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ANALYSIS

Reflections On Governance, Communication, And Equity: Challenges And Opportunities In COVID-19 Vaccination

ABSTRACT The US response to coronavirus disease 2019 (COVID-19) has been plagued with politics driving public health and messaging. As a result, COVID-19 vaccine roll out is occurring in an environment ill-equipped to achieve broad acceptance of the vaccine. Addressing Public concerns unlocks the potential for high vaccine coverage; this is best achieved when science and values, not politics, informs public health. A multifaceted and thorough engagement and communication plan responsive to the concerns and values of different groups must be swiftly yet carefully implemented in a coordinated manner by federal, state, and local governments. Effective communication will require rapid and rigorous science to promptly differentiate between adverse events following immunization which are causally related versus simply coincidental. Health care providers, in particular, will need support to process the otherwise potentially overwhelming amount of relevant information and effectively integrate it into discussions with their patients to support their decision-making. An equitable COVID-19 immunization program could substantively reduce the disproportionate risks associated with this pandemic. [*Editor's Note: This Fast Track Ahead Of Print article is the accepted version of the peer-reviewed manuscript. The final edited version will appear in an upcoming issue of* Health Affairs.]

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Developing and producing vaccines within a year of the discovery of a viral pathogen is an achievement beyond previous imagination. Molecular, genomic, immunologic and technical advances have overcome what would have been an impossible consideration just a few years ago. Unparalleled investments and collaborations included an advance market commitment, enabling millions of doses to be produced for each vaccine candidate in anticipation that the vaccine would be safe and effective, and enabling distribution of the vaccine for use immediately following regulatory review and authorization. These hopes have already come to fruition: two vaccine products to protect against coronavirus disease 2019 (COVID-19) received Emergency Use Authorization (EUA) by the United States (US) Food and Drug Administration (FDA) in December 2020 based on evidence of their safety profile and efficacy of >90%.[1,2] Several other candidates are on the horizon.

Operation Warp Speed may be successful in its principal purpose and objective: "ensuring that every American who wants to receive a COVID-19 vaccine can receive one, by delivering safe and effective vaccine doses to the American people

beginning January 2021".[3] However, COVID-19 vaccines may have a limited impact on controlling the pandemic and returning to normal social and economic life because vaccines do not save lives, vaccination saves lives. An estimated 70%+ of the population requires immunity to COVID-19 to effectively control disease through herd or community immunity.[4] These estimates assume homogeneous uptake of the vaccine, however; we have ample evidence that clustering unvaccinated persons can lead to disease outbreaks such as recently seen with measles, even when vaccine coverage at the state or national level is very high.[5] Disease-induced immunity comes at a heavy price and likely wanes over time. Vaccine-induced immunity is very straightforward to calculate: vaccine effectiveness multiplied by vaccine uptake. Operation Warp Speed seems to be based on the principle that if we build it, they will come. In this article, we characterize public perceptions during the roll out of the vaccine and the impact on vaccine informed decision-making, the potential for vaccine equity to help address underlying health disparities, vulnerabilities of the vaccine program, and the role of health care providers and science to impact vaccine decision-making and communications.

Vaccine Roll Out Environment

Public polling data demonstrate that COVID-19 vaccine roll out will occur in an environment that is not prepared to widely accept the vaccine. We may build it, but many may not come.

US adults may underestimate COVID-19. Polls from early in the pandemic found that nearly two-thirds underestimated the overall risk of death from COVID-19 and over half severely underestimated their own susceptibility to death.[6] The percentage of US adults intending to vaccinate against COVID-19 decreased substantially from over 70% in late spring to only about half in September, before rebounding to above 60% by late fall. Although the exact starting and ending points varied, this u-shaped pattern was generally seen regardless of race/ethnicity, political affiliation, gender, age, and education. Common concerns among those not intending to vaccinate were safety, efficacy, and the perceived rushed timeline for development.[7–10] Factors consistently associated with lower intention to vaccinate include: Black race, younger age (less than 60 years old), lower education, and conservative political ideology.[6–11] Having more fear of COVID-19 and receiving a provider recommendation were both associated with greater intention to vaccinate.[11]

