AMERICAN MEDICAL WRITERS ASSOCIATION
WWW.AMWA.ORG

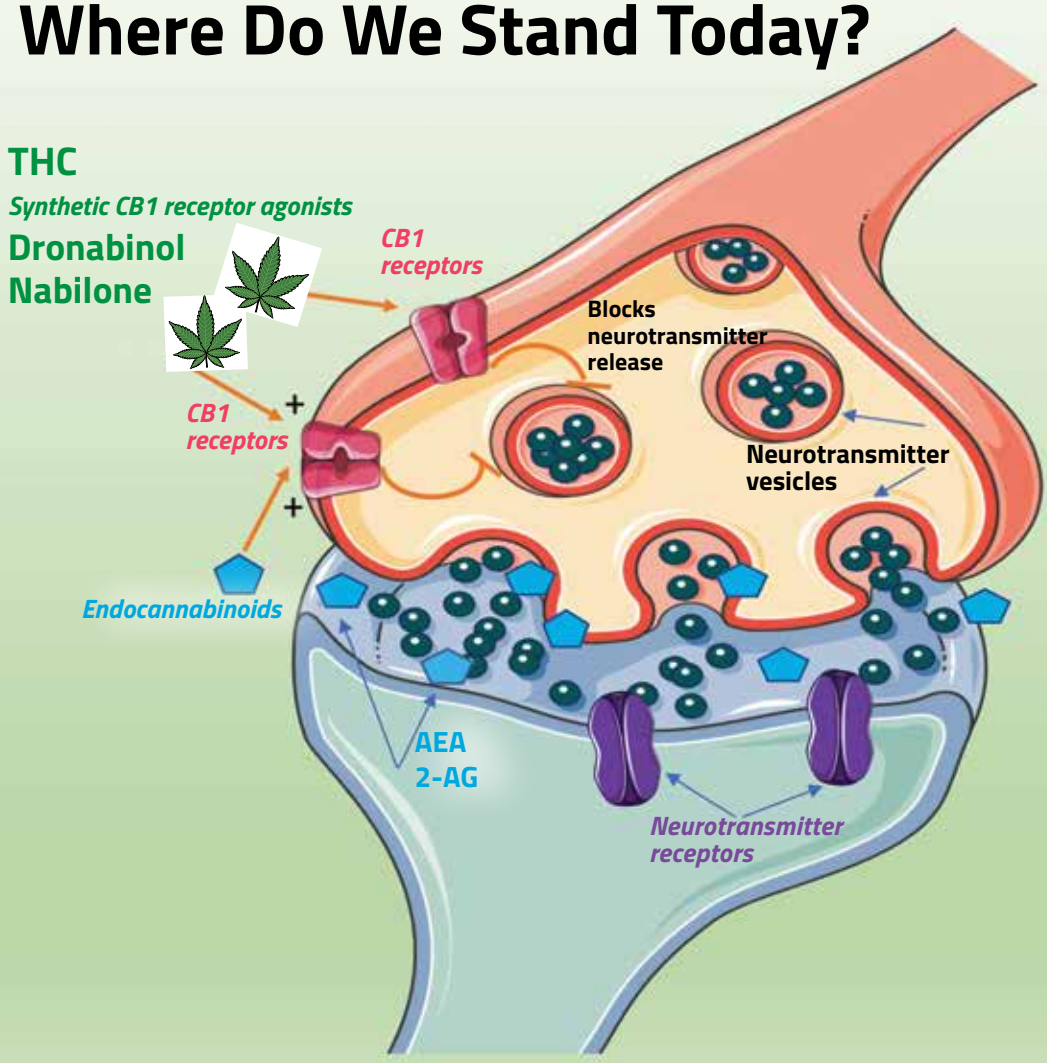
Volume 33 Number 2 / Summer 2018

AMWA JOURNAL

ELECTRONIC EDITION

INSIDE

SCIENCE SERIES:
Medical Cannabis
Where Do We Stand Today?



THE OFFICIAL JOURNAL OF THE
AMERICAN MEDICAL WRITERS ASSOCIATION,
THE RESOURCE FOR MEDICAL COMMUNICATORS

2018 AMWA

Medical Writing & Communication Conference

NOVEMBER 1-3, 2018
WASHINGTON, DC

Trends and Opportunities for Medical Communicators

REGISTER ONLINE BY SEPTEMBER 30 TO SAVE!

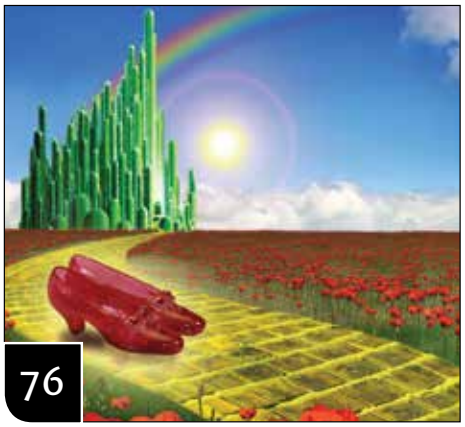
Pre-Conference Education and Networking Activities on October 31

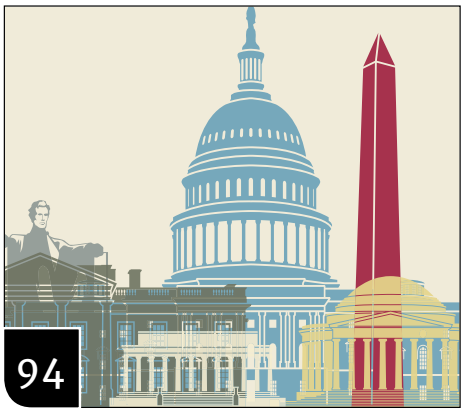
Link. Learn. Lead.

Great Location. Great Rates.
Book Your Room Now at the Renaissance Hotel Washington, DC.
www.amwa.org/conference

Contents

V33 N2
SUMMER
2018





MORE Contents

***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.

AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL

V33 N2 / 2018

EDITORIAL OFFICE: ManagingEditor@amwa.org. Instructions for authors available at: www.amwa.org/journal.

ADVERTISING: Contact marketing@amwa.org or (240) 239-0940. All advertising is subject to acceptance by AMWA and should be for products and services relevant to professional medical communicators. AMWA is not responsible for the content of advertising and does not endorse any advertiser or its products or services.

SUBSCRIPTION: The *AMWA Journal* is published quarterly. Subscription is included with AMWA membership. Nonmember subscriptions cost is $75 per year.

CONTACT: American Medical Writers Association, 30 West Gude Drive, #525, Rockville, MD 20850-4347. Phone: (240) 238-0940; Fax: (301) 294-9006; Email: amwa@amwa.org.

The *AMWA Journal* is in the MLA International Bibliography and selectively indexed in the Cumulative Index to Nursing and Allied Health Literature (CINAHL) print index, the CINAHL database, and the Cumulative Index of Journals in Education (CIJE).

ISSN 1075-6361

NEW
ETHICS SERIES

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

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

SERIES INTRODUCTION

We medical writers walk in a world of evidence-based medicine, and this series of articles was built on both public health data and trial results. At the same time, we medical writers typically pay careful attention to the policies, positions, and guidelines of certain responsible, impartial organizations. It is thus significant that multiple organizations are committed to the widespread effort to reduce health disparities in America, including the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the American Heart Association (AHA), the American Society of Clinical Oncology (ASCO), the American Hospital Association, and the National Academy of Medicine (NAM).[1-8]

Thus, when the AHA saw recently that, despite great efforts, the improvement in Americans' cardiovascular health targeted by the CDC's "Healthy People 2020" would not be achieved, AHA leaders grasped that they "had not touched adequately the populations at highest risk, the underserved, those people with highest needs in heart disease," and that in pursuing "Healthy People 2030" targets it would be necessary to "combine clinical, social, economic, and educational efforts," explained Keith B. Churchwell, MD, chair of the AHA's Health Equity and Determinants of Health Outcomes Task Force and Senior Vice President, Operations, at the Yale School of Medicine, who spoke in an interview on April 20, 2018.

In this first article in our series we present evidence relevant to the current state of health disparities and social determinants of health in the United States. The second article will describe some of the peer-reviewed publications that discuss interventions that have reduced health disparities. It will also report on current efforts 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.

ARTICLE 1: THE PROMISE OF EQUALITY

"That all Men are created equal"
–The Declaration of Independence

Tamara's account: As an emergency department physician, my morning typically began with a patient like Mr G, a 67-year old Latino male with diabetes and hypertension whom I had admitted 2 months earlier for a stroke. He now, per his son, was "talking funny again." I asked his son if he had filled the 2 blood pressure medications that had been prescribed at his previous discharge. "We couldn't afford those pills," he sheepishly admitted. Mr G's family doctor was Dr Swan, so I asked his son, "When you saw Dr Swan, did she offer you a less expensive alternative?" He acknowledged that they hadn't been for a follow-up visit. "We owed her money," he explained. "And besides, the car was broke down." My nurse checked Mr G's blood pressure: 210/114. I quietly sighed and ordered a head CT. I had grown weary knowing that some patients had access to incredible advances in medicine while others struggled to get even basic care. It seemed that 70% to 80% of my patients were in the latter group. Each day, I served witness to patients and their families as they braved the undue burden of pain, suffering, trauma, disability, and death allotted to the disenfranchised of America, the richest country on earth.

Bob's account: In August of 1970, I was participating in a civil rights project in the American South, and one day a few of us drove into town. We reached the downtown area, and the driver pointed out "the hanging tree." It was spectral and

hostile, gloomy and unforgiving. The tree represented a history not only of inequality but also of unequal access to healthy environments (assuming a lynching can be thought of as an unhealthy environment).

HEALTH DISPARITIES IN THE UNITED STATES

These experiences left a mark upon each of us clear and deep in memory, in gut feeling, and in moral outrage—our personal perceptions of health disparities in our country. The state of health disparities in the United States is a national crisis, an international embarrassment, a drain on future resources, and a violation of our founding principles as stated in the Declaration of Independence. Indeed, it is such a crisis that the National Academy of Medicine (NAM) commissioned 19 white papers to authoritatively assay just what is going on.

A qualitative synthesis of these white papers was published in the *Journal of the American Medical Association* in March of 2017.[9] The report stated that "health disparities are persistent and worsening" and that the current "trajectory of health care spending is unsustainable" and is placing the "fiscal capacity" of the United States "at risk." The NAM initiative concluded that in relation to "the steps necessary to deliver better health to all people of the United States at a sustainable cost," it is clear that "the urgency is as compelling as the opportunities."[9] Recently, the American Hospital Association and the Association of American Medical Colleges released a joint statement that "addressing disparities is no longer just about morality, ethics and social justice: it is essential for performance excellence and improved community health."[10,11] So the US health care system must change, and we medical writers and editors have an opportunity—and perhaps an obligation—to help further that positive change toward health equity.

The word "equality" belongs front and center within discussions of health disparities; however, "equity" more precisely focuses on the issues at hand. Whereas equality implies all things are equal, "[h]ealth equity is achieved when every person has the opportunity to attain his or her full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances."[2] Yet, as the nonpartisan NAM initiative states, decades of research have shown that "the leading health determinants are outside of healthcare."[9,12]

Equity touches such things as 2 neighborhoods—one with a well-run, well-financed hospital, the other with an overcrowded clinic with outdated technology; one with a high school with magnificent sports facilities, the other with no swimming pool and no doors on the bathroom stalls; one with little air pollution and no boarded-up houses, the other with pervasive air pollution and trash-strewn vacant lots; one where almost all families can easily afford to purchase sunscreen, the other where purchasing a year's worth of sunscreen for the entire family is a financial burden. Health equity may be further measured across subpopulations in terms of rates of adherence to physician-prescribed medical and exercise regimens; of preventive services such as blood pressure, mammography, and prostate screenings; and of premature births; of length of survival postdiagnosis with cancer or acute myocardial infarction; or even of levels of air pollution in neighborhood schools.

DEFINING HEALTH DISPARITIES

It is daunting to define and describe the health disparities existing in our country today—not because of lack of data but because the magnitude of the problem becomes all the more apparent as the evidence is examined.

Racial health disparities exist. Babies born to African Americans are "more than twice as likely to be born with low birth weight or to die in their first year of life," relative to whites.[12] In contrast, the corresponding rates for mothers who emigrated from Africa are similar to those for whites.[12] "American Indians and Alaska Natives born today have a life expectancy that is 4.4 years fewer than the US all-races population."[13] And from 1960 to 2009, blacks had a 2-fold excess risk of premature mortality, as compared with whites.[14]

According to the National Cancer Institute, "African Americans have higher death rates than all other groups for many, although not all, cancer types."[15] "Hispanics have lower rates of the most common cancers in the United States (ie, female breast, colorectal, lung, and prostate) but among the highest rates of cancers associated with infectious agents" (eg, cervical, liver, and stomach cancers).[16]

According to the American Heart Association (AHA), the prevalence of hypertension in African Americans in the United States "is among the highest in the world."[17] An analysis of Medicaid claims and enrollment files for 2006-2008 identified that women of racial or ethnic groups were less likely to get screening mammography as compared with white women.[18] According to the US Department of Health and Human Services, rates of obesity differ among populations. In 2015, "African Americans were 1.4 times as likely to be obese as non-Hispanic whites" and "about 4 out of 5 African-American women are overweight or obese."[19] "That same year, Hispanic Americans were 1.2 times as likely to be obese than non-Hispanic whites," while 77% of Mexican-American women were overweight or obese.[20] "Obesity is twice as common among American Indian children compared with their white and Asian counterparts."[13] That the poor do not have equal access to quality food will be briefly discussed later in this series of articles.

SOCIAL DETERMINANTS OF HEALTH DISPARITIES

Decades of research have demonstrated that underlying health disparities are such matters as where a person lives, who is poor, who has access to good schools and healthy food options, who breathes air with less pollution, how government policies and laws are shaped, and who bears the brunt of racial discrimination.

Environment: Where People Live, Neighborhoods, and Housing

Some neighborhoods have lower-quality schools, less access to quality food, greater levels of air pollution, and more mice and cockroaches in the homes. They also may have access to relatively fewer clinicians, who themselves may not be as well trained as the clinicians in other neighborhoods (Table 1).[21]

Education

According to NAM, "education level is the most powerful determinant of lifelong health prospects."[12] Education can affect health through multiple pathways (Table 2). These include better health literacy and increased health knowledge; better employment opportunities, including healthier physical and psychosocial working conditions; greater earnings, which permit better control of living conditions; better social support; and a greater sense of personal attainment, which may help buffer stress.[34,35]

Government Policies

Government policies have a good deal to do with how resources are allotted, but reducing disparities is not the only item on the government's agenda (Table 3).

Income and Poverty

While not the whole story, income and poverty play a significant role in health disparities (prejudice and ethnic interactions are independent factors), and apparently there has not been improvement over time. For example, the National Academies of Sciences, Engineering, and Medicine measured the gap in life expectancy between the top and bottom income quintiles for 2 distinct sets of people, one of whom had reached 50 years of age in 1980 and the other in 2010: for women born in 1930, the gap between the top and bottom income quintile was 3.9 years; for women born in 1960, the gap was 13.6 years. For men born in 1930, the gap between the top and bottom income quintile was 5.1 years; for men born in 1960, the gap was 12.7 years.[42,43] For men, that gap continues to widen; according to 2016 reports, compared with the richest 1% of Americans, the poorest 1% are on the wrong end of a life expectancy gap of 14.6.[44] There is a direct, measurable effect of income on health; in the United States, nearly the same pattern is seen for almost all chronic

Table 1. Disparities in Environment

Residential patterns in the US support an unofficial segregation of African Americans associated with "adverse birth outcomes, increased exposure to air pollutants, decreased longevity, increased risk of chronic disease, and increased rates of homicide and other crime. Residential segregation also systematically shapes healthcare access, utilization, and quality at the neighborhood, healthcare system, provider, and individual levels."[21]
Rural hospitals typically do not include intensive care units, skilled nursing facilities, psychiatric units, or rehabilitation units, and have fewer medical practitioners, especially medical specialists such as neurologists, anesthesiologists, and psychiatrists.[22]
After adjustment for individual and neighborhood-level covariates, a strong relationship was found between healthy food availability and hypertension rates, and a lower risk of type-2 diabetes mellitus correlated with greater cumulative exposure to indicators of neighborhood healthy food.[23,24]
Air pollution analyzed according to geographic location across the entire continental US found a "greater risk of death associated with air pollutants among blacks" and found that "among black persons, the effect estimate for $PM_{2.5}$[a] was 3 times as high as that for the overall population."[25,26]
Air pollution can trigger heart attacks, strokes, and irregular heart rhythms, particularly in persons with relevant risk factors.[27]
"The estimated percentage of the population living within 150 meters of a major highway" ranged from 3.1% for non-Hispanic whites to "a high of 5.0% for Hispanics and 5.4% for Asians/Pacific Islanders."[28]
"Strategic placement of bus garages and toxic waste sites in or close to neighborhoods where marginalized, racialized groups predominantly reside, selective government failure to prevent lead leaching into drinking water (as in Flint, MI, in 2015-16), and disproportionate exposure of workers of color to occupational hazards" are among the factors making some neighborhoods healthier than others.[21]
Higher levels of mouse allergen, dust mites, and cockroaches and their droppings in housing are known triggers of disease.[29-31]
"Health-care infrastructure and services are inequitably distributed, resulting in predominantly black neighborhoods having lower-quality facilities with fewer clinicians than those in other neighbourhoods. Moreover, most of these clinicians have lower clinical and educational qualifications than those in other neighborhoods."[21]
Studies show the existence of "residential, educational, and occupational segregation of marginalized, racialized groups to low-quality neighborhoods, schools, and jobs (both historical de jure discrimination and contemporary de facto discrimination)."[21]
Rural Americans are more likely to die from heart disease, cancer, unintentional injury, chronic lower respiratory disease, and stroke than their urban counterparts.[32]

[a] *$PM_{2.5}$ is a measure of small particles in the air and is used as an indication of air quality.*[33]

Table 2. Disparities in Education

A 2017 study of air neurotoxicant exposure at 84,969 US public schools found "racial/ethnic minority children are bearing the brunt of air neurotoxicant exposures at school, which may be unequally impacting their school performance and future potential."[36]
"During 2009-2010 the prevalence of smoking was 46.4% among 12th grade-aged youth who had dropped out of school compared with 21.9% among youth who were still in the 12th grade."[37]
In areas of high crime and high density of off-premise alcohol outlets, children between 10 and 18 years of age report fears of violence during their morning travel to school.[38]
Currently available technologies possess the capacity to nearly eliminate the particulate pollution that is emitted from a diesel engine bus and seeps into its interior. Yet, some children and adolescents continue to be exposed to this particulate pollution during school bus rides, which indicates a failure to use these technologies.[39]

Table 3. Disparities in Government Policies

Most studies have shown that "Medicaid patients are less likely to have access to physicians" in outpatient practices and are less likely to have access "to specialists and others who may be perceived as more qualified."[7]
Many states have paid physicians very poorly for treating Medicaid patients.[7]
While organizations that serve communities with limited economic resources, such as safety-net health centers, have a particular role to play in ensuring equitable access to cancer-prevention programs, "given limited resources and high demand, it can be difficult to integrate new [prevention] practices into such organizations."[40]
"Environmental and policy approaches (eg, taxation and restrictive policies) that reduce the rate of risky behaviors and that increase access to treatment are particularly important for tobacco control at the population level. However, the current federal excise tax on tobacco, $1.01, is low as compared with the average of about $3.15 per pack in high-income countries worldwide."[40]
According to a CDC statement about local health departments, "many disadvantaged, disenfranchised persons not only distrust the government, but they may also fear it."[41]

conditions, from stroke to heart disease to arthritis—prevalence increases as income declines.[45]

More than 1.4 million households in the United States, including 2.8 million children, report incomes of less than $2 per person per day. Things were not always this severe: between 1996 (when welfare reform went into effect) and 2011, the prevalence of extreme poverty rose sharply, with the growth of poverty concentrated among those most directly affected by welfare reform (Table 4).[46] In 2013, family wealth for the non-

Table 4. Disparities in Income and Poverty

"76% of orthopedists' offices in a nationwide audit study refused to offer an appointment to a Medicaid-insured child with a fracture, whereas only 18% refused a child with private insurance."[45,47]
"19% of non-elderly adults in the US who received prescriptions in 2014 (after full implementation of the Affordable Care Act [ACA]) could not afford to fill them."[45]
Multiple US studies show that "marginalized, racialized groups" have been subject to "reduced salary for the same work, and reduced rates of promotion despite similar performance evaluations."[21]
Exclusively breastfed infants were significantly less exposed to tobacco smoke and pets, had solid foods introduced later and belonged to higher social classes.[48]

Hispanic white population was 10 times that of the Hispanic population and more than 12 times that of the African-American population.[45] There is no indication that things are steadily improving: the decades extending from 1980 to 2015 have seen increased geographical segregation by income in the US.[42] Further, income and poverty connect to such factors as unequal access to technological innovations; reduced economic mobility, which, in turn, leads to the multigeneration persistence of poverty; expanded exposure to the costs of medical care; differential access to fresh fruit and vegetables; and differential access to information on risk factors and new medical procedures.[42]

The poor and middle classes in the United States pay a relatively larger share of their incomes for health care, which translates into their having less disposable income.[45] Yet, we all use disposable income to relieve stress; and stress, as will be discussed later, carries its own health consequences.

Structural Racism

As a recent overview in *The Lancet* explains, racism in America is frequently viewed in relation to interpersonal bias; however, much health inequity rests upon the messy, distasteful, historical and cultural roots of social structures that support or embody racism. *Lancet*'s series "America: equity and equality in health" describes structural racism as referring to "the totality of ways in which societies foster racial discrimination, through mutually reinforcing inequitable systems (in housing, education, employment, earnings, benefits, credit, media, health care, criminal justice, and so on) that in turn reinforce discriminatory beliefs, values, and distribution of resources, which together affect the risk of adverse health outcomes."[21]

A different and equally important definition of structural racism appeared recently in *The New England Journal of Medicine*, where it is described as "a confluence of institutions, culture, history, ideology, and codified practices that generate

and perpetuate inequity among racial and ethnic groups." This definition highlights the fact that "a large and growing body of literature documents disparate outcomes for different races despite the best efforts of individual health care professionals."[49]

Speaking at a 2017 conference at the New York University School of Medicine, Tom Frieden, MD, MPH, Director of the CDC from 2009 to 2017, stated that the health effects of racism are "huge." Further, he explained that to understand structural racism today it is important to include the awareness of what has happened in the past, including the legacy of slavery and the Tuskegee experiment.[50]

As Mary Bassett, MD, MPH, Commissioner, NYC Department of Health and Mental Hygiene, said at this NYU conference, simply using the word "racism" is uncomfortable. Many of us want nothing to do with racism or the word—nothing at all. Contemporary data and the history of our country both show all too clearly, however, that recognizing racism is something we cannot avoid if we want to look at health disparities objectively and in an evidence-based manner.[51] Nancy Krieger, PhD, professor at Harvard's School of Public Health, supported this assertion. "Naming racism is very important," she said, advocating that we look at how we can use this focus to improve health.[52] As Dr Bassett said, it is a misconception that health disparities are "just a reflection of income disparities."[50]

According to Dr Bassett, "by talking about health for everyone we give ourselves an opportunity to speak about racism and inequality. Our focus should be on "equity in all policies. Because if we begin to talk about equity it will support health."[51] (Table 5).

Table 5. Disparities in Structural Racism

A 2017 comparison of Hispanic and non-Hispanic white mothers finds the former "more likely to deliver at hospitals with higher risk-adjusted severe maternal morbidity rates, and these differences in site of delivery may contribute to excess morbidity among Hispanic mothers." This study points to specific deficits in relation to organizational characteristics and the less-than-excellent technology found in certain hospitals.[53]
According to a 2016 study, "black mothers are more likely to deliver at higher risk-standardized severe maternal morbidity hospitals than are white mothers, contributing to black-white disparities."[54]
Nearly 1 in 3 black men are imprisoned.[55] This translates to nearly half of black women having a family member or extended family member in prison. Current literature indicates that the children and adolescents of imprisoned fathers suffer increased rates of behavioral and mental health problems, including depression, anxiety, asthma, and obesity.[55]
As minority patients encounter health systems, even the administrative and clerical staff may be "expected to mirror social attitudes and trends" in relation to race and ethnicity; thus, bias and partiality may appear even as a patient arrives for treatment.[7]

Biologic Effects of Racism

A recent study found that drivers in a high-income neighborhood in Las Vegas were less likely to yield to an African-American pedestrian in a crosswalk in the same half of the roadway than they were to yield to a white pedestrian in the same situation.[56] The NY Times reported on secret recordings of a New York City Deputy Inspector who told policemen to frisk "male blacks 14 to 20, [or] 21" years of age.[57] The experience of racism is embedded in such low-key activities as "walking while black," in seeing landmarks associated with segregation, in applying for a job, in looking for a promotion at work, and in being a patient in certain medical clinics.

