
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<td></td>
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<tr>
<td>6</td>
<td>X (0.XX – XX)</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>X (0.XX – XX)</td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>X (0.XX – XX)</td>
<td></td>
</tr>
<tr>
<td>36</td>
<td>X (0.XX – XX)</td>
<td></td>
</tr>
</tbody>
</table>

Figure 3. A, Data arranged to be compared vertically (7 lines of type × 5 columns). B, Data arranged to be compared horizontally (8 lines of type × 6 columns).
requires wider columns and 2 or more lines of type. Placing the same information in a single row heading can reduce the number of lines of type or allow more columns, which is a more efficient use of space.

The Arguments for Horizontal Comparisons

We scan horizontally more rapidly, easily, and efficiently than we scan vertically.\(^3,4\) Our eyes are positioned on a horizontal axis, which gives “our perceived world a roughly horizontal tableau.”\(^5\) Horizontal eye movements require only one pair of muscles, whereas eye movements in other directions require more than one pair.\(^5\) Further, the spatial density of rods and cones in the retina is higher along the horizontal than along the vertical.\(^6\) We scan left to right 5 times faster than we scan up and down, mostly because one eye takes over when the other gives up. “Scanning vertically is like having a single eye” and is often accompanied by lifting or lowering our heads.\(^3\)

We enter a table through the column and row headings.\(^7\) Column headings appear side by side in a prominent position at the top of the table. Because native English speakers universally read from left to right and top to bottom, column headings are read before row headings. In addition, column headings are usually bolded, whereas row headings are not.\(^8\) The cumulative effect is that column headings draw more attention than do row headings. Thus, the argument is that the primary relationship—the comparison between groups—is more apparent (and perhaps more natural) in the column headings (Figure 2) than in the row headings (Figure 1). In addition, at least in clinical research, dependent variables outnumber independent ones, so for spatial reasons alone, the independent variables are more likely to be named in the column headings and the dependent variables are more likely to be named in the row headings.

METHODS

I spent several hours searching the internet and the reference lists of articles and books addressing this issue for studies explicitly comparing how well we use tables with vertical and horizontal arrangements or that compared numbers presented in vertical lists with numbers presented in horizontal rows. Search terms included “data tables,” “visual comparisons,” “data tables AND research,” “designing data tables,” “tabular displays,” and “numerical comparisons.”

I also reviewed dozens of books on scientific or medical writing published since 1900, some style manuals, and a few books on data displays (Appendix). Books exclusively about graphs were not included. For each book, I determined whether the authors specifically recommended using vertical or horizontal comparisons or did not address the issue. In books not specifically recommending one arrangement over the other, I looked to see if the examples indicated a clear preference for either one.

RESULTS

Studies on How Readers Use Tables

Few studies appear to have considered whether numbers are compared more easily vertically or horizontally, and their results are conflicting. Currency conversions were made faster and with fewer errors in a vertically arranged table.\(^9\) Searching for a single item in a random list was faster if the items were arranged vertically rather than horizontally.\(^10\) Similarly, subjects asked to compare pairs of numbers in a table to determine whether they were the same or different made the comparison more quickly if the numbers were printed one above the other than if they were printed side by side.\(^11\)

Other studies have found no important differences between the 2 arrangements. In one, subjects were asked to scan arrays of pairs of numbers and to mark the pairs containing nonidentical numbers. The average time required to complete the task was 73 seconds for the vertical array and 44 seconds for the horizontal array (\(P = .005\)).\(^12\) In a study to determine the relative effectiveness of visual displays containing alphanumeric material presented vertically and horizontally, the differential effects of vertical and horizontal arrangement were negligible.\(^13\)

Wainer,\(^14\) Ehrenberg,\(^1\) and Clark,\(^15\) all experts in data display, each promote vertical comparisons in their published works, in which they often cite the above studies.

Reviews of Books on Scientific, Technical, or Medical Writing

Of 109 books on scientific, technical, or medical writing and data displays (Appendix), 21 specifically recommended vertical comparisons, 11 did not specifically recommend vertical comparisons but used examples favoring vertical comparisons, and 8 had examples of both arrangements or considered each arrangement appropriate. Only 13 specifically recommended horizontal comparisons, and 56 did not address the issue. Most of these 56 books did not mention tables (or figures) at all, and in those that did, few spent more than a paragraph on either topic.

Reviews of Style Manuals

The *AMA Manual of Style* considers tables reporting independent and dependent variables to be a special type of table.\(^8\) For most tables, it recommends horizontal comparisons: “Because the English language is first read horizontally (from left to right) and then vertically (from top to bottom), the primary comparisons should be shown horizontally across the table” (page 84). However, for tables reporting independent and
in tables for studies that have independent and dependent variables, the independent variables are conventionally displayed in the left-hand column (stub) and the dependent variables in the columns to the right” (page 86).

Scientific Style and Format (published by the Council of Science Editors)\(^1\)\(^6\) says that “numbers are usually more easily compared if they are presented side-by-side” (page 653) but later acknowledges that “the question of which data should be in rows and which in columns has no simple answer” (page 660).

The Chicago Manual of Style specifically calls for vertical comparisons (page 140),\(^1\)\(^7\) and the Government Printing Office Style Manual uses examples consistent with this recommendation.\(^1\)\(^8\) The Publication Manual of the American Psychological Association specifically calls for horizontal comparisons (page 128).\(^1\)\(^9\) The American Chemical Society Style Guide\(^2\)\(^0\) and the European Association of Science Editors’ Science Editors Handbook\(^2\)\(^1\) do not address the issue.

**DISCUSSION**

**The Book Reviews**

Both horizontal and vertical arrangements have been promoted in the literature at least since the early 1900s. The earliest references I found recommending vertical comparisons were from the 1920s. Maude Mellish, a librarian and later an author's editor at the Mayo Clinic, in her 1922 book, The Writing of Medical Papers,\(^2\)\(^2\) said simply that:

“Vertical (not horizontal) columns should consist of like data.” (page 22)

George Simmons and Morris Fishbein were both long-time Editors-in-Chief of the Journal of the American Medical Association (now JAMA). (Fishbein is also a past president of AMWA). In their 1925 book, The Art and Practice of Medical Writing,\(^2\)\(^3\) the predecessor of the AMA Manual of Style, they say:

“The headings at the top of the vertical columns should indicate the subjects chiefly concerned [the dependent variables]. The variations should be indicated by the left-hand column, in which can be given the period of the various observations, or the record numbers of the animals, cases or other objects to be contrasted [the independent variables]. In other words, the vertical columns contain like data (emphasis added).” (page 110)

In the first half of the 1980s, Robert Day, the head of ISI Press\(^3\)\(^4\); Ed Huth, the long-time Editor-in-Chief of the Annals of Internal Medicine\(^3\)\(^5\) (and another past president of AMWA); and Peter Morgan, the Editor-in-Chief of the Canadian Medical Association Journal,\(^3\)\(^6\) all published what became standard books on preparing scientific articles. Day’s book (now with AMWA member Barbara Gastel, MD, as the primary author) is in its 8th edition (2011) and continues to reach an international audience. All these books specifically recommend vertical comparisons.

However, Huth, in both his 1987 book, Medical Style and Format: An International Manual for Authors, Editors, and Publishers,\(^2\)\(^7\) and his 1999 book, Writing and Publishing in Medicine, 3rd edition,\(^2\)\(^8\) no longer specifically advocated for vertical comparisons, although the examples in the books still used this arrangement. Huth is one of the most experienced and influential journal editors of modern times, so when he no longer specifically recommends one table arrangement over another, in two books published 12 years apart, it seems unlikely that the issue is important.

In the late 1970s, Mauve O’Connor and Peter Woodford, of the then Council of Biology Editors (now, Council of Science Editors), published Writing Scientific Papers in English.\(^2\)\(^9\) They did not specifically recommend vertical comparisons, but the examples support this arrangement. However, in her 1986 book, O’Connor recommended horizontal comparisons (page 36).\(^3\)\(^0\)

The earliest specific recommendation I found for horizontal comparisons was in a 1936 book by Walker and Durost, Statistical Tables: Their Structure and Use\(^3\)\(^1\):

“The present arrangement [of horizontal comparisons] facilitates the making of important comparisons between the boys and girls [column headings] . . . since it is easy to compare numbers in adjacent columns” (page 15).

The authors also note that “The [example] table fits the page better in this way than it would if the rows and columns were exchanged” (page 14), and they use examples of both arrangements.

Aside from O’Conner’s reversal, the only major texts to promote horizontal comparisons were Burnett’s 1990 textbook, Technical Writing,\(^3\)\(^2\) and Lang’s books, How to Report Statistics in Medicine (1997 and 2006)\(^3\)\(^3\) and How to Write, Publish, and Present in the Health Sciences (2010),\(^3\)\(^4\) both of which include detailed chapters specifically on preparing tables.

Two other books should be mentioned. Those by Hewitt (1957)\(^3\)\(^5\) (another AMWA past president and Senior Consultant, Section of Publications, at the Mayo Clinic) and Davidson (1957),\(^3\)\(^6\) which are still current in many respects, used examples of both arrangements, but neither specifically recommends one over the other.

Of the 56 books that contained no information about tables, 43 (75%) were specifically on medical writing (Appendix), and most also had little or no information about graphs, despite the claims of their titles (eg, Mastering
Scientific and Medical Writing: The Complete Guide to Medical Writing: Sourcebook of Medical Communications. The absence of these topics, especially in books written by professional medical writers, is concerning, given the importance of data displays in medical writing. These books present medical writing as a profession limited to communicating with words in print and not as a subset of technical writing that includes communicating with tables, graphs, and images in other media, such as posters, slides, and online texts.

The Implications
In general, as noted above, we tend to prefer side-by-side or horizontal comparisons for physiological reasons. That numbers are more easily compared vertically is also possible and is supported by some (but not all) evidence and by some (but not all) expert opinions. Perhaps comparing numbers is a special case. If so, horizontal comparisons would seem to be better in most tables, and vertical comparisons would seem to be better in tables reporting independent and dependent variables. This dual approach is evident in the AMA Manual of Style8 and in Scientific Style and Format.16

However, if horizontal comparisons are just as easy to make and are acceptable in most circumstances, creating an exception for tables reporting independent and dependent variables seems unnecessary. At least in medical articles, many if not most tables are relatively short (say, less than half a page), which means that readers will likely be able to compare values quickly and easily, no matter the orientation of the table.

A Recommendation
Tables first appeared in print in the 1600s.37 That the question of horizontal versus vertical comparisons remains unresolved after 400 years seems to indicate that there is no consensus on which is preferred, and perhaps even that the question is seldom asked. Although numbers may be more easily compared vertically, as described above, column headings are more prominent than row headings. This greater emphasis favors horizontal comparisons. It seems reasonable to suggest that readers would have to learn to ignore this greater emphasis and look intentionally at the row heads to appreciate vertical comparisons. In other words, perhaps readers first expect to compare groups side by side, rather than numbers up and down.

Comparing numbers in either direction may involve looking for a specific value (one perhaps above or below a threshold value) or the maximum or minimum values, determining whether one number is larger or smaller than another, or identifying groups of similar values. If the comparison can be anticipated, the appropriate cells can be emphasized, perhaps with a border (Figure 4),14 thereby improving the utility of either arrangement.

In the basic and physical sciences, “the published literature is used almost exclusively by working scientists who are familiar with a given field and its methodology and who are usually capable of interpreting data for themselves.”38 These readers are a more or less homogeneous audience who are familiar with the conventions of their discipline. Therefore, it may be reasonable to make vertical comparisons a convention in the basic sciences (if they are not already). In contrast, clinical journals are read by a more heterogenous audience,38 which may include physicians, nurses, patients, lawyers, reporters, the public, and so on. For this audience, horizontal comparisons might be more appropriate.

Table 2. Surgeries and Outcomes among 462 Preterm Neonates with Congenital Heart Defects. Highlighted cells indicate the most common risk category, surgery, and diagnoses and the highest and lowest mortality and median length of stay.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Cardiac surgery, No. (%)</th>
<th>Mortality, %</th>
<th>Hospital LOS, median (IQR), days</th>
</tr>
</thead>
<tbody>
<tr>
<td>RACHS risk category (all categories)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>36 (7.8)</td>
<td>16.1</td>
<td>100 (83-124)</td>
</tr>
<tr>
<td>2</td>
<td>71 (15.4)</td>
<td>11.5</td>
<td>94 (49-132)</td>
</tr>
<tr>
<td>3</td>
<td>329 (71.2)</td>
<td>12.1</td>
<td>101 (80-123)</td>
</tr>
<tr>
<td>4</td>
<td>26 (5.6)</td>
<td>31.8</td>
<td>92 (45-136)</td>
</tr>
<tr>
<td>Surgical specifications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Open heart with bypass</td>
<td>74 (16.0)</td>
<td>16.6</td>
<td>94 (74-132)</td>
</tr>
<tr>
<td>Blalock-Taussig shunt</td>
<td>42 (9.1)</td>
<td>10.7</td>
<td>106 (82-132)</td>
</tr>
<tr>
<td>Pulmonary artery banding</td>
<td>319 (69.0)</td>
<td>19.0</td>
<td>101 (80-124)</td>
</tr>
<tr>
<td>Cardiac catheterization</td>
<td>27 (5.8)</td>
<td>21.4</td>
<td>106 (77-131)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transposition of great arteries</td>
<td>88 (19.0)</td>
<td>30.0</td>
<td>92 (79-110)</td>
</tr>
<tr>
<td>Double outlet right ventricle</td>
<td>110 (23.8)</td>
<td>46.2</td>
<td>97 (75-127)</td>
</tr>
<tr>
<td>Ebstein anomaly</td>
<td>50 (11)</td>
<td>33.3</td>
<td>82 (82-82)</td>
</tr>
<tr>
<td>Tetralogy of Fallot</td>
<td>37 (8.0)</td>
<td>14.0</td>
<td>108 (61-149)</td>
</tr>
<tr>
<td>Ebstein anomaly</td>
<td>50 (11)</td>
<td>33.3</td>
<td>82 (82-82)</td>
</tr>
<tr>
<td>Hypoplastic left heart syndrome</td>
<td>24 (5.3)</td>
<td>42.9</td>
<td>107 (56-162)</td>
</tr>
<tr>
<td>Coarctation of aorta</td>
<td>103 (22.3)</td>
<td>20.0</td>
<td>74 (49-103)</td>
</tr>
</tbody>
</table>

LOS, length of stay; RACHS-1 Risk Adjustment for Congenital Heart Surgery score; LOS, length of stay

Figure 4. Scanning time in either direction might be reduced by highlighting the values most likely to be of interest in each row or column.
Limitations of the Study
The biggest limitation of this study is the lack of definitive research into how we access information from tables and what features improve or inhibit our ability to understand, find, and use the information they present. To be sure, such research may exist, but like much research into written communication, it may be spread over several disciplines (eg, perceptual psychology, linguistics, human factors, graphic design), where it is difficult to find. On the other hand, the lack of such research may indicate that the question is unimportant.

