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Perspective

"When Will *We* Have a Vaccine?" — Understanding Questions and Answers about Covid-19 Vaccination

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In recent months, epidemiologists in the United States and throughout the world have been asked the same question by clinicians, journalists, and members of the public, "When will *we* have a vaccine?"

The obvious answer to this question would be, "When a candidate vaccine is demonstrated to be safe, effective, and available. That can be determined only by scientific data, not by a target calendar date." But we realize that such a response, although accurate, overlooks much of what people are ultimately seeking to understand.

The emphasis on "we" reveals that most people want much more than an estimated vaccine-delivery date. Their inquiry typically involves three concerns. First, when will the public be able to have confidence that available vaccines are safe and effective? Second, when will a vaccine be available to people like them? And third, when will vaccine uptake be high enough to enable a return to prepandemic conditions? Often, the inquiry is also assessing whether the biotech and vaccine companies, government agencies, and medical experts involved in developing, licensing, and recommending use of Covid-19 vaccines realize that the responses they provide now will influence what happens later. There is often a sense that messages regarding Covid-19 vaccines can have problematic framing (e.g., "warp speed") and make assertions that involve key terms (e.g., "safe" and "effective") for which experts' definitions may vary and may differ considerably from those of the general public and key subpopulations.

As Covid-19 vaccines move into phase 3 clinical trials, enthusiasm

about the innovative and sophisticated technologies being used needs to be replaced by consideration of the actions and messages that will foster trust among clinicians and the public. Although vast investments have been made in developing safe and effective vaccines, it is important to remember that it is the act of vaccination itself that prevents harm and saves lives. Considered fully, the question "When will we have a Covid-19 vaccine?" makes clear the many ways in which efforts related to both the "when" and the "we" can affect vaccination uptake. Recognizing the significance of both aspects of the question can help public health officials and scientists both to hone current messaging related to Covid-19 vaccines and to build a better foundation for clinicians who will be educating patients and parents about vaccination.

The recently released guidelines from the Food and Drug

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Administration (FDA) on testing of Covid-19 vaccine candidates are scientifically sound and indicate that no compromises will be made when it comes to evaluating safety and efficacy.1 This commitment needs to be stated repeatedly, made apparent during the vaccine testing and approval process, and supported by transparency. Assurances regarding the warp speed effort to develop a vaccine or to issue emergency use authorizations accelerating availability must make clear the ways in which clinical trials and the review processes used by federal agencies (the FDA, the National Institutes of Health, and the Centers for Disease Control and Prevention [CDC]) will objectively assess the safety and effectiveness of vaccines developed using new platforms. Clinicians and the public should have easy access to user-friendly materials that reference publicly available studies, data, and presentations related to safety and effectiveness. The FDA's and CDC's plans for robust longerterm, postlicensure vaccine safety and monitoring systems will also need to be made visible, particularly to health care professionals, who are essential to the success of these efforts.²

The second key part of this question pertains to when a safe and effective Covid-19 vaccine will become available to some, most, or all people who want one. This question has technical and moral components, and the answers on both fronts could foster or impede public acceptance of a vaccine. Data from antibody testing suggest that about 90% of people are susceptible to Covid-19. Accepting that 60 to 70% of the population would have to be immune, either as a result of natural infection or vaccination, to achieve community protection (also known as herd immunity), about 200 million Americans and 5.6 billion people worldwide would need to be immune in order to end the pandemic. The possibility that it may take years to achieve the vaccination coverage necessary for everyone to be protected gives rise to difficult questions about priority groups and domestic and global access.

Given public skepticism of government institutions and concerns about politicization of vaccine priorities, the recent establishment of a National Academy of Medicine (NAM) committee to formulate criteria to ensure equitable distribution of initial Covid-19 vaccines and to offer guidance on addressing vaccine hesitancy is an important step. The NAM report should be very helpful to the CDC's Advisory Committee on Immunization Practices, the group that traditionally develops vaccination recommendations in the United States. The NAM's deliberations about which groups will be prioritized for vaccination involve identifying the societal values that should be considered, and the report will communicate how these values informed its recommendations. Will the people at greatest risk for disease - such as health care workers, nursing home residents, prison inmates and workers, the elderly, people with underlying health conditions, and people from minority and low-income communities — be the first to obtain access? Alternatively, will the top priority be reducing transmission by prioritizing the public workforce, essential workers, students, and young people who may be more likely to spread infection asymptomatically? And how will the United States share vaccine doses with other countries, where infections could ultimately also pose a threat to Americans?