Poverty, difficult work conditions, dangerous neighborhoods, feeling disenfranchised or inadequately franchised, structural racism—all of these entail stress. Scientists have researched the biological effects of stress and, specifically, the effects of stress on a person's health. Accumulating evidence links racial discrimination to parameters associated with the effects of chronic stress. According to Bailey et al, "there is burgeoning evidence linking experiences of discrimination to biomarkers of disease and well-being, including allostatic load, telomere length, cortisol dysregulation, and inflammatory markers."[21] In looking at the effects of the various ways people perceive their neighborhood environments, differences in levels of cellular aging and, specifically, telomere length, may be relevant.

Furthermore, accumulating research has linked obesity in African-American women and elevated lipid levels in African-American men and women with the effects of racism.[58,59] Studies of how stress affects biological dysregulation are somewhat preliminary, but the field may be of great importance in relation to causes of health disparities.[21,35,60-65]

WHAT ABOUT PERSONAL RESPONSIBILITY?

On the one hand, personal responsibility is essential. Nobody can brush your teeth for you. Or exercise for you. Or keep you from eating foods with large quantities of salt and fat. On the other hand, it should be obvious that people cannot pull themselves up by their own bootstraps if they cannot afford to purchase boots.

As James Baldwin said in conversation with Margaret Mead in the book *A Rap on Race* (1971), people might look at someone like Harry Belafonte and at "those people rioting on the South Side" and conclude "that if those people on the South Side washed themselves and straightened up, they could all be Harry Belafonte."[66] Since that time, an enormous quantity of research has completely and utterly discredited the notion that disparities are essentially the product of a deficit in personal responsibility.

If someone lives near the city incinerator, in a part of town where the air is much polluted, where billboards advertise

alcohol, and where vermin are abundant; or if a child attends school in shabby, broken buildings with outdated or missing technology and absent or closed sports facilities; or if fresh produce and other quality food is scarce or unaffordable—that environment will have a negative effect on the residents. If someone else lives in a neighborhood with fresh air and greenspace, with no billboards, and where vermin are not a major concern; or if a child attends school in solid buildings with updated technology and modern sports facilities; or if fresh produce and other quality food is readily available—that environment will have a positive effect on the residents. All this is beyond the reach of personal responsibility. Nothing any individual or community can do substitutes for clean air and water, adequate nutrition, homes free of vermin, good schools, and a lack of chronic stressors.

CONCLUSION

As we conclude this article it seems right to note that a major concern of medical writers and editors is being effective and current in our work. So, it is relevant that the NIH, CDC, AHA, NAM, physician and nurse professional organizations, major foundations, leading medical centers, and schools of both medicine and public health are all engaged in major efforts to reduce health disparities. As these important and influential organizations focus on health disparities, we might pay attention; in fact, to be competent in our work we have no choice *but* to pay attention.

Now that some of the social determinants of health disparities in the United States have been identified, the next articles in this series will spotlight efforts being made by national organizations and relevant thought leaders—including those in the medical industry; in local, state, and national politics; in mass media (filmmakers, novelists, TV personalities, popular musicians); as well as in religious groups—to address these health disparities and social determinants of health and will offer specific suggestions and insights as to how we medical communicators can support those efforts.

Author contacts: *Bob Kirsch, bk292@columbia.edu; Tamara Ball, tballmd@gmail.com*

References

1. National Institute on Minority Health and Health Disparities. Overview. https://www.nimhd.nih.gov/about/overview/. Accessed May 11, 2017.
2. Centers for Disease Control and Prevention (CDC). Attaining Health Equity. https://www.cdc.gov/nccdphp/dch/programs/healthycommunitiesprogram/overview/healthequity.htm. Updated October 25, 2013. Accessed August 2, 2017.
3. Centers for Disease Control and Prevention (CDC). Health equity. https://www.cdc.gov/chronicdisease/healthequity/index.htm. Updated August 10, 2017. Accessed December 11, 2017.
4. American Heart Association. Health equity: eliminating bias by age, ethnicity, gender and more. http://www.heart.org/HEARTORG/Conditions/More/ConsumerHealthCare/Health-Equity-Eliminating-Bias-by-Age-Ethnicity-Gender-and-More_UCM_444722_Article.jsp#.WM5_Em8rLIU. Updated October 26, 2015. Accessed on May 11, 2017.
5. American Society of Clinical Oncology. Health disparities initiatives. https://www.asco.org/advocacy-policy/policies-positions-guidance/health-care-access/health-disparities-initiatives. Accessed May 11, 2017.
6. Institute for Diversity and Health Equity: An affiliate of the American Hospital Association. http://www.diversityconnection.org/. Published 2017. Accessed April 5, 2018.
7. Smedley BD, Stith AY, Nelson AR, eds; Institute of Medicine (US) Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care. Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care. Institute of Medicine. Washington, DC: The National Academies Press (US); 2003. https://www.nap.edu/catalog/10260/unequal-treatment-confronting-racial-and-ethnic-disparities-in-health-care. Accessed July 23, 2017.
8. Knickman JR; National Academies of Medicine. Getting serious about the social determinants of health. https://nam.edu/perspectives-2013-getting-serious-about-the-social-determinants-of-health. Published on May 9, 2013. Accessed May 11, 2017.
9. Dzau VJ, McClellan MB, McGinnis JM, et al. Vital directions for health and health care: priorities from a National Academy of Medicine Initiative. *JAMA*. 2017;317(14):1461-1470.
10. De Filippi R. Equity of care: The business imperative. *H&HN*. November 1, 2013. https://www.hhnmag.com/articles/5894-equity-of-care-the-business-imperative. Accessed April 3, 2018.
11. Johnson JA, Rossow CC. *Health Organizations: Theory, Behavior, and Development*. 2nd ed. Burlington, MA: Jones & Bartlett Learning; 2019:187.
12. McGinnis JM, Berwick DM, Daschle TA, et al. National Academy of Medicine. Systems strategies for better health throughout the life course: a vital direction for health and health care. https://nam.edu/wp-content/uploads/2016/09/Systems-Strategies-for-Better-Health-Throughout-the-Life-Course.pdf. Published on September 19, 2016. Accessed July 23, 2017.
13. Indian Health Service. Disparities. https://www.ihs.gov/newsroom/factsheets/disparities. Updated April 2017. Accessed March 28, 2018.
14. Krieger N, Chen JT, Coull BA, Beckfield J, Kiang MV, Waterman PD. Jim Crow and premature mortality among the US Black and White population, 1960-2009: an age-period-cohort analysis. *Epidemiology*. 2014;25(4):494-504.
15. National Cancer Institute. Cancer disparities. https://www.cancer.gov/about-cancer/understanding/disparities. Updated October 21, 2016. Accessed March 27, 2018.
16. American Society of Clinical Oncology. Policy Issue Brief: Disparities in Cancer. https://www.asco.org/advocacy-policy/asco-in-action/policy-issue-brief-disparities-cancer. Updated October 11, 2017. Accessed March 27, 2018.
17. American Heart Association. High blood pressure and African Americans. http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/UnderstandSymptomsRisks/High-Blood-Pressure-and-African-Americans_UCM_301832_Article.jsp#.Wk6MPVWnHIU. Reviewed October 2016. Accessed March 27, 2018.
18. Tanngka FK, Subramanian S, Mobley LR, et al. Racial and ethnic disparities among state Medicaid programs for breast cancer screening. *Prev Med*. 2017;102:59-64.
19. US Department of Health and Human Services. Obesity and African Americans. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=25. Last modified August 25, 2017. Accessed April 2, 2018.
20. US Department of Health and Human Services. Obesity and Hispanic Americans. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=70. Last modified September 15, 2017. Accessed April 2, 2018.
21. Bailey ZD, Krieger N, Agenor M, Graves J, Linos N, Bassett MT. Structural racism and health inequities in the USA: evidence and interventions. *Lancet*. 2017;389(10077):1453-1463.
22. Agency for Healthcare Research and Quality (AHRQ). Chartbook on rural health. https://www.ahrq.gov/research/findings/

nhqrdr/2014chartbooks/ruralhealth/index.html. Published September 2015. Accessed April 4, 2018.
23. Kaiser P, Diez Roux AV, Mujahid M, et al. Neighborhood environments and incident hypertension in the Multi-Ethnic Study of Atherosclerosis. *Am J Epidemiol*. 2016;183(11):988-997.
24. Christine PJ, Auchincloss AH, Bertoni AG, et al. Longitudinal associations between neighborhood physical and social environments and incident type 2 diabetes mellitus: the multi-ethnic study of atherosclerosis (MESA). *JAMA Intern Med*. 2015;175(8):1311-1320.
25. Berger RE, Ramaswami R, Solomon CG, Drazen JM. Air pollution still kills. *N Engl J Med*. 2017;376(26):2591-2592.
26. Di Q, Wang Y, Zanobetti A, et al. Air pollution and mortality in the Medicare population. *N Engl J Med*. 2017;376:2513-2522.
27. Gold DR, Samet JM; American Heart Association's Cardiology Patient Page. Air pollution, climate, and heart disease. http://circ.ahajournals.org/content/128/21/e411.full. Published November 18, 2013. Accessed November 15, 2017.
28. Boehmer TK, Foster SL, Henry JR, Woghiren-Akinnifesi EL, Yip FY; Centers for Disease Control and Prevention (CDC). Residential proximity to major highways — United States, 2010. *MMWR Morb Mortal Wkly Rep*. 2013;62(03):46-50.
29. Centers for Disease Control and Prevention (CDC). Common asthma triggers. https://www.cdc.gov/asthma/triggers.html. Updated September 8, 2016. Accessed August 3, 2017.
30. Sheehan WJ, Rangsithienchai PA, Wood RA. Pest and allergen exposure and abatement in inner-city asthma: a work group report of the American Academy of Allergy, Asthma & Immunology Indoor Allergy/Air Pollution Committee. *J Allergy Clin Immunol*. 2010;125(3):575-581.
31. Arshad SH, Tariq SM, Matthews S, Hakim E. Sensitization to common allergens and its association with allergic disorders at age 4 years: a whole population birth cohort study. *Pediatrics*. 2001;108(2):E33.
32. Centers for Disease Control and Prevention (CDC). About rural health. https://www.cdc.gov/ruralhealth/about.html. Updated August 2, 2017. Accessed January 13, 2018.
33. United States Environmental Protection Agency. Particulate Matter (PM) Pollution: Particulate Matter (PM) Basics. https://www.epa.gov/pm-pollution/particulate-matter-pm-basics. Updated September 12, 2016. Accessed April 29, 2018.
34. Braveman P, Egerter S, Williams DR. The social determinants of health: coming of age. *Annu Rev Public Health*. 2011;32:381-398.
35. Braveman P, Gottlieb L. The social determinants of health: it's time to consider the causes of the causes. *Public Health Rep*. 2014;129 Suppl 2:19-31.
36. Grineski SE, Collins TW. Geographic and social disparities in exposure to air neurotoxicants at US public schools. *Environ Res*. 2018;161:580-587.
37. Garrett BE, Dube SR, Winder C, Caraballo RS; Centers for Disease Control and Prevention (CDC). Cigarette smoking — United States, 2006-2008 and 2009-2010. *MMWR Morb Mortal Wkly Rep*. 2013;62(3):81-84.
38. Wiebe DJ, Guo W, Allison PD, Anderson E, Richmond TS, Branas CC. Fears of violence during morning travel to school. *J Adolesc Health*. 2013;53(1):54-61.
39. Borak J, Sirianni G. Studies of self-pollution in diesel school buses: methodological issues. *J Occup Environ Hyg*. 2007;4(9):660-668.
40. Emmons KM, Colditz GA. Realizing the potential of cancer prevention—the role of implementation science. *N Engl J Med*. 2017;376(10):986-990.
41. Centers for Disease Control and Prevention (CDC). Prevention guidelines database (archive). https://wonder.cdc.gov/wonder/prevguid/p0000389/p0000389.asp. Reviewed January 27, 2016. Accessed May 11, 2017.
42. Bor J, Cohen GH, Galea S. Population health in an era of rising income inequality: USA, 1980-2015. *Lancet*. 2017;389(10077):1475-1490.
43. National Academies of Sciences, Engineering, and Medicine. *The Growing Gap in Life Expectancy by Income: Implications for Federal Programs and Policy Responses*. Washingon, DC: The National Academies Press; 2015.
44. Chetty R, Stepner M, Abraham S, et al. The association between income and life expectancy in the United States, 2001-2014. *JAMA*. 2016;315(16):1750-1766.
45. Dickman SL, Himmelstein DU, Woolhandler S. Inequality and the health-care system in the USA. *Lancet*. 2017;389(10077):1431-1441.
46. Shaefer HL, Edin K. Extreme Poverty in the United States, 1996 to 2011. The National Poverty Center Policy Brief #28, February 2012. Available at http://www.npc.umich.edu/publications/policy_briefs/brief28/policybrief28.pdf. Accessed March 26, 2018.
47. Iobst C, Arango D, Segal D, Skaggs DL. National access to care for children with fractures. *J Pediatr Orthop*. 2013;33(6):587–591.
48. Halken S. Prevention of allergic disease in childhood: clinical and epidemiological aspects of primary and secondary allergy prevention. *Pediatr Allergy Immunol*. 2004;15 Suppl 16:4-5, 9-32.
49. Hardeman RR, Medina EM, Kozhimannil KB. Structural racism and supporting black lives—the role of health professionals. *N Engl J Med*. 2016;375(22):2113-2115.
50. Frieden TR. Broad-based vs targeted strategies in improving population health. Plenary discussion presented at: Health and Racial Equity and Urban Well-Being conference at the NYU School of Medicine; May 22, 2017; New York, NY.
51. Bassett M. Health *and*…Racism. Keynote address presented at: Health and Racial Equity and Urban Well-Being conference at the NYU School of Medicine; May 22, 2017; New York, NY.
52. Krieger N. Addressing health impact: racism and violence. Panel discussion presented at: Health and Racial Equity and Urban Well-Being conference at the NYU School of Medicine; May 22, 2017; New York, NY.
53. Howell EA, Egorova NN, Balbierz A, Zeitlin J, Hebert PL. Site of delivery contribution to black-white severe maternal morbidity disparity. *Am J Obstet Gynecol*. 2016;215(2):143-152.
54. Howell EA, Egorova NN, Janevic T, Balbierz A, Zeitlin J, Hebert PL. Severe maternal morbidity among Hispanic women in New York City: investigation of health disparities. *Obstet Gynecol*. 2017;129(2):285-294.
55. Wildeman C, Wang EA. Mass incarceration, public health, and widening inequalities in the United States. *Lancet*. 2017;389(10077):1464-1474.
56. Coughenour C, Clark S, Singh A, Claw E, Abelar J, Huebner J. Examining racial bias as a potential factor in pedestrian crashes. *Accid Anal Prev*. 2017;98:96-100.
57. The Editorial Board of the New York Times. Walking While Black in New York. *The New York Times*. March 22, 2013. http://www.nytimes.com/2013/03/23/opinion/walking-while-black-in-new-york.html. Accessed December 11, 2017.
58. Mwendwa DT, Gholson G, Sims RC, et al. Coping with perceived racism: a significant factor in the development of obesity in African American women. *J Natl Med Assoc*. 2011;103(7):602-608.
59. Mwendwa DT, Sims RC, Madhere S, et al. The influence of coping with perceived racism and stress on lipid levels in African Americans. *J Natl Med Assoc*. 2011;103(7):594-601.
60. Ong AD, Williams DR, Nwizu U, Gruenewald TL. Everyday unfair treatment and multisystem biological dysregulation in African American adults. *Cultur Divers Ethnic Minor Psychol*. 2017;23(1):27-35.
61. Liu SY, Kawachi I. Discrimination and telomere length among older adults in the United States. *Public Health Rep*. 2017;132(2):220-230.
62. Hanssen LM, Schutte NS, Malouff JM, Epel ES. The relationship between childhood psychosocial stressor level and telomere length: a meta-analysis. *Health Psychol Res*. 2017;5(1):6378.
63. Gebreab SY, Riesra P, Gaye A, et al. Perceived neighborhood problems are associated with shorter telomere length in African American women. *Psychoneuroendocrinology*. 2016;69:90-97.
64. Tomfohr LM, Pung MA, Dimsdale JE. Mediators of the relationship between race and allostatic load in African and White Americans. *Health Psychol*. 2016;35(4):322-332.
65. Paradies Y, Ben J, Denson N, et al. Racism as a determinant of health: a systemic review and meta-analysis. *PLoS ONE*. 2015;10(9):e0138511.
66. Mead M, Baldwin J. *A Rap on Race*. Philadelphia, PA: Lippincott; 1971.

An Examination of Microsoft® Word™ Features Used by Medical Writers

By Rowan Valenzuela, MS[1] and Dan Benau, PhD[2]

[1]Submission Medical Writer, Pfizer Inc., Collegeville, PA; [2]Director, Biomedical Writing Programs, University of the Sciences, Philadelphia, PA

ABSTRACT

Training for medical writers generally includes an overview of features in word processing, spreadsheet, and presentation software, but information on which features and practices are most useful to medical writers is sparse. Data regarding Microsoft® (MS) Word™ features most regularly used by medical writers were collected by using an online survey consisting of 30 questions. The anonymous survey was distributed to medical writers both online (identified primarily through LinkedIn®) and in person at the American Medical Writers Association's 2015 Annual Conference. The survey secondarily explored additional tools: Excel™ features, other software, hardware, and best practices. This report focuses only on the MS Word results, with some highlights regarding computer monitor use. To assess differences according to years of experience and type of medical writer—regulatory or nonregulatory—the responses of these subgroups were compared for select survey questions. A total of 88 survey responses were recorded over about 1 month of active solicitation. The results showed that keyboard shortcuts, Find and Replace, split screen, AutoCorrect options, and customized ribbons were the most regularly used MS Word features. Additional tools cited as essential for the profession included review tools, Styles, Insert:Captions/Cross-references, formatting tools, and Table of Contents features. Seasoned writers were more likely to employ Find and Replace techniques, while newer writers appeared to use split screen more. Regulatory writers were more likely to use Insert:Captions, Insert:Cross-references, and formatting functions, while nonregulatory writers were more likely to use Insert:Footnote, Insert:Endnote, and bibliographic features in Word.

INTRODUCTION

Personal experience and informal conversations with many medical writers at various industry meetings have revealed that training on word processing, spreadsheet, and presentation software has frequently been of a general nature. Useful specific software features are often picked up in practice through interactions with colleagues rather than through training. When viewing medical writing itself as a profession, it becomes important to distinguish the most useful tools and practices from the limited information provided during general training so that these may be communicated outside the training environment. The purpose of this study was to answer the question: What are the most important tools being used by medical writers, and how do these improve the way work is done in the industry? Data on Microsoft® (MS) Office™ software, other software, hardware, and best practices were collected; this report focuses on data on MS Word™ features and use of computer monitors. Medical writers, who were classified as either regulatory or nonregulatory writers, were the intended target population of this research.

There has been limited research into the tools used specifically in the medical writing industry. In 2011, Hitt Medical Writing, LLC, a company that develops content for medical education, e-learning, and publishing industries,[1] sent an email to its subscribers requesting feedback regarding what software and equipment they used and why. Responses were compiled by Emma Hitt Nichols in a 2011 online document and a 2013 eBook titled *The Write Tool for the Job*.[2,3] Both compilations directly quoted responders; no data analyses were conducted. This compilation provided a foundation for the research being addressed in the current study. In the current study, however, responders were obtained differently, additional information was collected, and data were analyzed to better answer the specific research question being addressed.

The discussion regarding tools has gained importance in the medical writing community. For example, Katz and Wood

have performed original research regarding the use of tools in medical writing.[4-6] More recently, Nicosia conducted a survey of tools used by freelance medical writers.[7] Nevertheless, finding additional published literature related to the current use of electronic tools specifically by medical writers proved to be difficult, especially in regard to comparing those tools used by regulatory writers with those used by nonregulatory writers. It is hoped that the results of the current research will provide a platform for medical writers to go beyond information spread through random colleague interactions and the generic training found in a typical MS Office training class.

METHODS

An anonymous survey consisting of 30 questions was created by using SurveyGizmo™ and was approved by the University of the Sciences (USciences) institutional review board. Entry criteria required only that the responder had current or previous experience as a medical writer. Survey responders were drawn primarily from LinkedIn® (group posts and cold contacting), the professional networks of the authors, and the American Medical Writers Association (AMWA) 2015 Annual Conference (with responses being recorded electronically at a kiosk within the USciences exhibitor booth). Responders were informed of where and when they would be able to find the results of this study posted online. Responders who took the survey at the booth during the AMWA conference were given either a stylus pen or a thumb drive for participating.

The survey consisted of demographic and qualifying questions, questions specific to MS Word and Excel, and questions pertaining to the use of other software, hardware, services, and best practices. There were 10 answers for the tools questions, with the last option being an open-ended response. Responders were allowed to give multiple answers to the questions, and they were not required to answer all survey questions.

To assess differences according to industry experience and type of medical writer, the responses from these subgroups were compared for select survey questions. The "types of writers" were regulatory writers (those who write documents for submission to regulatory agencies) and nonregulatory writers (all others hired to write scientific or medical content).

As noted in the Introduction, the current report focuses primarily on results for Word.

RESULTS

A total of 88 completed surveys were recorded in about 1 month of active solicitation for responders. Seventy-four responses (84%) were obtained using the online survey link and 14 responses (16%) were recorded in person at the USciences booth. The responses to qualifying and demographic questions are presented in Table 1. Of the 88 responders, 42 (48%) had more than 10 years of experience, 62 (70%) were regulatory writers, and 67 (76%) were from the United States.

Table 2 summarizes the responses to MS Word survey questions regarding the most regularly used and most

Table 1. Responses to Qualifying and Demographic Questions

Survey Question *Question Options*	n	%
How many years of medical writing experience do you have?		
<2 years	9	10.23
2–5 years	26	29.55
6–10 years	11	12.50
>10 years	42	47.73
TOTAL	88	100
Are (were) you a regulatory medical writer?		
Yes	62	70.45
No	26	29.55
TOTAL	88	100
What state or country (if working outside the US) do you work in? **CONTINENT** Country *Region*		
NORTH AMERICA	**69**	**78.41**
United States of America	67	76.14
Northeast	35	52.24
Midwest	14	20.90
South	10	14.93
West	8	11.94
Canada	2	2.27
EUROPE	**10**	**11.36**
United Kingdom	7	7.95
Germany	1	1.14
Denmark	1	1.14
Switzerland	1	1.14
ASIA	**5**	**5.68**
India	5	5.68
ZEALANDIA	**2**	**2.27**
New Zealand	2	2.27
UNKNOWN	**2**	**2.27**
Unknown	2	2.27
TOTAL	88	**100**

Table 2. Responses to Microsoft Word Questions and Cross-Tabulations

Survey Question			Cross-Tabulation #1				Cross-Tabulation #2	
			Survey Question				Survey Question	
Question Options (≥10% of all responders)	n	%	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
			How many years of medical writing experience do you have?				Are (were) you a regulatory medical writer?	
Which MS Word features do you regularly use that increase your work efficiency the most? Check all that apply. (N = 88)			*<2 years (n = 9)*	*2–5 years (n = 26)*	*6–10 years (n = 11)*	*>10 years (n = 42)*	*Yes (n = 62)*	*No (n = 26)*
Keyboard/click shortcuts (built-in, customized, or for macros)	78	88.6	8 (88.9)	24 (92.3)	10 (90.9)	36 (85.7)	53 (85.5)	25 (96.2)
Find and Replace techniques (including Wildcards)	66	75.0	5 (55.6)	18 (69.2)	8 (72.7)	35 (83.3)	48 (77.4)	18 (69.2)
Split screen	64	72.7	5 (55.6)	23 (88.5)	8 (72.7)	28 (66.7)	46 (74.2)	18 (69.2)
AutoCorrect options	54	61.4	5 (55.6)	15 (57.7)	7 (63.6)	27 (64.3)	37 (59.7)	17 (65.4)
Created/customized ribbon(s)	51	58.0	7 (77.8)	14 (53.8)	6 (54.5)	24 (57.1)	43 (69.4)	8 (30.8)
Format painter / set default paste	46	52.3	5 (55.6)	14 (53.8)	6 (54.5)	21 (50.0)	38 (61.3)	8 (30.8)
Macros (recorded, simple codes [within Word], or complex codes)	43	48.9	4 (44.4)	12 (46.2)	5 (45.5)	22 (52.4)	32 (51.6)	11 (42.3)
Write-in (optional)—add as many other features as you'd like here	21	23.9	0	3 (11.5)	3 (27.3)	15 (35.7)	13 (21.0)	8 (30.8)
Think back on when you first started as a medical writer. What MS Word features did you discover for the first time, which you now consider are absolutely essential for any medical writer to know? Check all that apply. (N = 86)			*<2 years (n = 9)*	*2–5 years (n = 25)*	*6–10 years (n = 10)*	*>10 years (n = 42)*	*Yes (n = 60)*	*No (n = 26)*
Review tools (including comments, tracked changes, and document comparison)	57	66.3	6 (66.7)	16 (64.0)	5 (50.0)	30 (71.4)	39 (65.0)	18 (69.2)
Styles (including use of heading styles)	52	60.5	4 (44.4)	17 (68.0)	5 (50.0)	26 (61.9)	37 (61.7)	15 (57.7)
Captions/cross-references/field codes	42	48.8	4 (44.4)	11 (44.0)	5 (50.0)	22 (52.4)	37 (61.7)	5 (19.2)
Formatting tools (including pilcrow icon [¶], page setup options, types of page breaks, etc)	40	46.5	4 (44.4)	11 (44.0)	5 (50.0)	20 (47.6)	32 (53.3)	8 (30.8)
Table of Contents (including List of Tables and Figures)	37	43.0	4 (44.4)	9 (36.0)	2 (20.0)	22 (52.4)	28 (46.7)	9 (34.6)
Headers & Footers (including linking/unlinking)	34	39.5	4 (44.4)	8 (32.0)	2 (20.0)	20 (47.6)	25 (41.7)	9 (34.6)
Add-ins (including templates)	29	33.7	4 (44.4)	10 (40.0)	1 (10.0)	14 (33.3)	24 (40.0)	5 (19.2)
Footnotes/citations/bibliographies	26	30.2	2 (22.2)	7 (28.0)	2 (20.0)	15 (35.7)	16 (26.7)	10 (38.5)
Write-in (optional)—add as many other features as you'd like here	9	10.5	0	1 (4.0)	3 (30.0)	5 (11.9)	8 (13.3)	1 (3.8)

Note: Options chosen by fewer than 10% of respondents are not displayed.

essential tools and also includes cross-tabulations showing how the responses are broken down by years of experience and type of writer.

