Kreps and colleagues' survey of a national sample of US adults provides insights into how we might achieve the level of vaccine uptake needed to prevent the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This study lands at a critical moment for US public health. The SARS-CoV-2 pandemic is surging, influenza season is looming, and the delivery of a vaccine to protect against coronavirus disease 2019 (COVID-19), the disease caused by SARS-CoV-2, appears imminent through the US government’s Operation Warp Speed initiative.

Not unexpectedly, Kreps and colleagues found that vaccine efficacy and safety are important factors associated with public acceptability of a COVID-19 vaccine. They also found that other characteristics were associated with respondents' self-reported uptake of any COVID-19 vaccine, such as the process by which a vaccine is authorized and by whom it is endorsed. These results reaffirm findings from studies of vaccine uptake during the 2009 H1N1 influenza pandemic and are consistent with the characteristics associated with preferences for vaccination during pandemics.

Of particular interest, however, is Kreps and colleagues' observation that a COVID-19 vaccine made available under an Emergency Use Authorization (EUA) by the US Food and Drug Administration (FDA) was associated with a decrease in the probability of acceptance relative to full approval by the FDA. This is of interest for several reasons. First, this finding is extremely pertinent given the stated willingness of the FDA Commissioner to use an EUA for a COVID-19 vaccine. Second, this finding is consistent with what is known about the association of an EUA with vaccine acceptability. In previous work during the H1N1 influenza pandemic, investigators found that most respondents would not accept a new vaccine made available through an EUA. Third, this finding by Kreps and colleagues likely underestimates the true negative association of an EUA with the probability of COVID-19 vaccine acceptance. Negative perceptions and confusion abound among the public regarding regulatory terms used for medical countermeasures, such as emergency use authorization or accelerated approval. Although Kreps and colleagues offered respondents a brief description of an EUA, this was almost certainly insufficient to promote a full understanding of what an EUA means.

Importantly, the standard path to vaccine licensing is the FDA Biologics License Application process. Its rigor, requirement for comprehensive data on vaccine safety and efficacy, and transparency through review by federal advisory committees has an extraordinary track record of promoting clinician confidence in vaccine recommendations and public trust in the approval process. Use of an EUA to make a vaccine available is nearly unprecedented, having only been used in 2005 to make the anthrax vaccine available to those at high risk of exposure to attack with anthrax.

If an EUA is indeed used to speed access to COVID-19 vaccines, strategies will be needed to mitigate its potential negative association with vaccine acceptance. At a minimum, the safety and efficacy data informing an EUA decision should be shared with relevant federal vaccine advisory committees. More broadly, the EUA process should be made fully transparent to the public to strengthen confidence in its outcome. In addition, although fact sheets are required to be distributed to recipients of an unapproved biologic made available through an EUA, obtaining recipients’ written informed consent is not required. This stands in contrast to requirements for written informed consent through other mechanisms that increase availability of unapproved biologics, such as through expanded access to an Investigational New Drug. If the data reviewed by the FDA to grant an EUA are not made available to the public or reviewed by relevant federal vaccine advisory committees, the same stringent standard for written informed consent should be used to help to
ensure that recipients fully understand the information needed to make a decision about a COVID-19 vaccine made available by an EUA.

Another key finding from the study by Kreps and colleagues\(^1\) was the association between a public health agency endorsement vs a politician’s endorsement with the acceptability of a COVID-19 vaccine: public health agencies were associated with higher acceptability rates than politicians. This may reflect the credibility of a public health agency in a public health crisis, an inherent mistrust of politicians, or increasing concern among the US public that politics, not science, are driving decisions about a COVID-19 vaccine.\(^8\) The policy implications are clear: to achieve confidence in COVID-19 vaccines, we need to build trust among the public in the processes being used for COVID-19 vaccine development, licensing, recommendation, and distribution. This requires a unified, proactive, highly visible communication structure within federal public health agencies to inform the public on a regular basis about these processes.

Lastly, there may be a temptation to interpret the results found by Kreps and colleagues\(^1\) as further evidence of the spread of vaccine hesitancy. We urge caution in doing so. Vaccine hesitancy, named as a global health threat in 2019 by the World Health Organization,\(^9\) refers to the reluctance or refusal to vaccinate despite an available vaccine. The forces giving rise to a state of indecision or doubt regarding a vaccine that has a known safety and efficacy profile, has been approved for use, and has been administered to millions of people are quite different than the forces giving rise to indecision regarding COVID-19 vaccines still in development and with safety and efficacy profiles that are, as of yet, wholly unknown. The former is steeped in a complex sociocultural milieu of consumerism, pervasive misinformation, and the rejection of objective, scientific evidence as truth. The latter may simply represent a deficit of the data needed to make an informed decision.

However, vaccine hesitancy and a reluctance to accept a COVID-19 vaccine are not completely distinct. There is overlap between them in terms of trust: trust in the processes and systems that develop, approve, and monitor the safety of vaccines as well as the people and agencies who recommend and endorse vaccination. The study by Kreps and colleagues is a helpful reminder that these components cannot be discounted if COVID-19 vaccines are to become part of a successful vaccination campaign. National and international public health agencies must prioritize facilitating a broad understanding among the public of these processes through frequent, consistent, and visible communication, including engaging with representatives from communities and populations who are disproportionally affected by the pandemic to leverage their knowledge, skills, and expertise and to listen to their concerns. To steer us out of the worst pandemic seen in a century, we see no other way.

**ARTICLE INFORMATION**

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