The immense investments in and achievements of the development of these vaccines will result in suboptimal public health benefit without a systematic approach to provide interpretable, context- and culture-specific, accurate and trusted information about the vaccines that promotes vaccine confidence. A one-size-fits-all vaccine information and "demand creation" effort will not succeed, given the size of the US and the wide range of cultural beliefs, political leanings, scientific understanding, trust in government leaders and agencies, and perceived motives of pharmaceutical companies. There is also the influence of anti-vaccine campaigns and the rapid spread of misinformation through a variety of electronic media to contend with. As described by the World Health Organization in the context of vaccine messaging broadly, "messages need to be tailored for the specific target group, because messaging that too strongly advocates vaccination may be counterproductive, reinforcing the hesitancy of those already hesitant".[12] The importance of tailored messaging is especially important in the COVID-19 context given wide variability in perceptions of disease susceptibility and severity, range of vaccine safety concerns, and underlying distrust of the vaccine program and government response to the pandemic.

Vaccine Impact Through Informed Decision-Making And Vaccine Acceptance

As a first step, we need to recognize that decision-making in a crisis is different and complicated by the fact that the pandemic's "waves" create heightened moments of crisis. The US population is not uniformly experiencing the pandemic, as some communities are disproportionately impacted due to increased exposure or severity of outcomes. Having the option to telework, living in households with multiple generations, relying on public transportation, having savings, and many other factors affect how the pandemic may impact interest and eagerness to be vaccinated. Layer on historical and cultural experience with experimental medical research for some communities (e.g., Black, Native American, Latinx), either in the US[13] or in countries they've recently migrated from,[14] and you have a complex set of lenses through which a pandemic and vaccination may be considered.

Building, implementing, and adapting effective community engagement for bidirectional communication and dialogue is essential to the success of a COVID-19 vaccination program. Partnering with community-based organizations that serve different geographic, racial/ethnic, age, religious/faith, and political belief groups can ultimately help reduce the dispropor-

tionate burden of COVID-19 disease on particular communities and increase vaccine acceptance. Community engagement activities need to be ongoing and responsive to the evolution of knowledge regarding COVID-19 disease and advances in vaccine development and vaccine roll out.

In particular, misperceptions around the severity of COVID-19 disease must be addressed to create an environment receptive to vaccination. Though there are indeed treatment options that are effective at reducing COVID-19 morbidity and mortality, a substantial proportion of the population believes that COVID-19 is not a serious disease.[6] Frequent (and inaccurate) statements such as "the flu is worse than COVID-19," "increasing incidence is a result of improved testing," and "mortality data are inflated to increase the profits of clinicians" can contribute to the misperceptions of the severity of COVID-19 disease and hinder vaccine demand. Narratives that prioritize personal autonomy without considering community benefit as well as inconsistent messaging around mask wearing and social distancing further complicate receptivity to vaccination. Correcting misperceptions is important to inform people's views as they develop rather than changing their minds, especially with regard to vaccines.[15] Public health must change the perception of COVID-19 severity to facilitate acceptance of vaccines as well as other disease control efforts.

The name Operation Warp Speed reflects its mission and focus; however, many perceived the rush led to short cuts around vaccine safety. To date, this is not the case. Phase III clinical trials have been adequately powered for determining whether the benefits outweigh the risks in the populations studied. The Emergency Use Authorization (EUA) process, though requiring less safety and efficacy data than is required for formal approval of vaccines through the standard Biological License Application process, included the Vaccine Related Biological Product Advisory Committee (VRBPAC) in its authorization process to share detailed clinical trial data, allow public review of all data, and include independent, non-governmental experts in determinations of whether the available evidence of COVID-19 vaccine safety and efficacy justified its emergency use. The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), comprised of independent, non-governmental experts, also provided vaccine recommendations regarding who should get which vaccines through public deliberations. The transparency of these processes may assist in overcoming perceptions that the vaccine has been rushed to market. However, transparency may not be enough. There should be focused efforts to engage the public regarding the rigorous approach to vaccine development, evaluation, authorization for use and post-roll out safety surveillance and how it provides assurance that the benefits of the vaccine outweigh the risks, and if adverse reactions result from the vaccine, how those individuals will be compensated. Engagement and messaging needs to be developed, evaluated for subpopulations which likely vary in information needs and credible sources for such information.