Table 3 summarizes the most common write-in responses to the questions on Word features. Twenty-one (24%) responders used the write-in option, citing Review tools (n = 13), Customized styles (n = 5), and the navigation pane (n = 3) as features that increased their efficiency the most; "Tracked changes [*sic*]" was the most frequently cited feature under Review tools.

Table 3. Write-in responses (≥2 responders) to question regarding most regularly used MS Word features (N = 88)

Response	n (%)
Review tools	13 (14.8)
Tracked changes	8 (9.1)
Document compare	3 (3.4)
Comments	2 (2.3)
Customized styles	5 (5.7)
View tools	3 (3.4)
Navigation pane	3 (3.4)
EndNote (in Word)	2 (2.3)

In addition, the survey asked whether a responder uses multiple monitors. Of the 84 responders to this question, the majority (54; 64%) used 2 monitors, whereas 13 used 3 monitors, 11 used a single monitor, and 6 used 4 or more. Of the 3 responders who used 4 monitors, 2 had more than 10 years of experience; all 3 responders who used at least 5 monitors also had more than 10 years of experience.

DISCUSSION

Industry standards for software change over time, requiring re-examination of which products are currently considered to be most useful. Although most changes are evolutionary, some, like the 1994 downfall of WordPerfect®, are almost cataclysmic.[9] Recent articles have been published that explore the software medical writers currently use.[7,8] These articles specify the brands of software, but the researchers limited their respondents to freelance medical writers. The results from the Nicosia survey published in the Fall 2017 *AMWA Journal* indicated that the MS Office Suite, especially MS Word™; Adobe Acrobat®; Endnote®; and PerfectIt® are the most commonly used software, with laptops, multiple monitors, and external hard drives being the most common hardware employed.[7] Interestingly, in terms of the overall software identified by medical writers, the results of the current study and the one by Nicosia are similar on a percentage basis.[7]

The current results, which are part of a larger study, focus on identifying the features within MS Word that seemed most useful for medical writing tasks and on examining whether there were differences due to years of experience or between medical writers who identified themselves as regulatory writers and those who identified themselves as nonregulatory writers. Of the 88 responders, 10% had less than 2 years of experience, 42% had 2 to 10 years, and 48% had more than 10 years. About 70% of responders were regulatory medical writers. Although it might have been preferable to have a more balanced proportion of regulatory to nonregulatory writers, there were enough nonregulatory responders to allow for some cautious inferences to be drawn.

The 3 Word features used most regularly by responders were keyboard/click shortcuts, Find and Replace features, and the split-screen function (Table 2). Keyboard shortcuts are either built in, customized, or used to access recorded macros. The most commonly cited were shortcuts using the Control key (MS Windows) or Command key (Macintosh) for the built-in features of cutting, copying, and pasting text (eg, Ctrl-X, Ctrl-C, and Ctrl-V, respectively). This finding is unsurprising and consistent with the experiences of both authors; once a colleague or student has been shown these shortcuts, they rarely resort to using the mouse for these functions afterward.

The second most regularly referenced Word features were Find and Replace features, which are found either in the Edit menu (with those versions of Word that still have a menu) or on the Home ribbon. A writer can find a word and replace it with another (eg, replace "patient" with "subject") either singly or globally. In addition to simple whole-word location, Word can also locate text by matching the exact case, format, Word Style, character type, or other special identifier. The use of Wildcards is a programmatic enhancement that allows advanced search and replace. As experience in years increased, so did the percentage of medical writers who regularly used Find and Replace features (Table 2).

The third most regularly used Word feature was the split-screen function, which allows a user to view 2 different parts of a single document at the same time. This might be employed while working on a list of abbreviations or when writing text based on a table located on a different page. The use of this feature correlated with level of experience to some degree. A greater percentage of responders with 2 or more years of experience used this feature compared with those with less than 2 years' experience. One responder began using this feature after observing it being used by another writer. While it may be tempting to attribute this to age versus experience alone, the survey analysis did not differentiate between a 30-year-old writer with 8 years of experience and a 50-year-old writer with less than 2.

As seen in Table 2, more regulatory writers (62%) compared with nonregulatory writers (19%) cited "captions/cross-references/field codes" as essential Word skills. Similarly, approximately 20% more regulatory writers cited formatting tools and add-ins as essential skills. This is probably a reflection of the highly formatted and complex documents and document parts in larger regulatory filings, which require the use of field codes and other such features to create the electronic navigation tools used in the review of submissions to regulatory agencies.

It is also interesting to note that, not including write-in options, "footnotes/citations/bibliographies" had the lowest number of responders among regulatory writers but had the third highest number of responders among nonregulatory medical writers. This may reflect the need for in-place referencing for work such as manuscripts and needs assessments. Regulatory writers do create reference lists, but these may be created using the cross-reference tool or a customized add-in template, or they may be part of a section created by information scientists rather than regulatory writers.

Tracked changes and customized styles were identified most often in the write-in responses for the question regarding most regularly used Word features (Table 3). The Word Track Changes feature allows the team to monitor editorial updates between document versions. Word Styles provide formatting consistency, assist in document navigation, and contribute to submission readiness.

Responders were also asked to share Word features they discovered and now consider to be essential knowledge for any medical writer (Table 2). The results are also consistent with the experiences of both authors. Review tools help track updates and provide a platform for feedback and resolution of issues during review cycles, Word Captions are primarily used for tables and figures, and Word Cross-references within a document maintain numbering for endnotes and other electronic indicators.

Data on the use of multiple monitors in this report were included because they indicate an amplification of results regarding Word. The split-screen Word feature was cited by 73% of responders. The side-by-side view between documents, cited within the full set of responses, serves a similar purpose. Therefore, the ability to simultaneously view more than 1 section of information within a single document seems to be valued by a large percentage of respondents. The use of multiple computer monitors in conjunction with extending the computer desktop accomplishes the same thing.

The results of our survey seem to suggest that the use of multiple monitors correlates with the writing role to some degree. Eleven of the 13 responders who used 3 monitors were regulatory writers, and all 6 responders who used at least 4 monitors were regulatory writers. This may indicate that regulatory writers need to work with multiple documents simultaneously more often.

Study Limitations

The sample size of 88 is a small percentage of the population of medical writers as a whole. In comparison, the study by Nicosia[7] had 381 respondents, which, although larger than our study, is nevertheless still a small fraction of that population. For this reason, the results of our study should to be viewed with caution in terms of extrapolation to the larger population of medical writers.

CONCLUSION

Although extrapolating the results of the current study to the general population of medical writers should be done with caution, our results do provide a helpful overview of which features within MS Word increase work efficiency for the medical writers who responded. Among the most regularly used tools within Word are keyboard shortcuts, Find and Replace features, split-screen, AutoCorrect options, and customized ribbons. Features that were identified as essential industry knowledge also included review tools, Styles, Captions/Cross-references, formatting tools, and Table of Contents features. Seasoned writers were more likely to employ Find and Replace features, while newer writers appeared to use split screen more. Regulatory writers were more likely to use Captions, Cross-references, and formatting functions, while nonregulatory writers were more likely to use Footnote, Citation, and Bibliographic features in Word. A larger pool of responders to these questions is needed to increase the confidence in the validity of the results.

Acknowledgments

The authors thank all survey respondents and Nancy Katz, PhD, MWC®, for her role as content advisor and manuscript reviewer.

Author contact: *d.benau@usciences.edu*

References

1. High-Quality, Fast Turnaround Medical Writing Services. Hitt Medical Writing, LLC website. http://hittmedicalwriting.com/hmw/. Accessed September 14, 2015.
2. Hitt E. Equipment and Software for Medical Writing http://www.hittmedicalwriting.com/Week2_EquipmentandSoftwareforMedicalWriting_012711.pdf. Accessed March 27, 2018
3. Hitt E. The Write Tool for the Job, 2013 edition. https://www.overdrive.com/media/1876359/the-write-tool-for-the-job. Emma Hitt. 2013.
4. Katz, NR. The Scope of Summary Documents ("The Paris Study"). Presented at the Drug Information Association (DIA) 8th Annual EU Clinical Forum; April 14-15, 2015; Paris, France.
5. Drug Information Association (DIA) 51st Annual Meeting. Washington, DC. June 2015.
6. Clinical Development Riding the iWave. 8th Annual Clinical Forum; April 2015; Paris, France.
7. Nicosia M. Results From the 2016 Freelance medical communicator tools of the trade survey. *AMWA J.* 2017;32(3):105-112.
8. Evans C, Bass B, Vakil R. Freelance forum: What key types of software programs would you recommend for a new freelancer? *AMWA J.* 2016; 31(2):72-73.
9. Morettini P. The Rise and Fall of Novell. https://www.pjmconsult.com/index.php/2011/05/rise-and-fall-of-novell.html. Accessed February 2, 2018.

Medical Cannabis: Where Do We Stand Today?

By Marielle Fares, PharmD, BCGP / Freelance Medical Writer, Washington, DC

ABSTRACT

The cannabis plant has been cultivated for thousands of years and has been traditionally used in medicine and agriculture, as well as in spiritual and psychological settings. Despite these deeply rooted ancient practices, there remains a strong stigma around its use that is associated with cultural, historical, and political connotations. To shatter the misconceptions surrounding the use of medical cannabis, this article differentiates the recreational uses of the plant from the medical uses of cannabis and their respective health effects. Scientists have identified numerous chemical compounds in cannabis, or phytocannabinoids, of which delta-9-tetrahydrocannabinol (Δ^9 THC) and cannabidiol (CBD) are the most relevant in medicine. The discovery of the human endocannabinoid system and its relation to phytocannabinoids was a breakthrough in cannabis-related research. The endocannabinoid system uses an intricate network of cannabis-like substances produced by the body that interact with cannabis cell receptors, influencing neurotransmitter release and ultimately producing physiologic effects in the body. Medical cannabis, when used under medical supervision, has proven beneficial and safe in several conditions. The FDA has approved 2 prescription formulations of cannabis for clinical use and additional formulations for inclusion in clinical trials. Unfortunately, medical cannabis research remains plagued by important legal, administrative, and logistical barriers. At the same time, the regulation of cannabis is evolving at a fast pace. Several states have legalized the use of cannabis for recreational and medical use. Medical cannabis can be obtained by eligible patients under state-specific marijuana access programs. Of noteworthy interest is the observed synergy between cannabis and opioids, raising the possibility of using cannabis to decrease the dosage of opioids and avoid their undesirable effects. This article reviews the latest scientific evidence about medical cannabis, discusses the officially recognized benefits of the plant, and identifies the limitations to its continued research.

INTRODUCTION

The cannabis plant belongs to the *Cannabis* genus, of which there are 3 distinct species that differ in chemical composition: *Cannabis sativa, Cannabis indica*, and *Cannabis rudealis*.

The botanical form of cannabis is thought to have originated in parts of Western and Central Asia in the ancient world, where it was cultivated for thousands of years and used for various spiritual, health, and psychoactive effects. It was introduced to the United States in the colonial period and cultivated until the turn of the 20th century.

The use of cannabis in medicine was very prominent in ancient history, and texts transcribed from the ancient Hindu, Greek, and Chinese cultures attest to its successful use against a wide range of ailments.[2]

The term "marijuana" refers to a cannabis plant, mostly of the *Cannabis sativa* species, that provides an important "high," euphoric, or psychoactive effect and is cultivated for recreational uses. In contrast, hemp or "industrial hemp" is a nonpsychoactive form of cannabis that was grown for its stalks and seeds to produce textile fiber, paper, ropes and sailcloth, and cellulose for plastic, and was an important source of essential oils, fatty acids, and protein for humans and animals.[2]

In the United States, cannabis was also used as a medicine throughout the 19th and early 20th centuries. It was officially recognized and added to the *United States Pharmacopeia* and the *National Formulary* (*USP-NF*) in 1850. The use of cannabis came to a progressively rapid halt because of socioeconomic factors leading to the federal "Marihuana Tax Act" in 1937, which prohibited possession and cultivation of cannabis. In recent national memory, cannabis is associated negatively with the psychedelic hippie movement of the 1960s and 70s. Additional regulations were enacted over time and culminated with the federal Controlled Substance Act (CSA) in 1970, placing further limits on cannabis research.

THE *CANNABIS* PLANT AND THE ENDOCANNABINOIDS

Phytocannabinoids

The most researched cannabinoid substances in the cannabis plant, or phytocannabinoids, are delta-9-tetrahydrocannabinol (Δ^9 THC), cannabidiol (CBD), and cannabinol (CBN). Approximately 104 different phytocannabinoids have been identified, in addition to terpenes, flavonoids, and other chemical compounds.[2,10]

These substances vary in composition with differences in cannabis strains, soil, weather conditions, and cultivation methods.[10] Most importantly, different varieties of cannabis plants have various absolute and relative concentrations of CBD and THC. For instance, the cannabinoid Δ^9 THC is responsible for most of the hallucinogenic or psychotropic effects of cannabis.

Cannabinoid research has pointed to receptors for these substances in the body and has isolated the cannabinoid type-1 (CB1) and cannabinoid type-2 (CB2) receptors. Cannabinoid receptors can be found in the brain and in other cells in the body. While Δ^9 THC produces the "high" effect of cannabis through binding and activation of the CB1 receptor, CBD has very weak affinity to CB receptors. Instead, CBD influences intracellular neurotransmitter release and triggers chemical cascades believed to produce beneficial effects such as anti-inflammatory, analgesic, anxiolytic, antinausea, and antiepileptic effects, without causing the psychoactive or "high" effects seen with THC.[6] In fact, CBD counteracts the psychoactive effect of THC by reducing anxiety and other negative effects of THC.[11]

The Endocannabinoid System

The endocannabinoid system (eCBs) is a signaling system present in all vertebrae that has important regulatory functions in the body. The eCBs plays a role in neural development, inflammation, appetite and metabolism, immune function, pain, memory, learning, the regulation of stress and emotions, psychiatric disease, reproduction, and many other physiologic and pathophysiologic processes.[10] Because of its importance in homeostasis regulation, it has been best described as an "eat, sleep, relax, forget, and protect" system.[3]

The eCBs consists of the CB receptors and their ligands, the endogenous cannabinoids anandamide (AEA) and 2-arachidonoylglycerol (2-AG), and ligand metabolic enzymes.[3] Endogenous cannabinoids are naturally occurring substances in the body that elicit cannabis-like effects through binding and activation of the CB1 and CB2 receptors. CB1 receptors are the most abundant G-protein–coupled receptors in the body. They densely populate brain cells and the nervous system, connective tissues, musculoskeletal cells, and virtually all organs in the body. CB2 receptors are concentrated in peripheral organs and especially on immune cells and, to a lesser extent, in bone, liver, and nerve cells.

GLOSSARY OF TERMS

Cannabidiol (CBD). A substance in the cannabis plant that has beneficial effects and is devoid of psychoactive and hallucinogenic properties.

Cannabinoids. Chemical compounds or substances isolated from the cannabis plant that elicit responses in the human body.

Chemotherapy-induced nausea and vomiting (CINV). The nausea and vomiting that results from the administration of chemotherapy to cancer patients. This is a well-recognized side effect of chemotherapy.

Controlled Substance Act (CSA). Comprehensive Drug Abuse Prevention and Control Act, a law enacted in 1970 that controls the distribution of all depressant and stimulant drugs with potential for abuse and enforced by the Drug Enforcement Administration (DEA) of the Department of Justice. Drugs with effect on the central nervous system are divided into 5 classes or schedules relative to their potential for abuse.

Delta-9-Tetrahydrocannabinol or Δ^9 THC. Substance with hallucinogenic or psychoactive effects isolated in the cannabis plant.

Endogenous. Produced by or originating internally in a cell, tissue, or organism.

Endogenous receptor. A naturally occurring molecule on the surface of a cell or inside it that recognizes another specific molecule as its substrate. When substrates bind to their specific receptors, they either activate or inhibit those receptors, eliciting specific responses in the body.

Endocannabinoids. Naturally occurring substances that exert cannabis-like effects and interact with cannabis receptor type-1 (CB1) and cannabis receptor type-2 (CB2) located in various areas of the body.

Endogenous opioids. Naturally occurring substances in the body that exert opiate-like effects, commonly termed endorphin or encephalin. They interact with opioid receptors in the brain and spinal cord and reduce the sensation of pain.

G-protein–coupled receptors. A large family of cellular structures that is activated by a substrate ligand and subsequently trigger events within the cell, producing a body response.

Ligand. A molecule or substrate that binds to its specific receptor and elicits a specific response in the body.

Neurons. Cells located in the brain and spinal cord.

Neurotransmitters. Chemical compounds such as serotonin, dopamine, and GABA that exist in the space between neurons and provoke different responses in the body.

Multiple sclerosis (MS). An autoimmune dysfunction causing the destruction of the protective layer around the neurons. MS causes a range of disorders affecting balance, strength, coordination, vision, and other functions.

Muscle spasticity. Muscle rigidity causing stiffness and restriction of movement. This symptom is frequently associated with MS and other disease conditions.

Opioid receptors. Cellular structures to which opioids specifically bind. The main opioid receptors are the mu, kappa, and delta receptors.

Physiologic. Characteristic of or appropriate to an organism's healthy or normal functioning.

Pathophysiologic. Functional changes that accompany a disease or medical condition.

Synapse. The space between neurons where neurotransmitters are released in response to chemical triggers. Neurotransmitters may be released from a presynaptic space to a postsynaptic neuron or to another organ of the body to produce a response.

AEA and 2-AG are synthesized from postsynaptic cells and diffuse backwards to act on CB receptors expressed on the presynaptic space. Activity on the CB1 receptor mediates the suppression of neurotransmitters released from intracellular vesicles into the synaptic space, such as dopamine, serotonin, glutamate, acetylcholine, Gamma Amino Butyric Acid (GABA), D-aspartate, and cholecystokinin (Figure 1).

Endocannabinoids and cannabis compounds also affect noncannabinoid receptors, as G-protein receptors compete with opioid receptors and with norepinephrine, serotonin, and dopamine receptors. Within the eCBs, cannabis effects are enhanced or suppressed by surrounding chemical compounds and metabolized by degrading enzymes. In the immune cells, activation of the CB2 receptors inhibits inflammatory cytokine production and cellular migration, affecting the immune response.[10]

Interestingly, a dysregulation or deficiency in the eCBs has been implicated in pathological or disease conditions such as migraine, fibromyalgia, irritable bowel syndrome, and possibly depression.[3,5,6,10]

Those intricate chemical interactions within the eCBs result in various physiologic and pathologic responses in the body, many of which are described in the literature and are still being studied to this day.

MEDICAL CANNABIS IN THE SCIENTIFIC LITERATURE

While anecdotal evidence about the benefits of cannabis abounds, the number of clinical studies of the potential benefits of cannabis is very limited but steadily increasing. Many of these clinical studies have tested recreational cannabis in its most commonly ingested form—smoked.[5,10] Smoking cannabis produces the fastest effect as THC reaches the brain within minutes, causing a euphoric or psychotropic effect.[6] The introduction of vaporizers with smoked cannabis allows cannabis substances to be effectively delivered while reducing lung irritation from smoke toxins and possible carcinogens.[3,4]

The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations report was published in 2017 by The National Academies of Science, Engineering, and Medicine. The report provided consensus on the efficacy of cannabis in various medical conditions and concluded with the highest strength of recommendation that cannabis or cannabinoids are effective in treating chronic pain and nausea associated with chemotherapy and in improving muscle spasticity in patients with multiple sclerosis (MS). In parallel, Health Canada, the United States Food and Drug Administration (FDA) equivalent, has published *Information*

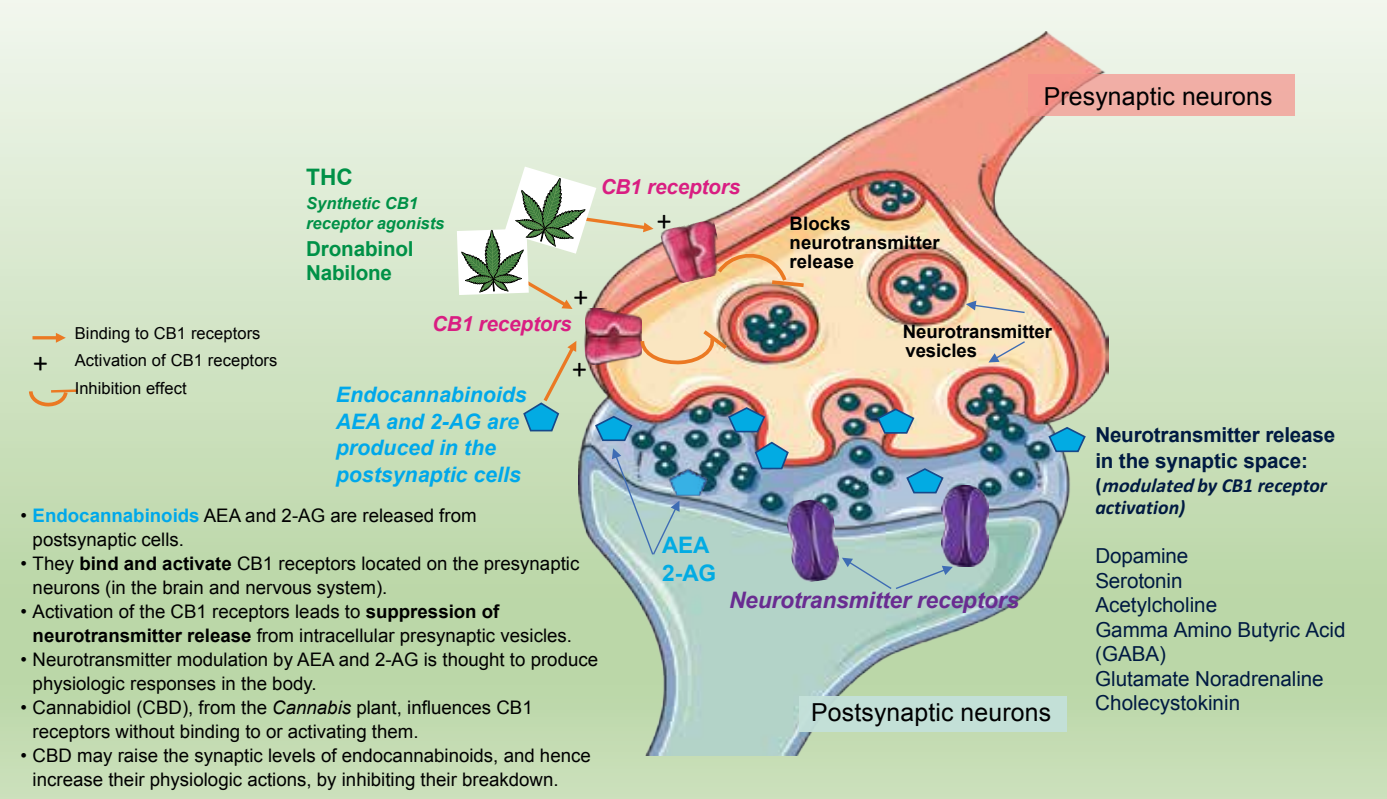


Figure 1. The Endocannabinoid System in the Human Brain. © All rights reserved. *Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids*. Health Canada, 2013. Modified, adapted and reproduced with permission from the Minister of Health, 2018.

for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids, an in-depth report about cannabis's medical benefits and side effects, modes of administration, and dosing suggestions for the clinical setting.[10]

One of the most well-substantiated medical uses of cannabis is to alleviate chronic pain, including neuropathic pain and pain resulting from rheumatoid arthritis or musculoskeletal conditions, cancer and chemotherapy, and MS. Endogenous cannabinoids, CBD, and Δ^9 THC all play a role in producing analgesia, yet the psychoactive effects of Δ^9 THC limits its use. Questions remain about the proper type of cannabis, as well as the dose, route of administration, and side effects, related to its use in the treatment of chronic pain.[5]

The eCBs modulates motor function, tremor and spasticity, and the neuroinflammatory response. Oral cannabis has shown efficacy in the relief of patient-reported muscle spasticity in MS.[5,12]

Nabiximols is now approved for the relief of muscle spasticity in MS in Europe, the United Kingdom, and Canada. Nabiximols (Sativex®) is a whole-plant extract of 2 different strains of cannabis in a 1:1 concentration of CBD and Δ^9 THC, available as an oromucosal spray. Health Canada has approved it for the adjunct treatment of neuropathic pain in MS and for moderate to severe cancer-related pain resistant to the highest doses of opioids. In the United States, the FDA has granted fast-track designation to Sativex® for the treatment of pain in advanced cancer and for MS spasticity.[5,6,10]

CB1 receptors are found in areas of the brain that control nausea and vomiting. Marinol (Dronabinol®) and nabilone (Cesamet®) are 2 synthetic Δ^9 THC formulations approved by the FDA for chemotherapy-induced nausea and vomiting in patients who do not respond to conventional treatments. Marinol (Dronabinol®) is also approved for patients who have lost weight because of acquired immunodeficiency syndrome (AIDS)–related anorexia.

