

## COVID-19 Vaccine: What Physicians Need to Know

**M**uch uncertainty surrounds vaccines for coronavirus disease 2019 (COVID-19) and the course of the pandemic in general. What is certain, however, is that physicians will have an important role in the implementation of a successful immunization program once a safe and effective vaccine becomes available. Patients, health care worker colleagues, family, friends, and others will seek advice from physicians on whether to get vaccinated. We will need to discuss the benefits and risks with them. Others will tell us they will refuse vaccination, and if those individuals and the community are likely to benefit from their vaccination, we will have an opportunity to try to alleviate their hesitancy in receiving the vaccine. If the vaccine is one that can be administered in our clinical settings, we will need to structure our practices to make receipt of the vaccine as accessible and efficient as possible for our patients.

Physicians must be prepared for this critical role in combatting the COVID-19 pandemic. Sound, scientific knowledge—untarnished by political views—is essential to this preparation. To help ready physicians with such knowledge, *Annals of Internal Medicine* and the American College of Physicians hosted the COVID-19 Vaccine Forum on 16 October 2020 to offer current, evidence-based information related to the science, approval processes, and development of clinical recommendations for vaccines. Emergency Use Authorization of COVID-19 vaccines would be the first time this process has been implemented for a vaccine in the history of the U.S. Food and Drug Administration. The implementation of Emergency Use Authorization must balance efficacy and safety with the risk for mitigating the ongoing pandemic in the nation. Given the reality of current times, the forum also addressed the political environment that threatens time-honored vaccine-related processes and fosters confusion and mistrust among clinicians and patients alike.

Forum speakers included Dr. Anthony Fauci (Director, National Institute of Allergy and Infectious Diseases), Dr. H. Clifford Lane (Deputy Director for Clinical Research and Special Projects, National Institute of Allergy and Infectious Diseases), Dr. David Kessler (Former Commissioner, U.S. Food and Drug Administration), Dr. Beth Bell (Member, Advisory Committee on Immunization Practices), and Dr. Rachel Levine (Secretary, Pennsylvania Department of Health). Readers can view their presentations in the video that accompanies this article (available at [Annals.org](https://www.annals.org)).

We do not yet know results from ongoing clinical trials; whether and when one or more vaccines will be approved; whether the supply of any approved vaccine will match demand; or specific details about the allocation, distribution, and administration of any approved vaccine. However, the forum provided accurate, baseline information and highlights several questions that physicians should ask when data become available and approval ensues, including:

- Did the vaccine or vaccines earn full approval or Emergency Use Authorization?
- What are the characteristics of the patients who participated in the trials that led to vaccine approval or Emergency Use Authorization? Did trial participants have risks for COVID-19 similar to those of the person who is asking me for advice?
- What are the clinical outcomes on which vaccine approval or Emergency Use Authorization is based?
- What adverse events were observed during the clinical trials? How will postmarketing of vaccines be monitored for safety concerns?
- Are the vaccine approval or Emergency Use Authorization and clinical recommendations for use limited to specific types of individuals? If so, are limits equitable and informed by scientific evidence?

Answers to these questions enable us to provide well-informed counsel to those who ask about the vaccine and to decide whether to receive the vaccine ourselves. Listening to what the speakers had to say at the forum on 16 October will help you to articulate these and other questions that emerge along with the data.

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*Ann Intern Med.* 2020;173:830. doi:10.7326/M20-6841

### See also:

Web-Only  
Video: COVID-19 Vaccine Forum  
CME/MOC activity