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COMMENTARY

Health Literacy: The Common Denominator of Healthcare Progress

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> People are the common denominator of progress … Conquest of illiteracy comes first [1].
>
> John Kenneth Galbraith

1 Introduction: Embracing the Lessons of COVID-19

Perhaps the most important lesson learned from the COVID-19 experience is that American health illiteracy kills. From confusion over the value of wearing protective masks and social distancing (*How are viruses transmitted?*) to vaccine skepticism (*How do vaccines work?*), from confusion over the value of hydroxychloroquine (*How are data collected and what do they mean?*) to doubts about the safety and efficacy of products available through Emergency Use Authorizations (*How does the US Food and Drug Administration review process work?*), the dearth of health literacy has not only slowed down the US response against COVID-19, it has placed thorny societal problems along the path to victory over the virus. Nature abhors a vacuum—and so does social media.

Health literacy comprises two parts [2]:

- *Personal health literacy* is the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.
- *Organizational health literacy* is the degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

As we study our national responses to COVID-19 to better plan for the next public health emergency, a key global learning is that health literacy is an integral part of pandemic preparedness and a broader facilitator of positive healthcare behavior and outcomes. Health literacy facilitates public health messages that are not only understandable but motivational and actionable.

According to the US Health Resources and Services Administration, health literacy is "the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions" [3]. Health literacy is capacity building. It is crucial infrastructure development. And it is being ignored.

2 The Value of Health Literacy

The value of health literacy extends far beyond the boundaries of COVID-19. Education leads to fact-based empowerment and an educated healthcare consumer can be a potent change agent.

Consider medication adherence and compliance. Medication nonadherence is widespread with nonadherence rates that range from 25 to 50% [4]. Every year, 125,000 Americans die from not taking their medications, a staggering number that also costs the US health system some $289 billion annually [5]. One potent tool for recapturing and redirecting these healthcare resources is health literacy. Safe and effective. Knowledge is power.

Low levels of health literacy are a source of health disparities among disadvantaged communities and minorities. Of the nearly 77 million Americans who struggle with health-related reading tasks, 65% are minorities [6]. The issue of health literacy and minority communities is not new, but it has been rediscovered because of COVID-19, specifically because of the problem of vaccine hesitancy driven by historic distrust of government-sponsored healthcare programs [7] and a perceived lack of clinical trial diversity.

One reason minorities and communities of color have been hesitant to embrace COVID-19 vaccines is that they

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do not see "people like me" in clinical trials [8]. An easy excuse is that groups are represented proportionally to their ranking in the general population. But that is an excuse. As with many health conditions (e.g., diabetes mellitus, cardiovascular disease, cancer), "diverse" communities suffer disproportionally. COVID-19 is only the most recent example with death rates and serious manifestations of the virus far outpacing the relative impact on white America. African-American individuals are experiencing COVID-19 death tolls exceeding 1 in 800 nationally, while White Americans are experiencing a death toll at 1 in 3125 nationally. African-American individuals have COVID-19 death rates of more than 2.7 times those of White Americans [9]. There are many reasons for this and there is no single "magic bullet" solution. Health literacy, alone and in combination with other "therapies," however, should be considered at or near the top of the list of post-pandemic public health priorities.

3 Health Literacy as a Tool in Achieving Clinical Trial Diversity

In an age of precision medicine [10], health literacy can be a powerful tool to improve both clinical trial diversity and overall data sensitivity. Addressing diversity in clinical trials is a bell-weather issue when it comes to advancing health literacy. We are all learning the nuanced differences between "equality" and "equity". *Equality* means each individual or group of people is given the same resources or opportunities. *Equity* recognizes that each person has different circumstances and allocates the exact resources and opportunities needed to reach an equal outcome [11].

A recent study of Pfizer-sponsored clinical trials [12] showed that between 2011 and 2020, Black or African-American participants made up 14.3% of 212 trials for which data on race were collected. African-American individuals represent about 13.4% of the US population. But when broken down by trial, only about half of Pfizer's studies (56.1%) surpassed census levels for Black participants. Only 15.8% of Pfizer's oncology trials reached census levels for Black participants, compared with 78.9% for White participants. The percentage of trials overall to exceed census levels for White participants was 51.4%.

Asian-American individuals made up 3.1% of trials compared with 5.9% of the US population. Hispanic or Latinx participants represented 15.9% of trials, vs 18.5% of the population. In total, 16% of Pfizer's trials surpassed census levels for Asian participants, compared with 14.2% for Native Hawaiian or Pacific Islanders, and just 8.5% for American Indian or Alaskan Native individuals.

Those numbers are par for the course in biopharma, where minority groups have historically been left out of clinical trials. Of the 53 drugs approved this past year, Black patients represented about 8% of participants in the trials that regulators based their decisions on (and for which data on race were collected) [13].