The CB1 receptor–mediated suppression of the neurotransmitters glutamate and GABA suggests a role in seizure activity. To date, studies of cannabis in epilepsy have been inconclusive, but newer studies of efficacy are awaiting publication.[5] Epidiolex® is an oral formulation of pure CBD (>98% CBD oil) approved in the United Kingdom and undergoing last-phase clinical trials in the United States for the treatment of rare and drug-resistant epilepsy syndromes.

Other disease conditions commonly discussed in relation to medical cannabis are irritable bowel syndrome, Tourette syndrome, amyotrophic lateral sclerosis, Huntington disease, Parkinson disease, dementia, glaucoma, addiction, anxiety, depression, sleep disorders, posttraumatic stress disorder, and schizophrenia and other psychoses. However, evidence from clinical trials in these conditions is limited, and the use of medical cannabis in these conditions is not warranted.[5]

Much of the available information about the side effects of cannabis comes from studies of the recreational use of smoked cannabis.[10] The acute, recreational use of cannabis or marijuana causes euphoria, relaxation, intensification of ordinary sensory experiences, short-term memory loss, impaired motor coordination, and paranoia or psychosis. Chronic and heavy users are at increased risk of addiction, cognitive impairment, psychiatric manifestations such as schizophrenia and depression, and chronic bronchitis.[10] The use of recreational and medical cannabis should be avoided in patients with a history of psychiatric and personality disorders.

A risk of overdose exists in patients taking different forms of cannabis concomitantly, such as taking vaporized cannabis with other prescription cannabinoids, or with edible cannabis forms such as teas and baked goods. The combination of cannabis and alcohol or other depressant medications is contraindicated and should be avoided at all costs.[10]

THE MEDICAL CANNABIS CHALLENGE

Cannabis Regulations and Patient Access

While many scientific societies and associations acknowledge the beneficial effects of cannabinoids on health, the larger public is divided between acknowledgment of its medicinal benefits and concern over its side effects and unknown risks due to the lack of rigorous testing, along with the lack of product standardization and purity levels.[3]

Nevertheless, the use of medical cannabis is legal in 28 states and in the District of Columbia, Guam, and Puerto Rico, where laws have been drafted defining its sale and distribution. A total of 8 states have legalized both medical and recreational uses of marijuana.[10] The state of California was the first in passing the Compassionate Use Act in 1996, allowing the use of medical cannabis for different ailments.[3,6] The Act allowed patients and their caregivers to use cannabis for medical conditions described as anorexia, cancer, AIDS, spasticity, chronic pain, arthritis, migraine, nausea, and glaucoma.[7]

States that have legalized cannabis operate what are referred to as "marijuana programs," allowing certified physicians to recommend cannabis to eligible patients. Patients can obtain cannabis from marijuana dispensaries through a state-issued marijuana ID. In clinics and hospitals, however, physicians are reluctant to prescribe cannabis because of federal restrictions and registration requirements. Moreover, medical cannabis is not reimbursed through private or government insurance, making cannabis treatment harder to access for patients.

Barriers to Medical Cannabis Research

The Controlled Substance Act (CSA) classifies all substances and prescription drugs from I to V, in decreasing order of potential for abuse and dependence. The CSA classifies

tetrahydrocannabinols as a schedule I substance that "has no acceptable medicinal use" and has "the highest potential of abuse and dependence."[8]

The schedule I classification of cannabis is a major hurdle for scientists trying to obtain it for clinical study. It impedes federal funding for cannabis research and limits the possibility of conducting large-scale trials. Scientists face a complicated application process at state and federal levels before they can obtain and research cannabis. The National Institute on Drug Addiction is the only agency that can approve cannabis research studies and only allows it in the context of addiction, a source of bias that adds another impediment to other avenues of clinical research.[6] In addition, it is difficult to obtain the quantity, quality, and purity required for research.

Cannabis: A Role in the Opioid Epidemic?

Cannabinoids mediate their analgesic effects through activation of the CB1 receptors. Evidence suggests that CB receptors and opioid mu receptors overlap or collocate in presynaptic membranes in the brain and spinal cord, sharing pathways responsible for processing pain stimuli and perception.[10] In addition, the acute and chronic use of Δ^9 THC was shown to increase the release of endogenous opioids—the naturally occurring substances with opioid-like effects in the body—and the expression of opioid precursor genes.[3,10,11]

Preclinical studies have shown that vaporized THC-rich cannabis administered with stable doses of opioids causes an increase in the potency of the opioids and enhances overall analgesia in a persistent manner.[9]

Though more studies are needed here, a possible "cannabinoid-opioid synergy" has been hypothesized that could allow a decrease in required opioid doses. This "opioid-sparing effect" avoids the negative side effects of opioids, especially tolerance and addiction.[9,11]

In a similar vein, Δ^9 THC has been shown to modulate reward pathways and addictive drug-seeking behavior within the eCBs, while CBD has been shown to limit these actions. Also, patients with substance abuse disorders often present with associated psychiatric symptoms such as anxiety, insomnia, and pain that may be relieved by CBD, suggesting a role for CBD in the treatment of addiction as well as in opioid-related behavior.[11]

CONCLUSION

The properties of cannabis have been extensively reported and increasingly studied in recent medicine. The beneficial effects of cannabis on conditions of chronic pain, nausea and vomiting, muscle spasticity, and others have been clearly demonstrated by evidence-based research and published in official reports. Though more studies are needed, researchers continue to face significant legal and administrative barriers to cannabis testing and research.

On the bright side, the regulatory landscape of cannabis in the United States has seen state legislatures improving patient access to medical cannabis through structured programs.

Moreover, the proven association between cannabis and opioids, and the potentiation of opioid analgesia by cannabis, provides a golden opportunity to discontinue or reduce the dosing of opioids in favor of safer cannabis.

By educating the public about the benefits and adverse effects of recreational and medical cannabis and the barriers facing the scientific community, this article stresses the importance of advancing cannabis research to better understand its role in medicine and, most importantly, to provide it to eligible patients.

Author contact: *mariellefares@gmail.com*

References

1. Ranalli P, Venturi G. Hemp as a raw material for industrial applications. *Euphytica* 2004;140(1-2):1-6.
2. Goldman R, Klatz R. *Anti-Aging Therapeutics*. Volume VII. Chicago, IL: A4M American Academy of Anti-Aging Medicine; 2015.
3. Bridgeman MB, Abazia DT. Medicinal cannabis: history, pharmacology, and implications for the acute care setting. P&T. 2017;42(3):180-188.
4. Notcutt W. Clinical use of cannabinoids for symptom control in multiple sclerosis. *Neurotherapeutics*. 2015;12(4):769-777.
5. National Academies of Science, Engineering and Medicine. The Health Effects of Cannabis and Cannabinoids: The Current state of Evidence and recommendations for Research. Washington, DC: The National Academies Press; 2017.
6. Baron, E. Comprehensive review of medicinal marijuana, cannabinoids, and therapeutic implications in medicine and headache: what a long strange trip it's been..... *Headache*. 2015;55(6):885-916.
7. The California Medical Association (CMA) information-on-demand service. Document 1315. The Compassionate Use Act. The medical marijuana initiative. www.cmanet.org. Accessed February 16, 2018.
8. Title 21 United States Code (USC) Controlled Substance Act §812. 1970. https://www.deadiversion.usdoj.gov/21cfr/21usc/index.html. Accessed April 16, 2018.
9. Abrams D, Couey P, Shade S, Kelly M, Benowitz N. Cannabinoid-opioid interaction in chronic pain. *Clin Pharmacol Ther*. 2011;90(6):844-851.
10. Abramovici H. Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids. Health Canada. https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf. Published February 2013. Updated May 2013. Accessed February 17, 2018.
11. Hurd Y, Yoon M, Manini A, et al. Early phase in the development of cannabidiol as a treatment for addiction: opioid relapse takes initial center stage. *Neurotherapeutics*. 2015;12(4):807-815.
12. Koppel BS, Brust JCM, Fife T, et al. Systematic review: Efficacy and safety of medical marijuana in selected neurologic disorders. Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2014;82(17):1556-1563.

For Safety's Sake
Part 1: Collection of Adverse Event Data

By Thomas M. Schindler[1] and Helen Bridge[2]

[1]Medical Writing Europe, Boehringer Ingelheim Pharma, Germany; [2]Medical Communications, AstraZeneca, United Kingdom

Judy was pleased to have found a free table by the window in her favorite burger restaurant. She watched as her husband Bill paid for the burgers, chips, and fruit juices. She was feeling exhausted. They'd been in the mall all morning, and she was so hungry she could eat a horse! As Bill approached the table, she stood up ready to help him unload the tray. She took a quick glance out of the window and stopped dead. There, just outside, was a familiar face she hadn't seen for years—it was Mr Firkettle, her old math teacher. She'd been secretly in love with him all through high school. Old emotions came flooding back, and Judy felt the color fading from her vision. Her hands felt sweaty, her knees went weak, the world began to spin, and then everything turned black and she crashed to the floor.

If this were romantic fiction, we might get to learn more about Judy's youthful passion for Mr Firkettle. But Judy is a patient in a clinical trial, and our story is about how the fainting attack in the burger restaurant is transformed into clinical trial safety data and then analyzed to help decide which side effects a new drug may have.

Judy is 51 years old, and 6 months ago she was diagnosed with type 2 diabetes. Her physician, Dr Chu, recently suggested she take part in a clinical trial testing the new antidiabetic Wonderdrug (WD), which promises not only to control blood glucose better than existing treatments, but also to reduce cardiovascular risk. This could be particularly beneficial for Judy, who has high blood pressure and a somewhat expanded waistline. She had been feeling tired a lot of the time and was easily fatigued when she had to climb a staircase or walk for a bit. Dr Chu explained that the trial is a double-blind trial comparing WD with metformin, an old antidiabetic medication that is still often used. After signing all the relevant paperwork, Judy started taking the trial medication. At first she didn't notice anything much out of the ordinary.

Then, 3½ weeks after starting the medication, she fainted in the burger restaurant. Bill, who had recently completed a first-aid refresher course, quickly rolled Judy over onto her back and put her feet up on a chair, while the restaurant staff called 911. When the ambulance arrived, Judy was awake again and was able to drink a few sips of juice, but she still felt dizzy. Her husband told the paramedics about the diabetes. Somehow Judy had injured her ankle as she fell and couldn't stand up. Without much ado, the paramedics took her to the hospital, where they measured her blood glucose level and found it to be very low. They decided to give her a glucagon injection, and she started feeling better again. Her ankle was x-rayed; luckily, it was not broken but only sprained. Nevertheless, by the time of the x-ray it had become very swollen and increasingly painful. The physicians decided to keep Judy in the hospital for a night for further observation. They treated her ankle with ice packs and gave her painkillers.

Recording Adverse Events in the Case Report Form

After the initiation of Judy's treatment, the hospital physicians called Dr Chu and provided her with an outline of what had happened. Based on this, Dr Chu reported the events to the sponsor immediately (see sidebar on the next page). A week after the fainting episode, Judy went for her scheduled study appointment with Dr Chu. First a study nurse took a blood sample to measure Judy's blood glucose and HbA1c levels and other laboratory parameters, weighed her, measured her waist circumference, blood pressure, and pulse, and asked whether she had been taking the trial medication as instructed. Dr Chu then asked for all the details of the fainting incident. She asked about the circumstances that day and the reasons why she'd fainted, so Judy told her about how hungry and tired she'd been after the morning

in the shops, how she'd sat down to rest but had stood up suddenly when Bill brought the food to the table. (She didn't say anything about Mr Firkettle!) She told her what the emergency doctors had said about her blood glucose being very low and how she'd returned to feeling normal after the glucagon injection. As Judy talked, Dr Chu made notes on the computer. Dr Chu asked about the sprained ankle, and Judy explained that she'd been in a lot of pain and that her ankle had been very swollen. She'd been taking ibuprofen 3 times a day and using ice packs on her ankle. By now the pain had subsided, even if she was still walking with a slight limp.

Dr Chu also asked her how she had been in general since their last appointment, and Judy told her about the ongoing tiredness. While they were talking, Dr Chu noticed a rash on Judy's lower left arm and asked to have a closer look at it. Judy had forgotten to mention it, but the rash had been there for about 10 days.

Dr Chu recorded everything she observed about Judy's health during their conversation in the electronic case report form (eCRF). The eCRF is a big questionnaire with special pages for recording any medical event that happens to a trial participant. The investigator, ie, Dr Chu, enters all data for each of her patients in the eCRF. The data in the eCRF are the source of all the analyses of the trial. When Dr Chu signed up as an investigator, she was trained on how to fill in the eCRF appropriately. Importantly, she received detailed instructions on entering information on adverse events. She was told to enter "any untoward medical occurrence in a patient" (ICH E6 Good Clinical Practice) regardless of whether she thought it was causally related to any of the study drugs or procedures. It is very important that Dr Chu follows the instructions on adverse event reporting closely, as there are strict legal requirements (see sidebar).

Dr Chu was also told only to enter medical events that started or worsened after the patient had been entered into the trial. Judy's tiredness, which began before she had entered the trial, was therefore not recorded as an adverse event but rather as a baseline condition or medical history.

Adverse events are collected from the moment the patient signs the informed consent form to participate in the trial until the end of the study. However, there is usually a period of time before study medication is started. During this time—called the screening period—the study doctors check whether the patient meets the entry criteria for the trial. Adverse events that occur after the patient has started taking the study drug (so-called treatment-emergent adverse events) are of particular interest because such events could potentially be related to the study treatments (Figure 1).

SAEs AND SUSARs

To protect study participants, it is important that safety data are collected and rapidly processed on an ongoing basis. For this reason, the investigator is required by law to report certain kinds of adverse event to the sponsor of the study without delay ("expedited reporting"). This means that certain events need to be reported to the sponsor within 24 hours of the investigator becoming aware of them. This always applies to events that are "serious," a word that has a special technical meaning in the context of clinical research. Serious adverse events (SAEs) are those events that are fatal, life-threatening, require a patient to be hospitalized or prolong his/her hospitalization, result in persistent disability, or are a birth defect. Not all SAEs indicate a potential problem with the drug being investigated: Judy's overnight hospital stay because of her sprained ankle is an example of an event that is categorized as serious (because of the hospital stay) but is unlikely to be associated with the study drug and may not be a cause of concern with regard to the safety of other patients in the trial.

When an adverse event occurs that is "unexpected" and is a suspected "adverse reaction," as well as serious, the sponsor must report the event, known as a SUSAR (serious unexpected suspected adverse reaction) to the regulatory authorities (eg, the FDA) within 15 days, or within 7 days if the event is life-threatening or fatal. Like "serious," the terms "unexpected" and "adverse reaction" have special meanings in this context. "Unexpected" means the event is not an already known side effect of the drug. Established or known side effects of a drug are listed either in the Investigator's Brochure, a document designed to provide investigators with a summary of everything that is currently known about the drug, or in the approved label. An "adverse reaction" or "adverse drug reaction" is one that is caused by the study drug. While a drug is still being investigated, it is unlikely we will know for sure whether a particular adverse event that happens to a patient is an adverse reaction or not; hence the use of the term "suspected" in defining SUSARs.

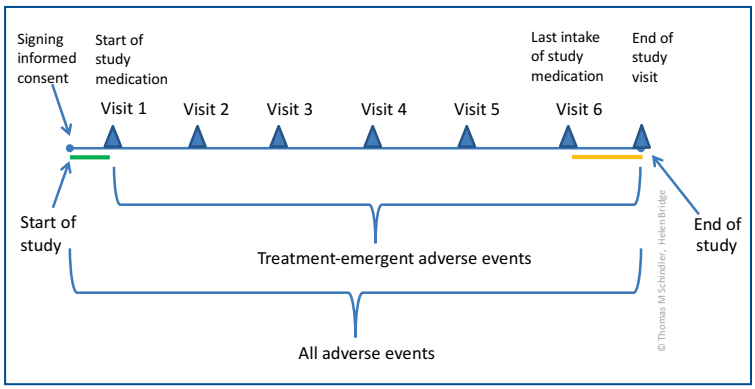


Figure 1. Depiction of the reporting periods for adverse events. Start of the study is the signing of the Informed Consent Form. The orange bar represents the "residual effect time," ie, the time after last drug intake that still counts as part of the treatment period because it takes some time before the drug is completely eliminated from the body. The green bar represents the screening period.

How Does Judy's Report Get Into the Safety Analysis of the Study?

As mentioned above, Dr Chu noted her medical observations based on everything Judy told her and everything she observed about Judy. In the adverse event form of the eCRF, she had to indicate whether each event was "serious" (see sidebar). Based on her clinical expertise, Dr Chu would also assess the "severity," or "intensity," of each event, and must categorize each event as being of mild, moderate, or severe intensity. She would have been given definitions of these categories. For example, a "mild" event is likely to be defined as one wherein the patient has signs or symptoms, can easily tolerate the symptoms, is able to go about her normal activities, and requires no therapy. An event of "moderate" intensity involves a low level of inconvenience and may interfere with daily activities, but may improve with simple therapeutic measures. Finally, a "severe" event is one that incapacitates the patient and prevents her from going about her normal activities. (It should be noted that, instead of these 3 categories, oncology studies use the 5-grade Common Terminology Criteria for Adverse Events [CTCAE] severity scale, in which each grade has an objective definition; grades 1 to 3 correspond to "mild," "moderate," and "severe;" grade 4 indicates a life-threatening event; and grade 5 indicates a fatal event.) Finally, Dr Chu also had to decide whether she believed that the event could have been caused by the study drug.

For some kinds of adverse event, Dr Chu will be asked to enter more detail in the eCRF. When a clinical study is planned and designed, the sponsor may define certain "adverse events of special interest," often abbreviated as AESIs. These events are known to be important in a particular clinical study population, either because they are known risks of one of the drugs used in the study or because they tend to occur in patients who have the medical condition being studied, or because they are particularly relevant to the study objectives.

In Judy's diabetes study, hypoglycemia was an AESI, and the clinical study protocol specified that additional information was to be collected on hypoglycemic events. For Judy's hypoglycemic fainting episode, Dr Chu is therefore directed to a special page in the eCRF dedicated to hypoglycemia. Here she is asked to enter details such as whether Judy experienced other symptoms accompanying the hypoglycemia and if so which ones, whether she required assistance, and her blood glucose level at the time of the event. In Judy's case, Dr Chu would consult the report she received from the hospital to fill in the details.

All the information that is entered in the eCRF is linked with the date of entry and the person entering it. Information already entered can be updated at a later point in time, eg, with data from a laboratory report. However, any information entered later is then linked to a new date. This ensures that there is a trail that connects all entries ever made in an eCRF. Such a trail allows an independent observer to clearly see which information is entered when and by whom. This "audit trail" supports the integrity of the study data.

The information Dr Chu entered in the adverse events section of the eCRF for Judy during their appointment is depicted in Table 1.

Dr Chu listened carefully to what Judy told her and, based on what she heard and using her medical experience, she entered her assessments in the eCRF. The terms she entered are called "verbatim terms" or "investigator-reported terms." As large clinical trials are conducted at hundreds of investigational sites, data about adverse events will be entered by a correspondingly large number of investigators. The verbatim terms that 2 different investigators might use to describe the same event may often differ, even before we take into account that a trial may have investigators in different countries, working in different languages, and that investigators sometimes have their own unique ways of spelling medical terms. The

Table 1. Judy's Adverse Events, as Entered by Dr Chu in the Electronic Case Report Form

Adverse Event (verbatim term)	Start Date	End Date	Intensity	Drug-related	Therapy	Action with Trial Medication	Serious	Outcome
Rash on left lower arm	19.04.17		Mild	Possibly	None	None	No	Ongoing
Fainting due to hypoglycemia and standing up quickly	22.04.17	22.04.17	Moderate	Unlikely	Glucagon injection; fruit juice (sugar source)	None	No	Resolved
Sprained ankle	22.04.17		Moderate	No	Ibuprofen 400 mg 3x daily; ice packs	None	Yes	Ongoing

data that Dr Chu entered from Judy are not entered under her name but under a patient number that is linked to the trial medication that Judy received. Neither Dr Chu nor Judy knew whether she was taking WD or metformin.

To summarize and analyze the adverse events in a clinical trial, it is necessary to standardize the reporting of these events. The aim is that all events that represent a particular medical phenomenon, ie, a diagnosis or signs and symptoms, are entered and analyzed in the same way. The standardization is done at the sponsor company by specialized personnel trained in handling medical data. In short, data managers use an internationally agreed-upon database of medical terms, the Medical Dictionary for Regulatory Activities (MedDRA), and align each verbatim term they find in the eCRF with an entry in this very large and complex dictionary. This alignment is called *coding*. The initial step is to align the verbatim term with a Lowest Level Term (LLT) in the MedDRA dictionary (Figure 2). One LLT may be used to represent several verbatim terms. For example, the verbatim terms "rash left arm" as well as "small rash on left lower arm" and "rash-like skin change lower left arm" would all be coded to the LLT "rash over arms." This process ensures a transparent aggregation of events into recognizable medical entities. The beauty of the MedDRA system is that all LLTs are linked (mapped) to Preferred Terms (PTs), which represent the next level of aggregation. The PTs are commonly used in the analyses of adverse event data and their reporting, eg, in statements such as "0.4% of patients in the WD group and 0.6% of patients in the metformin group had rash."

The PTs are then mapped onto higher-level terms and ultimately into so-called System Organ Classes (SOCs), which represent wider medical concepts. With each level, more data are subsumed under one term. This summarization and aggregation ensures that no potential signal is lost in the amount of data. If we were to remain on the level of reported terms, eg, "rash on the left lower arm," we could compare treatment groups only on this level and would have to have another category for "rash on the lower right arm." Concentrating on the detail, we would fail to see the broader medical issue.

Aggregation allows us to see the bigger picture and to identify patterns. In other words, it allows us to see the forest (the overall picture) for the trees (the individual events). By coding events to a MedDRA term, the analysis of adverse events becomes more independent of national or cultural aspects. Only after coding can comparisons across different regions be made.

Table 2 shows how some of Judy's adverse events were coded using MedDRA LLTs, and the PTs and SOCs to which these LLTs belong.

Table 2. Coding of Judy's Adverse Events Using MedDRA

	MedDRA Terms After Coding		
Verbatim Term	**Lowest Level Term**	**Preferred Term**	**System Organ Class**
Rash on left lower arm	Rash over arms	Rash	Skin and subcutaneous tissue disorders
Fainted due to hypoglycemia and standing up quickly	Hypoglycaemia[a]	Hypoglycaemia	Metabolism and nutrition disorders
Sprained ankle	Ligament sprain	Joint injury	Injury, poisoning and procedural complications

[a]For obscure historical reasons, the MedDRA dictionary uses British spelling.

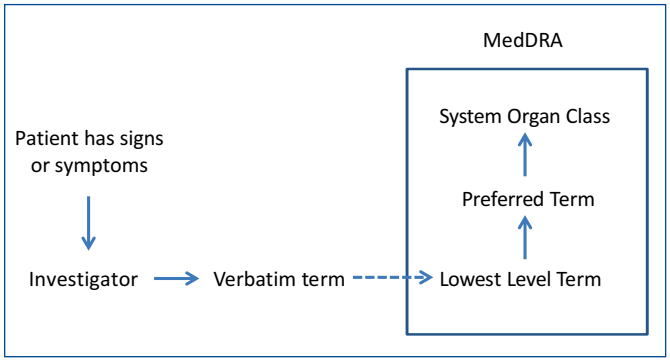


Figure 2. Flow of adverse event information from the patient to the coding in MedDRA (Medical Dictionary for Regulatory Activities). This is a simplified depiction of the MedDRA hierarchy, which has 2 additional levels between the Preferred Term and the System Organ Class; these are called High Level Term and High Level Group Term.