Assurance of safety goes beyond clinical trials and authorization for use. Adverse reactions that are uncommon, have delayed onset, and/or occur in subpopulations excluded from clinical trials or subpopulations included in inadequately powered trials require study after vaccines are deployed. Post-authorization safety evaluation to detect real adverse reactions is particularly important for COVID-19 vaccines given many are using novel technologies. Examples of real adverse reactions caused by vaccines but not identified until widely used in the population include Guillain-Barré Syndrome following the 1976 swine flu vaccine,[16] narcolepsy following ASO3 adjuvanted pandemic 2009 H1N1 vaccine (Pandemrix),[17] and enhanced disease following Dengue vaccine.[18]

Additionally, vaccination of large numbers of people will be coincidentally related to health outcomes (e.g., heart attacks, strokes, COVID-19 disease) that would have happened anyway. Mass vaccination programs that rapidly vaccinate large numbers of people are at high risk of being undermined by coincidental adverse events following immunization (AEFI), such as recently occurred in South Korea where several deaths following a mass influenza vaccine campaign largely brought the program to a halt.[19] Rapid and rigorous science is needed to determine if AEFI are causally related to vaccination, are more likely in some individuals or subpopulations, or are simply coincidental. The process for separating real adverse reactions from coincidental events must be credible and communication programs must be prepared to respond to real or coincidental vaccine safety scares that arise domestically or are imported from other countries.

Vaccine Equity

There are disproportionate risks for COVID-19-associated illness, hospitalization, and death among people whose exposure to the virus is increased because of living and working environments and transportation requirements. The increased risks of COVID-19 are linked to systemic

social injustices and underlying medical conditions. An equitable COVID-19 immunization program prioritizes these populations to receive a COVID-19 vaccine in order to mitigate health inequities.

It must be acknowledged, however, that many communities at disproportionate risk for COVID-19 may also not accept immunization. Some individuals within these communities are unlikely to trust an immunization program brought along at warp speed by the government and large corporations. To realize the goal of a COVID-19 immunization program to mitigate health inequities, it is essential for it to include engagement that facilitates trust, provides accurate and interpretable information, and honors and incorporates their values and lived experience. Failure to gain acceptance of vaccines and equitable access and use will represent a tragic public health failure.

Mounting an effective vaccine program will require understanding and responding to the concerns and values of different groups. We can anticipate that the communication challenges will become more complex as additional vaccines are authorized. Health communication principles shown to improve trust should be emphasized, such as transparency, tailoring, and trusted messengers.[20,21]

The Role Of Health Care Providers

Health care providers will play a critical role in any COVID-19 vaccination strategy. Health care providers have been consistently cited by parents and patients as a trusted source of vaccine information.[12,22] This mirrors recent national survey data in which over 90% of US adults reported "some" or "a lot" of trust in doctors and other health care professionals,[23] a trustworthiness that has persisted during the COVID-19 pandemic.[24,25] One of the most consistent predictors of acceptance among patients and parents of routine vaccinations is a health care provider recommendation.[26–28] Similarly, parents who have their vaccine concerns addressed or are given reassurance by their child's health care provider have accepted vaccines after initially being hesitant.[29]

Health care provider communication practices regarding a COVID-19 vaccine, however, will be contingent upon healthcare providers themselves being confident in the safety and effectiveness of any approved vaccine. Historically, this confidence has been achieved through trust in the processes and systems to develop, approve, and monitor the safety of vaccines. For COVID-19 vaccines, this trust has been damaged by the politicization of these processes and systems. The effect on vaccine uptake could be equally damaging if this loss of trust translates into health care providers only giving a weak recommendation to patients for an approved COVID-19 vaccine, or no recommendation at all.