Why are there not more minorities and people of color recruited for clinical trials in the USA? The usual and customary explanation is because of historic distrust of the government (e.g., Tuskegee, Henrietta Lacks) [14]. But this is only one of many issues. Participation in clinical trials research is a rigorous and demanding enterprise. Another associated long-term impediment is that physicians and other research professionals have their own cognitive biases concerning who they believe will comply with difficult therapeutic regimens [15] required for proper participation in clinical trials. Many physicians believe African–American individuals are two thirds as likely to be adherent as are their White patients [15].

We must be aware of and fight against such normative bias (aka 'racism'). Despite these factors, research demonstrates that minorities are, in fact, willing to participate in clinical trials. Minority groups are as willing to participate as White American individuals but that are not asked to (literally) sit down and roll up their sleeves [16]. In a health literacy issue brief, the Secretary's Advisory Committee noted, "As health literacy research and practice have accumulated, we now more fully understand that responsibility for health literacy extends beyond individuals to include the organizations and professionals who create and deliver health information and services [17]." Physicians and healthcare professionals must also advance their own health literacy. Perhaps we need continuing medical education for health literacy.

4 Health Literacy and Pharmacovigilance

Pharmacovigilance traditionally relies on physicians and pharmaceutical manufacturers as the two main pillars of reporting, with the overwhelming volume coming from industry (as well as a small but growing and significant contribution coming directly from patients and healthcare providers) [18]. Pharmacovigilance has not been a large experimental ground for patient participation; on the one hand, this is because it has always been perceived as an area where only healthcare professionals have the right competence to deal with adverse events and the associated risks, and on the other hand, because patients have not historically been encouraged to play an active role in this issue. With an increasing number of drugs being approved on shorter trials that involve fewer patients, obtaining timely and accurate reports of adverse events and side effects after approval from all members of the post-marketing ecosystem is more important than ever [19].

In both the USA and the European Union, proactive pharmacovigilance efforts by both regulators and pharmaceutical companies have escalated in recent times through (among other efforts) an increased use of real-world data, gathered and validated across multiple sources after a medicine has been approved [20]. A more health literate population can make post-marketing surveillance a more complete three-dimensional proposition.

The value of obtaining the patient perspective regarding the benefit–risk profile of medicinal products is being increasingly acknowledged by regulatory authorities [21]. Enhanced health literacy has the very real potential to enable a more significant contribution from a broader constituency of patients and caregivers of timely and accurate knowledge on issues that arise in the post-marketing environment including adverse event reporting, quality-of-life information [22], and the collection of real-world data [23]. Health literacy is a potent tool to advance 21st century pharmacovigilance.

5 The Need for a National "Health Literacy Czar"

Health literacy programs will not spring fully developed and ready for action from the head of Zeus, Anthony Fauci (the director of the US National Institute of Allergy and Infectious Diseases) or anyone else. Another lesson learned from the COVID-19 experience is that, when it comes to healthcare communications, one size does not fit all, but that the Federal Government can play the role of Convener-in-Chief. Content, curriculum, funding, logistics, measurement, and other details must be a consensus-driven proposition. And it must be politics free. Step one is to agree on what 'success' looks like. Nobody said it was going to be easy.

We suggest the US President appoint a 'Health Literacy Czar,' empowered (initially) to develop a long-term national strategy aimed at increasing the levels of knowledge on a wide range of topics across a broad national constituency. Such a plan could include a national K-12 educational curriculum for students, more advanced modules for medical and pharmacy schools, and professional and post-graduate professional education courses (e.g., continuing medical education). America's Health Literacy Czar. A good first step would be to establish a Presidential Blue-Ribbon Commission on Advancing America Health Literacy in the 21st Century.

6 The Urgency of Personal Responsibility

To advance an honest and robust health literacy agenda, we must understand and embrace another key learning from the COVID-19 experience—that when we all work together (e.g., government, academia, industry, healthcare providers, caregivers, educators, community leaders, patients) we can achieve miraculous things at warp speed. Seneca said "Life speeds on with a hurried step." When it comes to a bold long-term national program to achieve a high national health literacy standard, the three key facilitators of success are trust, transparency, and broad participation.

7 Conclusions

Health literacy is not passive, it is participatory and a foundation for positive behavioral change. Individuals with adequate levels of health literacy have the ability to take responsibility for their own health as well as family and community well-being [24]. The Office of Behavioral and Social Sciences Research was created by Congress in 1993 and is responsible for coordinating the health-relevant behavioral and social sciences and identifying challenges and opportunities to advance these sciences at the National Institutes of Science [25]. Increasing its funding should be a top post-pandemic priority. Just as there is no 'magic pill' for good health, there is no 'magic solution' for health literacy. It will take time, hard work, and commitment to convene the critical disciplines that can inform programs, practices, and metrics. There will be mistakes, set-backs, and frustration. Most importantly, success rests on personal responsibility.

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