Summarizing and Interpreting Adverse Event Data in a Clinical Study Report: The First Steps

About 9 months after Judy's fainting attack, PDF files containing some 7500 pages of data tables and patient listings land in Jeremy's email inbox. Jeremy is the medical writer responsible for writing the clinical study report (CSR) of the trial in which Judy participated. Much of the data he receives will relate to the demographic and baseline characteristics of the trial patients, the efficacy outcomes of the trial, and safety parameters other than adverse events, such as clinical laboratory assessments. For the purposes of this article, however, we are interested in the adverse event data he receives.

Jeremy's colleagues from statistics and statistical programming have supplied him with long tables in small print that detail the number of patients and the frequency in the

WD group and in the metformin group of each kind of event reported in the trial (by MedDRA PT and SOC). "Frequency" simply means the percentage of patients who had this event out of all the patients in the treatment group.

Being an experienced medical writer, Jeremy understands that the tables provide the number of patients who had a particular adverse event and not the number of adverse events. He also knows that this is often misunderstood: Each patient is only counted once for each event (at each MedDRA level). If a patient has an adverse event once, this is counted once in the table; if a patient has the same adverse event multiple times, this is also only entered once. If the same patient has several different adverse events, he or she is counted for each adverse event (PT) separately. (If the various PTs are all mapped to the same SOC, then the patient will be counted only once for the SOC.)

Jeremy's first task is to correctly describe the adverse events that occurred in both treatment groups of the trial and to identify any differences between the treatment groups. He therefore looks first at the adverse event summary tables. Judy is included in the numbers and percentages of patients in the WD group (the data have now been unblinded) reporting events with the PTs "rash," "hypoglycaemia," and "joint injury" (and their associated SOCs). Jeremy seeks to provide a concise description that focuses on the most frequent adverse events. To accomplish this, he decides to make an in-text table. (In a CSR, all of the data tables produced by the statisticians are included in a section after the text part, but because these tables are usually very lengthy and detailed, the medical writer creates "in-text tables" that are placed in the text part of the CSR. These present a selection of the most important data.)

After scrutinizing the adverse event data, Jeremy chooses to focus on adverse events that occurred in at least 5% of patients in either treatment group. He selects a cutoff of 5% for both pragmatic and medical/scientific reasons. It is helpful to the reader if the in-text table of the most common adverse events fits on a single page. However, the choice of a cutoff also needs to take into account whether the truly important medical events will be included in the table. The events that Judy reported to Dr Chu appear in the source table that Jeremy uses for his in-text table. Of course, her data are combined with the data from other patients. The source table may look similar to Table 3 (an actual table will contain many other SOCs and PTs as well). Of the events in this table, only hypoglycaemia will appear in the in-text table.

Table 3. Summary Data for the Whole Trial Population for the Kinds of Adverse Events Judy Experienced (all AE table)

MedDRA SOC PT	Wonderdrug n = 652	Metformin n = 326
Metabolism and nutrition disorders	156 (23.9%)	63 (19.3%)
Hypoglycaemia	122 (18.7%)	46 (14.1%)
Skin and subcutaneous tissue disorders	9 (1.3%)	6 (1.8%)
Rash	3 (0.4%)	2 (0.6%)
Injury, poisoning, and procedural complications	7 (1.1%)	5 (1.5%)
Joint injury	2 (0.3%)	0

What can Jeremy conclude from these data? Part 2 of this article will explain how Jeremy will analyze these data in the CSR to draw conclusions about the safety profile of WD. It will also consider why classical statistics is of little help in answering the question of which adverse effects a drug causes.

Author contact: *Thomas.Schindler@boehringer-ingelheim.com; Helen.Bridge@astrazeneca.com*

RESOURCES

Food and Drug Administration, Expedited Safety Reporting Requirements for Human Drug and Biological Products, 21 CFR Parts 20, 310, 312, 314, and 600. October 7, 1997 (Volume 62, Number 194). https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm120262.htm

ICH E2A Harmonised Tripartite Guideline, Clinical Safety Data Management: Definitions and Standards for Expedited Reporting. October 27, 1994. https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2A/Step4/E2A_Guideline.pdf

ICH E6 (R2), Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice, Current Step 4 version. November 9, 2016. http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf

Medical Dictionary for Regulatory Activities. https://www.meddra.org/

National Cancer Institute, National Institutes of Health, US Department of Health and Human Services, Common Terminology Criteria for Adverse Events (CTCAE), Version 5.0. November 27, 2017. https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf

Industry Insight

By Kristina Wasson-Blader, PhD, ELS / Editor-at-Large, Clearly Communicating Science, LLC

Accessing Clinical Trial Data

Starting January 2, 2018, Shire (Shire.com), a biopharma company that focuses on treatments for rare diseases, began a new open access policy.[1] Research supported by Shire will need to be available free to the public promptly after publication. This unrestricted access will be for preclinical, clinical, and postmarketing data. However, open access policies at medical journals appear to still restrict dissemination of pharmaceutical company-supported medical research. According to a recent cross-sectional study of 37 peer-reviewed journals with an impact factor of 15 or greater, only one of these journals offered Creative Commons Attribution license to commercial funders.[2]

References

1. Shire Continues to Uphold High Standards of Ethics and Transparency with Adoption of Open Access Policy for Publication of Shire-Supported Research. https://www.shire.com/en/newsroom/2018/january/xajhds Accessed March 29, 2018.
2. Ellison T, Koder T, Schmidt L, Williams A, Winchester C. Open access policies of high impact medical journals: A cross-sectional study [preprint, posted January 22, 2018]. *bioRxiv*. https://www.biorxiv.org/content/early/2018/01/22/250613

* * *

Predatory Publishing Revisited

On March 16, 2018, *Nature* published a brief news article[1] reporting that a European academic has retrieved Beall's list of predatory journals from internet archives and is providing access to the list as it was last represented. It appears that the list is also being updated on the weekends by the same academic, who wishes to remain anonymous. You can visit the website (https://beallslist.weebly.com/) and use at your own risk.

A cross-industry initiative has been established to help authors choose appropriate journals for publishing study results. It provides guidance to authors on how to identify credible journals and submit their research. The Think Check Submit campaign (think.check.submit.org) is supported by various organizations, some of which are the Committee on Publication Ethics (COPE), BioMed Central, and Springer *Nature*.

Reference

1. Singh Chawla D. The undercover academic keeping tabs on 'predatory' publishing. *Nature*. March 16, 2018. https://www.nature.com/articles/d41586-018-02921-2

* * *

On the Possibility of Changing the *P* Value

For most clinical studies, a *P* value of .05 or less is often set to report significance; however, whether *statistical* significance has *clinical* significance is the subject of continued debate. A recent viewpoint by Dr John Ioannidis in *JAMA* suggests that a *P* value of .005 should be used for new discoveries.[1] By lowering the *P* value, Ioannidis postulates that the research agenda may reform through designing "fewer, larger and more carefully conceived and designed studies" that have sufficient power to identify "true effects." Yet, he does indicate that lowering the *P* value may escalate bias in attempts to make the results have a lower *P* value.

References

1. Ioannidis JPA. The proposal to lower P value thresholds to .005. [published online March 22, 2018]. *JAMA*. doi:10.1001/jama.2018.1536.

SOCIAL MEDIA

Find Your Social Media Comfort Zone

By Eleanor Mayfield, ELS,[1] with *commentary* by Cynthia L. Kryder, MS[2]

[1]Freelance Medical Communicator, Pittsburgh, PA; [2]Social Media Section Editor and Freelance Medical Communicator, Phoenixville, PA

As Greek philosopher Heraclitus observed, "The only thing that is constant is change." This is particularly true for the technologic aspects of medical communication, where innovations have taken us from mainframes to desktops to laptops to tablets. When I started my career, I had to drive to the medical library with enough quarters in my pocket to copy the research articles I needed. Enter the internet and the emergence of Lonesome Doc, Grateful Med, and Medline…we had to learn new technology and practices, but work became so much easier!

Social media is yet another advancement to enter medical communicators' work environment to which we must adapt. And while some people considered social media to be a flash in the pan, we've seen how quickly it has become a business necessity to maintain relevancy and remain competitive.

Some people and organizations have embraced social media more than others, with varying levels of sophistication. In his report for Digital Tourism Think Tank, William Bakker, Chief Strategist from Think! Social Media, identifies 5 levels of social media sophistication as they relate to destination marketing organizations.[1] With minor adaptations, I have delineated 4 levels that apply to medical communicators (Figure 1).

Our level of social media sophistication directly relates to our comfort with social media. Each of us has a social media comfort zone—that behavioral space where activities and behaviors feel familiar, thus minimizing levels of stress and anxiety. Below, Eleanor Mayfield, AMWA's 2017 President's Award Winner, describes her approach to dealing with the new technology and practices involved in social media.

Eleanor Mayfield

Full disclosure: I came of age in the pre-internet era. As a college student, I typed my assignments on a manual typewriter. My first computer had 64 kilobytes of memory (no, that's not a misprint). I began my freelance medical writing business in the "Dark Ages" before email—let alone social media—existed.

In other words, I am a "digital immigrant"—someone who grew up before the advent of digital technology. The rap on digital immigrants is that we are forever destined to lack the comfort level with technology of "digital natives"—people born or brought up in the digital age, who have no memory of life before the existence of computers, smart phones, or the internet.

I plead guilty. Even though I now find it difficult to imagine how I ever found my way anywhere before I had navigation on my phone to direct me, I'm aware

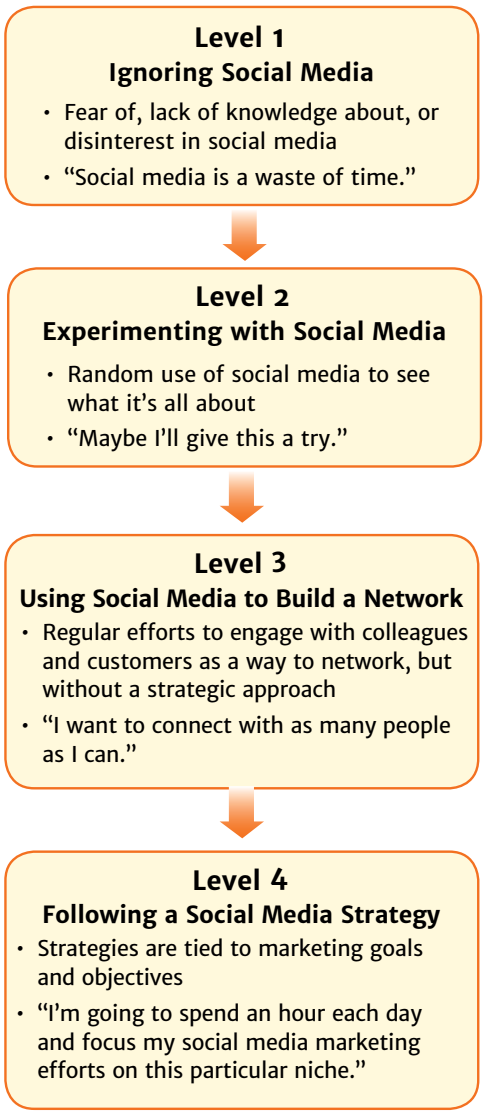


Figure 1. Four levels of social media engagement[1]

that my attitude toward digital technology will likely always be shaped to some extent by the fact that my formative years occurred before such technology existed.

So when Cyndy Kryder, who edits this section of the *AMWA Journal*, invited me to submit a piece about how social media has changed how I operate my business, I initially demurred. Although I have a business-related social media presence, I am far from being a social media maven. I did not think I was the right person to write about this topic because I had difficulty at first thinking of ways that social media has significantly changed my business.

When I considered the topic more deeply, however, I realized that social media has indeed affected my business in subtle but important ways. I will focus my comments on LinkedIn, because it is the dominant social media site for professionals as well as the site that I make the most regular and consistent use of for business purposes.

LinkedIn has made it much easier for me to maintain connections with people despite job changes and other professional moves. Before, if a business contact moved to another job, it was easy to lose track of that person. Now, when they update their LinkedIn profile, as a connection I'm notified of the move and prompted to send a note of congratulations—a perfect opportunity to get in touch and offer them all the best in their new position. LinkedIn notifications of job anniversaries offer a similar opportunity.

Reconnecting with my LinkedIn contacts is a strategy I've used in recent years whenever I've needed to drum up new business. This has been quite successful for me; a few years ago, reconnecting with someone I had worked with several years earlier led to that person recommending me to replace her in a contract position she was about to leave. I landed the job, and it became a major source of income for me over the next couple of years.

Last year, when that client made a business decision to terminate the project I'd been working on, I reached out to my LinkedIn network again. This led to my reconnecting with another former client, for whom I'm now working on a couple of ongoing projects.

Earlier this year I reached out to another LinkedIn contact after receiving a notification that she had left a job she had been doing for several years to return to freelancing. It turns out she's planning to write a book on a topic with which I had gained experience in the contract position that terminated last year. We've agreed

continued on page 82

DIGITAL IMMIGRANTS ⟷ **DIGITAL NATIVES**

Bridging the Communication Gap

TIPS FOR DIGITAL IMMIGRANTS

Do	Don't
Be open to approaching an issue or topic in a non-linear fashion—e.g., instead of proceeding one step at a time from beginning to end, start at a random point and work both forward and backward from that point.	Assume that the way you have always approached learning and communicating is the "best" or "only" way.
Be willing to admit what you don't know about digital technology and commit to improving your "digital literacy."	Assume that all members of the digital-native generation have had the same level of exposure to technology while growing up. Young people from families of limited means may not have had computers and video games at home or their own cell phone.

TIPS FOR DIGITAL NATIVES

Do	Don't
Appreciate the life experience that digital immigrants have accumulated. They were your age once and had many of the same experiences that you and your friends are dealing with, albeit without the same technology. Be willing to seek advice or guidance.	Dismiss digital immigrants as "old fogeys" whose thinking is outdated.
Be patient with digital immigrants when sharing technological know-how. Support and encourage their use of technology.	Expect digital immigrants to have the same comfort level with certain types of technology (e.g., digital payment apps) that you and your friends do.

TIPS FOR BOTH DIGITAL NATIVES AND DIGITAL IMMIGRANTS

- Consider the communication preference of the person you want to communicate with and defer to their likely preference. Once the connection is made, ask how the person would prefer to communicate going forward and then defer to that method.

Digital immigrant ➪ Digital native	Text, instant message
Digital native ➪ Digital immigrant	Email, phone, face-to-face meeting

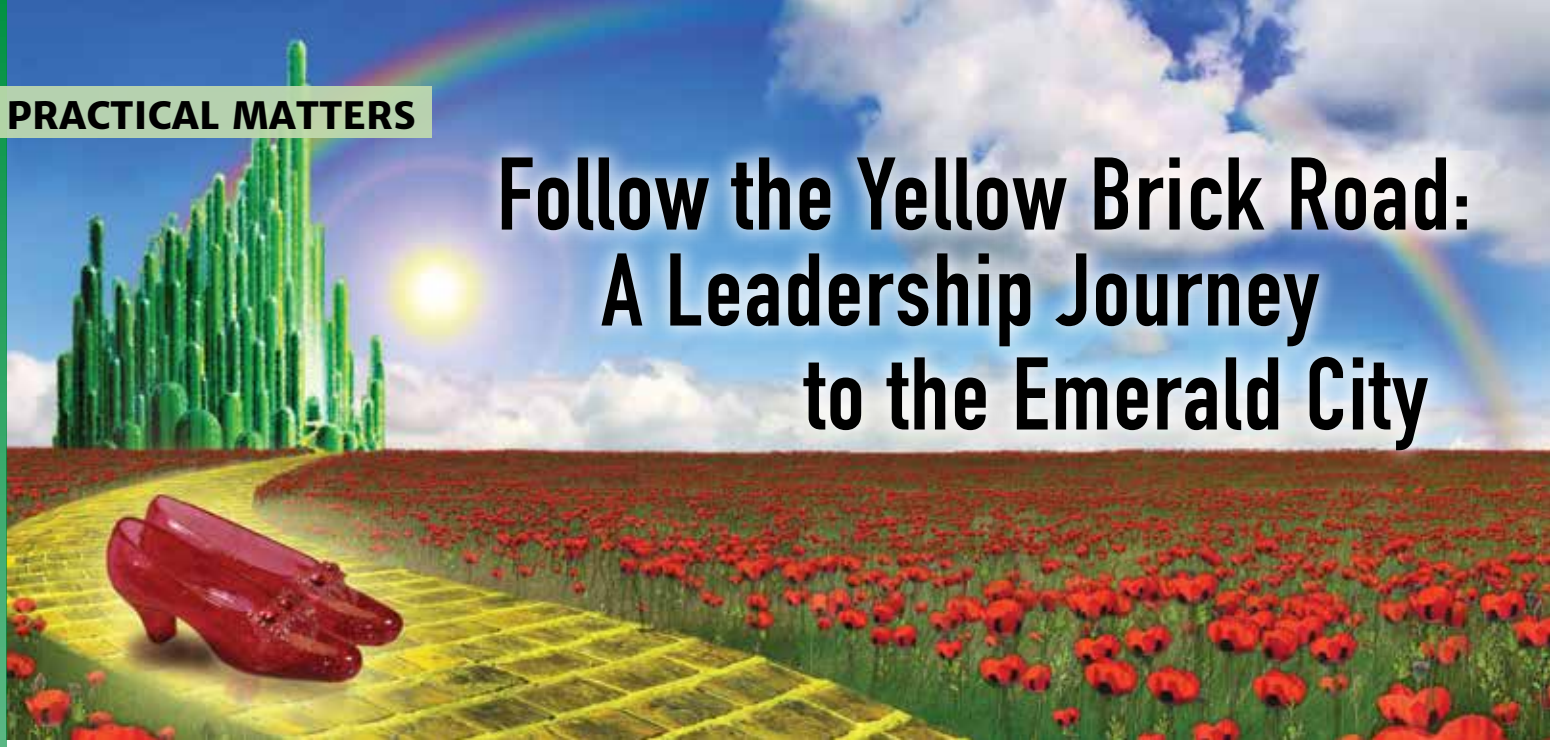
- Learn from each other.

Digital natives can teach digital immigrants about	New technology
Digital immigrants can teach digital natives about	Career development, professionalism

Sources: Gimbel T. How to Help Millennials and Baby Boomers Get Along. *Fortune*. April 1, 2017. http://fortune.com/2017/04/01/leadership-career-advice-millennials-conflict-feud-mentorship/

Jenkins R. How to Bridge the Millennial/Baby Boomer Communication Gap. Inc. March 8, 2016. https://www.inc.com/ryan-jenkins/1-tip-to-eliminate-miscommunications-across-generations.html

Venzer E. Bridging the communication gap between Generation Y and the Baby Boomer generation. *Int J Adol Youth*. 2017;22(4):497-507. DOI: 10.1080/02673843.2016.1267022



Follow the Yellow Brick Road: A Leadership Journey to the Emerald City

By Ben Woelk, CISSP, CPTC / ISO Program Manager, Rochester Institute of Technology, Rochester, NY
Vice President, Society for Technical Communication

Have you ever felt as if your professional journey has a surprise around every bend? Much like Dorothy in The Wizard of Oz*, have you found unexpected challenges along your career path? Are there lessons that can be applied from these challenges? Follow the Yellow Brick Road and discover lessons about leadership from* The Wizard of Oz *characters we've grown to love.*

I've had a lifelong fascination with MGM's *The Wizard of Oz*,[2] being both afraid of and intrigued by the flying monkeys and amused by Scarecrow, Tin Woodman, and Lion, but I've felt mostly engaged by a storyline that drew me along on their journey. For the last several years, I have studied leadership development, participated in leadership podcasts and webcasts, delivered presentations and workshops on leadership development, mentored emerging leaders, and championed the leadership abilities of introverts. I thought it would be interesting to see what lessons we might draw for leadership by applying Keirsey Temperament Theory to the 4 protagonists of *The Wizard of Oz*: Dorothy, Scarecrow, Tin Woodman, and Lion. Even a cursory look at how they handled obstacles and interacted with each other might provide valuable lessons for the workplace and personal life.

Kerisey Temperament Theory and *The Wizard of Oz*

In *Please Understand Me II*,[3] David Keirsey discusses how 4 main temperament types—Guardian, Rational, Idealist, and Artisan—may apply to these characters from *The Wizard of Oz* as well as to our own leadership styles.

Dorothy, the Guardian Leader

Keirsey describes Guardians as the "glue" that holds society together. Guardians are concerned with order, with right actions, and with providing a secure environment for those under their charge. They are also helpful and concerned with the welfare of others. Guardians are stabilizing leaders. In both the book *The Wonderful Wizard of Oz*[1] and the movie, Dorothy is the glue that holds the travelers together. Although she provides both stability and security to the party, Dorothy seeks a way to return to a safe environment: her home in Kansas with Auntie Em and Uncle Henry. Throughout their journey, Dorothy leads the party to the Wizard, convinced that he will help her to find her way home.

Scarecrow, the Rational Leader

Rational leaders are innovative, and they are typically highly intelligent, in addition to being problem solvers. The Scarecrow believed that he had no brain. To the contrary, the Scarecrow was clearly the most creative in being able to analyze a situation and pose innovative solutions. For example, he devised the plan to get apples from a hostile apple tree by tricking the tree into throwing apples at the traveling party and coordinated the plan to rescue Dorothy by stealing and wearing the Winkie guards' uniforms after Dorothy's capture by the Wicked Witch.

Tin Woodman, the Idealist Leader

According to Keirsey, Idealist leaders are catalysts because they energize productive human relations. Idealist leaders are enthusiastic, strive for harmony, and care deeply for those in their charge. They are people-centered, intuitive, and patient, often putting the needs of individuals above the needs of the business or task at hand. The Tin Woodman believes that he has no heart or feelings and is unable to express love. Despite this, as an Idealist, he cares deeply for the well-being of the party. He races into action when the travelers face

the Kalidahs (ie, beasts with bodies like bears and heads like tigers), the most feared predators in the Land of Oz.

Lion, the Artisan Leader

Keirsey describes Artisan leaders as practical, with an eye for the realities around them. Artisan leaders deal with concrete problems (clear and obvious problems), not abstractions about what *might* occur. Artisans will do whatever it takes to solve a problem, are expeditious, and move rapidly to arrive at a solution. They excel at on-the-spot decision-making but are impulsive and prefer to "fly by the seat of their pants." Most of all, they are risk takers. Although lions are commonly considered to be the kings of the beasts, Lion believes that he lacks courage. However, Lion displayed bravery by protecting the team along the way to see the Wizard. For an Artisan leader, courage means doing what needs to be done against all odds, even in the face of fear.

Applying the Lessons of Oz in the Real World

In Oz, 3 of our protagonists gain physical tokens from the Wizard that are related to their temperament types. Scarecrow (the Rational leader) receives a diploma (testimonial). Lion (the Artisan) receives a medal of courage. Tin Woodman (the Idealist) receives a heart. These physical tokens helped these 3 characters understand their internal strengths and make it outwardly obvious what these character strengths are for each of them. Although we may not have physical tokens that help remind us and others of our inner strengths, we are much more attuned to the role of these strengths in our workplaces. The Wizard tells Dorothy that ever since she came to Oz, she's always had what she needs to return home, the slippers.

Since the 1995 publication of Daniel Goleman's *Emotional Intelligence*, there has been increasing recognition of the role of social and emotional intelligence in building productive workplace environments.[10] The development of our emotional intelligence grows from understanding what drives us and how we interact with others. That's where temperament theory comes in. Understanding our temperament type helps us perform more effectively, both as individuals and as a team. Learning about our strengths (and weaknesses) can help us become better leaders and relate better to our colleagues in the workplace. Keirsey's temperament types provide additional insights.

In my own leadership journey, I've found that learning more about temperament types through inventories available online (humanmetrics.com, 16personalities.com, keirsey.com), and discussions with trained Myers-Briggs Type Indicator (MBTI) practitioners has helped me identify what drives me. Understanding the strengths and weaknesses of my Rational temperament type (INTJ), helps me understand how I can best lead, playing to my strengths and compensating for my weaknesses.

That understanding has also helped me understand how to best work with a manager who does not have the same temperament that I have. For example, an Artisan manager will be concerned with results. The Artisan manager may not care about the details of the journey to achieve those results. An Idealist team leader who wants to talk about the contributions of the individual members of the team may find the conversation with an Artisan manager frustrating because what's important to the team leader (the people) may not matter to the Artisan manager—the Artisan manager cares about the results. Different temperament types have different expectations and priorities. I have a good friend who's an Idealist leader. She's very conscious of the potential impacts of a decision on team members. As a Rational leader, in my pragmatic approach to problem solving, the impact of a decision on individuals may not even occur to me.