Determining the influence of a given book on this issue would be difficult to determine. One would have to consider how many copies were sold, the geographic range of its marketing and sales (regional, national, international), how long it was in print, which audiences tended to rely on it, and what books were competing in the same market. Further, style manuals might have a greater effect than textbooks, which might have a greater effect than trade books.

The books reviewed are in my personal library. Although the collection is large and contains most of the major books on medical writing published since 1900, as well as many related books, it does not contain some more recent (and expensive) titles, and how representative it is of the field of medical writing or of the advice on designing tables is unknown.

CONCLUSIONS
I believe the information presented above supports 4 conclusions:
1. We are physiologically inclined to scan and compare side by side. Naming the independent variables in the column headings of a table—a location of emphasis—builds on this inborn preference. Other variables notwithstanding, tables should probably be designed to facilitate horizontal comparisons between columns.
2. Some research and expert opinion indicate that numbers are likely more easily compared vertically than horizontally. However, these vertical comparisons may be counterintuitive; readers may have to learn to look for, or be directed to, the independent variable in the row headings. Therefore, vertical comparisons might be preferred for large tables in which many numbers are likely to be compared, or to be compared often, such as multipage tables of demographic data. Vertical comparisons might also be useful for tables likely to be read by more homogeneous audiences, such as basic scientists, who are or who can be conditioned to see such arrangements. Likewise, tables with relatively few numbers and those likely to be read by a more heterogenous audience, perhaps including the public, may be more effective if they use horizontal comparisons.
3. The difference between arrangements does not appear to substantially burden readers and appears to be seldom considered by readability researchers and by many authors who have published books on scientific and medical writing and data displays.
4. The need to efficiently fit a table on a page is probably a more compelling justification for assigning the position of independent and dependent variables than is the direction of the comparisons.

Robert Harris, an electrical engineer and graphic designer, summarizes the issue nicely:
“In tables, there is no generally accepted standard as to which axis the independent variable is placed on… In many tables, the row and column headings can be transposed with no degradation of the information. To a large extent, the decision as to which variable goes on which axis depends on such things as: which combination makes the data more meaningful, the number of variables, the number of entries, and the length of the headings.”

Appendix to this article

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References
continued from previous page

ARTICLE 2: INTERVENTIONS

“Health disparities are not inevitable; they are a product not only of health care access and quality, but also of community-based social, economic, and environmental conditions that can be changed.”
—The National Academy of Medicine Initiative

Should we fail to ameliorate the disparities in social determinants of health (SDH), a sketch of which appeared in the first article of this series (Summer 2018 issue), we not only fail to realize the American ideal of “equality for all” but also face both financial bankruptcy as a nation and continued poor health outcomes. For example, in a 2001 ranking of 191 developed nations by the World Health Organization, the United States placed thirty-seventh; in a 2017 study with a similar ranking, the United States placed last.

Countless interventions described in the literature target health disparities (HD) and SDH; some have been shown to be more effective than others, as will be discussed. The Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and National Academy of Medicine (NAM) make clear that addressing HD/SDH is not a goal for some future date. Sufficient research, clinical and community experience, and expert opinion call on us to reduce disparities and bend SDH in the direction of health—and to start doing so immediately.

While there are no authoritative guidelines on addressing disparities in SDH, recommendations by the CDC and NIH are available on the Internet.

“People Who Cannot Afford Boots Cannot Pull Themselves Up by the Bootstraps: An Evidence-Based Exploration of Health Disparities, Social Determinants of Health, and How Medical Writers Can Help

Tamara Ball, MD and Bob Kirsch, MA / Freelance Medical Writers

In the first article in our series, we presented evidence relevant to the current state of health disparities and social determinants of health in the United States. This article discusses some of the peer-reviewed publications describing interventions that have reduced health disparities and reports on efforts currently underway by thought leaders, the CDC, and medical foundations to further address the issues. The third article will offer practical and concrete actions that medical communicators can take to support these efforts in the name of better health for all Americans.

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• In “exploring factors that would improve outcomes,” Ana Maria Lopez, MD, Chair of the American Academy of Clinical Oncology (ASCO) Health Disparities Committee, stated in an interview (personal communication, June 2018) that “efforts at prevention tend to be less expensive and more effective since they save the patient the burden of disease.” Such efforts “require clinicians and health professionals to work with community constituencies such as grocery stores, community gardens, nutritionists, and school lunch funders and preparers.”

• "As part of the American Academy of Family Physicians’ (AAFP) The EveryONE Project,10 we are forging partnerships with medical and nonmedical organizations to lead positive community change, advocate for public policies that will support health equity, and identify new insights and evidence-based practices to help family physicians address social determinants of health,” explained Julie Wood, MD, MPH, AAFP, Senior Vice President, Health of the Public and Interprofessional Activities in an interview (personal communication, June 2018).

• Some physicians, though certainly not all, are taking action to respond to social determinants that affect children and youth. “The AAP has lobbied on such matters as gun violence, water safety, immigration, childhood obesity, and Zika virus, and in 2015, pediatricians in California participated directly in efforts to influence legislation on vaccination,” stated Alice Kuo, MD, PhD, MBA, in an interview (personal communication, June 2018). Dr Kuo is a Professor of Internal Medicine and Pediatrics at the David Geffen School of Medicine at UCLA, and of Health Policy and Management in the Fielding UCLA School of Public Health. She is also Chief of Medicine-Pediatrics at UCLA and a spokesperson for AAP California. “As many as 25% of American children experience food insecurity, which is a challenge for individual pediatricians to address directly. To meet the social needs of their patients, pediatricians must take action outside of the clinic. Many pediatricians advocate through op-eds and media interviews on critical issues facing children—such as the recent attention paid to immigrant children being separated from their parents at our borders—as part of their efforts to improve all children’s health.”

• “The American College of Physicians recommends policymakers adopt a ‘health in all policies’ approach and supports the integration of health considerations into community planning decisions through the use of health impact assessments” and “supports increased interprofessional communication and collaborative models that encourage a team-based approach to treating patients at risk to be negatively affected by social determinants of health.”11 (Emphasis present in the original document.)

Third, consideration of low health literacy (LHL) and numeracy is pivotal when planning any intervention. The Institute of Medicine defines health literacy as “the degree to which individuals have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions.”12 An estimated 90 million Americans live with LHL and, while it may occur with people of any age, race, education level, or socioeconomic group, it is particularly prevalent in underserved populations, where it results in poor health outcomes and higher costs of care.13,14 Both the CDC7 and NIH8,15 offer guidance for providers working with patients with LHL, instructions that can serve as a resource for medical writers and editors.

Federal and state governments, universities, and communities are also engaged. Many professional associations have recognized LHL’s impact on quality of care and are responding. Further, NAM’s 2017 Vital Directions report identified communicating “in a way appropriate to literacy” as being an “Action Priority.”11

Promising interventions have included enhanced written and print-based materials, group-based education in primary care settings, education aimed at the elderly, media approaches, 1-on-1 coaching, and technology-driven interventions.16-18 These interventions have resulted in increased health-related knowledge, comprehension, and adherence to treatment.18-20 However, the link between improved LHL and improved health outcomes remains unproven.

Medical writers are needed to create documents at all literacy levels, and many of us have long had expertise in this field. Opportunities requiring such expertise will be discussed more fully in the third article of this series.

**MEDICAL EDUCATION INTERVENTIONS**

“The American College of Physicians (ACP) recommends that SDH and the underlying individual, community, and systemic issues related to health inequities be integrated into medical education at all levels.”11 (Emphasis present in original.)

The ACP is far from the only organization insisting on such change. “There is a shift in medical schools and residencies to include population health and to include community and social needs. It’s important to continue support of that education and to support our physicians established in practice so we are all working together and speaking the same language.” (The AAFP’s J. Wood, personal communication, June 2018.)

Changes in what is taught are not the only focus. Diversity among students in health-related fields and in the physician workforce is an essential component for promoting health care excellence.21 Minority providers often care for underserved urban and rural patients,22 are more likely to choose primary over specialty care,23 and increase patient comfort with their...
caregivers. Nonwhite physicians care for a disproportionate share of minority and non–English speaking patients (53.5% and 70.4%, respectively).

Change in the diversity of medical school graduates has not kept pace with change in the overall US population. In 2014, 75% of practicing physicians were white, 12.8% were Asian, 6.3% were African American, 5.5% were Hispanic, and 0.5% were American Indian or Alaskan native. These percentages have remained stable for 30 years. One study calculated that to reach parity with the distribution of subpopulations in the United States, incoming classes would need to double the number of African Americans and Hispanics, triple the number of American Indians, reduce Asians by two-fifths, and reduce whites by two-thirds. More research is needed to identify the most effective strategies for recruiting and retaining medical professionals from all backgrounds.

The Diversity Policy and Programs (DPP) was established at the American Academy of Medical Colleges “to ensure diffusion of promising practices that increase diversity within the faculty and student body of the nation’s medical schools and teaching hospitals.” New collaborative projects include a minority faculty development seminar, a certificate program for minority students aspiring to executive positions within health care, and a webcast that helps schools assess their culture and climate. Faculty at individual institutions are also creating content to help future doctors have greater facility in a multiethnic world. For example, Dr Christina Gonzales at the Albert Einstein University School of Medicine developed a 3-month elective on HD and SDH for medical students that covered the topic and engaged students in role-play. Students who chose the elective demonstrated increased knowledge and confidence.

Following the success of this program, Dr Gonzales and her colleagues developed a similar program for medical residents.

HEALTH SYSTEM INTERVENTIONS
Discriminatory behavior is so ubiquitous in American society that it is seldom recognized in the medical workplace. However, it exists as implicit bias, and health professionals and staff can benefit from targeted, experiential exercises to recognize implicit bias based on adult-learning principles. There are many programs available, but one that has proven effective in a randomized controlled trial equates implicit bias with “bad habits” and asks participants to do the following:

- Be alert to stereotypic responses by you or others in your environment and replace them with nonstereotypic alternatives.
- Identify the characteristics of minorities as individuals rather than as members of a group (ie, “As a novelist, editor, teacher, and Professor Emeritus at Princeton University, it is unlikely that Pulitzer prize-winner Toni Morrison was stupid”).
- Take a first-person perspective of a stereotyped group by imagining how you would feel if you were walking in the targeted person’s shoes.
- Increase opportunities for positive contact with minorities (ie, attending services at a church with a predominantly African American congregation).
- Take a positive step toward supporting a stereotyped group by donating to or urging your government representatives to fund minority institutions, such as African American colleges and universities.

As large employers, hospital systems should each have their own discrimination policies. The Joint Commission on Accreditation of Health Care Organizations (JCAHO) could connect education about and review of integration efforts to the granting of certification.

Large health system outreach through complementary community screening for diabetes, hypertension, or breast cancer has repeatedly failed to change long-term outcomes and, thus, has not reduced HDs. For example, a study by Masi et al showed that increased breast cancer screening for African American women improved outcomes only when a structure was in place to provide subsequent diagnosis and treatment.

Hospitals are financially penalized by Medicare for readmissions within 30 days of discharge; therefore, much attention has been paid to improving the patient transition from hospital to home or long-term care facility. The providers’ ability to communicate discharge instructions such that patients understand them is key; hence, providers are being taught skills such as the “teach-back” method, in which patients repeat back to the provider their understanding of specific instructions.

COMMUNITY CLINIC INTERVENTIONS
At a time when cost containment is highly valued, community health clinics are often seen as politically soft targets for budget cuts, but such cuts can widen the disparity gap. Community clinics care for and educate individual patients and their families and have increasingly focused on recognizing and optimizing a community’s health capacity, which may include resources such as strong local churches and additional religious organizations, previously identified community leaders, and the presence of existing organizations that secure basic needs (food pantries, fair housing advocates, neighborhood watch organizers, etc). It is widely believed that a high degree of community ownership (not financial) and participation is essential for sustained success in population-level health outcomes. Therefore, community members are often invited to provide input on programming through advisory committees.
Though every employee at a community clinic contributes to reducing HDs, we focus here on one type of lower-level, front-line employee, often called a community health worker (CHW; though the labels delineating paid employees from community members who volunteer or receive a small stipend are fluid at this time). Community health workers often live in the area they serve and are everyday drivers of equity and community empowerment. In one controlled trial, CHWs visited homes, called patients, and led group classes for Hispanic individuals with poorly controlled type 2 diabetes, resulting in significant improvement in fasting glucose and hemoglobin (Hb) A1c. A study of stroke risk reduction in underserved patients who had a stroke in the previous 90 days found that home visits by a CHW produced significant improvement in glucose control, but not blood pressure or other cardiovascular risk factors. We have likely not accessed the full potential of CHWs to influence health outcomes in their communities.

INTERVENTIONS BY MEMBERS OF THE LAY COMMUNITY

Individuals with little formal health training are also being asked to serve in capacities likely to lessen HDs. These lay workers are usually chosen by the community to receive brief, issue-focused health training for a problem specific to their community.

Navigators

One category of community helper is the navigator, who, for example, assists patients in traversing the complex pathway of cancer care. The very large Navigation Research Program screened 10,521 participants, and those with a positive screen for breast, cervical, colorectal, or prostate cancer (n = 2,105) were randomized either to support from a navigator or to usual care. At 1 year, the navigator group had better compliance for breast, cervical, colorectal, or prostate cancer and hypertension and included engaging in educational discussions with clients, providing written health information, taking blood pressures to screen for hypertension, and referring clients to local clinics when appropriate. Barbers were able to increase clients’ knowledge and positive health behavior, but outcomes were variable and not consistently documented. Studies of interventions at salons for African American women have yielded comparable results.

Faith Community Interventions

Churches are foundational settings across all populations and subgroups, including many underserved ethnic/cultural communities, where they often also serve as health education centers. Knowing that African Americans are disproportionately represented on organ transplant waiting lists but are themselves reluctant to donate, trained peer leaders in local churches were randomized to lead discussions and show a movie on either organ donation or good diet. In the following year, state donor registries showed greater registration rates for those present at the donor discussion. Similar results were seen from church-based discussions of clinical trial participation.