Releasing expert-committee reports, however, should not be equated with successfully communicating with the public about vaccine candidates and availability.3 In the United States and many other countries, new vaccines and vaccination recommendations are rarely released with substantial public information and educational resources. Most investments in communication with clinicians and the public happen when uptake of newly recommended vaccines, such as the human papillomavirus vaccine or seasonal influenza vaccine, falls short of goals. Not since the March of Dimes's polio-vaccination efforts in the 1950s has there been major investment in public information and advocacy for new vaccines. There is already a flood of misinformation on social media and from antivaccine activists about new vaccines that could be licensed for Covid-19. If recent surveys suggesting that about half of Americans would accept a Covid-19 vaccine4 are accurate, it will take substantial resources and active, bipartisan political support to achieve the uptake levels needed to reach herd immunity thresholds.5

High uptake of Covid-19 vaccines among prioritized groups should also not be assumed. Many people in these groups will want to be vaccinated, but their willingness will be affected by what is said, the way it is said, and who says it in the months ahead. Providing compelling, evidence-based information using culturally and linguistically appro-

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priate messages and materials is a complex challenge. Having trusted people, such as public figures, political leaders, entertainment figures, and religious and community leaders, endorse vaccination can be an effective way of persuading the portion of the public that is open to such a recommendation. Conversely, persuading people who have doubts about or oppose a particular medical recommendation is difficult, requires commitment and engagement, and is often not successful.

Finally, surveys suggest that physicians, nurses, and pharmacists remain the most highly trusted professionals in the United States. Extensive, active, and ongoing involvement by clinicians is essential to attaining the high uptake of Covid-19 vaccines that will be needed for society to return to prepandemic conditions. Nurses and physicians are the most important and influential sources of vaccination information for patients and parents. Throughout the world, health care professionals will need to be wellinformed and strong endorsers of Covid-19 vaccination.

A more complete answer to the common question is therefore, "We will have a safe and effective Covid-19 vaccine when the research studies, engagement processes, communication, and education efforts undertaken during the clinical trial stage have built trust and result in vaccination recommendations being understood, supported, and accepted by the vast majority of the public, priority and nonpriority groups alike." Efforts to engage diverse stakeholders and communities in Covid-19 vaccination education strategies, key messages, and materials for clinicians and the public are needed now.

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 Food and Drug Administration. Development and licensure of vaccines to prevent Covid-19: guidance for industry. June 30, 2020 (https://www.fda.gov/regulatory-information/ search-fda-guidance-documents/development -and-licensure-vaccines-prevent-covid-19).

2. Edwards KM, Orenstein WA. Anticipating severe acute respiratory system coronavirus 2 vaccine testing, licensure, and recommendations for use. J Pediatr 2020;224: 124-8 10.1016/j.jpeds.2020.06.048.

3. Nowak GJ, Karafillakis E, Larson H. Pandemic influenza vaccines: communication of benefits, risks, and uncertainties. In: Bahri P, ed. Communicating about risks and safe use of medicines: real life and applied research. Singapore: Springer Nature, 2020: 163-78.

4. Cornwall W. Just 50% of Americans plan to get a Covid-19 vaccine. Here's how to win over the rest. Science. June 30, 2020 (https:// www.sciencemag.org/news/2020/06/just-50 -americans-plan-get-covid-19-vaccine-here-s -how-win-over-rest).

5. Schoch-Spana M, Brunson E, Long R, Ravi S, Ruth A, Trotochaud M. The public's role in Covid-19 vaccination: planning recommendations informed by design thinking and the social, behavioral, and communication sciences. Baltimore: Johns Hopkins Center for Health Security, 2020 (https:// www.centerforhealthsecurity.org/our-work/ publications/the-publics-role-in-covid-19 -vaccination).

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