The Wizard of Oz is as much about the travelers discovering their hidden strengths as it is an exciting story for children and for adults. Each of the travelers follows the Yellow Brick Road to self-discovery, finding that they possess the strengths they believe they lack. Much like Scarecrow, I've discovered that I already possess many of the strengths I thought I lacked. I encourage you to follow your own Yellow Brick Road to identify and harness your strengths.

Author disclosure: *This article is based in part on my presentation at the Society for Technical Communication International Summit Conference in 2017.*

Author contact: *ben@benwoelk.com*

References

1. Baum LF. *The Wonderful Wizard of Oz*. Chicago, IL: George M. Hill Co; 1900.
2. Fleming V, director. *The Wizard of Oz* [videotape]. Hollywood, CA: Loew's Inc; 1939.
3. Keirsey D. *Please Understand Me II*. Delmar, CA: Prometheus Nemesis Book Co; 1998.
4. Myers IB. *Gifts Differing*. Palo Alto, CA: Consulting Psychologists Press; 1980.
5. Stutz J. The Scarecrow's brains: leadership lessons from the Wizard of Oz. *CEOWORLD Magazine*. http://ceoworld.biz/2014/06/15/the-scarecrows-brains-leadership-lessons-from-the-wizard-of-oz-198165/. Published June 15, 2014. Accessed April 29, 2017.
6. Woelk B. An introvert's journey to leadership. Paper presented at: STC Summit Conference; May 15-18, 2016; Anaheim, CA.
7. Woelk B, guest ed. Personality, temperament, and technical communication. *Intercom*. 2017;64(2, theme issue).
8. Woelk B. Lessons learned on an introvert's journey to leadership. EDUCAUSEreview. https://er.educause.edu/blogs/2016/10/lessons-learned-on-an-introverts-journey-to-leadership. Published October 17, 2016. Accessed April 18, 2018.
9. Spectrain.Co.Uk Blog. Leadership lessons from the Wizard of Oz. https://spectrain.wordpress.com/2010/04/08/leadership-lessons-from-the-wizard-of-oz/. Published April 8, 2010. Accessed April 17, 2017.
10. Goleman D. Emotional intelligence. http://www.danielgoleman.info/topics/emotional-intelligence/. Accessed April 22, 2018.

The Big Bad Wolf Wore a Tasteful Little Black Cocktail Dress

By Laurie Endicott Thomas, MA, ELS

Nouns are words that represent a person, place, thing, or idea. Adjectives are words that modify nouns. Adjectives can be used to answer the following questions about the nouns they modify: *Which ones? How many? What kind?* Together, a noun and any adjectives that are modifying it make up a noun phrase. If you want to use more than one adjective to modify a particular noun, you must figure out the proper order in which those adjectives should appear. You must also figure out whether and how to punctuate the list of adjectives. The Royal Order of Adjectives is the key to figuring those things out.

Royal Order of Adjectives

Why does it make perfect sense to say "a tasteful little black cocktail dress" but it would make no sense to say "a cocktail tasteful black little dress"? The reason is that English speakers tend to put their adjectives in a predictable order, which is called the Royal Order of Adjectives (Table 1). The Royal Order of Adjectives is a feature of the English language. Native English speakers tend to follow it without realizing that they are doing so. Other languages have different rules for placement and ordering of adjectives. Thus, people who are learning English as a second language may need to be taught about the Royal Order of Adjectives.

Which Ones?

If you are using a determiner, it goes first in the Royal Order of Adjectives. Determiners are adjectives that help to indicate which items you are talking about. There are several different kinds of determiners:

- Definite determiners (which imply that the resulting noun phrase refers to something that is being specifically defined)
  - The definite article: *the*
  - Demonstratives: *this* and *that*, and their plural forms *these* and *those*
  - Possessives
    - Possessive pronouns: *my, our, your, his, hers, its, their, whose*
    - Saxon genitives (formed by adding 's to a noun, pronoun, or noun phrases), which can be made more emphatic by adding *own* or *very own* (eg, Newman's Own food products).

Table 1. Royal Order of Adjectives

Determiner	Number	Observation or Opinion	Physical Description						Origin	Material	Qualifier	Noun
			Size	Shape	Condition	Age	Color	Pattern				
her		cute	little				red		Italian		sports	car
a	dozen	sterile								nitrile	surgical	gloves
		expensive							imported		cat	food
his					clean		green	striped				shirt
that					rusty	old				metal		bucket
							white			plastic	venetian	blinds

–Interrogatives: *which, what* (can be followed by *-ever* for emphasis, as in "Whatever did you mean by that?")
–Relative determiners: *whichever, whatever*

- Indefinite determiners (do not specify a particular item or set of items)
  – The indefinite article: *a* (*an*, if followed by a vowel)
- Quantifying determiners: *all, both, any, every, some, no*

When you have more than one determiner, the quantifying determiner usually goes first (eg, *all my children*).

How Many (or How Much)?

Quantifying determiners straddle the categories of determiner and quantifier. Quantifying determiners can be definite (*all* or *no*) or indefinite (*some, many*, or *a few*). Some quantifying determiners express a large or small quantity (eg, *many, more, fewer*) or a maximum, sufficient, or zero quantity (*all, both, sufficient, no*). Quantifying determiners should go before other kinds of quantifiers (such as cardinal numbers). Thus, you would say "all 12 children."

What Kind?

The adjectives that describe what something or some things are like come after the number and determiner. These adjectives also tend to follow a particular order. First come the adjectives that express the speaker or writer's personal opinion or observation (eg, about whether something is good, bad ugly, priceless, or outdated). Next come any adjectives that provide a physical description of the noun. Those descriptions tend to come in the following order: size, shape, condition, age, color, and pattern. Next comes the adjective that describes origin, such as *American* or *Chinese*. After that comes the adjective that describes the material out of which something is made, such as *wooden* or *metal*. The qualifier, which explains the type of noun, would come last in the list of adjectives. Sometimes, the qualifier is an attributive noun, which is a noun that serves to modify another noun (eg, cat food). Sometimes, a qualifier and a noun are so tightly associated with each other that they become a single concept (eg, *red* wine, *French* fries) or even a single word (eg, *schoolteacher*, *homework*).

Exceptions to the Rule

The Royal Order of Adjectives is a useful rule of thumb, particularly for people who are not native speakers of English. But in many situations, you may wish to break this rule. For example, you would not say the bad big wolf, even though an opinion adjective would come before the size adjective in the Royal Order of Adjectives. In those situations, you have to depend on your ear for language.

Some apparent exceptions to the Royal Order of Adjectives result from the slippery meaning of some words. For example, the word *Venetian* originally meant that something came from Venice (origin). However, the term *venetian blinds* refers to a type of window covering. In that context, the word *venetian* is a qualifier, not an expression of origin. So, you would say plastic venetian blinds, not venetian plastic blinds.

Commas and Coordinate Adjectives

Once you understand the Royal Order of Adjectives, it becomes much easier to figure out how to punctuate a list of adjectives.

- **Don't** use a comma after a determiner
- **Don't** use a comma between adjectives from different categories (cumulative adjectives)
- **Don't** use a comma between the final adjective and the noun it modifies.
- **Do** use a comma (or the word *and*) between adjectives from the same category (coordinate adjectives).

If you are not sure whether 2 adjectives are coordinate, ask yourself the following questions:

- Does the sentence still sound good and make sense if you put *and* between the adjectives?
- Does the sentence still sound good and make sense even if you reverse the order of those adjectives?

If the answer to those questions is yes, then the adjectives are coordinate. Separate them either with a comma or with the word *and*.

- His cruel AND callous behavior startled me.
- His cruel, callous behavior startled me.

- We can expect cold AND rainy weather this weekend
- We can expect cold, rainy weather this weekend

- Cold and clammy hands can be a sign of the fight or flight response.

So, feel free to enjoy some full-bodied Italian red wine, but not immediately before you drive your sporty new red Italian sports car.

Laurie Endicott Thomas is the author of several books, including Not Trivial: How Studying the Traditional Liberal Arts Can Set You Free *(http://www.nottrivialbook.com). Her book* No More Measles! The Truth About Vaccines and Your Health *was reviewed in the Winter 2016 issue of* AMWA Journal*: http://www.amwa.org/files/Journal/2016v31n4_online.pdf.*

Author contact: *laurie@gorillaprotein.com*

Journey from PharmD to Medical Writing: Tips for Making the Transition

By Lauren McMahan, PharmD / Clinical Knowledge Analyst, Hospital Corporation of America, Nashville, TN

The great thing about the field of pharmacy is that opportunities abound. Most people have a specific idea of who a pharmacist is and what a pharmacist does. But what most people don't know is that a PharmD is a versatile degree that can open up many different opportunities. Many pharmacists work at drug stores and hospitals; however, with the growing number of pharmacists and more competition for jobs, nontraditional career paths are becoming more common.[1,2]

Medical writing is a nontraditional career path for a pharmacist that, I'll admit, was never mentioned when I was in school. Nevertheless, earning a PharmD degree does provide the right education and opportunities for pharmacists to enter a medical writing career. In my case, researching and writing were my strengths, and I was able to forge a career path that has played into those strengths. I feel that what I learned during my pharmacy school journey can be helpful to anyone, but specifically for PharmD students and graduates who have found themselves conflicted over career paths or struggling to fit into traditional pharmacy roles.

My Lessons Learned

1. Take the time to think about and identify your strengths and weaknesses. What comes naturally to you and what doesn't? Where do your natural talents lie?

Everyone has talents. Yet it can be hard to think self-critically or be introspective, especially if that introspection brings up conflicting feelings or requires you to take a hard look at yourself or your life. I know it was hard for me to identify my strengths and weaknesses without consulting family, friends, colleagues, and preceptors. Listen to these people in your life and the people you meet because they can provide good insight into what you can't see about yourself. Be aware and listen to the advice others can provide. This insight can help to direct your career path. Also pay attention to what interests you and where you excel. I discovered an interest in biology and writing in high school and developed that throughout college.

It can be challenging to be going in a different direction than your other pharmacy school classmates. I struggled with feeling there was something wrong with me or wrong with my choice to go to pharmacy school because I had a different skill set than most of my peers and colleagues in pharmacy. I knew that I wanted to do something different. I knew that I wanted to write, but I had no idea how to actually get a job doing something like writing and researching. Many new pharmacy graduates will at least start out in hospital or retail pharmacy jobs, although this seems to be changing even since I graduated almost 6 years ago. Even so, if you love writing and researching and you have a PharmD, you have the right skill set to be a medical writer. Pharmacists who like medical writing often most enjoy the academics and learning associated with pharmacy.

2. Take advantage of the unique opportunities afforded by your PharmD education: scientific curriculum, experiential learning rotations, work experiences, and preceptor feedback. Pay attention to what activities you like and don't like during these experiences. Treat every experience like a job interview because others are always watching.

Scientific Curriculum: If you're in pharmacy school and you think you want to be a medical writer, pay attention in your drug information, research, and statistics classes. During my third year of pharmacy school, I had a year-long course on analyzing literature, scientific writing, and presenting research. I really enjoyed researching and writing during that time. The beneficial part of this course was that it was self-guided; we only met as a class at the beginning of the

summer and spring semesters, but the research and writing for the big end-of-semester presentations was all independent, requiring personal discipline to complete the research and analysis and come up with a timeline to do so. The final hour-long presentations were given in front of other students and guest pharmacists who would ask questions at the end of the presentation. This was good practice for the independence and dedication needed to complete medical writing projects.

Experiential Learning: In addition to learning about disease states, drugs classes, how to counsel patients, and how to retrieve and read scientific literature during my third year of pharmacy school, I also did more experiential learning in real pharmacies. Even for those not planning on a clinical pharmacy career, experiential learning rotations in hospital or retail pharmacies during pharmacy school help to provide a foundation for clinical practice and understanding, which will in turn help with effectively communicating medical concepts in writing.

Pharmacy school rotations provide a unique opportunity to gain insight into many different career options. If writing and research is something you are really interested in, I would recommend taking advantage of nontraditional experiential rotations in areas such as managed care, the pharmaceutical industry, or corporate operations. My pharmacy school didn't have a specific rotation dedicated to medical writing, but these nontraditional rotations gave me more exposure to writing and research.

Even those difficult required rotations can be valuable. I remember one particular hospital rotation in cardiology that was by far the hardest rotation I had in pharmacy school. I didn't like it at all and was honestly terrible at it. When I look back at that rotation I can admit that, while it was not completely enjoyable, it helped me learn a lot about my personal strengths and weaknesses. Remember to always do your best work even when you're working on something you don't like, because you get to know a lot about yourself and can impress others who are watching.

Work Experience: For all pharmacy students, graduating means that you have to obtain a certain number of hours of real work experience in a retail or hospital setting. I worked as a pharmacy intern in a retail drugstore during weeknights and weekends in pharmacy school. This work experience reinforces hands-on clinical practice and knowledge of drugs but focuses less on research and writing. Even so, this clinical experience can help to solidify your confidence as a pharmacist and improve your medical writing.

Preceptor Feedback: Listen to feedback from your preceptors, good or bad. I had both while in school. My interests and skills focused less on hospital and retail pharmacy and more on nontraditional pharmacy roles. My skills were praised more often in my nontraditional roles and experiences. I still remember when one of my preceptors used the phrase "you are really good at this" to describe my research and writing skills. That one statement validated my desire to pursue medical writing and boosted my confidence in my abilities.

3. Who you know DOES matter. Network, network, network!

This goes back to my second point about investing in your pharmacy school rotations or work experiences. Pharmacy school exposes you to a lot of different people and work environments. These opportunities are a great time to do your best work AND network. Even for those introverts like me, who struggle to meet the right people and say the right things to land those impressive opportunities, remember that any work experience means you are making connections and networking with others. The research and writing job I have today is a direct result of the work I did and the interest I showed while on a nontraditional pharmacy school rotation. Managed care, pharmaceutical, and corporate settings are often hiring for positions, especially if they already know you through pharmacy school rotations or your prior work with them.
Here are some tips on networking and confidence, especially for introverts:

a. ***Do the best you personally can in networking and reaching out to others to land the job you want.*** Everyone is different, and you may have to push yourself out of your comfort zone. Do your best and your natural talents will be visible. You don't have to be the loudest person in the room to get noticed.

b. ***Acknowledge that some part of landing that perfect job comes down to luck.*** Pharmacists are fortunate in that our experiential learning puts us in the path of a lot of people and opportunities, so pay attention. Do your research and put yourself in as many rotations or job experiences that interest you as you can. The more you can align your interests with your work, the more opportunities will come your way.

c. ***Be confident that a PharmD has prepared you for a career in medical writing or whatever other path you choose.*** Pharmacists are the perfect hybrid between clinician and academic. Pharmacists can provide direct patient care, but they can also understand research and analysis. Pharmacists are well trained in reading, understanding, and interpreting scientific literature and in writing. So, be confident in your abilities.

d. ***Seek out involvement with organizations and with people who have similar interests.*** When I graduated 6 years ago, there wasn't any support or guidance from my pharmacy school on how to become a medical writer. Nontraditional career options focused on managed care or the pharmaceutical industry. I discovered my current position through my pharmacy school rotations and, from there, researched other jobs like mine that focused on researching scientific literature, analysis, and writing. My position was new for my organization, so I was really looking to see if there was a title for what I did or if it was common in other organizations. That is how I stumbled across AMWA and the concept of a medical writer.

Pharmacists can be great medical writers because they have hands-on clinical training, an analytical mindset trained to focus on detail, the ability to manage projects and people, and the ability to prioritize lots of work.

Advice for College Students and Pharmacy School Grads

Even if you didn't go through pharmacy school but are still interested in medical writing, steer your college education and work experiences to science-, medical-, and writing-related classes and jobs. My first introduction to reading and understanding scientific literature came in college when one of my biology professors suggested I enroll in an elective on reading scientific literature. Take advantage of similar research/writing classes in college or as continuing education because practice in researching and writing always helps you to improve. You may not like every course you take, but you will get a better understanding of what medical writing is and whether you are good at it or like it. Several colleges offer medical writing degrees or programs. The AMWA website lists some of these degree or certificate programs that you can enroll in at colleges around the country.

If you have already graduated, I would strongly suggest making the most of your involvement with organizations like AMWA, such as talking to other medical writers in your city and using the AMWA jobs directory. Reach out to pharmacy colleagues who have a career path you are interested in following for advice and guidance.

Final Thoughts

Having the PharmD training is an added bonus as a medical writer. It shows that you are educated in medicine, drugs, and research. Pharmacists can be great medical writers because they have hands-on clinical training, an analytical mindset trained to focus on detail, the ability to manage projects and people, and the ability to prioritize lots of work. Look for opportunities to steer your career in the direction you want it to go, even if that means it's scary or different from what your colleagues are doing. If you are interested in medical writing, make every effort to direct your education and career toward that field. Really evaluate what you are good at and what you want to do; invest in your education and work experiences; and network as much as you can.

Author contact: *Lauren.McMahan@HCAhealthcare.com*

References

1. United States Department of Labor: Bureau of Labor Statistics. https://www.bls.gov/oes/current/oes291051.htm. Accessed March 28, 2018.
2. Forecasting opportunities in nontraditional pharmacy. http://www.pharmacytimes.com/contributor/the-nontraditional-pharmacist/2016/10/forecasting-opportunities-in-nontraditional-pharmacy. Accessed March 28, 2018.

Social Media Comfort Zone *continued from page 75*

to stay in touch and may end up working together on the book.

In each of these situations, reaching out to an existing LinkedIn contact led to a new business opportunity for me—an opportunity that is unlikely to have occurred had we not been connected on LinkedIn. So, in my own way, embracing at least one type of social media has helped me to maintain/grow my business.

Whether we are digital natives or digital immigrants influences our use of social media as well as our communication preferences. As Eleanor Mayfield describes, she has found her social media comfort zone as a digital immigrant. Although her approach is likely different from that of a digital native, it works for her—and that's what counts!

Do you consider yourself a digital immigrant? A digital native? *Please share your experience with me at clkwriter@comcast.net. Your social media experience may appear in a future article in this section!*

Author contact: *eleanor@elmcommunications.com*

Reference

1. Bakker W. 5 levels of social media sophistication for DMOs. Digital Tourism Think Tank. April 2012. https://www.danskturismefremme.dk/sites/default/files/asp/danskturismefremme/6_5-levels-of-social-media.pdf . Accessed April 10, 2018.

Best Science (BS) Medicine Podcast: Getting Higher than a Kite on Medical Cannabinoids

https://therapeuticseducation.org/bs-medicine-podcast

The "Best Science (BS) Medicine Podcast" is a popular medical podcast that delves into the best available evidence to inform rational patient treatment in the primary care setting. In educating both patients and healthcare professionals, the podcast strives to enable patients to engage in shared and informed decision making.

The podcast is hosted by the Therapeutics Education Collaboration and presented by Dr James McCormack, a pharmacist and professor in the Department of Pharmaceutical Sciences at the University of British Columbia, and Dr Michael Allen, a family physician and professor in the Department of Family Medicine at the University of Alberta. Healthcare providers themselves, the podcast hosts seek to critically evaluate the evidence and present it in a succinct manner to time-scarce individuals in the podcast medium. With 378 episodes to date, these podcasting veterans have covered a wide range of topics since their first episode in 2008. Most episodes focus on 1 particular medical issue (eg, obesity, anxiety, back pain), interspersed with episodes dedicated to wide-ranging listener questions. Some topics are covered in 1 episode, while others require a 2- to 4-episode series. Medical cannabinoids were recently covered in a 4-part series, "Getting Higher than a Kite on Medical Cannabinoids." Medical cannabinoid use is a controversial topic, and the self-described "mythbusters" of drug therapy found medical cannabinoids to be promoted for a variety of conditions, even with a lack of high-level research to support their use. In this series they sought to determine exactly what was supported by the data.

The series begins by defining medical cannabinoids (medical marijuana and pharmaceutical cannabinoids) and the various routes of administration. Over the course of the series, the evidence for medical cannabinoid use is discussed and recommendations are made accordingly. The presenters and their colleagues conducted systematic reviews of randomized controlled trials (RCTs)—essentially meta-analyses of RCTs. Owing to the quality of evidence available, they focused on 4 clinical areas: pain, spasticity, nausea and vomiting, and adverse effects.

The hosts conclude that the use of medical marijuana is not supported by the evidence and recommend only very limited pharmaceutical cannabinoid use, in general. They suggest that use be limited to palliative and end-of-life pain, neuropathic pain, chemotherapy-induced nausea and vomiting, and spasticity due to multiple sclerosis or spinal cord injury, and almost never as a first- or second-line treatment. Adverse events (side effects) are significantly higher for cannabinoids compared with placebo, and because many studies enrolled patients with a history of cannabinoid use, the benefit of intervention may be exaggerated, and the number of adverse events is almost certainly higher than currently suggested by the data. A corresponding research article and clinical practice guideline were published in a peer-reviewed journal, supporting the legitimacy of the claims and associated recommendations made in this cannabinoid series.

The hosts inject humor to the conversation (eg, suggesting that certain side effects such as "getting high" and euphoria may not be viewed negatively by all patients) to bring a more casual tone to their discussion of the evidence, engaging the audience even as the terminology becomes more technical as the details of clinical trials are discussed. For a listener not adept with clinical trial terminology, it may be difficult to fully comprehend on first listen, but with a few quick online searches, one can quickly get up to speed.

I found this series to be highly informative, well researched, and light enough to digest on an evening stroll. It may serve as a valuable resource in decision making for patient care.

To learn more, visit therapeuticseducation.org or subscribe to the podcast on iTunes or Podcast Addict (Android).

Reviewer: *Hazel O'Connor, PhD*

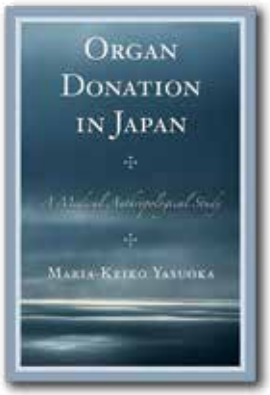
Hazel O'Connor is an R&D Scientist at Sciteck in Asheville, North Carolina.

* * *

Organ Donation in Japan: A Medical Anthropological Study

Maria-Keiko Yasuoka

Lanham, MD: Lexington Books, 2015; Hardcover, 186 pages, $89.00



Although Japan boasts one of the finest health care systems in the world, organ transplants are far less common there than elsewhere. Many types of Japanese religious belief abhor the mutilation of the body, and while Japan was home to one of the world's first heart transplants, it was a high-profile failure that raised serious ethical questions and led to a 30-year ban on organ transplants from the brain dead. In her book *Organ Donation in Japan: A Medical Anthropological Study*, Maria-Keiko Yasuoka explores Japanese feelings toward organ transplantation

through in-depth interviews with practitioners, the family members of donors, and the recipients themselves.

These interviews make up the core of the book, and they are by turns touching and harrowing. Most of the interviewees' reactions to their experiences are universal. Although the process is grueling for everyone involved, recipients are deeply grateful for a new chance at life, while those who make transplants possible are proud to provide that chance. Some of their reactions may be more surprising to non-Japanese readers, and these are explored in fascinating depth. Some recipients hide their experiences because they face disapproval so extreme that they may be considered cannibals. The paucity of donated organs in Japan means that donors and their families have enormous power, eclipsing that of practitioners, who are used to playing a far more paternalistic role than in other countries. Finally, in a culture in which mutual exchanges of gifts play an outsized role, receiving a gift of life that can never be repaid can leave organ recipients with a sense of obligation that is impossible to expiate.

This obligation leads interviewees to consider organ transplantation a form of "rebirthable life," the key concept in Yasuoka's analysis. Donors' families speak of them as "missing children" who live on inside organ recipients' bodies, and some even avoid getting to know recipients because hearing of their deaths would mean hearing that their loved one has died completely. Recipients describe deeply personal relationships with donors they have never met, often to the point of feeling obligated to live as long as possible to keep the donor's organ alive. Some even describe taking their donor's wishes into consideration when making decisions.

As the title states, Yasuoka's approach is rooted in anthropology, so her focus is on exploring the thoughts of participants in the Japanese organ transplant system on their own terms. This may disappoint readers who desire a well-organized introduction to the medical and legal foundations of that system. Even by her own standards, the author is not always successful. Because so few transplants have taken place in Japan, she has had no choice but to recycle a small number of interviews in a way that can be repetitive, and additional material on Japanese funeral practices is enlightening but ultimately irrelevant. Furthermore, the clarity and depth with which the author explains her conceptual framework doesn't strike me as entirely satisfying.

Still, this book provides a penetrating and affecting glimpse at the human side of health care in Japan. For those of us familiar with that field, it provides many valuable insights into a controversial and high-profile issue. Other readers will, at the very least, find it intriguing and thought-provoking.

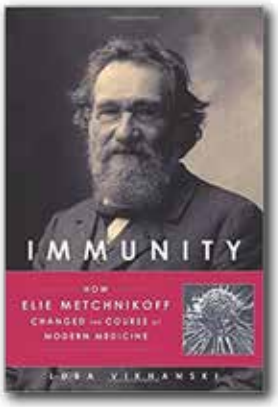
Reviewer: *David Newby*

David Newby is a Japanese translator and medical writer in Philadelphia, Pennsylvania.