Also complicating healthcare provider communication regarding a COVID-19 vaccine are unique communication challenges. One prominent communication challenge is that COVID-19 vaccines are currently available to the public through an EUA, an event that is wholly unprecedented for vaccines outside of only one other instance in which anthrax vaccine was made available to high-risk groups.[30] This poses a challenge because, not only is there confusion among the public about what an EUA means,[31] but also use of an EUA to make a vaccine available has been associated with a decrease in vaccine acceptability.[32]

Some evidence-based provider vaccine communication strategies may also be problematic in the context of COVID-19 vaccine discussion while the vaccine is only available through an EUA. One such strategy is clinician use of a presumptive format to initiate the vaccine discussion with a patient. This format linguistically presupposes that the patient or parent will vaccinate, such as "So, we'll do vaccines today." Though use of this format has been shown to improve vaccine acceptance among parents,[33,34] the appropriateness of this strategy is dependent on the presence of a comprehensively studied, highly beneficial, low burden, minimally invasive intervention for which simple consent is justifiable. Unlike routine vaccinations, a COVID-19 vaccine authorized for emergency use does not yet qualify as this type of intervention. Therefore, non-presumptive formats that facilitate a discussion with patients and parents that approximates full informed consent are more appropriate with a COVID-19 vaccine authorized for emergency use.

Motivational interviewing—a patient-centered framework for behavior change that helps leverage inherent motivation for behavior—may be especially relevant here regarding how providers pursue a patient's reluctance to vaccinate. Motivational interviewing can deepen rapport, broaden understanding of patient motivations, communicate support, and improve receptivity to information being shared. Furthermore, it has been shown to be effective at improving acceptance among those who initially voice vaccine concerns or resistance.[10,35]

Science Rather Than Politics Driving The Process

The US response to COVID-19 has been plagued

with politics, which has driven public health and messaging. Throughout the pandemic, then-President Donald Trump downplayed the seriousness of the disease, and as late as October 2020, as a major surge of disease was starting, as predicted by many scientists, Trump announced "It's going to disappear. It is disappearing." The President acknowledged that his approach was intentional.[36,37] In addition to downplaying the course of the pandemic, often attributed to increased testing, the FDA came under scrutiny that politics impacted their decision to grant an EUA for hydroxychloroquine and later convalescent plasma.[38] The CDC, which normally would lead efforts around pandemic response and related communications, has largely been sidelined in the response to COVID-19 with widespread accounts of political officials interfering with CDC COVID-19 reports.[39] The effect has been devastating. These messages have misinformed the public and resulted in false beliefs about the seriousness of and projections on the pandemic and have led to poor compliance with mask wearing and other recommended prevention methods. Moreover, the impact of politics on public health agencies has undermined their credibility. These very same agencies must now authorize use, make vaccine recommendations, and launch a massive immunization program.

Shortly after retiring as CDC Director in 2002, Jeffrey Koplan wrote a timely and timeless article titled "Plagues, Public Health, and Politics", warning of the potential for politics to undermine public health and science.[40] Koplan argued that science must drive public health, which, in turn, must drive policy. He provides many successful examples that have followed this pathway from science to public health to policy (e.g., vaccination, family planning, and the control of infectious diseases). Aspects of our early response to HIV/AIDS exemplifies the perils when this pathway is reversed. Public perceptions that politics has driven public health that has in turn impacted science has undermined the credibility of these agencies that we now must rely on in order for COVID-19 vaccines to effectively control the pandemic.

Fortunately, preliminary phase III trial data from Pfizer[41] and Moderna[42] of their respective COVID-19 vaccines occurred weeks after and not before the Presidential elections. These data were subsequently reviewed by FDA's VRBPAC and CDC's ACIP in a transparent manner by independent scientists. This transparent process of science driving public health then driving policy will hopefully help to overcome public concerns that have plagued other aspects of the US COVID-19 response, but likely will not be enough on its own without a prompt and thorough communication and engagement plan.

Conclusion

The potential for vaccines to control a pandemic, impacting everyday life and demonstrating the value of vaccination and public health, has never been greater than this moment with COVID-19. Despite multiple vaccines with extremely high efficacy and reasonably good safety profiles, the success of COVID-19 vaccines to accomplish this tremendous potential is not assured. Public health has the tools to understand and engage the public, with particular attention to subpopulations at increased risk of COVID-19 and/or immunization refusal, to improve vaccine informed decision-making, vaccine acceptance and disease control. Health care providers have a very important role and well validated approaches to informing their patients and assisting them with their vaccine decisions. Elevating science over politics provides the opportunity to realize the potential of COVID-19 vaccines. ■

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NOTES

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