MEDIA INTERVENTIONS

Health messages are widely distributed through a variety of media, including print and digital advertising, videos and infographics seen in clinic waiting rooms, text messages, social media, and public service announcements (PSAs) seen on television and the Internet. Nearly every medium has been shown to influence patient action, so media messages may be a pathway to reduce HDs. Medical communicators are frequently involved in such projects.

Public service announcements have changed significantly in recent years. They increasingly feature actors with a range of ethnicities, socioeconomic backgrounds, abilities, and disabilities, allowing underserved people to more easily relate. However, PSA runtime has been sharply reduced, competition is fierce, and television airtime is no longer free. Still, PSAs have a robust life on platforms such as YouTube. The ways in which they can be targeted to specific cities or communities should increase their potential to diminish HDs. Even though Internet platforms have decreased airtime expense, production remains costly, and organizations advocating for the underserved may find themselves excluded. And while there is literature on assessing PSA impact and production best practices, little is known about health PSAs directly targeting the underserved. Future research is needed.
**LEGAL AND POLITICAL INTERVENTIONS**

Physician professional organizations are actively lobbying within political and governmental landscapes likely to influence HD/SDH. Furthermore, voter registration and participation of underserved subpopulations is important, as nonparticipation by the people who most need representation may not lead to policies that favor their health.49-51

Neighborhood structure is often the result of legislation that can be modified in ways that diminish HDs. For example, children raised in more diverse neighborhoods are more likely to attend college, have greater future income, and are less likely to be single parents, all of which can affect health and life expectancy.52 Homes in which control of dust mites, cockroaches, and mice was taught had improvements in the overall quality of life for children with asthma.53 Greening vacant lots, adding street lighting, and improving public transportation may reduce assaults and homicide.54-56 Importantly, an economic assessment of return on investment reported that for every $1 spent for blight remediation of abandoned buildings and vacant lots (which may create physical opportunities for violence by sheltering illegal activity and illegal firearms), $13 to $15 were returned through reductions in costs related to firearm violence.57

Many education-related changes in public schools are also dictated at state and local levels. New York City schools have combined the efforts of 2 city departments to provide School-Based Health Centers, where much-needed primary care is provided to students, reducing absenteeism and producing a healthier population better prepared to learn.58 The demand for mental and behavioral care in schools is immense. The very successful Healthy Environments and Response to Trauma in Schools program teaches educators skills to guide traumatized children away from behavioral blowups by using empathy rather than harsh punishment.59 Also, cognitive behavior therapy has been used in schools for groups of immigrant children to reduce symptoms of post-traumatic stress disorder and depression.60

**FUTURE TRENDS**

In the field of interventions targeting HD/SDH, approaches that were merely single strands of effort are being wrapped round one another to create a very strong lifeline for our nation’s underserved. A movement is underway, including The Health-in-all-Policies (HIAP) strategy, which seeks to include health considerations in policy making across all sectors that influence health, such as transportation, agriculture, land use, housing, public safety, and education.51 The HIAP strategy was included in the Patient Protection and Affordable Care Act of 2010,62 along with the creation of a National Prevention Council led by the Surgeon General.63

“To improve the health of populations, we have to realize that our care environment extends beyond the walls of our operating rooms, ambulatory care clinics, and patient care rooms in hospitals. As clinicians and clinician educators, we need to address factors such as health behaviors; health care and payer systems; health disparities; and the economic, social, and physical environments of our patients. At the ACCME, we believe these issues are so essential that we included them in our new criteria for commendable practices in continuing medical education (CME), our mechanism for rewarding CME programs that focus on areas beyond clinical care. Issues such as health care disparities are best addressed by teams; that’s why we encourage educators to be inclusive and create opportunities for patients, families, caregivers, and care teams to learn from and with each other. We are all in this together—all sectors need to collaborate to implement effective solutions to the challenges we face.”

—Graham McMahon, MD, MMSc, President and CEO, Accreditation Council for Continuing Medical Education (ACCME) in a statement directed explicitly to AMWA members (personal communication, June 2018)

In 2016, Marshall Chin, MD, MPH, program director of the Robert Wood Johnson Foundation, published “Creating the Business Case for Achieving Equity” in *The Journal of General Internal Medicine*.64 In that article, he states, “Commitment to social justice is essential to achieve health equity, but insufficient without a strong business case that makes interventions financially feasible.” Incentivizing payment systems to reduce HDs is an active area of both research and practice.

In health-related education, a Commission established by the publishers of *The Lancet* identified a fundamental mismatch between what students are taught and what patients need. The Commission proposes an approach that takes advantage of the worldwide flow of information so that education reaches “beyond the confines of countries and the silos of individual professions.” Physicians, nurses, midwives, pharmacists, social workers, public health professionals, and educators worldwide would stand shoulder-to-shoulder in the struggle to create a health system that worked for everyone.65

In the 20th century, the global life expectancy doubled following a complete reform in the way medicine was taught. In the 21st century, however, the US life span initially increased only gradually and is now in decline. A prime factor underlying these figures was the inequitable way in which medical advances were distributed. Social characteristics have been identified as the primary determinant of health outcome, and approaches to modifying these characteristics have been employed, many with some degree of success. Lisa A. Cooper, MD, MPH, Vice President for Health Care Equity for Johns Hopkins Medicine and professor of medicine at Johns Hopkins University School of Medicine, outlined the next step:
“Addressing these influences by gathering more data, learning how to increase the reach of interventions, and moving beyond disease-focused approaches is part of the next wave of health equity research.”

In the third article of this series, we will discuss the actions we medical communicators might take to help ameliorate disparities in SDHs and further strengthen the lifeline.

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All living things have a metabolism, which is a set of chemical reactions. For these chemical reactions to happen, some chemicals must enter the organism and others must leave it. This article explains why it matters if a substance dissolves in water or fat. Future articles may be developed to explain how transport proteins are used to transport fat-soluble materials in the bloodstream, how membrane transport proteins are used to carry water-soluble materials across the oily membranes that surround cells and that separate one body compartment from another, and how drugs are delivered to the tissues where they are needed.

BASIC PRINCIPLES
To understand the transport of substances in the body, you need to understand 6 basic principles. Three of them were known even in ancient times:

• Water runs downhill.
• Oil and water do not mix.
• To pass through a wall, you must find a doorway.

The other 3 principles were discovered only after the invention of the microscope:

• Blood goes round and round.
• All living things are made up of cells and the materials produced by cells.
• Every cell is surrounded by an oily membrane that controls the flow of materials into and out of the cell.

BARRIERS AND COMPARTMENTS
To enter the human body, a substance must pass between or through the cells that line the outer and inner surfaces of the human body (eg, the skin cells or the cells that line the lungs or gastrointestinal tract). These sheets of cells, as well as the membranes that surround each cell and enclose various spaces within cells, can be viewed as barriers that define various compartments, especially the following:

• The exterior of the body (this includes the space inside the gastrointestinal tract and the air spaces of the lungs)
• The blood plasma
• The extracellular space (the fluid that surrounds the cells in the body)
• The intracellular space (the fluid within a cell membrane)
• The brain (which is walled off from the rest of the body by the blood-brain barrier)

A barrier is permeable if it allows something to pass through. Some barriers are more permeable than others. For example, the capillaries (tiny blood vessels) in most of the body have tiny gaps or pores between the endothelial cells that line their walls.1 These pores allow many substances to pass from the bloodstream to the local tissue. In contrast, the endothelial cells that line the capillaries in the brain are held together by tight junctions. To enter the brain, a substance must therefore pass through the bodies of the endothelial cells, as opposed to slipping between the endothelial cells.2

OIL AND WATER
To be carried in the bloodstream, a substance must be able to mix with water, because blood is a water-based fluid. Yet this poses a dilemma:

• Substances that dissolve in oil can easily pass through cell membranes to enter the bloodstream and pass from the bloodstream to the brain—but they are hard to carry in the blood.
• Substances that are easy to carry in the blood often have a hard time passing through cell membranes because they cannot dissolve in oil. As a result, they have a hard time getting into the blood plasma, into the intracellular space, and into the brain.

In other words, fat-soluble molecules can easily pass into or out of cells, but they have a hard time making their way to...
the cells. In contrast, water-soluble molecules can easily make their way to cells but have a hard time making their way into or out of the cells. To solve this dilemma, the body makes substances, including phospholipids and various proteins, that can mix with water or oil.

Transport proteins allow fat-soluble molecules to be carried in the bloodstream. Examples include hemoglobin (the oxygen-carrying protein in red blood cells) and the sex hormone-binding globulin that carries sex hormones in the bloodstream. In contrast, membrane transport proteins that are embedded in the cell membranes allow water-soluble substances to cross those cell membranes. Examples include the glucose transporters, which allow glucose to pass into or out of cells.

Proteins can serve these purposes because they are made up of long chains of up to 20 different amino acids. Each protein has a predictable shape, which depends on the sequence of amino acids in the protein. That sequence of amino acids is encoded in DNA in the gene for that protein. Each of the 20 amino acids that are used in building proteins has a unique side chain. Some amino acids have a side chain that is attracted to water, while others have a side chain that is attracted to fat. As a result, a protein may have some domains, or regions, that are attracted to water and others that are attracted to fat.

Substances that easily dissolve in water or are attracted to water are described as hydrophilic, which means water loving. In contrast, the substances that dissolve poorly in water and seem to repel water are called hydrophobic (water fearing). Molecules that have at least 1 hydrophilic domain and at least 1 hydrophobic domain are called amphiphilic (loving both).

THE SHARING AND TRANSFER OF ELECTRONS

Chemists can accurately predict whether a chemical species is hydrophilic, hydrophobic, or amphiphilic by looking at the chemical species’ net electrical charge as well as the chemical species’ electrostatic potential map (which shows the distribution of the electrical charge around the molecule). Ions and ionic compounds are hydrophilic. So are polar molecules. In contrast, nonpolar molecules are hydrophobic. Amphiphilic (also called amphipathic) molecules have at least 1 polar domain as well as at least 1 nonpolar domain.

- **Ions** are atoms or molecules with a net positive or negative electrical charge. A cation (pronounced “cat-eye-on”) is positively charged because it has more protons than electrons. An anion is negatively charged because it has more electrons than protons (Figure 1).
- An **ionic bond** represents the transfer of 1 or more electrons from 1 atom or molecule to another. For example, sodium atoms give up an electron to become sodium ions (Na⁺). Chlorine atoms pick up an extra electron to become chloride ions (Cl⁻). The Na⁺ and Cl⁻ ions can then be held together by electrostatic forces.
- In a **covalent bond**, 2 atoms evenly share a pair of electrons. These bonds are nonpolar and occur between atoms that have a similar ability to attract electrons (ie, a similar electronegativity). Because 2 atoms of the same element have identical electronegativity, you would find nonpolar bonds between atoms of the same element (eg, between 2 carbon atoms or between 2 oxygen atoms). You would also find nonpolar bonds between atoms of different elements that have similar electronegativity (eg, between a carbon atom and a hydrogen atom).
- A **polar bond** is almost like a hybrid between an ionic bond and a nonpolar covalent bond: a pair of electrons is shared between 2 atoms, but the electrons are pulled more strongly toward the atom with greater electronegativity. Fluorine has the highest electronegativity, followed by oxygen and then nitrogen. For this reason, a bond between an oxygen atom and an atom of carbon or hydrogen would be polar, with the negative pole near the oxygen atom.
- Sometimes, an ionic or polar bond can split, resulting in the production of a cation and anion. For example, a water molecule (H₂O) can split into a hydrogen ion (H⁺) and a hydroxide ion (OH⁻). This splitting into ions is called **ionic dissociation**.

![Figure 1](https://via.placeholder.com/150)

Figure 1. In a covalent bond, 2 atoms share a pair of electrons equally. In a polar bond, 2 atoms share a pair of electrons, but the electrons are attracted more strongly to one atom than to the other. As a result, the bond has a positive pole and a negative pole. The strength and direction of this polarity is measured by the dipole moment. An ionic bond represents the transfer of 1 or more electrons from one atom to another. The result is a positively charged ion (cation) and a negatively charged ion (anion), which are held together by electrostatic forces.

The polarity of a bond is measured by its dipole moment. The dipole moment is a vector quantity, which means that it has a magnitude and a direction. If you have more than 1
bond in a molecule, then the dipole moment of the molecule as a whole is the vector sum of the dipole moments of all of the bonds. For example, if a molecule contains 2 polar bonds whose dipole moments are equal in magnitude but point in opposite directions, their dipole moments cancel out. The result is a nonpolar molecule (Figure 2). Carbon dioxide is a nonpolar molecule because it is linear in structure. As a result, the dipole moments of its 2 double bonds cancel each other out. In contrast, a water molecule has a V-shaped structure. As a result, the dipole moments of its 2 single bonds do not cancel each other out. This is why carbon dioxide is nonpolar but water is strongly polar.

**Figure 2.** In these electrostatic potential maps, areas of net positive charge are shown in black, and areas of net negative charge are shown in white. Oxygen (\(\text{O}_2\)) is a nonpolar molecule because it contains nonpolar bonds. Carbon dioxide is a nonpolar molecule because its polar bonds point in opposite directions, canceling each other out. The polar bonds in a water molecule do not point in opposite directions. As a result, the vector sum of the dipole moments of the 2 bonds yields a dipole moment for the molecule as a whole. Ethanol (beverage alcohol) and glucose are also polar molecules. Nonpolar molecules and small polar molecules (eg, water and ethanol) can diffuse through a cell membrane. Larger polar molecules and ions cannot. To enter or leave a cell, an ion or a large polar molecule must pass through an opening created by a membrane transport protein. (From Thomas LE. *Thin Diabetes, Fat Diabetes: Prevent Type 1, Cure Type 2*. Chatham, NJ: Kermit Press, 2016.)

**WATER IS HIGHLY POLAR**

Because of their polarity, water molecules are connected to other water molecules by hydrogen bonds. A hydrogen bond is the electrostatic attraction between a hydrogen atom that is bound to a highly electronegative atom (fluorine, oxygen, or nitrogen) and a nearby highly electronegative atom. The existence of these hydrogen bonds between water molecules (Figure 3) explains why water can remain liquid at room temperature and atmospheric pressure, while other compounds of a similar molecular weight are gases.

**Figure 3.** The hydrogen atom that represents the positive pole of a polar molecule may be attracted to a fluorine, oxygen, or nitrogen atom that represents the negative pole of another polar molecule. The result is a weak bond called a hydrogen bond. The hydrogen bonds among water molecules explain why water has such a high boiling point compared with other molecules of similar molecular weight. Courtesy of Qwerter, via Wikimedia Commons.