Immunity: How Elie Metchnikoff Changed the Course of Modern Medicine

Luba Vikhanski

Chicago, IL: Chicago Review Press, 2016; hardcover and digital formats, 336 pages, $26.99



He was lauded as the father of innate immunity. News of his experiments graced the front pages of newspapers worldwide. In 1911, he was named one of the world's greatest men. Yet 50 years after his death, Nobel-laureate scientist Elie Metchnikoff had fallen into obscurity.

In the mid-1800s, infectious diseases such as typhus, cholera, and tuberculosis devastated cities across Europe. By the 1880s, new hope arose following vaccinations that successfully provided immunity against anthrax. However, the mechanism by which immunity was created remained a mystery.

As a Russian zoologist, Metchnikoff began questioning why some people were more susceptible to life-threatening disease than others. In transparent invertebrates, he injected a number of materials—milk, blood, dyes, food, germs—and watched under a microscope as the intruding particles were surrounded and often engulfed by wandering cells. Contrary to most physicians of the time, Metchnikoff became convinced that these cells were part of an active defense system present in all living beings, even humans. In 1883, he presented his theory of innate immunity, which described the immune system with eerie accuracy. When met with scathing criticism, Metchnikoff stubbornly sought more evidence to defend his theory. For this work, he was awarded the 1908 Nobel Prize in Medicine jointly with his rival, Paul Ehrlich.

At the Pasteur Institute in Paris, Metchnikoff founded the field of gerontology. Believing diet could improve health, he prescribed "sour milk" to cultivate healthy gut microbes and prolong life. This research pioneered probiotics and attracted enormous public attention, eventually launching the yogurt industry. However, these longevity theories were ridiculed by critics. In his final days, he agonized over the fate of his theories.

After his death, Metchnikoff faded into obscurity everywhere except his homeland, where Soviet propaganda had exalted him as a national hero. When Luba Vikhanski, the child of Soviet dissenters, first learned about Metchnikoff, she assumed he was a fake. She was surprised when, years later while working as a science writer, he was recommended to her

as a "little-known but key" figure in science history. A decade of research following Metchnikoff's trail led her from a zoological station in Naples to a safety deposit box at a Parisian bank on the Champs-Élysées. While unraveling the mysteries of Metchnikoff's life, Vikhanski gained access to an exhaustive collection of primary sources, including his previously inaccessible personal letters.

As the first biography of this scientist in decades, this book reanimates Metchnikoff for the 21st century, revealing a towering figure of science complete with complex human flaws. He was a vigorous reader, prolific writer, and fiery lecturer who routinely attracted large crowds. His writing, in particular, served to vigorously defend his theories throughout the "immunity wars" and to preserve his stunningly prescient science for rediscovery.

Immunity adds an important chapter to science history, balancing quality scholarship with clear language. Aided by its concise but engaging chapters, readers will be pleased by the accessibility of the science. The book will be especially engaging to medical writers with an interest in immunology, microbiology, and gerontology.

Reviewer: *Kristin A. Roynesdal, MS*

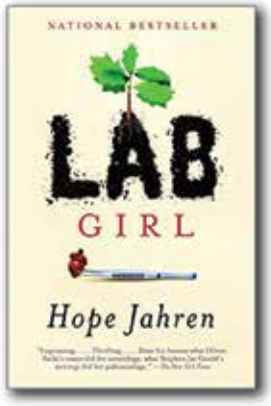
Kristin is a freelance medical editor and writer in Charlottesville, Virginia.

* * *

Lab Girl

Hope Jahren

New York, NY: Vintage Books, 2016; Paperback, 290 pages, $16.00



Even for avid gardeners, I wager that the thrill of discoveries in the dirt has never been more passionately expressed than in *Lab Girl*, written by geobiologist Hope Jahren. This is a delightful read, and the author is that rare scientist who can write a page-turner intended for a general audience.

Although much of *Lab Girl* is autobiographical and written in the first person, sections alternate between anecdotes of the author's scientific and life journey, and mini-lectures about the natural world. These disparate sections are, however, thematically linked. For example, a description of how trees begin their growth from seeds precedes a chapter about Jahren's undergraduate job in a hospital blood-typing lab. It was in that meticulous tedium that she began to envision herself as a future scientist—the seeds, so to speak, that would bear fruit in her career.

I especially enjoyed the sections where Jahren discusses the business of being a scientist. "My laboratory is a place where the lights are always on," she says—but it is a refuge and many other things, too. Foremost on her mind is money—writing grants, keeping lab members paid, tinkering with old equipment held together with duct tape (literally). Her experiences with peer review, both speaking at scientific conferences and submitting manuscripts to journals, are thought-provoking. Remember, this is a woman who's achieved tenure, grants, and awards. She juggles teaching responsibilities, working with students, research field trips to Norway and Ireland, and a family life. Her description of a road trip to a scientific conference, with her lab assistant and graduate student bundled into an old van, is particularly entertaining and sobering at the same time.

Lest you roll your eyes and think "Great, yet another Wonder Woman!" Jahren's accomplishments have not come easily. In what may be the most powerful sections of the book, she discusses her struggle with mental illness, including a vivid anecdote about a harrowing psychotic break. She recovers, but her illness resurfaces when she becomes pregnant and medication side effects pose new difficulties.

Jahren's book begins with a lovely homage to her father, a community-college instructor in a small town in Minnesota. But her family is almost never mentioned again, except elliptically. We fast-forward through her meeting and marrying her husband, their moving from Johns Hopkins to Hawaii, and her relationship with her young son. Although some readers may find it jarring to encounter important personal matters mostly in offhand comments, I sense that Jahren is a modest Midwesterner who just doesn't like talking about those things. For you sticklers for detail, Jahren even includes an endnote explaining how she arrived at some of the calculations in the book (such as Federal funding for "curiosity-driven" research, or the length of wooden planks made in the United States in the last 20 years, if stretched end to end).

"Carefully writing everything down is the only real defense we have against forgetting something important that once was and is no more," writes Jahren. If this idea moves you, this book will please you—with the joys of thinking deeply about science and reading thoughtfully written prose.

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

Karen (2014-2015 AMWA President) is Director of Grant Development and Medical Editing at Wake Forest University Health Sciences in Winston-Salem, North Carolina.

YOU CAN DO IT TOO! CREATING SCIENCE VIDEOS FOR THE PUBLIC

Speaker
Jessica Meade
Office of Science Policy and Communications, National Institute of Biomedical Imaging and Bioengineering, Bethesda, MD

By Kelly Schrank

Jessica Meade works for the National Institute of Biomedical Imaging and Bioengineering, a part of the National Institutes of Health, and she was quick to say that she has no government endorsement. Her goal in giving the presentation was to simply show others her journey from novice to creating animations. You can see some of her videos on the National Institute of Biomedical Imaging and Bioengineering website at https://www.nibib.nih.gov/. One that she showed was "6 Awesome Technologies Your Tax Dollars Are Paying to Create."

Meade started the session by answering the question, "Can I make videos without buying any software?" Her answer was "yes" as Mac has iMovie and Windows has MovieMaker.

She continued by answering the question, "Why create videos?" The first part of her first answer was a quote from Haig Kouyoumdjian, PhD: "I believe the right visuals can help make abstract and difficult concepts more tangible and welcoming, as well as make learning more effective and long lasting." The second part of her answer was to only make a video if it serves the content. If visuals such as video don't add anything to your story—or if you don't have the right visuals that add to the story—then use a different medium. Meade advised attendees to not waste time and energy making a video if it adds nothing to the content.

Research

Learning how to create videos was a passion for her; Meade admitted to spending some of her personal time on learning how to make good videos. But she also researched and created videos at work when she had time between projects. Meade said that making the videos was not a requirement of her job, but a passion they let her pursue on the job as she had time.

Part of her research involved watching other videos and seeing what works for others. Meade estimates spending 2 to 3 hours per week watching YouTube videos, and she tries to copy those she loves.

Sites she watches and recommends include

- TED-Ed (https://www.youtube.com/user/TEDEducation)
- AsapSCIENCE (https://www.youtube.com/user/AsapSCIENCE)
- minutephysics (https://www.youtube.com/user/minutephysics)
- NIH (https://www.nih.gov/news-events/videos)
- PBS Nova Profiles (http://www.pbs.org/show/nova-science-now/)

Things to think about

- Audience
- Attention span
- Titles and thumbnails
- Gaps

Audience

In thinking about audience, Meade recommends thinking about what the video will accompany. Will it be paired with some type of PR, a blog post, or an article? While creating, keep in mind people's attention spans: the sweet spot is 2 to 3 minutes, up to 4 to 5 minutes if it's something that grabs them or is important. Speaking of attention-grabbers, Meade talked about how she did not realize just how important titles and thumbnails would be to the popularity of a video. The title needs to be short and sweet. The good thing is you can change the title and thumbnails after the fact, so if they don't seem to be getting any traction, you can try something else. Last but not least, she discussed gaps. If you Google a topic and you can't find anything, then there is a gap: fill it!

Elements of Video

Meade touched on many of the elements involved in a video, including music, images, and words.

Music

She finds free background music online. Her recommendation was to Google "free background music," but when pressed, she admitted that her favorite is Longzijun (https://longzijun.wordpress.com/).

Images

When you need a static image or an image to make into an animation, search Google for an .obj object file. For example, if you search "lungs .obj free," you will be provided with images of lungs.

You can use 1 image for 10 to 15 seconds or longer while there is voice behind it. Seven seconds is about average. Meade discourages you from having a talking head, but if you have one, have a clean and neat background and only show for 30 seconds. Always check that the mic is working, because you

can replace bad video with a still photo or B-roll, but "if you don't have the audio, you don't have the audio."

Text

When you have text in a video, do not use light text on a dark background. When asked for a word requirement, Meade stated that there was not a clear answer. She estimated that a 3- to 4-minute video might contain 600 words.

Storyboards

To help illustrate how she moves forward with a video, she provided a copy to attendees of one of her rough-sketch storyboards and walked us through it. Meade started with empty boxes and some text typed below them. They were numbered by hand and there were rough sketches inside the boxes, also written by hand. There were also a bunch of handwritten notes around the boxes, showing how her thought process progressed from her initial thoughts to more detailed instructions for herself. She thought this was an important step in the process, but also cautioned not to spend too much time making it perfect, as the project will continue to change as you start to put it together.

Meade mentioned that analytics in YouTube are helpful to see how your video is doing, but she felt that was out of scope for this beginning session.

Kelly Schrank is a Contract Technical Writer and Editor near Syracuse, NY.

Author contact: *headbookworm@gmail.com*

Tips:

- Have a watermark on the video to ensure branding
- Strive for 2 to 3 minutes for a video
  - 5 seconds of an intro with branding at the beginning and again at the end
- Use the "Ken Burns effect," wherein you focus in on something then zoom out

REGULATORY INSIGHTS

From the Editor / Jennifer Bridgers, MWC®

Greetings! It is my pleasure to be serving as the editor for the Regulatory Insights section.

This section focuses on topics relevant to global regulatory medical writing, such as submission formats, specific document types, and ethics relative to research and regulatory documents. I am grateful to the originators of the series, Peggy Boe and Barbara Snyder, and the previous section editors, and I appreciate their initiative.

The regulatory environment is dynamic, but I think there has been even more rapid change in the last few years. Just as CORE helped revise the clinical study report process, current initiatives are helping invigorate protocol development. In the Winter 2017 issue, Lisa Ambrosini Vadola and Robin Whitsell presented an excellent, detailed look at the National Institutes of Health–Food and Drug Administration Clinical Trial Protocol Template. In a future issue, we will discuss the Common Protocol Template developed by TransCelerate. We will also begin to take a critical look at structured authoring tools and how they affect the medical writer role.

Regulatory medical writers work in a global environment where our documents may be submitted to multiple health authorities and read by a global audience. Planning ahead for and an awareness of global requirements is critical. I recently attended my first European Medical Writers Association (EMWA) conference in Barcelona, Spain. I learned about the revised MEDDEV guidance for medical devices and new revisions to the risk-management plan (RMP) guidance. I heard about writing lay summaries and clinical data protection and transparency. All of these topics directly affect our work as regulatory writers in the United States. I look forward to sharing with you a balance of content about US and global regulatory insights.

If one of these topics resonates with you, or if you have other suggestions, I welcome your input. Please contact me at coolwriterj@yahoo.com. The *AMWA Journal* is a great way to be involved with AMWA and build your exposure through a peer-reviewed publication. Also, the *AMWA Journal* has a blog within AMWA Engage. This is another great way to contribute in a shorter format.

About me:

Medical writing is my passion—to encourage scientific exploration through quality communication. I have been a regulatory medical writer for 18 years, primarily with contract research organizations. Protocols are my specialty, but I enjoy working in all aspects of drug development.

The AMWA community is my muse. I have attended 14 annual conferences and continue to be inspired at each one. I love sharing experiences with other attendees and learning new developments in the profession. It is fascinating to me the plethora of ways the term "medical writer" can be defined.

It has been my honor to support AMWA as a workshop and a roundtable leader; on the Educational Committee, Constitution and Bylaws Committee, and Regulatory Education Advisory Group; and with the Carolinas Chapter as president and as a delegate to the AMWA Board of Directors, and now to the Chapter Advisory Council.

I am currently a Managing Medical Writer with Merck and Co., Inc., and am based in Raleigh, North Carolina. I look forward to exploring the evolving regulatory environment with you!

Sample Size: Ethical Considerations

Tamara Ball, MD / Freelance Medical Writer

Disclaimer: This column is based almost exclusively on a video, "Evidence-based Medicine or Evidence Bias" by Michael Greger, MD, FACLM, that was posted by NutritionFacts.org in 2014 and is available at https://nutritionfacts.org/video/evidence-based-medicine-or-evidence-biased/ (last accessed 21 April 2018).

Sometimes in life, bigger is not always better. In fact, there are times when "bigger" can border on unethical—I'm talking here about sample size in clinical trials. When a statistical difference is found between outcomes for groups A and B, both sampled from a larger population but randomized to different interventions, the likelihood that the difference was due to chance (that is, that there was no actual difference between groups) is less than 5 in 100 (assuming a *P* value <.05). Since the introduction of evidence-based medicine in the early 1990s, medical practice has been increasingly shaped only by large (N ≥ 200) randomized clinical trials in which the results were statistically significant but for which the effect size—that is, the size of change in outcome produced by the intervention—was rather small. But what about small studies in which the effect is very dramatic? Is it even ethical to proceed with a randomized clinical trial following such a study?

Rabies is an extreme example of this scenario. Since early times, rabies infection had been recognized as universally fatal and had been described as "a most awful death." In 1885, 9-year-old Joseph Meiste, who was mauled by a rabid dog, was given a new vaccine and became the first human to survive the illness.[1] Neither the efficacy nor the safety of the vaccine had been shown in a randomized clinical trial, but, after treatment of 1 additional patient (who also survived), the vaccine was accepted worldwide.[1]

A slightly less extreme example involves a study from the 1980s with a small number of patients but a dramatic effect: the introduction of extracorporeal membrane oxygenation (ECMO) in neonatology. A highly invasive technique, ECMO has been used in neonates with severe, reversible cardiac and respiratory illness unresponsive to maximal medical therapy. Pioneers in the field noted that in very ill neonates (those with a mortality risk ≥80%), ECMO therapy upended the outcome, such that survival was now 80%. These results looked good—almost too good. Even though researchers felt strongly that they were "condemning" some children to death, they were also concerned that their colleagues would not accept this undeniably risky procedure without a randomized controlled trial. After the fourth death in the control group (n = 10), the trial was terminated. At that time, 9 of 9 neonates receiving ECMO had survived.[2]

In 1995, Esselstyne et al[3] published a more controversial dietary intervention in which patients with angiographically documented, severe coronary artery disease were coached on a plant-based diet containing <10% fat. Of the 22 patients enrolled, 5 dropped out within 2 years, and 11 of the remaining 17 maintained the diet through a mean of 5 years. These 11 patients reduced their serum cholesterol levels and saw an angiographic reduction in or stabilization of their coronary artery lesions. None had a new cardiovascular event. In contrast, the 5 patients who resumed their pre-study diet had an additional 10 cardiovascular events. Extended follow-up through 10 years showed that the 6 patients who had continued the extremely low-fat diet had no further coronary events. This study demonstrated a dramatic response to dietary intervention but was roundly criticized for its small sample size and for not having been a blinded study.

We've grown accustomed to seeing larger randomized controlled trials that are rigorously blinded (not possible in most outpatient nutritional trials) but that often show only a modest effect compared with standard of care—yet these studies often change practice patterns. The Esselstyne arti-

cle described a 100% response rate with no safety issues. If a plant-based diet was a pill and the control therapy was the average American diet, scientists would argue whether it was ethical to even have a control group in future studies of the intervention.

Traditionally, phase 3 trials have committed sponsors to a large sample size with no possibility of early termination for benefit, harm, or futility. If a phase 2 trial suggests that an intervention is markedly beneficial, is it ethical to randomize half or a third of phase 3 patients to placebo before we are more certain of the interventional outcome? Or if early studies suggest that the intervention is no different from placebo or even harmful, can we argue that it is ethical to randomize patients to the intervention in order to confirm initial impressions?

Adaptive design allows for an interim analysis in which accumulating data are used to decide how to modify aspects of the trial as it continues, without undermining validity and integrity. "In such trials, changes are made 'by design,' and not on an ad hoc basis; therefore, adaptation is a design feature aimed to enhance the trial, not a remedy for inadequate planning," wrote Dr Paul Gallo in a 2006 publication.[4] Many adaptations are possible, including modification of dose, treatment, randomization, sample size estimation, early stopping rules, hypothesis, primary outcome variable, eligibility criteria, or statistical analysis plan. There are pitfalls associated with each adaptation, so adaptive trial design requires careful and extensive planning. Even with that planning, adaptive design still poses multiple concerns, including increasing the probability that the drug will be deemed effective when it is not, introducing unanticipated sources of bias, or misinterpreting results. Also, there are logistical and procedural issues associated with adaptive design.

Done right, interim analyses may help us straddle the gap between small studies with large effect and large studies with small effect. Ethical trials should include only as many patients as are needed to answer a specific clinical question. It is easy to get caught up in statistical significance; but statistical calculations should be used to identify a plan that will be effective in answering the clinical question—not the other way around.

Author contact: *tballmd@gmail.com*

References

1. Geison GL. Pasteur's work on rabies: reexamining the ethical issues. *Hastings Cent Rep.* 1978;8(2):26-33.
2. Bartlett RH, Roloff DW, Custer JR, et al. Extracorporeal life support: the University of Michigan experience. *JAMA.* 2000;283(7):904-908.
3. Esselstyn CB Jr, Ellis SG, Medendorp SV, Crowe TD. A strategy to arrest and reverse coronary artery disease: a 5-year longitudinal study of a single physician's practice. *J Fam Prac.* 1995;41(6):560-568.
4. Gallo P, Chuang-Stein C, Dragalin V, Gaydos B, Krams M, Pinheiro J. PhRMA Working Group Adaptive designs in clinical drug development. *J Biopharm Stat.* 2006;16(3):275-283.

CALENDAR OF MEETINGS

2018 AMWA Medical Writing & Communication Conference
NOVEMBER 1-3, 2018
WASHINGTON, DC
Trends and Opportunities for Medical Communicators
https://www.amwa.org/conference

DIA 2018 Global Annual Meeting
June 24–28, 2018
Boston, Massachusetts
http://www.diaglobal.org/en/flagship/dia-2018

International Society of Managing and Technical Editors North American Conference
August 2–3, 2018
Baltimore, Maryland
http://www.ismte.org/page/2018NAConference

International Conference on Communication in Healthcare
September 1–4, 2018
Porto, Portugal
http://www.each.eu/events/conferences/icch-porto-2018/

Plain Language Association International
September 27–29, 2018
Oslo, Norway
https://plain.difi.no/

RAPS Regulatory Convergence
October 1–4, 2018
Vancouver, British Columbia
https://www.raps.org/convergence-2018/home

National Association of Science Writers
October 12–16, 2018
Washington, DC
https://www.nasw.org/events

European Medical Writers Association
November 8–10, 2018
Warsaw, Poland
https://www.emwa.org/conferences/future-conferences/

American Public Health Association
November 10–14, 2018
San Diego, California
https://www.apha.org/events-and-meetings/annual


Brian Bass


Melissa L. Bogen


Lori De Milto


Gail Flores

Q Have you ever taken a writing test or completed a writing assignment as a sample for a potential freelance client? Why or why not? Do you think it is a good idea for new writers to complete such a test? What about experienced writers?

A Yes, I have taken a test, several years ago. This test was part of a full-time job application, not a freelance project/contract. It took 1.5 hours. It was not an intelligent test, I felt, in terms of assessing a candidate's writing skills. (The test, for example, demanded that the writer understand a rather complex statistical concept that most writers do not actually need to know well; the writer simply needs to know which statistician to ask for interpretation.) When I asked, the HR department told me the company was legally within its rights to give the test as part of the job application, as long as "all applicants" had to take the test. I did not get that particular job (not because of the test but because another very good candidate was able to be onsite 100%).

Another very large CRO wanted me to take a test before accepting a full-time, long-term contract working remotely; the work was for clinical study reports and other regulatory projects, an arena in which I have extensive experience. After reading their test, I refused to complete it because (1) it was complex and clearly would take more than 1 hour, and (2) it was not relevant to the tasks of a medical writer for regulatory projects. In my opinion, a "writing" test should not demand skills in either strategic marketing plans, marketing, or advertising. This CRO's test required marketing assessments pertinent to MarCom and, perhaps, MedCom—but *not* to regulatory writing.

So first we have the issue of intelligent and specific testing. Duh! Neither of the above tests was intelligent nor specific to the work actually being requested.

And then we have the issue of whether it is *appropriate* to ask a candidate to take a writing test. I definitely do not believe writing tests are appropriate for an experienced writer; in fact, they are particularly insulting to those of us with extensive experience. I think an experienced writer should *not* be asked to take a writing test for either a full-time job or a freelance project—providing samples and references should suffice. An experienced and savvy hiring manager (not necessarily the HR person) who knows the field can discern, quite quickly, whether a candidate is being dishonest about his/her experience and, especially in regulatory affairs and MedCom, can know after a brief conversation whether the candidate understands the field, truly has hands-on experience, and how extensive the person's hands-on experience is. Wasting my time on an unpaid test is an insult, and it starts off a relationship in a sphere of distrust: the interviewer does not trust my word; do I want to work for her/him? Not really.

Note also that asking a freelance or self-employed medical writer to take a test is not only a professional insult, but it cuts into the person's time without offering financial compensation; this shows lack of understanding, consideration, and respect for the self-employed writer whose time should be paid. (An employee, however, ostensibly has another full-time position and is receiving a salary while interviewing.)

Now we come to the question of testing an inexperienced or novice writer. Well, in the first place, why would you hire an inexperienced writer for a writing job? And certainly not for a freelance project! Are you crazy? The novice wannabe writer (in pharma/biotech) should be considered, instead, for a full-time job (FTE) to do proofreading, editing, checking and cross-checking data, and other administrative/coordinating tasks that will help him/her develop both understanding and experience. While in such a position, the novice can essentially become a trainee-writer and learn the industry, the process of drug development and clinical research, the demands and specificity of clinical writing, etc. Then, perhaps after 2 or 3 years, the person will have accrued sufficient bona fide credentials to apply for a job as a medical writer. And I would suggest that a person remain for ~5 years as an FTE medical writer, in-house, before considering freelance work in pharma/biotech. However, if someone is willing to

hire an inexperienced person as a medical writer, then yes, a writing test would be appropriate. **Nevertheless, *writing* is the skill that needs to be assessed, not statistics, finance/budgets, graphic design, or marketing strategy.**

Outside of pharma/biotech, there are more opportunities for a new, inexperienced person to gain hands-on writing experience: nonprofit and professional medical/nursing/pharmacy associations, trade journals, local newspaper health sections, websites and blogs, hospital and other newsletters. These and other organizations are more amenable to trying out a new writer. If they choose to test your writing skills, yes, by all means, take the test! Just be sure you are not writing something without pay that they are going to use in any way other than as a test of your skills; this would be unethical on their part. Avoid these types of companies and individuals (and they are definitely out there).

—Cathryn Evans

In my opinion, writing tests or provision of writing assignments are OK only if the writer is being adequately compensated for the work. This applies to both new and experienced writers, neither of whom should ever work for free. Writing for free (or for a reduced or discounted rate) decreases the value of the writer and hurts all of us. Why hire a qualified writer at market rate when you can get the work done for far cheaper… or even free?

Imagine a company that needs to develop a booklet about a particular topic containing 10 articles that are 500 words each. They advertise a writing position and ask 10 candidates to each write an article as part of an unpaid "writing test." Guess what—the client just got an entire booklet written for free! Not only is this practice unethical, but it's also predatory.

