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COVID-19 Vaccination: Potential Challenges and Reforms

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Abstract: Minority groups continue to suffer disproportionately from COVID-19’s impact, with Blacks and Hispanics three times more likely to die from the disease than their White counterparts. The COVID-19 vaccine rollout has the potential to provide relief to these most adversely impacted communities. However, historic mistrust within racial minority communities threatens to derail the effective implementation of a vaccination program. The origin of this mistrust is multifactorial. Current day experience with structural racism and research abuses like Tuskegee Study collectively influence our perception of biased healthcare system. We outline issues and propose solutions that must be addressed to achieve a successful vaccination agenda. Mishandling of public expectations at any point may lead to an avalanche of vaccine opposition which might be unrecoverable.

Keywords: COVID-19 ■ Healthcare disparity ■ Health policy ■ Equity ■ Structural racism ■ Minority groups ■ Vaccine

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HOPE TAINTED WITH AMBIGUITY

Recent data from the CDC revealed that Blacks and Hispanics continue to suffer disproportionately from COVID-19’s impact with those groups four times more likely to be hospitalized and three times more likely to die from the disease than their White counterparts. This disproportionate impact has been attributed to a higher prevalence of underlying health conditions, social determinants such as residential crowding, higher rates of essential worker status and the insidious effects of day to day racism on one’s immunity or “weathering.”

The COVID-19 vaccines represent the near term possibility of relief for these most adversely impacted communities. However, historic levels of institutionalized mistrust within racial minority communities and poor Whites threaten to derail an effective implementation of a vaccination program. As a Black physician, I sit on both sides of this equation understanding the potential “lifeline” medical innovation that COVID-19 vaccine technology represents. Alternatively, having been born in the tail end of the civil right era, I have heard the stories of unethical medical research from family members, studied the sordid Tuskegee Study and witnessed immediate family members receive disparate medical recommendations before I was formally trained in medicine and understood what, in fact, was happening. Experiences like the Flint water crisis continue to demonstrate broad gaps in oversight of public health especially as it pertains to Black Americans.

Trust is a complex notion extending across several domains. A patient’s trust in her personal physician may occur by way of the borrowed credibility of a friend or family member’s referral. Ultimately, as with other human interactions, trust must be earned by the physician over time and it requires an investment of effort. Trust in our general society and in the healthcare delivery system, is derived from personal experiences, family and community observations over time as well as media representations.

The US Public Health Services Study at Tuskegee is one of the most widely cited examples of unethical medical research behavior directed at African Americans, yet less than half of Americans are aware of this event. From 1932 to 1972 African American men living in Macon County, Alabama and known to have syphilis, were enrolled in this trial. These men were followed over time by researchers to observe the effects of syphilis. Although effective treatments for syphilis became available in the 1940’s, the trial participants were not made aware. As a result, the participants and their family’s suffered avoidable medical illness.

In 1972, after a newspaper published a description of the trial, a congressional committee opened an investigation into the events. As a result, in 1978 historical regulations around the design and conduct of medical research in human subjects were issued in the form of the Belmont Report. This document, to this day, is the primary guidance in the conduct of medical research. The revelation of this egregious violation of the African American communities’ trust was addressed in a public apology by President Clinton in a 1997 White House ceremony.

STRUCTURAL RACISM

The Covid-19 pandemic’s disproportionate impact on minority communities has underscored the impact of
structural racism. Structural racism is not the act of a few individuals or organizations but instead represents the combined impact of socioeconomic, educational, criminal justice, healthcare and political societal inequity. Structural racism is the collective, current result of our societies past actions accompanied by a failure to acknowledge the inequitable impact of those actions across a diverse group of Americans. At its foundation, structural racism, contradicts the promise of our founding fathers that “all Americans are equal” and have an “unalienable right of life, liberty and the pursuit of happiness”.

Indeed, I, as a Black person in the US, do understand the irony in the suggestion being made to minority communities to “trust” society and the medical community to assume a paternal role in making appropriate and ethical decisions around the delivery of the COVID-19 vaccination to our community. I too believe it’s not enough for society and healthcare providers to say “just trust us”. I propose that the following issues should be addressed to ensure that we use this current public health crisis to do right and to do better. We, as a society and healthcare providers, should not miss this opportunity to advance our relationship with historically marginalized and under resourced communities. It is in our overall society’s self-serving best interest to do so.