Because of their polarity, water molecules are also strongly attracted to ions (such as \(\text{Na}^+\) and \(\text{Cl}^-\)) and to other polar molecules (such as glucose molecules). That is why ionic compounds and polar compounds are hydrophilic. The solubility of an ionic compound depends on how strongly its cations and anions are attracted to each other. If that attraction is weaker than the pull exerted by water molecules, the ionic compound will be highly soluble in water. Likewise, the solubility of a polar compound depends on whether water molecules can exert enough pull to separate the polar molecule from others of its kind.

If the electrostatic force exerted by water molecules is strong enough to pull a compound apart into ions (ionic dissociation), then the solution will contain electrically charged particles. As a result, the solution will be able to conduct electricity. That is why a solution of table salt (an ionic compound) conducts electricity, but a solution of glucose (a polar compound) does not. The solutes (dissolved substances) that allow a water-based solution to conduct electricity are called electrolytes.

**OIL IS NONPOLAR**

Oil and water do not mix because water molecules are so strongly attracted to each other that they tend to squeeze out
nonpolar molecules, such as the molecules of oils. Meanwhile, the nonpolar molecules are attracted to each other by weak forces called van der Waals forces. This explains why nonpolar compounds are hydrophobic.

The organic hydrophobic compounds of biological origin are often called lipids. Examples include fats, waxes, sterols, and the fat-soluble vitamins. Hydrophobic compounds tend to dissolve in nonpolar solvents (such as chloroform and ether). In contrast, hydrophilic compounds generally do not dissolve in nonpolar solvents. That’s why salt and sugar do not dissolve in gasoline.

### Amphiphiles Like Oil and Water

Amphiphilic molecules (Figure 4) have at least 1 hydrophilic domain and at least 1 hydrophobic domain. Examples include the phospholipid molecules that make up cell membranes. A phospholipid molecule consists of a molecule of glycerol bonded to 1 phosphate group (the hydrophilic “head”) and 2 fatty acids (the hydrophobic “tails”). In a watery environment, amphiphile molecules will come together to form aggregates, such as a ball, a hollow shell, or a bilayer sheet. In these aggregates, the hydrophilic heads face the water, while the hydrophobic tails cluster with each other and sometimes with other hydrophobic substances.

Amphiphilic molecules can create a hydrophilic surface around a particle or droplet of hydrophobic material. Thus, the amphiphilic substance allows the hydrophobic material to mix with water. This is how soap works. The same principle is important in the digestion of fats and in the transport of fatty substances, such as fat and cholesterol, in the bloodstream. It is also important in the development of targeted drug delivery systems.

Because a cell membrane is oily, a fat-soluble substance (eg, oxygen, carbon dioxide, and lipids) can diffuse right through it. However, the cell membrane presents an effective barrier to ions and to large polar molecules. (Some small polar molecules, such as water and ethanol [beverage alcohol], can seep through the cell membrane.) For this reason, the cell membrane is semipermeable; water can pass through, but ions and large polar molecules cannot.

### Membrane Transport Proteins

Ions and large polar molecules, such as glucose, cannot flow in or out of a cell unless the cell membrane has some sort of doorway. These doorways are created by membrane transport proteins. These proteins contain hydrophobic domains that keep the protein anchored in the cell membrane, as well as hydrophilic domains that face or even extend into the watery environments inside and outside the cell.

Membrane transport proteins can be sorted into 2 broad categories: passive and active. The passive ones simply allow a substance to diffuse into or out of the cell. As a result, they allow a net flow of a substance from an area of greater concentration to an area of lesser concentration (ie, down a concentration gradient). They also allow electrically charged particles to flow toward particles of the opposite charge (ie, up or down a voltage gradient). Sometimes, the membrane transport protein involved in passive transport can open or close in response to a specific stimulus: a change in voltage, binding by a ligand, or (in the cochlea of the ear) pressure. Thus, these transport proteins can regulate the passage of substances into or out of the cell.

In passive transport, the net flow is always “downhill” with respect to the electrochemical gradient. Some of the transport proteins (uniporters) allow only 1 substance to cross the membrane (Figure 5). Co-transporters allow 2 or more different substances to cross the cell membrane. Symporters carry those substances in the same direction. For example, we can absorb sodium and glucose from our food because the Na⁺/glucose symporter allows a sodium ion and a glucose molecule to flow into the cell at the same time. (The glucose and sodium can flow passively into these cells because the cells are actively pumping sodium and glucose out the other side, into the interstitial fluid and the bloodstream.)
An antiporter carries 2 substances in opposite directions. It lets 1 substance flow passively according to its electrochemical gradient; this passive flow yields the energy to drive another solute “uphill” against its electrochemical gradient. For example, the sodium/calcium exchanger removes calcium from cells. By allowing 3 sodium ions to enter the cell, the transporter gains enough energy to push 1 calcium ion out of the cell.

Active transport, in contrast, involves the use of the cell’s metabolic energy to power the transport of substances “uphill” against their electrochemical gradient. This energy is stored in the form of adenosine triphosphate (ATP) in the cell. For example, the sodium-potassium pump uses the energy that it gets from removing a phosphate group from a molecule of ATP to drive 3 sodium ions out of the cell. Then, it allows 2 potassium ions to enter the cell (Figure 6).9

ENDO- AND EXOCYTOSIS

Endocytosis (bringing something into the cell) and exocytosis (expelling something from a cell) are other ways for a cell to transport substances across a cell membrane (Figure 7). They are particularly important for the transport of polar molecules that are too large to be passed through a membrane transporter protein.10

Cells can use a process called pinocytosis (cell drinking) to pull fluid into the cell.10 Cells can also use receptor-mediated endocytosis to pull specific materials into the cell. In pinocytosis and receptor-mediated endocytosis, the cell membrane forms a pit that deepens to form a pocket surrounding the material to be brought into the cell. This pocket is then pinched off to form a membrane-bound compartment called a vesicle within the cell.

![Figure 5. Three types of membrane transport protein are involved in passive transport: uniporters, symporters, and antiporters. Courtesy of Lupask, via Wikimedia Commons.](image-url)

![Figure 6. The sodium-potassium pump takes energy that it gets from removing a phosphate group from adenosine triphosphate. That energy is then used to push 3 sodium ions (Na+) “uphill” against a concentration gradient and out of the cell. The sodium-potassium pump then allows 2 potassium ions (K+) to flow into the cell in response to its electrochemical gradient. Image courtesy of OpenStax via Wikimedia Commons.](image-url)

![Figure 7. Types of endocytosis. In phagocytosis (only in animal cells), the cell reaches out to surround a solid particle. In pinocytosis, a dimple in the cell membrane gets pinched off to make a vesicle. In receptor-mediated endocytosis, a substance binds to a receptor on the cell surface. This part of the cell surface is then pinched off to form a vesicle inside the cell. Courtesy of Mariana Ruiz Villarreal, LadyofHats, via Wikimedia Commons.](image-url)
Some cells, including some white blood cells, can also use a process called phagocytosis to bring large particles into the cell. In phagocytosis, the cell membrane reaches out to surround a particle, such as a bacterium. The pouch is then brought into the cell and pinched off to form a membrane-bound compartment called a phagosome or food vacuole. The material in the vacuoles that result from endocytosis can then be digested by enzymes before being released into the cytosol in the cell. Note that prokaryotes (e.g., bacteria) generally cannot perform phagocytosis, partly because they are surrounded by a rigid cell wall and partly because they lack the internal structure (cytoskeleton) that would allow them to engage in this kind of movement.

Exocytosis is merely endocytosis in reverse. In exocytosis, a membrane-bound secretory vesicle is brought to the surface of the cell. There, the vesicle membrane fuses with the cell membrane. As a result, the material in the secretory vesicle is released to the extracellular space. Exocytosis of neurotransmitters into the gap (synapse) between nerve cells plays an important role in the conduction of nerve signals.

CONCLUSION

Ions and polar molecules mix easily with water. For this reason, they can easily be carried in the bloodstream and diffuse through the watery fluid that bathes the cells (extracellular fluid). However, ions and large polar molecules cannot easily pass through the lipid bilayer that surrounds each cell. As a result, ions and large polar molecules have difficulty in passing from one body compartment to another, unless they can pass through a membrane transport protein. Although fat-soluble molecules can easily pass through cell membranes, they cannot easily mix with water unless they are bound to a transport protein.

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References

As members of the American Medical Writers Association, we adhere to a code of ethics. One of the principles of this code is: “Medical communicators should apply objectivity, scientific accuracy and rigor, and fair balance while conveying pertinent information in all media.”

I believe this principle speaks to our continual effort to avoid bias while we report on research and clinical trial results. It also speaks to the fact that in order for us to be “objective,” “accurate,” and “balanced,” there has to be transparency in the information we are reporting. At the same time, we are required to give patients full disclosure of their role in a trial and to respect their privacy.

Darshan Kulkarni, PharmD, MS, Esq, has agreed to share some thoughts with us on these topics. Dr Kulkarni is Vice President of Regulatory Strategy & Policy at Synchrogenix, where he provides regulatory and clinical assistance to FDA-regulated companies based on his legal, regulatory, and clinical background. He is also a visiting professor at the University of the Sciences in Philadelphia.

Journal: Is there any such thing as true data transparency in medical writing?

Kulkarni: If by true transparency you mean that, today, every pharmaceutical company, physician, caregiver, and patient has access to all raw data produced and documented in every clinical trial, I would say no.

Transparency is a goal that we as an industry are evolving toward, while at the same time focusing on maintaining patient privacy, industry credibility, and the ability of pharmaceutical companies and other medical research facilities to remain viable and competitive.

This evolution is the result of the Empowered Patient Movement, which began more than 2 decades ago. So far, it has produced such results as the Sunshine Act, which requires the disclosure of pharmaceutical companies’ payments to physicians, and the Centers for Medicare and Medicaid Services, disclosure of a range of patient-level information regarding procedures, prescriptions, and payments collected by hospitals, physicians, and other service providers. The movement also has led to the creation and ongoing expansion of www.ClinicalTrials.gov, where information on clinical trials is made available publicly. Still, much of the raw data in clinical trials are not available.

Pharmaceutical companies are continually facing pressure to reach complete transparency. In recent years, British physician Ben Goldacre has voiced strong criticism of the pharmaceutical industry, describing research practices as “bad science.” He has gained a wide audience through his books, public speaking, and television appearances. In 2005, Jennifer Miller, PhD, and others founded the non-profit Bioethics International to advance industry ethics and patient-centricity in medicine. In recent years it has created the Good Pharma Score Card, which rates companies on their transparency.

In January of this year, FDA commissioner Scott Gottlieb, MD, announced a new pilot program to improve transparency by having pharmaceutical companies post, on a public FDA website, more information on newly approved drugs. Its focus is on improving patient care by sharing information with providers and other stakeholders. As part of the FDA’s new clinical data summary pilot program, volunteering sponsors will share on the Drugs@FDA database portions of clinical study reports from approved new drug applications (NDAs) from the pivotal trials submitted to the FDA. The pilot program is underway, and the goal is to have 9 NDAs participate. The FDA will seek public comment through the Federal Register once the pilot is complete.
Journal: Are we impinging on patient privacy as we try to create true transparency?

Kulkarni: This is an excellent question and reflects a real worry. As we move toward the sharing of raw granular data collected in clinical trials, we face the possibility that patients will be able to be identified. The European Medicines Agency already has issued transparency policies to have full data disclosure, and that information will be available soon. At the same time, efforts are underway to protect patient identification through different strategies, including the blacking out of names, the use of ranges, and even the creation and use of synthetic data.

Journal: Who owns the data collected in clinical trials?

Kulkarni: Today, it is often the pharmaceutical companies. But the question of ownership is going to be affected by the changing regulatory climate. I routinely negotiate these agreements between pharmaceutical companies and hospitals, who also want to own the data collected from their patients. Not only do the hospitals want access to the data, but so do the doctors and other providers who focus on patient care.

Questions have arisen as to whether patients should also not only have access to the information but actually own it. Experiences like the Henrietta Lacks situation have shed light on companies and science profiting from individually identifiable information but leaving patients and their families out of any such profits. On the other hand, how do we continue to incentivize pharmaceutical companies to spend billions of dollars on research if they will not own the data they collect? Companies, including Synogenix, are already looking for ways to help these patients, and early indications suggest that all their needs can be met. However, this requires a rethinking of some of our current legal and regulatory paradigms.

Journal: How can medical writers avoid bias as they base their writing on the clinical study results shared by the sponsor or researcher?

Kulkarni: There is no easy answer, and this is directly connected to where our industry is now and where we are going. It is connected to the pharmaceutical companies’ efforts to remain competitive and to how they respond to regulatory demands. While writers strive to be accurate and impartial and to hold themselves to a high standard of work, sometimes bias is inescapable. That is human nature, and, in fact, that is the first thing we learn in law school. We need to continue to be aware of our own biases and work to remain impartial. As transparency evolves, so will the writer’s ability to obtain raw data.

Journal: Ancestry websites and services are collecting genetic information from consumers. Could this information have an impact on medical research?

Kulkarni: Absolutely, though we are at the early stages of how this genetic data will be used for research. Consumers generally think that they are sharing their genetic information to learn about their ancestors. In fact, these websites, which may not be subject to certain privacy laws like HIPAA [the Health Insurance Portability and Accountability Act], are already using the information to come up with ways of identifying diseases themselves and are also looking at ways to sell the information to the pharmaceutical industry. Theoretically, as gene therapy research advances and the ability to have clinical trials becomes approved, these new databases could create new recruiting processes and provide new therapy targets. At the moment, however, only a handful of genetic therapies have reached the point where clinical trials on human participants can be initiated.

ED: As we were going to press, we learned that one such consumer genetic ancestry company, 23andMe, has received FDA authorization for the first-ever direct-to-consumer genetic test for an inherited risk for cancer. Specifically, it tests for variants in the BRCA1 and BRCA2 genes known to significantly increase chances of developing breast and ovarian cancer. For more information, please see https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm599560.htm and https://www.statnews.com/2018/04/09/consumers-23andme-genetic-risk-reports/.
Countless organizations and individuals, including patients, research participants, and funders, call for greater transparency in the reporting of clinical trials research, and there is a growing body of legal and regulatory requirements to this end. However, a definition of transparency is surprisingly elusive. For some, transparency means meeting the minimum legal reporting requirements in a timely fashion. Others have higher ethical expectations and define transparency as accelerating and broadening the release of information about medical and scientific advances. Some feel that transparency is incorporating patient input into the design, execution, and publication of clinical trials. Calls for transparency in the publication process involve requests for sharing published data and for opening and unblinding the peer review system. What does transparency mean for medical writers? Some medical writers and publications professionals may define transparency for the medical writing profession as ensuring complete disclosure of conflicts of interest, financial support, and medical writing assistance.