Clients who want to try out new writers often give them small projects or revisions/updates of existing pieces to determine whether the writer or editor will be a good fit for the client, which is perfectly acceptable as long as the writer is paid for the work. While I have never completed a writing test or writing assignment as a sample for a potential client, I once took an editing test with the agreement that I would be compensated whether or not the client team was happy with my work (they were happy, I was compensated, and I'm still working for them 18 years later!).

Interestingly, a recent LinkedIn post revealed (to me) that this concept is not unique to our industry. In other fields, job candidates may be asked to complete small projects as part of the interview process. As with writing tests, the client gets the work for free. The point is that this practice is considered both unethical and predatory.

—Gail Flores

I have never taken a writing test or completed a writing assignment as a sample for a potential freelance client. Early in my freelance medical writing career, the request to do so arose only a few times, and I was so busy working with paying clients that I didn't have the time to prove myself to a potential client I didn't know. If I had been hungry for work, it may have been a different story.

As my career advanced and my professional experience grew, I turned down several other requests to take a writing test—not because I was too busy, but because I felt that my body of work and list of long-standing and satisfied clients should speak for themselves. I probably lost a couple of clients this way. But I'm not sorry for my decision. I can't imagine an attorney being given a law test before they're hired to handle a case, or an account supervisor a client management test. Would you ask a plumber to fix a leaking pipe for free so you can see how well they do, on the promise of future work to come? I don't think so.

Professional medical communicators have to prove themselves every day, on every assignment, for every client. When you're doing that, I don't think you should consent to a writing test or a sample writing assignment. Your samples—and if you cannot show samples for confidential or ethical reasons, your references—should be enough. If they're not, you probably don't want to work for the company anyway.

But I do think there's a time and place when completing such a test is reasonable and a good idea. When you're new to the profession and honestly don't yet have the experience, samples, or references to demonstrate your ability, a writing test or a sample writing assignment is an appropriate request and a way for you to demonstrate that you can do the job. I think it's also appropriate if you have experience in a specific area of medical writing, such as in the regulatory field or in publications, and you want to break into a new area in which you don't yet have experience, such as writing for lay audiences, or experience writing a certain type of deliverable, such as PowerPoint presentations.

—Brian Bass

Q What are some advantages and disadvantages of mentoring new writers or subcontracting work to new writers?

A Actually, there are 2 separate questions here: *mentoring* new writers, and *subcontracting* work to inexperienced writers. I have done both.

Most of my mentoring has been a professional courtesy, and I like helping new people. To me it is especially naive, if not arrogant and disrespectful of the profession, for an ESL

graduate with a science degree (PhD or otherwise) to "decide" to be a professional medical writer in English—unless, of course, that person is 100% fluent in English and already a very good English-language writer. I have been contacted by a number of such individuals, and I always ask, "Why do you want to be a professional writer?" (Most often they want to write in pharma/biotech because they have heard the money is good; money is NOT the right reason to choose a career in medical writing, in my opinion.) In any case, for serious candidates who actually have the capacity to become a professional medical writer, I often provide mentoring without charging. I also offer a mentoring service for which I charge a fee; I have provided this service to many new medical writers as well as to experienced medical writers who wish to switch from their present field to pharma/biotech.

The primary advantage of mentoring is that it makes you feel good to help someone else; deep down I feel that we all wish to help others in whatever way we can. Mentoring is one way to do this. Even with my paid mentoring service the money is not much, and I offer much more than what most people could get for the price—again, I do this because I wish to. When I gave workshops at AMWA and other conferences, nothing made me happier than to find out that one of my "students" had surpassed me. This is what all teachers, mentors, and parents want for their students and children. There are no disadvantages, in my opinion, unless you personally feel you are wasting your time on the person; I've not had that experience.

Subcontracting to inexperienced writers is definitely a double-edged sword. For more than 15 years I had an office with a full-time word processing person and up to about 7 subcontractors at any given time. Most were freelance writers who worked in their own offices/homes. Often, I had 2 "in training": they came into the office every day when I had large projects, and we all worked together on various aspects of the projects. They learned on the job; it was highly stressful for me because I had multiple clients, several projects, and sometimes hard deadlines. Too often, I had to redo their work—it was particularly hellish and time-consuming when I had to redo tables because the person did not understand how to interpret/extract the data properly (or simply made too many errors) from voluminous data printouts (despite having been told and shown). Of course, I always had to edit, which is expected—and frequently I had to rewrite—but they eventually did learn and improve so that the necessity for that lessened over time.

The advantage of hiring subcontractors is that you can leverage your business and make more money because the inexperienced "trainee" can be hired for less. Also, it is energizing and fun to work with others; I became very good friends with several subcontractors. **The disadvantage is that you can lose your shirt** if you have to rewrite and rethink too many projects—because, of course, you cannot charge your client for the time you spend redoing an inexperienced person's work! Training others can be very time-consuming, as can revising their work. You need to have a very good reason for doing this. Large companies perhaps have policies about hiring interns and trainees, and this is where I suggest the new person search for opportunities first. For me, subcontracting was one of the most difficult aspects of my business, except when I farmed out to the good, experienced writers—in those cases, my profit was less because I paid the experienced writers a fee corresponding to their experience.

Some of the writers I have mentored, trained, and hired ended up becoming great writers and taking full-time jobs with other companies and/or agencies. They have all been truly grateful for the experience.

I have chosen not to continue subcontracting and/or training new writers. I continue to provide mentoring services, both paid and unpaid.

—Cathryn Evans

I'll answer this question as an editor mentoring new editors or subcontracting work to new editors.

Mentoring new editors is a way to give back to our industry and create good working relationships. I have mentored 2 people closely (reviewing work and giving feedback for several months) and numerous others to varying degrees (eg, answering questions about equipment, software, and how to find clients; discussing rates; sharing samples of contracts and useful emails; suggesting good organizations to join, like AMWA).

Some of the advantages are that I have the opportunity to share my expertise with friends breaking into the industry and I feel good about helping others. Mentoring helps alleviate the sense of isolation from working alone; we bond by email while discussing work issues, much like colleagues in an office would bond in the break room or by the cooler.

The disadvantages to mentoring new editors are few. I very much want editors in the field to succeed, and I'm willing to help out when someone who demonstrates self-motivation reaches out to me for guidance. A common concern is that the person being mentored will take up too much time that could be spent billing clients. Yet I haven't found that to be the case. Most people appreciate the help and go off on their own path. I set clear boundaries: for example, if I'm swamped I'll indicate in an email that I'm working under a deadline and can answer questions later.

I do not subcontract work, but when clients contact me and I'm busy or I don't have expertise in their project, I do refer them to new (and seasoned) editors whose work I have come to know well through working together. Referring other free-

lances reflects well on me because I am helping the client, helping my colleagues, and everyone benefits.

—Melissa L. Bogen

For the Winter 2015 issue of the *AMWA Journal*, Freelance Forum, I provided an answer to the question/topic: *Do you work with subcontractors? How do you hire and manage them effectively?* Much of that same advice applies to working with new writers, whether they are (or become) a subcontractor to you or they are a person you are mentoring (a "mentee"). I will tailor my response here more toward the mentoring aspects.

I get a lot of requests for advice from people who want to be a medical writer and want to know how to break into the field. It's probably true that the best way to enter into the profession is to have a mentor from whom you can gain a little knowledge and experience; however, potential mentors may be hard to find and are very likely busy! Although I can't take on a mentorship role for everyone who asks me for advice (or for a job), I always try to help them in some way. For example, I tell people about the different kinds of medical writing and give them website links, reading materials, or other resources (AMWA is always at the top of the list!).

Some of the people I mentor do become my subcontractors—after a confidentiality agreement is signed, expectations/timing are discussed and put in writing, etc. (See my response about working with subcontractors in the Winter 2015 issue of the *AMWA Journal*.) The advantages of mentoring are what you might expect: it makes you feel good to help others, it can bring talented people into the profession, and it allows you to take on more projects and expand your business when you hire your mentees as subcontractors. The disadvantages are also what you might expect: your mentee might not "catch on" like you had hoped, you have to spend more time than expected training them or correcting their work, and the good ones might become your new competition!

I am very proud of the people I have mentored in the medical writing profession. Many of them have gone on to become very successful freelance writers (and mostly not my competition). However, this means, unfortunately, that they don't have time for me anymore. Nevertheless, some have become lifelong friends and colleagues—and that is the greatest reward of mentoring I can think of!

—Sherri Bowen

Q Do you utilize online free or paid webinars, courses, and/or podcasts to expand your knowledge in your field? What are some of your favorite/recommended webinars, courses, or podcasts?

A I'm a big believer in continuous learning, so I'm always listening to podcasts, attending webinars, and taking courses. Podcasts are always free, so I'll start with them. My favorite podcasts are "Unemployable" by Brian Clark, which provides advice and resources for freelances and others, and Ed Gandia's "High-Income Business Writing" and "Marketing Mentor" podcasts.

I don't have any favorite sources for webinars, other than AMWA, which has a section on its website for webinars on freelancing. I usually hear about other webinars from the various email lists I'm on. The free webinars almost always include a sales pitch for a product or service, but they usually have enough relevant content that they're worthwhile.

Often, I find out about courses from the podcasts or webinars. I took Seth Godin's "Freelancer Course" on Udemy after learning about it from an "Unemployable" podcast. Udemy is my go-to platform for courses. I've taken 3 Udemy courses (developing videos and infographics along with the freelance course). These self-paced courses have been interesting and informative, and Udemy is very easy to use. The courses are reasonably priced; I paid between $29 and $49 for each.

—Lori De Milto

I've participated in several free and paid webinars over the years. Most of these have focused on the business of freelance medical writing, such as maximizing freelance medical writing income, marketing, and using LinkedIn. I've found them all to be beneficial. I've also taken a couple of cancer therapy webinars through Fierce Biotech, which were not quite as useful, but still worth my time. I usually set up my webinars on one computer monitor and do busywork on my other monitor if the webinar gets slow or boring; if it's really bad, I can just end it and move on with my day—although that hasn't happened yet.

—Gail Flores

Join Us in Our Nation's Capital: The 2018 Medical Writing & Communication Conference

Ann Winter-Vann, PhD / Senior Writer & Manager at Whitsell Innovations, Inc., Chapel Hill, NC

An embarrassment of riches! As we reviewed the proposals for the 2018 Medical Writing & Communication Conference, this was the phrase that came to my mind. In every category and across every level of expertise, the submissions were exceptional. The 2018 Annual Conference Committee had to work hard to pare down the number of proposals to fit the conference program—resulting in an outstanding selection of open sessions and featuring invited speakers from the US Food and Drug Administration (FDA) and the National Cancer Institute (NCI). We think you will be thrilled with the program for this year's conference, to be held November 1-3 in Washington, DC.

Join us for preconference sessions and AMWA Workshops on Wednesday, October 31. Attendees who are new to the field of medical writing will want to attend the *New to AMWA and Medical Communication* session and stick around to learn how to identify the experience and expertise needed to succeed and how to make a career out of medical writing. Experienced writers can participate in a session to discover how a writer turned her freelance business into a successful company. And everyone can learn new tricks by joining us for a Word masterclass. Perhaps you are thinking about winding down your career? Then consider attending our preconference session on retirement planning.

Once again, AMWA is pleased to host the Board of Editors in the Life Sciences certification examination. The exam will be held from 9 AM to noon on Wednesday, October 31 (application process and fees apply; see www.bels.org for more details). For those who are interested in taking the Medical Writing Certified (MWC) examination, we will be holding roundtable discussions on Friday and Saturday to share the best strategies for preparing for the certification exam, which is now offered at testing centers worldwide. (Sign up quickly, as space at these tables is severely limited!)

Many of this year's hottest topics are represented in the conference program, including precision medicine, the opioid crisis, cancer immunotherapy, pitch decks, instructional design, and yes, fake news in medicine.

AMWA Workshops are offered every day of the conference, providing many opportunities to brush up on writing skills or gain in-depth knowledge of a topic of interest. See the conference brochure (www.amwa.org/resource/resmgr/conference/2018/2018AMWABrochure.pdf) for a full listing of AMWA Workshops. In the mood for a taste of something new? Join a small group of attendees for breakfast or lunch at one of almost 60 roundtable sessions. Back by popular demand is the *Jam Session for Seasoned Freelances*—intended for experienced freelances. Those just getting started in a freelance career can join us for a new tradition: a *Jam Session for Early Career Freelances*. Not a freelance? Mid-career writers in the corporate world will have the opportunity to chat about challenges and strategies for success in our *Jam Session for Mid-Career Managers*.

Many of this year's hottest topics are represented in the conference program, including precision medicine, the opioid crisis, cancer immunotherapy, pitch decks, instructional design, and yes, fake news in medicine. New regulatory writers can follow data from a protocol to a package insert, learn about pharmacovigilance writing, and discover how to avoid QC detours. Those with several years of regulatory experience can learn how to respond to questions from regulatory agencies, understand the new requirements for writing clinical evaluation reports, and discover the benefits of the common protocol template. Publications writers can pick up some new *Tips for Efficiently Writing Scientific*

Link. Learn. Lead.

Publications and review the *Writes and Wrongs of Publication Ethics*. Grant writers can dissect the Specific Aims page, put the National Institutes of Health biosketch to work, and learn how edit grants to appeal to reviewers.

We are thrilled to announce this year's Alvarez Award winner, Robert Califf, MD, MACC, Professor of Cardiology at the Duke University School of Medicine, and former Commissioner of the US FDA. Dr Califf will present the Alvarez Address in a general session on Friday, November 2. In addition, we hope that you will join us earlier that day in welcoming invited speakers Cynthia Lollar and James Mathews of the NCI as they present their acclaimed workshop *The Power of Story in Science Communication.*

Robert Califf, MD, MACC

This year, the conference will return to Washington, DC for the first time in 50 years! Not only do a large number of direct flights make it easy to travel to the city, but the Renaissance Washington, DC Downtown Hotel is centrally located within the city. Craving Cuban food? Greek, Spanish, French, Cajun, or Asian cuisine? These options and more can be found within 4 blocks of the hotel. For anyone who wants to come early or spend time after the end of the conference, Washington, DC has an extraordinary selection of museums, monuments, and attractions, many of which are within walking distance or an easy Metro ride from the hotel.

Hurry! Early bird registration is a steal, but it's only available through June 15. However, even the regular member rate of $795 for the full conference registration is a great deal for this exceptional program—and the opportunity to Link, Learn, and Lead with AMWA this November in Washington, DC.

From the President
Time Flies...

By Kathy Spiegel, PhD, MWC / 2017–2018 AMWA President

I am finding it hard to believe that I am already halfway through my presidential year! However, as I sit down to write up this column and I reflect on how much the organization has accomplished, it is hard to believe that it has only been a few months. They say time moves fast when you are having fun, and I am certainly having an amazing time serving as the leader of this professional home we all share.

One of the most exciting things we debuted this year is a series of professionally produced videos. Those of you who attended the 2017 Medical Writing & Communication Conference in Orlando may remember the film crew we had onsite conducting interviews and recording live footage from the event. We are so grateful to all the members who took time to share their thoughts on the value of their AMWA membership with us. The first video, "The Value of AMWA Membership," can be found on the website at www.amwa.org/Membership. We encourage you to share it via social media and spread the word about all AMWA has to offer medical communication professionals. The next video is about AMWA's Medical Writing & Communication Conference (www.amwa.org/conference), and more videos are in development. Be sure to follow us on Twitter, Facebook, and LinkedIn to see all the videos as they are posted.

In other digital news, AMWA now offers the Essential Skills Workbooks in digital format. Authored by industry experts, the workbooks are designed for medical communicators at all levels of experience and provide long-term value as refer-ence guides. By offering the workbooks online, AMWA can fur-ther its mission to deliver relevant and accessible educational resources for medical communicators. Digital delivery of the workbooks will enhance AMWA's ability to meet the different learning needs of medical communicators as well as expand the audience for these highly rated and well-regarded educational products.

An added benefit of taking the workbooks digital—it is now more convenient than ever to earn credit for AMWA's Essential Skills (ES) Certificate Program. In fact, it is now possible to complete the ES Certificate Program entirely online! The ES Certificate Program is designed to help you refine your editing, writing, communication, and bibliographic skills. AMWA's ES Express package includes certificate program enrollment, all 7 workbooks, and study guides.

AMWA really is on a roll in delivering products and creating services that are more accessible to the medical writing community. You may have seen the announcement in the last issue of the *Journal* that the Medical Writer Certified (MWC) Examination will now be administered via computer-based testing at IQT testing centers near major cities across the globe in June and December. As this issue of the *Journal* arrives in your inbox or your mailbox, medical writers will be taking the exam to earn the MWC credential through computer-based testing during the June exam window. This is a great time to put earning the credential on your list of career goals for 2018. There is another testing window in December, and the Medical Writing Certification Commission (MWCC) has just released a new Applicant and Candidate Handbook and Study Guide to help candidates prepare for the exam.

I am very proud of the work AMWA has done to expand its digital presence and publish more content online. This work would not be possible without the strong partnership between the AMWA Board of Directors (BOD), staff, and dedicated members. The heart of AMWA remains its members. The relationships that members form with each other, online or in person, are what make AMWA the warmest and most welcoming professional community in the medical and scientific space! AMWA Chapters are designed to ensure that this unique and valuable community experience is available to members at the regional and local level. AMWA has 2 new volunteer groups working to support chapter leaders in their important roles to bring members together and provide educational and networking opportunities. The Chapter Advisory Council (CAC) serves to connect chapter leaders and the AMWA BOD by advising the BOD on the organization's strategic direction as it affects the chapters. It also acts as a sounding board for issues that have an impact on chapters, the national organization, or both. The Chapter Support Committee identifies and creates resources that support AMWA Chapter leaders and activities. This group also facilitates quarterly chapter leader teleconferences to help expand the network and share resources between AMWA members working to enhance the value of AMWA Chapters. The CAC and Chapter Support Committee work closely together and with the national BOD to enhance the local chapter experience.

AMWA Chapters host at least 4 education and/or networking events each year. More than half of chapters host monthly events, and 7 chapters (Carolinas, Delaware Valley, Mid-Atlantic, Greater Chicago, Indiana, Southwest, Northern California) planned conferences this year. Several chapters have embraced the regional networking concept and have developed unique ways to meet the geographic challenges that exist where chapters span several states or even regions within a large state. In areas without chapters, Local Networking Coordinators (LNCs) help coordinate events in cities and suburbs around the country. I am so grateful for the support of all chapter leaders and local volunteers who are so supportive of AMWA members in their area. Thank you!

While we are doing more online, AMWA's in-person networking and learning experiences are the hallmark of our community. AMWA Workshops, which are 3-hour, intensive, small-group programs featured at the AMWA annual conference and at chapter conferences, continue to be a valued and important part of AMWA's education portfolio. In addition, interest in AMWA's onsite corporate training workshops has spiked over the past several years, and we are expanding the pool of workshop leaders to meet the demand. As the breadth of our educational activities increases, so does the need for qualified trainers. The AMWA Education Committee is soliciting candidates to join the AMWA faculty. If you or someone you know is interested, please email education@amwa.org to find out more about this opportunity.

Looking back over the past few months, I am truly amazed by the efforts of our volunteers at both the local and national level that have enabled AMWA to accomplish so much. Looking ahead, I'm excited for all the initiatives underway to build on that momentum. From the AMWA Board of Directors to national committees, chapter leaders, and Local Networking Coordinators, AMWA's success comes from the collective efforts of its members. You are always welcome to join us in these efforts, even if you have limited time to spare. If you are interested in learning more about volunteer opportunities at the national or chapter level, visit www.amwa.org/page/About_Us or contact me at president@amwa.org.

Check out the *Journal's* Expanded Footprint at the AMWA Blog

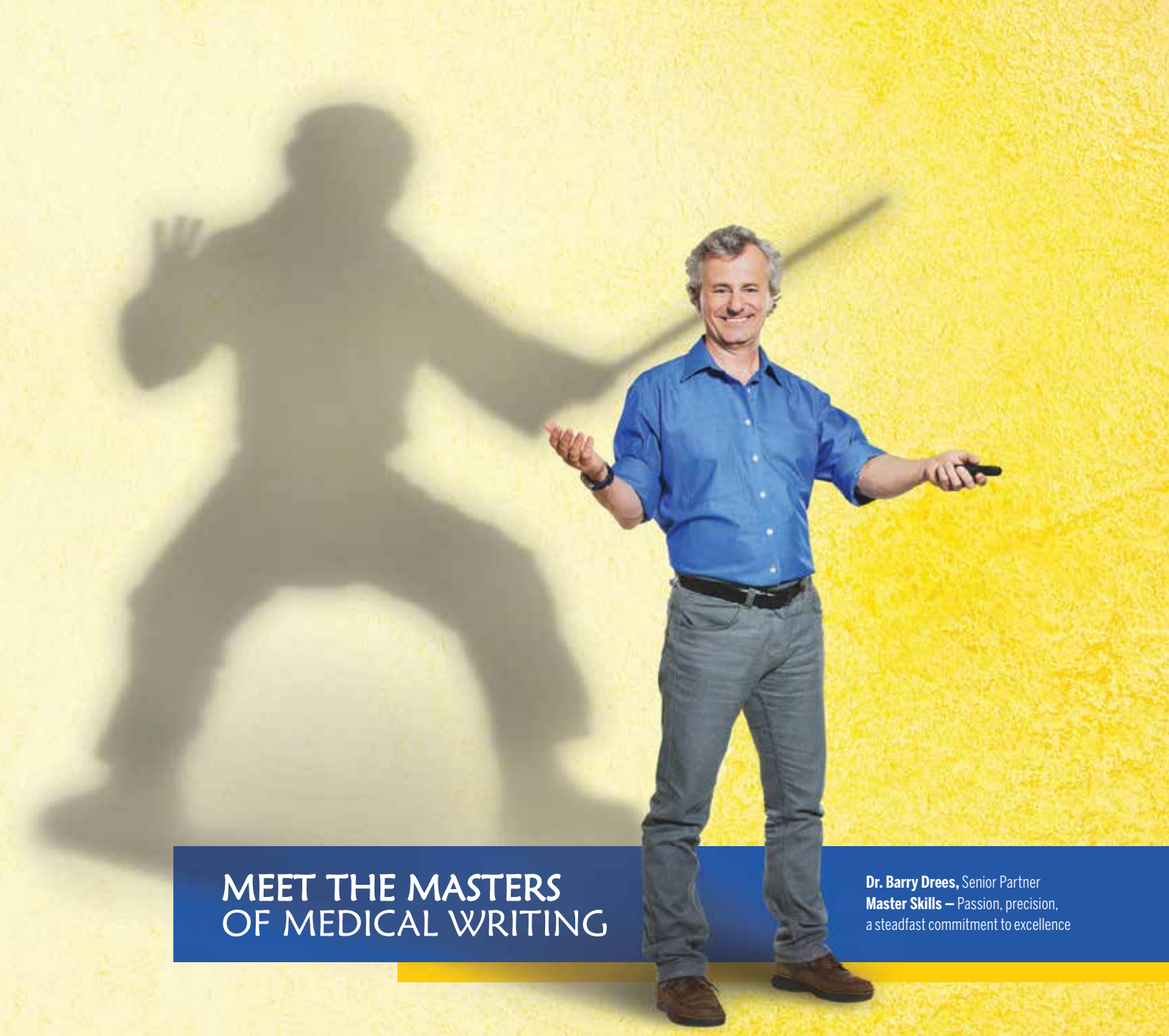
Cynthia L. Kryder, MS / Social Media Section Editor

In 2017 the *AMWA Journal* launched a series of monthly blogs to inform you about additional resources available through "sister" organizations in our industry. We're continuing to blog each month, but this year with a focus on *Journal* content you may have missed when it was first published.

Check out some of our recent posts by *Journal* section editors:

- Jennifer Bridgers, Regulatory Insights Editor, shared some resources from the *AMWA Journal* that discuss ways to plan ahead in clinical trials.
- Kim Korwek, Around the Career Block Section Editor, highlighted 3 past *Journal* articles that offer tips for advancing your career.
- Dom De Bellis, Science Series Section Editor, plowed deep into *Journal* archives and found 2 foundational articles about the nervous system. What does Paul Simon's recording of *You Can Call Me Al* have to do with the nervous system? Read his post to find out.

If you haven't yet checked out the AMWA blog (at engage.amwa.org/blogs), make sure you do. The *Journal* shares blog space with other AMWA members who write about topics to educate and entertain you. If you have a topic you'd like to write about, get in touch with me.



MEET THE MASTERS OF MEDICAL WRITING

Dr. Barry Drees, Senior Partner
Master Skills – Passion, precision, a steadfast commitment to excellence

Mediocre medical writing has met its match. At Trilogy, we do more than get to the point quicker. We get to your point quicker. Because when it comes to getting a drug approved, a well-written story is a well-read story. With so much on the line, doesn't it make sense to hire the medical writing masters?

Visit us at TrilogyWriting.com
writers@trilogywriting.com

TRILOGY
Writing & Consulting

REWRITING
MEDICAL WRITING