CRISIS OPPORTUNITY

First, the primary authoritative role of data driven medical science and ethical research in the guidance of COVID decision making must be actively promoted by the Federal government in partnership with State and Municipal healthcare agencies. One major concern to the public is that for political reasons the goal to rapidly innovate a vaccine may impact the FDA’s judgment in a way that reduces the vaccines’ safety. The politicization of COVID-19 must be overcome by the dissemination of a consistent message from governmental and public health organizations. This goal is supported by the pharmaceutical companies’ public pledge that they will “stand with science” and not submit a vaccine for approval until it has been favorably vetted for safety and efficacy. Existing community facing organizations should be involved to assist with dissemination of accurate vaccine information. Trusted and knowledgeable minority physicians within local communities should lead the way.

Second, a historical lack of trust within minority requires a promise of transparency regarding the methodology and strategy of the equitable distribution of the vaccine. After roll out of the vaccine program, prompt and ongoing disclosure of the treatment side effects are essential. This is particularly important for the Pfizer® and Moderna® vaccination whose administration will require two separate dosages approximately 4 weeks apart. All vaccinations have side effects-mostly mild that go away within few days. Mishandling of public expectations at any point may lead to an avalanche of “vaccine opposition” which might be unrecoverable. Additionally, racial minority communities and poor Whites experience lower rates of health insurance. Consideration should be given to creating a fund to cover any unexpected medical costs that patients incur as a result of receiving the vaccine.

Finally, funding for a broad community directed informational campaign is necessary “to make the case” that broad uptake of the COVID vaccine in all communities is necessary for the US to overcome the pause in every citizen’s life and our economy. Epidemiologists suggest that 70% of Americans must have COVID-19 immunity i.e., herd immunity, to halt the pandemic’s spread. The vaccination program must succeed in every community across America. A message which is culturally, socioeconomically, educationally diverse and speaks to the local concerns of a broad America is essential.

Martin Luther King said, “of all forms of inequality, injustice in healthcare is the most shocking and inhuman”. This idea is no less compelling today than it was in 1966 when Dr. King first lamented. Let us not miss this shared opportunity to change the course of this generational health crisis.

REFERENCES

1. CDC. (2020). Coronavirus Disease 2019 (COVID-19). Centers for disease control and prevention. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html. Accessed December 15, 2020.
2. Tai, D. B. G., Shah, A., Doubeni, C. A., Sia, I. G., & Wieland, M. L. (2020). The disproportionate impact of COVID-19 on racial and ethnic minorities in the United States. Clin Infect Dis. https://doi.org/10.1093/cid/ciaa815.
3. Gilson, L. (2003). Trust and the development of health care as a social institution. Soc Sci Med, 56(7), 1453–1468.
4. McCallum, J. M., Arekere, D. M., Green, B. L., Katz, R. V., & Rivers, B. M. (2006). Awareness and knowledge of the U.S. Public health service syphilis Study at tuskegee: implications for biomedical research. J Health Care Poor Underserved, 17(4), 716–733.
5. Tuskegee Study - Timeline - CDC - NCHHSTP. https://www.cdc.gov/tuskegee/timeline.htm, (2020). Accessed December 18, 2020.

6. Institutional review boards and the Belmont principles. https://sphweb.bumc.bu.edu/otlt/mph-modules/ep/ep713_researchethics/ep713_researchethics3.html. Accessed December 15, 2020.

7. Egede, L. E., & Walker, R. J. (2020). Structural racism, social risk factors, and covid-19 - a dangerous convergence for Black Americans. N Engl J Med, 383(12), e77.

8. Declaration of Independence: A Transcription. (2015). National Archives. https://www.archives.gov/founding-docs/declaration-transcript. Accessed December 15, 2020.

9. Pogue, K., Jensen, J. L., Stancil, C. K., et al. (2020). Influences on attitudes regarding potential COVID-19 vaccination in the United States. Vaccines, 8(4), 582.

10. Thomas, K. (2020). 9 Drug Companies Pledge to ‘Stand with Science’ on Coronavirus Vaccines. The New York Times. https://www.nytimes.com/2020/09/08/health/9-drug-companies-pledge-coronavirus-vaccine.html. Accessed December 15, 2020.

11. Vaccines: Vac-Gen/Side Effects. https://www.cdc.gov/vaccines/vac-gen/side-effects.htm, (2020). Accessed December 16, 2020.

12. Randolph, H. E., & Barreiro, L. B. (2020). Herd immunity: understanding COVID-19. Immunity, 52(5), 737–741.