Medical writers and editors are clearly critical to the implementation of publication best practices. Their roles have been validated both in principle, in the form of a joint statement from AMWA, the European Medical Writers Association, and the International Society for Medical Publication Professionals (ISMPP); and in practice, as research has found that involvement of medical writers is associated with improved reporting of clinical trial results, that authors value many aspects of the role of medical writers, and that medical writers (and the pharmaceutical industry) are rarely involved in publications retracted for misconduct. Medical writers have the opportunity to continue to serve as gatekeepers for appropriate transparent practices in publications. In particular, medical writers have the responsibility of working with authors and clinical trial sponsors to encourage adherence with best practices and sponsor policies, including appropriate and complete reporting of contributions and disclosures, disclosure of medical writing and editorial support (putting an end to ghost and guest authorship), and thorough and accurate reporting of efficacy and safety results with correct clinical context.

As publications professionals, we can all appreciate the writing discipline as an evolving and dynamic space with shared values at its core. Because expectations within the publications arena continuously evolve as new requirements are implemented, medical writers must continuously educate themselves on these changes to continue to be valued partners in the development of publications that adhere to contemporary best practices.

Ultimately, improving transparency as expectations and requirements evolve rests with each individual engaged in the content development and disclosure process. Fortunately, there are a number of tools to guide us as we consider what transparency means and how we, as individuals, can incorporate transparent practices in our day-to-day work. Professional guidelines, including Good Publication Practice (ie, GPP3) and recommendations from the International Committee of Medical Journal Editors (ICMJE), are an excellent starting point and are supplemented by the work of others, including that of Medical Publishing Insights & Practices (MPIP), a collaborative initiative founded by the pharmaceutical industry (current corporate sponsors include Amgen, AstraZeneca, Biogen, Bristol-Myers Squibb, GlaxoSmithKline, Janssen Global Services, LLC, Merck, and Pfizer) and ISMPP. In 2010, a group of journal editors and industry representatives from MPIP member organizations met to discuss actions within the publications industry that could improve transparency and credibility in publication of industry-sponsored research, which led to the publication of 10 recommendations.
Building on these general recommendations and complementing existing guidance from the CONSORT group, journal editors and MPIP collaborated again in 2014 to provide consensus recommendations on the reporting of adverse events. While industry-sponsored studies were the focus of both of these guidelines, they can equally be applied to the reporting of all research, regardless of funding source or research type.

MPIP (https://www.mpip-initiative.org/) was founded to elevate trust, transparency, and integrity in reporting the results of industry-sponsored research. Through collaboration with key stakeholders, MPIP works to understand the issues and challenges in reporting industry-sponsored research, publish its findings, and develop tools to improve credibility and transparency. At the core of these efforts is Transparency Matters (https://www.mpip-initiative.org/transparencymatters/index.html), a global education platform and call to action. At this resource hub, all interested parties, including medical writers, authors, life-science companies, journal editors, and others with a vested interest in the transparent reporting of clinical trials results, can find research, tools, and recommendations to improve the level of transparency when reporting the results of clinical research.

We invite you to join us in our mission and add your voice to the conversation! Transparency Matters encourages stakeholder engagement through 2 key initiatives:

1. Take the Transparency Pledge (https://www.mpip-initiative.org/transparencymatters/takethepledge.html) and commit to transparent publication practices when reporting pharmaceutical and biomedical research.
2. Contribute to What Transparency Means to Me (https://www.mpip-initiative.org/transparencymatters/wttmlm.html)—a space for those involved in reporting research to share their perspectives on transparency and how it can be best achieved when disclosing data. Expert insight on relevant and timely topics such as the ICMJE data sharing statement, predatory journals and congresses, and future perspectives in peer review is shared on the Transparency and Data Sharing Blog (https://www.mpip-initiative.org/transparencymatters/wtmtmblog.html).

Tell us! What does transparency mean to YOU? Submit a quote or imagery to be published on our website and be a voice in this conversation! https://www.mpip-initiative.org/transparencymatters/wtmtmquotes.html

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In January 2017, the American Medical Writers Association (AMWA), the European Medical Writers Association (EMWA), and the International Society for Medical Publication Professionals (ISMPP) released a Joint Position Statement (JPS) on the Role of Professional Medical Writers,1-3 the first unified position on the role of professional medical writers from the 3 leading professional organizations.

On May 30, 2018, these 3 organizations joined with the EQUATOR Network4 to provide a joint educational webinar on the importance of reporting guidelines and the role of professional medical writers as guideline champions. The webinar, titled “Joint Position Statement on the Role of Professional Medical Writers: Positioning and Advocating for Writers as Guideline Champions,” was hosted through the ISMPP University (or ISMPP U) platform and attracted more than 140 attendees from around the world. This webinar underscored the mission of the AMWA-EMWA-ISMPP JPS and its expanding influence and reinforced the shared goal of the JPS and the EQUATOR Network to promote good reporting practices.

The JPS has increased its reach since its initial release in 2017. It has been translated into 10 languages and has gained broad endorsement and recognition from multiple stakeholders, such as the EQUATOR Network, the European Association of Science Editors, the Council of Science Editors, the Board of Editors in the Life Sciences, the Association of Regulatory and Clinical Scientists, and the Australasian Medical Writers Association.

According to the JPS, professional medical writers are responsible for consulting appropriate guidelines and ensuring that authors and sponsors are aware of their obligations under these guidelines. These responsibilities call for professional medical writers to be guideline champions. Medical writers should have the time and expertise to help authors identify and adhere to relevant reporting guidelines. Reassuringly, when attendees of the webinar were asked if professional medical writers should be guideline champions, 95% (119/125) responded “YES.”

A free and practical online tool to help medical writers and publication professionals achieve good reporting is the reporting guideline library from the EQUATOR Network. Caroline Struthers introduced the history of the Network and its ongoing development. Founded by the world-renowned statistician Doug Altman, Professor of Statistics in Medicine at the University of Oxford, the EQUATOR Network was launched in 2008 (Figure 1). The mission of the EQUATOR Network is to achieve accurate, complete, and transparent reporting of all health research studies to support research reproducibility and usefulness. Essentially, the Network aims to provide researchers around the world with “a one-stop-shop for writing and publishing high-impact health research,” as Struthers noted. The EQUATOR Network’s free, searchable online library contains more than...
400 reporting guidelines, covering a wide range of study types and clinical areas. Additional resources are also available, such as the JPS and Good Publication Practice 3 guidelines, as well as examples of good reporting, guideline extensions, add-ons, and translations, and various toolkits for writing research reports.

In the last decade, the EQUATOR Network has gained increasing recognition from the health research community and has been especially embraced by professional medical writers and publication professionals. Published evidence indicates that professional medical writing support is associated with better adherence to reporting guidelines and a lower risk of retractions for misconduct.5-9

How can medical writers and publication professionals better support the EQUATOR Network? Woolley stressed that writers can serve as reporting guideline champions by raising awareness of the relevant reporting guidelines and the EQUATOR Network to authors and sponsors. Medical writers and publication professionals may also be able to advance their careers by being advocates for the EQUATOR Network and for the JPS. Woolley suggested several career-enhancing activities, such as monitoring the EQUATOR Network and alerting their teams to new and relevant reporting guidelines, auditing and updating their teams’ training regarding the use of reporting guidelines, and promoting the JPS proactively to authors and sponsors, especially by citing published evidence supporting the benefits of writing support. Through these activities, writers can provide practical and tangible support to their teams and contribute to best-practice reporting, which should be valued by managers, editors, peer reviewers, and readers. Medical writers and publication professionals should also advocate for and contribute to the evidence base on the integrity and value of professional medical writing support. By conducting and publishing research in this area, writers can gain respect as published authors and may even be invited to help develop new reporting guidelines.

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A note from Professor Woolley: Professor Doug Altman (shown above with me holding a copy of the JPS at the Peer Review Congress; Chicago, September 2017) recognized the merit of the JPS and commended the speakers on this webinar. Professor Altman passed away only a few days after this webinar. We can honor his memory by helping authors to adhere to reporting guidelines.
What advice would you give to freelance medical writers/editors/communicators who are new to the field of medical writing and have limited writing experience?

First, I must mention an exceptionally experienced woman I met recently who couldn’t find a medical writing job because her CV’s 3 full pages of publication credits she had authored left her dismissed as overqualified. Second, my own wobbly start as a medical writer/editor followed from my college major in English, minor in science. I scratched advertising as a career goal because the work felt like lying (this mattress beats all others on the market because...). So I produced some short feature articles for small-time publications, eg, city newsletters, travel folders, quarterly magazines. All of them had pages to fill and needed unique text to do so. Soon, my articles on local scuba diving were accepted by a few sports and travel magazines, providing me with a short publication list and writing samples to show.

Employers don’t interview readily these days, so a new writer’s awesome personality may not yield a job. However, the prospective medical writer/editor/communicator can benefit from familiarity with online or physical libraries: those filled with medical, pharmaceutical, and engineering subjects. Even the physician who wishes to write does well to observe and internalize the classic writing and format style. The basic format for delivering scientific information remains what it has always been: Title, Introduction, Methods, Results, Discussion, Conclusion. Eventually, some likely employer or publisher will want a writing sample, possibly a 300-word abstract, and using this format will automatically organize your work for sale.

—Phyllis Minick

As I’ve been a freelance medical writer for 18 years, I could write pages and pages of advice for those who are new to the field! I’ll summarize that part by recommending that new freelance writers and editors visit the AMWA Engage online forum and read through the discussion threads, network like crazy (live and virtually), read everything written about running a freelance business, and consider doing any courses or webinars by Brian Bass, Bette Frick, Lori DeMilto, Deb Gordon, Cyndy Kryder, and Ruwaida Vakil.

To focus on one topic, I suggest that new medical communicators open their minds as to what they consider medical writing or medical editing. They must have some experience (and likely ability) in writing or editing; otherwise, they would not have chosen this career path. For example, writing or editing scientific manuscripts, abstracts, posters, and slide decks for themselves or lab colleagues and writing newsletter articles or blog posts for universities or hospitals all count as medical communications. I became a freelance medical writer straight after my postdoctoral fellowship. My first few jobs included writing e-learning storyboards for online high school Advanced Placement chemistry and biology courses, writing articles for a genomics newsletter started by graduate school colleagues, and assisting in writing a thesis for a student obtaining her Master’s degree in forensic science. I didn’t think any of these were medical writing, but later realized they were. Working on these projects taught me many, many things about medical communications and how to run a successful freelance business, even though they have nothing to do with the type of writing I do now. Trying many different types of communications can also help you narrow down the types of writing or editing you do and do not like to do.

—Gail Flores

The age-old question is, “If employers/clients want experienced writers, how does a newcomer to writing gain that experience if nobody is willing to take a chance on a newcomer?”

If you want to gain more writing experience, the 4 most important tips to success I have are to network within our organization, take AMWA courses, use a LinkedIn profile, and sign all emails with complete contact information.

Networking involves listening, giving, and being helpful to colleagues. In talking about editing and writing with others at various industry meetings, listen for ways to help someone else’s career. I also talk about nonwork-related adventures, so people get to know me outside of the business environment. The most fruitful networking has happened when I wasn’t talking about work but about raising chickens in my backyard. As we learn about each other’s personalities, we begin to make mental notes of who would be a good fit for a particular project. Sometimes opportunities arise to collaborate with others on a project, and then you gain direct experience working with them. That’s a great way to build a team. Clients or
employers may become willing to take a chance on someone with limited writing experience if they know that person is a reliable, smart, and resourceful team player, especially if a colleague can vouch for that person.

Taking AMWA courses is one way to build a portfolio of writing clips. If applicable, ask the instructor if you can use your written assignment as a clip to show potential clients/employers. If the end product of an AMWA class cannot be used as a writing sample, you have nonetheless gained important knowledge, so you are better positioned than a non-AMWA member to write something worthwhile.

My suggestion to set up and maintain a free profile at LinkedIn (www.linkedin.com) is so that you can advertise your skills, knowledge, and abilities. Be active in LinkedIn forums; answer questions in your area(s) of expertise to become known as someone who shares useful information generously. If you become known and respected online, you may eventually be offered the opportunity to write.

Put your name and contact info on all correspondence. Each email you send should contain a closing “signature” with at least your name, your company’s name (if you have one), your email address, and the URL for your website or LinkedIn profile. That way, colleagues can easily copy and paste your contact info into an email to a potential client or employer.

—Melissa Bogen

What are the key criteria that you feel a freelance medical writer/editor/communicator needs to be successful?

No freelance medical writer, editor, or communicator can be successful without being good—no, great—at what they do. But I wouldn’t call that a key criterion because it’s inherently required and expected.

So in my opinion, the key criteria you need to be successful are as follows:

Be honest with yourself about how good you are, what you’re good at, what you can and cannot do, and what you should and should not try to do. Freelancing is a great way to get paid while you learn and expand your capabilities, but you always have to be able to deliver the goods.

Be flexible because you continually have to adapt to changing client needs, the varying practices and protocols different clients have for doing the same thing (eg, annotating), evolving project demands, and shifting timelines. The only constant in this business is change, and freelances must be ready for it at every turn.

Be positive in your attitude and demeanor. Clients can smell apprehension over the phone and in an email. If you’re not positive in your ability to get the job done and done well, then be positive that you’re not the right person for the job and help your client find someone who is. It’s better to at least be a part of the solution than to be the focal point of the problem.

Be confident in yourself and your abilities. Clients want to work with people who are confident in their ability to get the job done. They can’t have confidence in hiring you for a project if you don’t project an air of confidence that communicates they’re making the right decision.

Be ethical at all times, in all circumstances, no matter what. Freelances need to be Guideline Champions (https://www.amwa.org/events/EventDetails.aspx?id=1113072&hshTerms=%22guideline+and+champion%22), so they can inform and help guide clients, authors, and others and ensure adherence to proper, legal, and ethical practices. If a client doesn’t want to hear about it, you don’t want that client!

