



Commentary

We have to get it right: Ensuring success

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Eleanor Roosevelt said, “Life is like a parachute jump; you’ve got to get it right the first time.” With a spate of Covid-19 vaccines on the horizon, we must prepare to jump.

In the span of a few weeks, promising results from three Covid-19 vaccine candidates trials were reported. In the United States (US), efforts to develop and deliver vaccines is under Operation Warp Speed (OWS). News of safe, effective Covid-19 vaccines injected a dose of optimism into a pandemic-stricken world. However, vaccinations—not vaccines—save lives [1]. The National Academy of Science, Engineering, and Medicine (NASEM) released *Framework for Equitable Allocation of COVID-19 Vaccine* [2]. *Framework* focused on initial vaccine access for healthcare workers and first responders followed by selected populations considered at greatest risk for contracting the virus or experiencing complications. The report is both thoughtful and timely but may require further details to monitor progress during the rollout of the vaccines. Here we offer suggestions to ensure success to this unprecedented public health challenge.

First, we must monitor the uptake of Covid-19 vaccines on a daily basis to ensure proper distribution and minimize geographic gaps. Faced with vaccine shortages during the 2004–2005 flu season, the Centers for Disease Control and Prevention (CDC) used its Behavioral Risk Factor Surveillance System (BRFSS) to assess vaccine uptake [3,4]. CDC officials changed their recommendations mid-season, and informed the public that anyone can take the vaccine. We now need this capacity to make nimble decisions during Covid-19 pandemic. BRFSS and other surveys should be repurposed to monitor vaccine uptake.

Second, we need to monitor the capacity of our healthcare systems to deliver vaccines to everyone. When are vaccines available? Where are supplies of vaccines? If there is a gap, how soon might it be filled? Therefore, building out surveys for local health departments across the country to assess their vaccine-delivery readiness would be wise. A growing body of scientific literature tells us that

Covid-19 disproportionately affects minorities in the US. A plan tailored to meet the challenges of ensuring vaccine access for these communities is imperative.

Third, we need to consider the geographic distribution of vaccine delivery. Our experience with the virus thus far has revealed its ebbs and flows. In early 2020, the northeast and western coastal states were hotspots; during the summer months, however, high cases and deaths appeared in southern states. At year's end, the Midwest, together with West Texas and New Mexico, became the hardest hit regions. We will need to estimate and model the level of transmission to identify regions where the epidemic is accelerating.

Fourth, the safety and efficacy of each vaccine must be paramount. Possible side effects or adverse reactions to vaccinations need to be tracked and monitored. Do they occur in specific sub-populations, for whom vaccines could be contraindicated or in the general population? What, if any, risk factors are identified? Determining whether these are isolated cases, misdiagnoses, or part of a larger problem—that is, whether they are causally or coincidentally related—will not only help us surveil the vaccine but also develop responsive communications strategies. With every new vaccine, the FDA and CDC has robust vaccine safety monitoring networks, including the Vaccine Adverse Events Reporting System, Vaccine Safety Datalink, and the Clinical Immunization Safety Assessment. We must increase our capacity to analyze the reports of any events and be ready to respond, especially since the first vaccines use new technologies.

Fifth, we need to effectively message and build the public's confidence in vaccine. Overcoming vaccine hesitancy is no small task in the current political and cultural climate. Honing a message across media that imparts to the public a trust in the process will help determine vaccination rates. We in the scientific community need to roll up our sleeves and show that fresh-to-market vaccines are safe, effective, and necessary. Popular public figures and trusted institutions need to promote vaccinations to accelerate us across the herd immunity threshold. In parallel, we must recognize the pervasive aspects of anti-vaccine messaging across the internet, including social media and e-commerce platforms. Anti-vaccination rumors, misinformation, and conspiracy theories swirl in a fractured media universe; their origins are diverse and include dedicated anti-vaccine organizations, political extremist groups, and even the Russian Government [5,6].

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Sixth, we need to monitor effectiveness. One approach is to have serologic monitoring of random samples of vaccine recipients to gauge whether there is a decline in antibody over time and presumed immunity by vaccine type and segments of the population. This will help us to answer who might need more doses and when and the long-term effectiveness of the vaccines or their durability of protection. We also need to better understand the performance characteristics of these new vaccines in terms of their ability to interrupt virus shedding. This will be critical for understanding whether widespread vaccination achieves herd immunity and thus leads to halting virus transmission.

We call on creating a national communications plan to address all the above to deliver a smooth vaccine rollout. Addressing the concerns and ensuring widespread use and compliance of vaccines means that we will require an unprecedented level of communication between federal agencies and the American people. The American public will need to hear public health information about vaccines from trusted organizations of the US Government and at frequent and regular intervals. We need fully engaged vaccine scientists and public health experts who possess top-flight communication skills to explain OWS priorities.

The US vaccine program and OWS represents one of the most ambitious biomedical programs ever undertaken. Ensuring its success will require us to address unprecedented complexity in the biomedical and social sciences, as well as being deft within the policy and communications domains.

Declaration of Interests

Dr. Hotez is a collaborator a low cost COVID19 vaccine for global health which was licensed by Baylor College of Medicine to a commercial third party for scale up and production. Dr. Mokdad has nothing to disclose. Dr. Orenstein is a Member of Moderna Scientific Advisory Board.

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