Addressing Concerns That the COVID-19 Vaccines Were "Rushed"

The Issue

Concerns about the speed with which COVID-19 vaccines were developed can reduce vaccine confidence. Some people fear that the vaccines were "rushed" at the expense of effectiveness or safety.

Sound Bites

- The COVID-19 vaccines used in the United States were developed in record time, but they were not "rushed."
- Speediness does not equal carelessness. All of the usual steps for testing, evaluation, and review were completed, and they were completed thoroughly.
- None of the usual steps in the vaccine development and approval process were skipped. Rather, some steps were conducted on an overlapping schedule so that important data could be gathered faster.
- The vaccine developers did not cut corners—they cut "red tape." Because the pandemic was a true global emergency, there was a worldwide effort to remove usual bureaucratic hurdles, with government funding to support concurrent activities.
- The vaccines were reviewed by independent panels of experts and approved under an Emergency Use Authorization (EUA) process that was set up in 2004, well before the COVID-19 pandemic. That process is used only when there is a serious and immediate risk to the public's health, especially when no adequate, approved, and available alternatives exist.
- COVID-19 vaccines were authorized for emergency use based on extensive clinical testing in tens of thousands of volunteers from diverse backgrounds, races, ethnicities, ages, and geographic areas. The vaccines went through the same safety tests and met the same standards as other vaccines produced and used through the years. And the COVID-19 vaccines continue to be monitored through multiple safety systems.
- Companies began making vaccines early in the process—before they were authorized for distribution by the U.S. Food and Drug Administration (FDA)—so that supplies would be available as soon as possible. The doses would have been thrown away if the vaccines were found not to be safe and effective.

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Questions for Exploring Patient Concerns

- How long do you think it should have taken to develop the vaccines? What timeline would have made you more comfortable?
- If your timeline had been followed, what would have happened differently that would have made you more comfortable?
- What is your biggest concern about the actual vaccine development timeline?

What We Know

As Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, noted in a Science editorial, "the development of several highly efficacious vaccines against a previously unknown viral pathogen [SARS-CoV-2] in less than 1 year from the identification of the virus is unprecedented in the history of vaccinology."[1] It usually takes 6 years or more to bring a new vaccine to market. But as the FDA has stated, there is no predetermined timeline for how long vaccine development should take.[2] Better scientific understanding of a pathogen and the disease it causes typically yields more efficient vaccine development.

The unprecedented timeline of the COVID-19 vaccines was due in part to "an extraordinary multidisciplinary effort involving basic, preclinical, and clinical science that had been under way—out of the spotlight—for decades" before the pandemic.[1] Researchers had been studying coronaviruses and the innovative vaccine technologies that would be used to create the vaccines for many years. So, it took weeks—rather than months or years—to sequence the SARS-CoV-2 viral genome and begin developing vaccine candidates.

The urgency of a global pandemic demanded that the usual schedules for testing and manufacturing vaccines be accelerated. Faster timelines were made possible by infusions of government and private funding; the U.S. government alone spent more than $12 billion. Significant financial investment was coupled with worldwide collaboration to improve efficiency, which reduced or removed many of the usual hurdles and delays in vaccine development, production, and distribution. None of the usual steps in the process were skipped, but as shown in Figure 1, some steps were conducted in an overlapping schedule to gather data faster.

Vaccine developers partnered with the National Institutes of Health to quickly enroll large numbers of volunteers in clinical trials. The phase 3 trials enrolled between 30,000 and 45,000 participants from diverse backgrounds, races, ethnicities, ages, and geographic areas. And because COVID-19 is so contagious and was so widespread while the phase 3 trials were being conducted, volunteers had a high chance of being infected, making it possible for researchers to tell within months whether a vaccine was effective in protecting the vaccinated groups (compared with the placebo groups).

To ensure vaccines would be available as quickly as possible, the government paid for large-scale "at risk" manufacturing for promising vaccine candidates while the phase 3 trials were underway. All parties agreed that those doses would be discarded if the vaccine did not receive Emergency Use Authorization (EUA) from the FDA, but the developers would not lose their investments.

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Figure 1. Vaccine Development and Approval Process

Inspired by Hackensack Meridian Health

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Typically, when a company seeks approval for a new vaccine, it submits a Biologics License Application (BLA) to the FDA—a process similar to a New Drug Application for other drugs. During public health emergencies like the COVID-19 pandemic, a developer can submit a request for EUA to facilitate the availability and use of vaccines (and other medical countermeasures). This allows a vaccine to be authorized for use before it is officially licensed (i.e., approved) for use.

To qualify for EUA, each COVID-19 vaccine candidate had to meet rigorous FDA scientific standards for efficacy, safety, and manufacturing quality. The FDA compressed the usual months-long review timeline to weeks by having parallel teams of people work days, evenings, and weekends. All of the data were evaluated as usual by both the independent FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) and the CDC Advisory Committee on Immunization Practices (ACIP).

Four vaccines have been authorized for use in the United States: the mRNA vaccines from Pfizer-BioNTech and Moderna in December 2020, and the viral vector vaccine from Johnson & Johnson/Janssen in February 2021. [The Janssen vaccine is no longer distributed in the United States.] A fourth subunit-protein vaccine from Novavax was authorized in July 2022. These vaccines continue to undergo the most intensive safety monitoring in U.S. history, using both established and new safety monitoring systems.

For the latest information on COVID-19 vaccine authorizations, approvals, dosing schedules, and the groups for which they are recommended, go to:

- **FDA:** *https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19*
- **CDC:** *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html*

References

1. Fauci AS. The story behind COVID-19 vaccines. *Science*. 2021;372(6538):109. doi: 10.1126/science.abi8397
2. U.S. Food and Drug Administration. Vaccine development – 101. Updated December 14, 2020. *https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101.* Accessed July 28, 2021.