—Brian Bass

Freelance medical communicators need to present a 100% professional image to their clients at all times. It’s fine to work from a laptop in sweats surround by cats on the couch, but never give clients the impression that’s what you’re doing—they want to picture us as professionals, dressed for a day’s work, in an office. Have top-notch computer hardware and software and excellent internet and cell phone service. Invest in a logo designer, order high-quality business cards, and use a professional-sounding email address. With regard to behavior, freelances should also act like professionals. Call into conference calls a few minutes early. Don’t start emails with “Hey.” Deliver everything on time (including invoices); if there will be a delay, let clients know as soon as possible. If you are unavailable during normal work hours, tell clients you have an appointment or a conference call—they don’t need any other information (child’s recital, dentist appointment, lunch with a friend, etc).

Conversely, freelance medical communicators should be treated as the professionals they are—don’t let clients walk all over you! You don’t need to be available before 8 or 9 AM or past 5 or 6 PM, regardless of the time zone you (not the client) lives in. You can’t be on call or drop your other work to take care of their emergency. You certainly don’t need to work on weekends or holidays. You need to be paid at your rate, on time. If the scope of a project increases, the client needs to pay you more. If the client is late giving you the materials you need, they should expect that the deadline will also be delayed. In summary, both the freelance and the client should treat each other professionally and with respect.

—Gail Flores

For starters, a successful freelance medical editor must consistently produce high-quality work and meet deadlines. To do that, a freelance medical editor must be

• smart;
• reliable;
FREELANCE FORUM

• resourceful;
• well versed in AMA style and other industry standards (eg, FDA guidelines, ICMJE recommendations);
• flexible;
• a team player and easy to work with, yet able to work independently;
• able to juggle multiple projects with shifting priorities; and
• a stickler for details.

Having a keen eye for detail, accuracy, and consistency is essential. Often an editor is the last person to review a project before it is sent to the client or is published, so attention to detail at that stage can be critical to the project’s success.

To be a successful freelance medical editor requires expertise in the most-used software programs: Word, PowerPoint, and Adobe Acrobat.

Lastly, to be a successful freelance medical editor requires good business skills, such as accurate and timely invoicing, timekeeping, and financial acumen (enough to pay quarterly taxes and health insurance and set aside some savings).

—Melissa Bogen

Q

What type of freelance medical writing opportunities are available for someone who does not have an advanced science degree?

A

I don’t have an advanced degree and, to date, I’ve written in almost every area of medical communications—abstracts, posters, manuscripts, symposia, continuing medical education (CME) and continuing education (CE), advisory board meetings, sales training, advertising and promotion, and patient education. I’ve even done some regulatory writing, although that experience is limited to patient narratives.

So I don’t think there’s any area of medical writing that someone without an advanced degree can’t write. However, there are limitations to the depth to which someone without an advanced science degree can write those materials, and perhaps also a difference in the time it might take someone without an advanced science degree to come up to speed on a specific topic. This is where being honest with yourself comes in.

There are times and circumstances in which someone without an advanced science degree should not attempt a project. For example, if the assignment is to write about the mechanism of action of a medication at a molecular level and you don’t already have deep knowledge and experience in molecular biology, it’s probably not the right project for you. Tight timelines can also pose a problem. For instance, if you’re asked to write in a therapeutic area that’s new to you, for a highly specialized medical audience, and the timeline would be tight even for someone who is already well-versed in the subject, it’s probably not the right project for you.

But there are also times and circumstances in which someone without an advanced science degree should attempt a project. For example, if the topic and audience is not so specialized and deeply scientific that you can’t learn and synthesize the material to the proper depth, and if the timeline is sufficient for you to come up to speed, it may be a good project for you to take on and challenge yourself. This is one of the reasons why freelances typically have such a broad range of experience.

Medical communicators who work on staff are not likely to be asked to work on a project that’s outside their area of expertise. I think that’s one of the things that makes it difficult for professionals who work on staff to stretch themselves, try new things, and expand their repertoire. On the other hand, freelances who do a consistently great job for their clients are often entrusted with assignments that are outside their known areas of experience and expertise. Clients often would rather call in a trusted freelance whose capabilities are known to do a project they know is new for them, than to call in an unproven freelance who appears to have the requisite experience but whom they don’t know can and will deliver.

—Brian Bass

There are many interesting and high-paying opportunities for freelance medical writers like me who don’t have an advanced science degree. I was a journalism major. Before starting my freelance business, I worked as a copywriter for an ad agency and then managed communications for Temple University’s business school.

My freelance medical writing clients include health care marketing agencies, hospitals, disease associations, an integrative health program, professional associations and societies, and even a medical communication agency. Health websites are another type of client for freelances without an advanced science degree. The projects I work on include newsletters, e-newsletters, magazine stories, Web content, blog posts, patient education guides, case studies, reports, and more.

In general, working directly with clients pays better than working with health care marketing agencies, and health websites pay the least. But there are plenty of high-paying clients out there if you’re willing to put the time and effort into finding them.

When I started my freelance medical writing business and learned about the scientific side of medical writing, I considered going back to school for a scientific degree. But I loved the work I was doing, and there were plenty of opportunities for me. I’ve been making a great living doing work I love for more than 20 years now.

—Lori De Milto
The National Guideline Clearinghouse Has Closed. What’s Next?

By Haifa Kassis, MD / President, Crisp Writing, LLC, Brookline, MA

The National Guideline Clearinghouse (NGC), a public database of evidence-based clinical practice guidelines, closed on July 16, 2018. According to the Agency for Healthcare Research and Quality (AHRQ), the federal agency responsible for operating the NGC, funds to maintain the database were no longer available.¹ The fiscal year 2017 budget for NGC was $1.2 million, down by $0.9 million from the year before.²

The NGC was established in 1997 with the mission of delivering “an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to further their dissemination, implementation, and use.”³ In 1999, a database-driven website (guidelines.gov) was made publicly available free of charge. The website provided a central repository of carefully vetted clinical practice guidelines that met stringent inclusion criteria.³ In addition, the website provided structured summaries of many of the guidelines, expert commentaries, and a wide variety of advanced search capabilities. These unique features made the NGC an invaluable resource for those seeking up-to-date, trustworthy, and easily digestible evidence-based medical information.⁴,⁵

AHRQ’s decision to close the NGC was met with criticism and appeals for reconsideration.⁶ Even though guidelines were no longer accepted for inclusion as of March 5, 2018—to allow time for summaries and National Guideline Clearinghouse Extent Adherence to Trustworthy Standards (NEATS) assessments to be posted to the NGC’s website by July 2018—the resource closed before an alternative could be created. As of July 2018, it appears that the ECRI Institute (formerly Emergency Care Research Institute), a nonprofit organization that had contracted with the federal government to help the AHRQ develop and maintain the NGC for 20 years, is planning to launch a similar resource in the near future.⁷

Karen Schoelles, MD, director of ECRI Institute-Penn Medicine Evidence-based Practice Center, through email said that at this time the ECRI Institute is planning its new resource without support or input from AHRQ. According to Dr Schoelles, several professional organizations have already expressed interest in sharing their guidelines with the ECRI Institute. These guidelines will be summarized and evaluated against the National Academy of Medicine (formerly the Institute of Medicine) standards for developing trustworthy clinical practice guidelines. She added that the new website will not be an exact replica of that created for the NGC, but much of its information will be similar. An interim version of the website is expected to launch this fall, and a subscription will be required to access its content for anyone who does not participate in guideline development. The ECRI Institute said that they are planning to keep the cost reasonable.

When asked through an email about the ECRI Institute’s plans by AMWA Journal, the AHRQ had no comments. Furthermore, the future of AHRQ itself remains unclear. The president’s fiscal year 2019 budget proposal calls for the agency to be consolidated into the National Institutes of Health (NIH) as a newly formed NIH institute—the National Institute for Research on Safety and Quality (NIRSQ).⁸

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Our conscious mind remembers a small fraction of the input it receives, but that does not mean the rest is lost. To protect us from sensory overload, our unconscious mind stores a tremendous amount of information that, while often vital to our functioning and survival, does not need to clutter our thoughts every minute of every day. And what the unconscious mind does not remember, it invents. Leonard Mlodinow, PhD, explores how the unconscious mind controls our behavior in ways we do not even realize in Subliminal: How Your Unconscious Mind Rules Your Behavior.

According to Mlodinow, the unconscious mind is everywhere. Advertisers have capitalized on it to build “brand preference,” despite there being no discernible difference between a product and its competitors. In addition to questioning the source of our preferences, Mlodinow challenges us to question our own memory. The unconscious mind can cause us to vividly remember experiences that actually never happened—a function of our mind making things up to fill in the blanks when we cannot actually recall.

As a species, our social and emotional connections often transcend the need for language. As humans evolved, our conscious mind helped us stay alive under harsh prehistoric conditions. However, as humans found social groups to be advantageous, our unconscious mind became valuable in helping us navigate the resulting complex network of social behaviors. Interestingly, the brain structure associated with the pain we feel in an awkward social situation is also associated with the emotional component of physical pain.

Mlodinow explores the role of the unconscious mind in stereotyping, including the judgments we form about people based not on what they say, but on how they say it. Pitch, timbre, volume, cadence, speed, and modulation all send signals the unconscious mind perceives, and that leads to judgments of the speaker's character and even their state of mind. Mlodinow observes that the mind constructs emotions based on limited data rather than from direct perception, much like it fills in gaps in memories the mind cannot recall and images the human eye cannot fully see. “[O]ur subliminal mind combines information about our physical state with other data arising from social and emotional contexts to determine what we are feeling.”

When directing the unconscious mind inward instead of outward, we perceive ourselves with exaggerated strengths and minimized weaknesses. Our unconscious mind provides our self-perception the ambiguity it needs to construct a narrative for ourselves that is bigger than life and that we believe because it comes from within. In this way, the distortion maintains what Mlodinow calls the “illusion of objectivity” that serves as the foundation for each individual's unique perception of reality.

Mlodinow does an outstanding job of combining scientific research with storytelling to bring the unconscious mind to life for lay readers as well as those who are knowledgeable in the neurosciences. His recounting of early, arguably unethical, psychological research involving actual sham surgical procedures is simultaneously alarming and engaging. Of particular value and applicability to medical communicators are the direct correlations of this narrative to ourselves and the indirect but easily extrapolated correlations to our interactions with employers and clients, and our work.

Reviewer: Brian G. Bass, MWC®

Brian is President of Bass Global, Inc., in Fort Myers, Florida.

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The Ethos of Medicine in Postmodern America: Philosophical, Cultural, and Social Considerations

Arnold R. Eiser

Lanham, MD: Lexington Books, 2014; hardback, 205 pages, $38.00

Dr Arnold R. Eiser's book The Ethos of Medicine in Postmodern America: Philosophical, Cultural, and Social Considerations discusses the burgeoning 21st-century health care corporate bureaucracy, along with the role of technology, the focus on consumerism, and the leveling of hierarchy in medicine. How has postmodern American culture contributed to the increase in centralized bureaucracies, the decrease in overall physician morale, and the change in the patient–physician relationship in the postmodern era? Drawing upon cultural observations from leading postmodern thinkers, Eiser strives to provide a perspective for understanding changes within health care delivery and what can be done to improve the system.

Our society should prioritize public discourse on the impact of what Eiser calls “the three big Cs” of American medicine: consumerism, computerization, and corporatization. He questions whether advancements in computer technology have improved patient care as much as they have increased corporate control and profits. He argues that corporate influence and bureaucratic control via the use of computerized performance measurements and protocols have led to a decrease in clinician decision-making with respect to the individual patient.
Over the past half century, bureaucracy has increased in the practice of medicine, and the patient–physician relationship has shifted. Eiser reflects on the erosion of the patient–physician relationship in clinical medicine and the potential reduction in individualized patient care, both of which have occurred during the same timeframe that physician burnout has been on the rise.

Eiser challenges the reader to consider difficult issues such as societal resource allocations, the cost effectiveness of technology, and the risk or benefit for patients within an improved American health care system. The author suggests that changes in patient responsibilities are an integral part of an improved system. He states that patients should complete advance directives to make known their preferences regarding treatment for serious health issues, and patients should modify their expectations to realistically reflect the capabilities of current medical practice. These changes could lead to a more responsible citizen-patient model versus a strict consumerist model. Lastly, Eiser ponders, “Would health-centered medical care that puts patient health and rational understanding of a full life expectancy at the center make more sense than a consumerist model of medical care?”

The author’s experience as a professor of medicine and researcher in medical education innovation, patient education, and bioethics is relevant to the ideas presented and questions posed in this book. The use of subheadings and mini-summary sections provides the reader with a clear idea of the purpose of each chapter. Although the author spends more time discussing the problems within the health care system than suggesting potential solutions, the interdisciplinary discussion gives the reader a solid framework for understanding the complex issues that constitute the American health care system. Shifting from the current profit-centered health care delivery system to a more patient-centered system, as Eiser suggests, would be a large collaborative undertaking that is worthwhile for patients, health care providers, and anyone working in health services research to consider.

Reviewer: Monique A. Pond, PhD

Monique is a former Medical Writer and Consultant at Whitsell Innovations, Inc, Chapel Hill, North Carolina.

* * *

The Role of Emotions in Preventative Health Communication

Jessica Gall Myrick, PhD

Lanham, MD: Lexington Books, 2015, Hardcover, 283 pages, $99.00

In The Role of Emotions in Preventative Health Communication, Jessica Gall Myrick, PhD, calls for more and higher-quality research on the topic introduced by the title of this scholarly work. About half of the volume focuses on theoretical foundations and what is known about individual emotions, such as guilt, sadness, and hope, from psychology and communication research. Myrick explores both the negative and well-studied, such as fear, and the positive and more newly recognized, such as elevation or inspiration. In nearly every negative case there is a discrepancy in reality, or a perceptually inevitable version of the future, with what the individual thinks they should experience. The positive cases are more nuanced, tapping into what a person thinks they are capable of or would like to be capable of. These initial chapters also include sections on engagement with public health policies, as studying the role of emotions in politics has a much longer history than in health communication.

The later chapters are spent on preventative health communication contexts in which a health communicator might apply different emotion-focused strategies, such as traditional campaigns or social media. For example, the antismoking truth® campaign, initiated in Florida in the 1990s, utilized the anger young people feel toward being manipulated by framing tobacco companies as manipulative. The typical reaction to feeling anger is to seek retribution, which the target audience enacted by not supporting the tobacco industry through product sales. More recently, exercise-focused video games with health messaging can evoke hope in an individual that they can replicate the success of characters with whom they identify or exemplars in the social community affiliated with the game.

Myrick treats each chapter as a stand-alone scholarly essay, with appropriate section headings, adequate context, and reference lists. The introduction and conclusion sections tie the chapters together into a metanarrative reflecting on what is known, but mostly on what is not known about emotion in communication in general, let alone the specific context of preventative health communication. Subsequently, Myrick frequently relies on studies on the role of emotion in entertainment messaging. Myrick expresses a keen awareness of the limitations of what had been researched up until the book was written and the methodology used in those studies.

