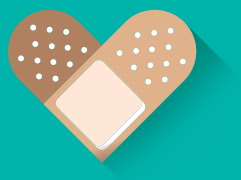

Addressing concerns that the COVID-19 vaccines were "rushed"

The Issue

Concerns about the speed with which COVID-19 vaccines have been developed can negatively affect vaccine confidence. People fear that the vaccines were "rushed" at the expense of effectiveness or safety.

Sound Bites

- The COVID-19 vaccines authorized for emergency use in the United States were created in record time, but they were not "rushed."
- Speediness does not equal carelessness. All of the usual steps for testing, evaluation, and review were done extremely well, very effectively, and very 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 critical 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 obstacles, with financial commitments made to support concurrent activities.
- The vaccines were reviewed by independent panels of experts and approved under an Emergency Use Authorization process that was put in place and used, when needed, before the COVID-19 pandemic. That process is used only when there is a serious and immediate risk to the public's health.
- COVID-19 vaccines were authorized for emergency use based on extensive clinical testing in large numbers of volunteers from many different backgrounds, races, ethnicities, ages, and geographic areas. The vaccines have gone through the same safety tests and meet the same standards as any other vaccines produced and approved through the years. And the COVID-19 vaccines continue to be monitored through established and new safety systems to make sure they are safe.
- Companies began making vaccines early in the process—before they were authorized by the 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.
- Vaccinated people can use the "v-safe" smartphone app to tell the CDC about any side effects after getting a COVID-19 vaccine and get reminders for future vaccinations. Go to cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

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?

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What We Know

As Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, noted in a recent *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 more than 6 years to bring a new vaccine to market. But the U.S. Food and Drug Administration (FDA) states outright that there is no predetermined timeline for vaccine development.[2] Better scientific understanding of a pathogen and the disease it causes typically yields more efficient vaccine development.

Dr. Fauci explained that the unprecedented speed 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 novel vaccine technologies that would be used to create the vaccines for many years. So, it took days, rather than months or years, to sequence the viral genome and begin developing vaccine candidates.

The urgency of a global pandemic demanded that the usual timelines for testing and manufacturing vaccines be accelerated. Faster timelines were made possible by an outpouring 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 the usual barriers and delays in vaccine development, production, and distribution. None of the usual steps in the process were skipped, but as shown in Figure 2, some steps were conducted in an overlapping schedule to gather data faster.

Drug companies partnered with the National Institutes of Health to quickly enroll large numbers of eager volunteers in clinical trials. The phase 3 trials enrolled between 30,000 and nearly 45,000 participants from diverse backgrounds, races, ethnicities, ages, and geographic areas; in contrast, some existing vaccines were approved based on data from trials that included as few as 3,000 participants. 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 exposed, making it possible for researchers to tell within months whether a vaccine was effective in the vaccinated groups versus the placebo groups.

To ensure vaccines would be available as soon as possible, the government paid for large-scale "at risk" manufacturing for promising vaccine candidates while the phase 3 trials were being conducted. The understanding was that the doses would be discarded if the vaccine did not get emergency authorization from the FDA, but the company would not lose any money.

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 a drug. During public health emergencies like the COVID-19 pandemic, a manufacturer is able to submit a request for Emergency Use Authorization (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.

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Figure 2. Vaccine Development and Approval Process

Inspired by Hackensack Meridian Health

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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, nights, and weekends. All of the data were evaluated as usual by both the independent FDA Vaccines and Related Biological Products Advisory Committee and the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices.

To date, three COVID-19 vaccines—the mRNA vaccines from Pfizer-BioNTech and Moderna and the viral vector vaccine from Johnson & Johnson/Janssen—have been authorized for emergency use. The authorized vaccines continue to undergo the most intensive safety monitoring in U.S. history, using both established and new safety monitoring systems.

The FDA granted full licensure (i.e., approval) to the Pfizer-BioNTech vaccine (now marketed as Comirnaty) on August 23, 2021. The approval applies to individuals 16 years of age and older; the vaccine continues to be available under EUA for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

Moderna has filed a BLA seeking full licensure for its vaccine. Johnson & Johnson/Janssen is expected to file a BLA soon.

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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.