Throughout the work, and particularly in the Health Information Seeking chapter and overall conclusion, Myrick discusses how life experience and mood prior to and at the time of message consumption affects reactions and behaviors based on consuming messaging. Although this information is pertinent to understanding how different audiences may alter their behavior differently, or choose not to alter their behavior, based on a health message, this information was continued on page 140
If you haven’t already made plans to join us for the 2018 Medical Writing & Communication Conference, November 1-3, in Washington, DC, it’s not too late! Regular registration rates are available through September 30, and onsite registration rates are available through the final day of the conference.

**Preconference Sessions**
- 6 preconference sessions on 10/31, including Planning for Retirement and a session for those New to AMWA and Medical Communication.

**Education Sessions**
- 54 education sessions open to all attendees.

**Workshops**
- 26 workshops from the basics of medical writing to advanced courses in data presentation or US and EU regulatory processes.

**Roundtables**
- 41 roundtables (breakfast on Friday, lunch on Saturday) where you can speak with an expert and network with peers on a wide range of specialty topics.

**Restaurants**
- 65 restaurants within 2 blocks of the conference hotel—at last count!

**Golden Apple Award**
- 6 Golden Apple Award-winning instructors.

**Education Sessions**
- 9 education sessions on Communication & Storytelling.
50 years since the conference has been in Washington, DC!

22 education sessions & workshops on regulatory writing.

9 education sessions for freelances or those who would like to become freelance writers.

3 meals and 5 beverage breaks included with your conference registration.

3 blocks from the conference hotel to the DC Metro.

12 education sessions on the Foundations of Medical Writing.

22 education sessions & workshops on regulatory writing.

1 jam sessions: Join your peers for a reprise of the popular Jam Session for Seasoned Freelances, or try the new jam sessions for early career freelances or midcareer managers.

3 beverage breaks included with your conference registration.

27 Tips for Efficiently Writing Scientific Publications—all in 1 session!

6 scheduled networking and social events—along with dozens of unscheduled opportunities!

Many thanks to the Annual Conference Committee for putting together an outstanding program:

- Ajay Malik, PhD, MWC
  Atara Biotherapeutics, Westlake Village, CA
- Brandi Talkington, PhD
  Talkington Technical Services, LLC, Uniontown, PA
- Fabiana Ebihara, MS
  PAREXEL International, Orlando, FL
- Jennifer Minarcik, MS
  Jennifer Minarcik Biomedical Communications, LLC, Moorestown, NJ
- Joanne Rosenberg, MS, ELS
  Jazz Pharmaceuticals, Philadelphia, PA
- Kristin Roynesdal, MS
  KLARITAS Media, Charlottesville, VA
- Larry Lynam, DSc, MA, SM, RM
  The Lynam Group, Coral Springs, FL
- Laura Cobb, PhD
  Spotlight Medical Communications, Valley Village, CA
- Maria Powell, PhD
  National Heart, Lung, and Blood Institute, Bethesda, MD
- R. Michelle Sauer, PhD, ELS, CRA
  Conference Administrator-Elect
- University of Texas Health Science Center, Houston, TX
- Sashi Nadanaciva, DPhil, CMPP
  Pfizer Oncology, Groton, CT
- Tara Ann Cartwright, PhD
  Freelance Medical Writer and Editor, Morrisville, NC
- Yanni Wang, PhD, CMPP
  International Biomedical Communications, LLC, Frederick, MD
- Becky Phillips
  Education Manager, AMWA, Rockville, MD

5 speakers from NIH, NCI, or FDA (including 1 former FDA Commissioner).
Harold Swanberg Distinguished Service Award

By Theresa E. Singleton / 2017-2018 Director-At-Large and Chair and Board Liaison, Member Recognition Committee

The Harold Swanberg Distinguished Service Award, named in honor of the physician who founded AMWA, is presented to an active AMWA member who has made distinguished contributions to medical communication or rendered unusual and distinguished services to the medical profession.

This year's Swanberg recipient is Bart J. Harvey, MD, MSc, PhD, MEd. Bart’s record of service to AMWA spans almost 2 decades. His passion for teaching is clear—he has developed and led several workshops, particularly on biostatistics and epidemiology, at annual and chapter conferences and onsite trainings. In recognition of his teaching excellence, Bart received AMWA’s Golden Apple Award in 2006. He became an AMWA Fellow in 2009 and received AMWA’s President’s Award from Karen Klein in 2015.

Bart has an MD, an MSc in biomedical engineering, a PhD in epidemiology, and an MEd in higher education. He is an Adjunct Professor in public health at the University of Toronto. From 1996 to 2006, Bart directed Toronto's Community Medicine Residency Program. He led the Royal College of Physicians and Surgeons of Canada (RCPSC) CanMEDS 2015 Research Expert Working Group, and he is a past president of the Canadian National Specialty Society for Community Medicine and Fellow of the American College of Epidemiology.

Bart is also a past chair of the RCPSC's Specialty Committee for Community Medicine, for which he successfully led an initiative that resulted in modernizing the name of the specialty in 2011 to “Public Health and Preventive Medicine.”

As an Ontario coroner since 2000, Bart has investigated more than 1,000 deaths. One such investigation of a 13-year-old boy led to changes in Ontario's Building Code as well as the Health Protection and Promotion Act, which made hot tubs safer. Bart also served for 9 years on the American College of Preventive Medicine Board and was a member of the American Board of Preventive Medicine's Public Health and General Preventive Medicine Examination Committee from 2002 to 2015. Bart’s extensive experience with certification examinations has made him an asset to AMWA’s Medical Writing Certification Commission. Serving as chair of the MWC® Exam Development Committee since 2014, Bart has been instrumental in developing the MWC® exam.

Bart has authored more than 50 papers published in peer-reviewed journals and has presented at national and international professional meetings. His excellence in writing was recognized in 2011 with an Eric W. Martin Award. This biography is but a snapshot of Bart’s range of contributions both within and outside of AMWA, and AMWA is proud to recognize Bart as this year's recipient of the 2018 Harold Swanberg Distinguished Service Award.

Dr Harvey will receive the Harold Swanberg Distinguished Service Award and deliver his address on Thursday, November 1, from 5:15 to 5:45 PM, at the AMWA Medical Writing & Communication Conference in Washington, DC.

Walter C. Alvarez Award

Robert M. Califf, MD, MACC
Vice Chancellor for Health Data Science; Director, Duke Forge (formerly Duke Health Data Science); Donald F. Fortin, MD, Professor of Cardiology at Duke University School of Medicine; former Commissioner of Food and Drugs (2016-2017)

Dr Califf has spent his career communicating health care information to the public, whether talking to patients as a cardiologist or discussing the implications of pharmaceutical development policies as FDA Commissioner. Dr Califf is an internationally recognized expert in cardiovascular medicine, health outcomes research, health care quality, and clinical research. He started his career with a fellowship in cardiology at the Duke University Medical Center and has since become a prolific researcher and one of the most frequently cited authors in biomedical science. Dr Califf has been a leader in improving methods for clinical research, including initiatives to engage patients, patient advocates, and caregivers in clinical research from design through sharing and implementation of results.

Since stepping down as FDA Commissioner in January 2016, Dr Califf returned to Duke as the Donald F. Fortin, MD, Professor of Cardiology at the Duke University School of Medicine. He is chair and a founding member of the board of the People-Centered Research Foundation, an organization that is dedicated to accelerating people-driven research. He is also the director of Duke Forge, a multidisciplinary organization dedicated to the development of actionable health data science. In this role, Dr Califf is continuing his work toward sharing research with the public: a key point in Duke Forge's mission statement is “organizing, curating, and disseminating information to improve its usefulness to researchers and the public.” He is also a member of the leadership team as Senior Advisor to Verily Life Sciences, a member of the Alphabet family of companies with a mission to make the world's health data useful so that people enjoy healthier lives.

An avid user of Twitter (@califf001), Dr Califf is not afraid of using social media to bring the public’s attention to relevant
John P. McGovern Award

Stacy Robison, MPH, MCHES
President and Cofounder of CommunicateHealth (https://communicatehealth.com)

A self-proclaimed health literacy geek and an expert in clear communication, Stacy Robison, President and Cofounder of CommunicateHealth (https://communicatehealth.com), will receive the esteemed John P. McGovern Award for her preeminent contributions to the field of medical communications at the 2018 AMWA Medical Writing & Communication Conference in Washington, DC. Recent recipients of the John P. McGovern Award include Lisa Schwartz, MD, MS, and Steven Woloshin, MD, MS (2017); Kevin Pho, MD (2016); Ivan Oransky, MD (2015); and Gary Schwitzer (2014).

Since cofounding CommunicateHealth at the age of 30, Ms Robison has been recognized as an innovative business leader by the US Women’s Chamber of Commerce. She has appeared in multiple media outlets, including the Washington Post, Boston Globe, and Healthcare IT News, in which she has discussed a variety of issues from entrepreneurship to health behavior change.

Ms Robison has been a leader in the field of health literacy for the past decade. She has played a key role in developing several tools and resources for health professionals, including Health Literacy Online and the quirky e-newsletter We Heart Health Literacy, which reaches more than 2,300 inboxes each week. She specializes in designing digital health information for diverse patient populations, especially adults with limited health literacy skills.

Under her guidance and leadership, CommunicateHealth has been named one of Inc. Magazine’s fastest growing companies in America for 5 years in a row. CommunicateHealth has also received numerous ClearMark Awards, which recognize the best in plain language communication, including Best Multimedia for Physical Developmental Delays: What to Look For, for the American Academy of Pediatrics (2016); Best Website for Don’t Mess With Mercury, for the Agency for Toxic Substances and Disease Registry (2014), healthfinder.gov, for the US Department of Health and Human Services (2013), and Environmental Public Health Tracking Network—Outdoor Air Quality, for the Centers for Disease Control and Prevention (2012); and Best Original Document for Lead Poisoning: Words to Know from A to Z, for the Centers for Disease Control and Prevention (2011). In 2017, CommunicateHealth was also named one of Inc. Magazine’s Best Workplaces.

Ms Robison will receive the John P. McGovern Award and deliver her address on Thursday, November 1, during the Opening General Session at the AMWA Medical Writing & Communication Conference in Washington, DC.

The Golden Apple Award

By Theresa E. Singleton / 2017-2018 Director-At-Large and Chair and Board Liaison, Member Recognition Committee

The Golden Apple Award is given to a member of AMWA in recognition of consistent, outstanding excellence in leading AMWA workshops.

This year’s Golden Apple recipient is Art Gertel. The Member Recognition Committee was impressed with Art’s long record of accomplishments and contributions to AMWA’s Education Program. Art has taught more than 70 workshops, including 8 credit and 2 noncredit workshops, and has also played an active role in developing several AMWA Workshops. An AMWA member who has taken all of Art’s workshops remarked that he is “a great teacher and brings incredible knowledge and energy to his sessions. He expects attendees to think, which is what we want from a leader.”

Art is an AMWA Fellow (1994) and past recipient of AMWA’s President’s Award (1990), the Harold Swanberg Distinguished Service Award (2009), and the Eric W. Martin Award (2014).

Please join AMWA in congratulating Art as he receives his award this fall at the Medical Writing & Communication Conference in Washington, DC.

The Member Recognition Committee members were Jim Cozzarin, Helen Hodgson, Jill Shuman, Theresa Singleton (chair), Barbara Snyder, and Barbara Zimmerman. Becky Phillips from AMWA HQ provided excellent guidance and support.
AMWA Fellowships

By Theresa E. Singleton / 2017-2018 Director-At-Large and Chair and Board Liaison, Member Recognition Committee

AMWA Fellowships are awarded to members who have made significant contributions to the goals and activities of AMWA as well as professionally. The 2018 Fellows are leaders with distinguished records of service at the chapter and national levels.

Andrea Gwosdow

Andrea is a member of the New England chapter, where she has served as secretary, president-elect, president, and immediate past president. She continues to serve the chapter as a member-at-large. At the national level, Andrea has led credit and noncredit workshops at 10 annual conferences, led multiple roundtable discussions, and developed 1 noncredit workshop. Andrea’s contribution to education also includes presenting a webinar. She is currently a member of both the Education Committee and the Chapter Advisory Council.

Marjorie Winters

Marjorie is a member of the Empire State–Metro New York chapter. At the chapter level, she has served 4 terms as secretary and is the current president-elect. At the national level, Marjorie has led klatches and roundtable discussions at multiple annual conferences and served as a member of the Education Committee. She has been a member of the Communications Committee since 2015. In addition to her role as president-elect, Marjorie is co-chair of her chapter’s Program Committee.

Please join AMWA in congratulating Andrea and Marjorie as they receive their awards this fall at the Medical Writing & Communication Conference in Washington, DC.

The Member Recognition Committee members were Jim Cozzarin, Helen Hodgson, Jill Shuman, Theresa Singleton (chair), Barbara Snyder, and Barbara Zimmerman. Becky Phillips from AMWA HQ provided excellent guidance and support.

AMWA President’s Award

By Kathy Spiegel, PhD, MWC® / 2017-2018 President

The President’s Award is given every year to a member of AMWA who has made distinctive contributions to the association at the chapter or national level. The nominee must have been an AMWA member for 10 years and cannot have served on the Board of Directors (formerly the Executive Committee).

This year’s President’s Award recipient is Larry Lynam. An AMWA member for 10 years, Larry is an active volunteer in the Florida Chapter. He has served as a chapter delegate, and as Events Chair he has been instrumental in setting regular, casual networking events for AMWA members in the Miami area. At the national level, Larry has served 6 terms on the annual conference committee, in addition to presenting a poster, leading multiple round table discussions, and speaking at 4 open sessions at annual conferences. In addition, he has presented a webinar and authored an article for the AMWA Journal. Larry currently serves on the Education Committee, the Annual Conference Program Committee, and the Chapter Support Committee at the national level and as Events Chair for the Florida Chapter.

Please join AMWA in congratulating Larry as he receives his award this fall at the Medical Writing & Communication Conference.

Media Reviews continued from page 135

underutilized in communication research design at the time of this book’s printing. Myrick supports longitudinal research on identity, emotional states, and behaviors surrounding message consumption as opposed to cross-sectional surveys immediately following message consumption.

Myrick’s primer on emotion in preventative health communication effectively argues for much-needed research to visualize the thin lines walked by health campaigns that motivate some but generate negative emotions with undesired behavioral consequences or attitudes toward the messenger in others.

Reviewer: Elizabeth Schiavoni, MS

Elizabeth is a freelance writer and editor in Buffalo, New York, working primarily with nonprofits.
Introducing Jen Minarcik, Co-Editor, Social Media Section

By Cynthia L. Kryder, MS / Social Media Section Co-Editor

When Lori Alexander, then AMWA Journal Editor, invited me nearly 10 years ago to create a new section of the Journal focused on social media, I jumped at the chance. LinkedIn was in its infancy, Twitter was spreading its wings, and digital immigrants like me were questioning whether we could leverage those tools for our businesses.

Dare I call them the dark ages?

Since then I’ve managed to develop social media–focused content for most issues with input from Journal editors and colleagues, writing some articles myself and seeking out guest authors for others. It’s not as easy as it sounds. And, frankly, it takes a lot of time.

As I prepare to begin my term as AMWA’s 2018-2019 President, I have realized that I will need some help. That’s why I reached out to Jen Minarcik, a fellow AMWA-Delaware Valley Chapter member whom I knew had researched social media in medical writing for her capstone project. Beginning with this issue, Jen and I will be working together to continue the social media section and bring our readers information about this constantly evolving area. I’m looking forward to our collaboration and appreciate Jen’s willingness to do the bulk of the heavy lifting over the next year.

Here are a few words from Jen:

“Ever since my millennial children introduced me to Facebook, I’ve been fascinated with all things social. Over the past 10 years, I’ve watched social media evolve and become an integral part of our daily lives. We share moments with family and friends, watch and react to events happening around the world, and recently we have been able to share experiences with health care professionals on these platforms. Because of my enthusiasm for the direction social media was heading, it was only fitting that I chose the role of social media in medical writing as my capstone research topic when graduating from The University of the Sciences. Since that time I’ve had the pleasure of working on projects ranging from developing social/digital content, managing platform campaigns, and publishing articles for online technical magazines. In addition, over the years I have had the honor of presenting at AMWA chapter and national events on this very topic.

I am very much looking forward to serving as co-editor for the social media section of the AMWA Journal. In this ever-changing social media landscape, I hope to bring new and informative stories relevant to the entire AMWA community.”

If you have social-media topics you’d like to see us cover, or if you’d like to write an article for the social media section, please email me at clkwriter@comcast.net or Jen at jenminarcik@gmail.com.
A
s you know from previous reports, AMWA’s leaders developed a new strategic plan in 2016. The first step in developing this plan was to put our mission, vision, core values, and overarching goals into words.

**Mission**
AMWA’s mission is to promote excellence in medical communication and to provide educational resources in support of that goal.

**Vision**
Creating clear medical communications that lead to better health and well-being

**Core Values**
- Professionalism
- Expertise
- Continuous learning
- Connection

**Overarching Strategic Goals**
- Enhance resources and educational opportunities for medical communicators across settings and career levels
- Connect and engage with more medical communicators
- Increase awareness of AMWA as a valuable resource for medical communicators

These important guiding concepts appear on our website to share AMWA’s purpose and passion with members and the wider medical writing community. They are reviewed at the start of each AMWA Board of Directors meeting to guide the development and review of organizational goals. In partnership with AMWA staff, they are used to help determine priorities to focus our limited resources on what is most important as we work to fulfill our mission and meet our members’ needs.

An incredible amount of progress has been accomplished since the strategic plan was implemented. AMWA Online Learning has grown considerably, and we now offer a robust catalog of online educational activities for medical communicators across settings and career levels. The content for AMWA’s conference has been aligned with this goal as well, as evidenced by the amazing program to be presented at this year’s Medical Writing & Communication Conference. The AMWA Essentials Skills workbooks and quizzes have been digitized and the entire Essential Skills Certificate can now be earned completely online, making the program more accessible, especially for our international members.

Recognizing that AMWA has a plethora of valuable resources for those transitioning into medical writing, the board identified a need to create more resources for our midcareer members. This fall, we will host the inaugural Medical Writing Executives Forum: *Preparing for the Future of Medical Writing*. Taking place alongside the annual conference, this event will bring together heads of medical writing groups, both publications and regulatory, from pharma and biotech. The Forum aims to help executives optimize the functioning of their departments while anticipating future challenges and opportunities. This annual invitational event for senior-level department heads and decision makers will foster discussion on workforce trends and advancements in medical writing and serve as a catalyst to align leaders, develop solutions to challenges, exchange ideas and strategies, and fuel collaboration. We hope it will provide AMWA with insights into what hiring managers at these companies are seeking in employees and how we can partner with them to provide the education their employees need.

To help increase awareness of AMWA, we have invested in marketing and increased our digital marketing efforts through growth in paid social media, Google display networks, and paid searches. We launched our first-ever promotional videos (membership, conference, corporate member-focused, volunteer, and freelance), which appear on our new AMWA YouTube channel as well as throughout the website. We kicked off 2018 with a successful member referral program. If you recommended a new member to the organization, liked us on Facebook, LinkedIn, or Twitter, or proudly displayed your AMWA member logo, we thank you for participating!
Another important focus of staff at headquarters over the past 2 years has been updating our technology and improving our member experience online. A new association management system was launched that included a beautiful new website with an enhanced Freelance Directory and seamless integration with the Engage online community and AMWA Online Learning. Staff helped lead the effort to implement computer-based testing for the MWC exam, making it available at testing centers around the globe. Although our marvelous headquarters staff did the heavy lifting on these technology projects, AMWA volunteers were involved in many ways, including providing consultation and acting as beta testers.

As our Immediate Past President, Lori Alexander, pointed out in her AMWA Journal article in early 2017 (AMWA J. 2017; 32(1):40-41), another important project stemming from the strategic plan was to update AMWA’s governance documents and structure. From the updated constitution to the new chapter agreements, AMWA leadership has worked hard to make sure our 78-year-old organization is prepared to meet the challenges and opportunities of today. Building on these governance updates, the Chapter Support Committee has just produced new chapter leader resources to help them successfully lead their chapters with a focus on providing high-quality education and a strong community at the local level. Staff have worked with the Membership Committee to refine and implement the Local Networking Coordinator (LNC) volunteer position, including new resources for LNCs, and expanded efforts to recruit and support these important volunteers. In addition, a “PacSW revival group” has formed, with plans to petition the Board of Directors to start a new Pacific Southwest chapter. We look forward to supporting these dedicated members in their efforts to provide the one-of-a-kind AMWA member experience to this important region of medical communicators.

Finally, I’ll repeat one of my standard pleas for help: please respond to the surveys we send out! Our AMWA leadership and staff are now very data driven in our decision making, but our decisions will only be as good as the data we are using to make those decisions. We gather data in many ways, but surveys of our membership are among the most important. Please let your voice be heard!

By Cynthia L. Kryder, MS / 2017-2018 AMWA President-Elect

One of the joys of serving as AMWA President-Elect, besides becoming president, is the opportunity to appoint and chair the Nominating Committee, the group charged with choosing a slate of AMWA officers each year. Members serving on the 2017-2018 Nominating Committee include Esther Asplund, PhD; Loretta Bohn; Erin Boyle; Sarah Dohney; Karen Potvin Klein, GPC, MA, ELS; and myself. Susan Krug, AMWA Executive Director, serves as an ex officio committee member but is not entitled to vote.

Let me describe the process we go through each year to create a slate of candidates to serve as AMWA officers. The Nominating Committee receives from AMWA headquarters the names and biographies of members who meet the criteria for the 3 elected offices: President-Elect, Secretary, and Treasurer. Criteria for each position are based upon experience as an AMWA leader, skills necessary to fulfill the role, and expressed interest in serving the organization.

Candidates express interest in the positions by submitting a Board Interest Form, which is then shared with the Nominating Committee. Members of the Nominating Committee discuss the potential candidates and select 1 candidate for each position. All nominees must have agreed to serve and must be members whose dues are current. The slate of officer candidates is then presented to the Board of Directors (BOD) for approval.

I’m pleased to present the following candidates, who were approved by the BOD at a special meeting in May:

**President-Elect:** Ann Winter-Vann, PhD

**Secretary:** Gail Flores, PhD

**Treasurer:** Julie Phelan, MD, MBA

**President-Elect Candidate:** Ann Winter-Vann, PhD, an AMWA member since 2007, currently serves as an at-large director and as chair of the 2018 Medical Writing & Communication Conference Committee. She previously served on the Executive Committee/BOD as Publications Administrator (2015-2017) and Awards Administrator (2014-2015). She was a member of the Constitution and Bylaws Committee (2015-2017), a member of the Regulatory Education Advisory Group (2013-2016), and a member of the Nominating Committee (2013-2014). At the chapter level, she served 3 years on the Executive Committee of the Carolinas Chapter and was President and Chapter Delegate in 2012-2013.
Meet the 2018-2019 AMWA Board of Directors
By Cynthia L. Kryder, MS / 2017-2018 President-Elect

The Board of Directors (BOD) is the group of members that carries out the business of the association. The BOD approves the budget, approves the slate of nominees for elected office, approves proposed amendments to the Constitution before submitting them to the membership, approves amendments to the Bylaws, approves the appointment of members to standing committees, approves all committees and ad hoc workgroups and task forces, and fulfills such other duties as are specifically mentioned in the Constitution and Bylaws and as required by law. The BOD has the power to establish reserve and endowment funds and approves the plans and regulations necessary to administer such funds. The BOD also empowers an Executive Committee to act between meetings. The AMWA Executive Committee comprises the President, President-Elect, Immediate Past President, Secretary, Treasurer, and Executive Director (nonvoting, ex officio).

AMWA strives to have a BOD that is representative of the organization’s membership, reflecting characteristics of the member population. The President-Elect nominates each at-large Director who will serve the following year, and a majority of the current year’s BOD must approve each nomination. Each of these at-large Directors will serve a 1-year term, but they may succeed themselves in office if so nominated by the subsequent year’s President-Elect.

At its meeting in July 2018, the BOD approved the following individuals to serve as at-large Directors for the 2018-2019 term:

- Lori Alexander, MTPW, ELS, MWC®
- Brian Bass, MWC®
- Katrina Burton, BS
- Noelle Demas, MSTC
- Elise Eller, PhD
- Melory Johnson, VN
- R. Michelle Sauer, PhD, ELS, CRA
- Theresa Singleton, PhD

According to the national Bylaws, the BOD must comprise at least 12 but no more than 17 voting Directors. The proposed 2018-2019 board comprises 13 Directors, including these officers and officer nominees:

- Cynthia L. Kryder, MS, President
- Ann Winter-Vann, PhD, President-Elect Nominee
- Gail Flores, PhD, Secretary Nominee
- Julie Phelan, MD, MBA, Treasurer Nominee
- Kathy Spiegel, PhD, MWC®, Immediate Past President

The 2018-2019 Board of Directors begins its service on November 3, 2018, at the conclusion of the 2018 Annual Business Meeting.

Meet the 2018-2019 AMWA Board of Directors
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- Cynthia L. Kryder, MS, President
- Ann Winter-Vann, PhD, President-Elect Nominee
- Gail Flores, PhD, Secretary Nominee
- Julie Phelan, MD, MBA, Treasurer Nominee
- Kathy Spiegel, PhD, MWC®, Immediate Past President

The 2018-2019 Board of Directors begins its service on November 3, 2018, at the conclusion of the 2018 Annual Business Meeting.

Meet the 2018-2019 AMWA Board of Directors
By Cynthia L. Kryder, MS / 2017-2018 President-Elect

The Board of Directors (BOD) is the group of members that carries out the business of the association. The BOD approves the budget, approves the slate of nominees for elected office, approves proposed amendments to the Constitution before submitting them to the membership, approves amendments to the Bylaws, approves the appointment of members to standing committees, approves all committees and ad hoc workgroups and task forces, and fulfills such other duties as are specifically mentioned in the Constitution and Bylaws and as required by law. The BOD has the power to establish reserve and endowment funds and approves the plans and regulations necessary to administer such funds. The BOD also empowers an Executive Committee to act between meetings. The AMWA Executive Committee comprises the President, President-Elect, Immediate Past President, Secretary, Treasurer, and Executive Director (nonvoting, ex officio).

AMWA strives to have a BOD that is representative of the organization’s membership, reflecting characteristics of the member population. The President-Elect nominates each at-large Director who will serve the following year, and a majority of the current year’s BOD must approve each nomination. Each of these at-large Directors will serve a 1-year term, but they may succeed themselves in office if so nominated by the subsequent year’s President-Elect.

At its meeting in July 2018, the BOD approved the following individuals to serve as at-large Directors for the 2018-2019 term:

- Lori Alexander, MTPW, ELS, MWC®
- Brian Bass, MWC®
- Katrina Burton, BS
- Noelle Demas, MSTC
- Elise Eller, PhD
- Melory Johnson, VN
- R. Michelle Sauer, PhD, ELS, CRA
- Theresa Singleton, PhD

According to the national Bylaws, the BOD must comprise at least 12 but no more than 17 voting Directors. The proposed 2018-2019 board comprises 13 Directors, including these officers and officer nominees:

- Cynthia L. Kryder, MS, President
- Ann Winter-Vann, PhD, President-Elect Nominee
- Gail Flores, PhD, Secretary Nominee
- Julie Phelan, MD, MBA, Treasurer Nominee
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Created especially for medical communicators, this 1-hour program is crucial for anyone working with research driven results.

Explore the importance of evidence-based medicine, review the formal steps of evidence-based practice, identify study types, and learn about research and review articles that contain quality information.
Successful medical writing requires **determination and tenacity**. Our expert writers are able to move the process forward. Break through team dysfunctions. And challenge assumptions. At Trilogy, conquering broken processes is what we do best. And it’s just one more way we’re leading the fight against mediocre medical writing.

Visit us at TrilogyWriting.com writers@trilogywriting.com
Appendix: Books Reviewed for Their Approach to Table Design

Books Specifically Recommending Vertical Comparisons in Tables


Simmons GH, Fishbein M. *The Art and Practice of Medical Writing*. Chicago: American Medical Association; 1925.


Books Whose Examples Acknowledge Vertical Comparisons


**Books Acknowledging Both Vertical and Horizontal Comparisons in Tables**


**Books Specifically Recommending Horizontal Comparisons in Tables**


Fishbein M. *Medical Writing*. Chicago: American Medical Association; 1938.


**Books Acknowledging Neither Vertical nor Horizontal Comparisons in Tables**


Gartland JJ. *Medical Writing and Communicating*. Frederick, MD: University Publishing Group; 1993.


