FAQ: COVID-19 Vaccines

December 8, 2020

Introduction to the FDA Vaccine Emergency Use Authorization Process

The eyes of the nation are on the Food and Drug Administration this month as it considers COVID-19 vaccine candidates from Pfizer and Moderna that, according to the companies, showed excellent results in their respective Phase 3 clinical trials.

To help you understand the FDA process so you can make an informed decision about the vaccine, we've outlined what it looks like, as well as the next steps you can expect.

Who is the FDA and why are they in charge of approving vaccines?
The United States Food and Drug Administration (FDA) is a federal agency under the Department of Health and Human Services and it provides independent scientific review of drugs, vaccines and medical products to ensure their safety and efficacy before they are widely distributed.

Vaccines undergo a rigorous approval process that uses clinical data and other information to prove that the medicine is both safe and effective for the intended use and that it can be made according to federal quality standards. The carefully monitored clinical trial process helps provide evidence and data to indicate a vaccine candidate is safe, effective and that the benefits of receiving the vaccine outweigh the risks.

What does the clinical trial process entail?
In the context of a vaccine candidate, pharmaceutical companies conduct clinical trials with volunteer participants to test the safety and efficacy of any potential vaccine. These trials are overseen by independent data safety monitoring boards (DSMBs), comprised of trusted independent experts. In addition to overseeing the health of patients within the trial, these DSMBs sometimes take on additional obligations; in the vaccine trials currently under review by FDA, DSMBs also worked to flag any concerning developments in a trial and to identify when a trial has produced enough clinical value that is appropriate for the FDA to consider approving it for widespread use. The FDA then analyzes the data that comes out of these trials, and an external expert advisor committee made up of health care professionals in pertinent fields reviews the clinical data and makes a recommendation to the FDA regarding approval or emergency use authorization.

I heard that the trials were paused for safety concerns. Is that true?
While it can be unnerving to hear on the news that clinical trials are paused, it indicates that the scientific oversight process is working and allows independent investigators to determine if a participant's medical issues are related to the vaccine, are completely unrelated, and/or if the medical issues are isolated to one person. During these pauses, which are standard operating procedure for clinical trials, the study does not resume until these investigations are completed and it is determined that it is safe for the patients in the trial to continue. Of the five COVID-19 vaccines in Phase 3 clinical trials, three of them were paused at some point to date; all were cleared to continue. The Moderna and Pfizer vaccines were never interrupted for investigations.

What is happening with the Pfizer and Moderna vaccines?
Both Pfizer and Moderna have completed their Phase 3 clinical trials and have submitted requests for emergency use authorization (EUA) of their respective COVID-19 vaccines to the FDA, which is currently conducting its own analysis of the companies' data.

While the development of these vaccines for a novel disease like COVID-19 have moved at a rapid pace, it is important to remember that **these vaccines have, and are still, undergoing the normal rigorous clinical trial and FDA authorization processes. No steps have been skipped.**

The data we have seen so far is extremely promising. Neither Moderna nor Pfizer have reported any serious adverse experiences in patients in their respective clinical trials. The Phase 3 studies for both vaccines are almost identically effective (around 95%) and neither of them reported any serious adverse responses to patients in the trial. They both use messenger RNA technology, which involves leveraging the genetic code of the virus to activate the immune system. Unlike other vaccines, neither of these vaccines use any actual virus particles. Both involve receiving two doses of the vaccine, between three weeks (Pfizer) and four weeks (Moderna) apart.

What is an FDA emergency use authorization (EUA)?
During public health crises like the COVID-19 pandemic, the FDA may grant an EUA of a vaccine or treatment. This means that the vaccine meets safety and efficacy standards based on currently available data, and that the evidence indicates that the benefits of using the vaccine outweighs the risks. EUAs are effective until an emergency declaration ends or until the vaccine candidate receives licensure (or regular FDA approval). The rigorous EUA review process is not very different from the traditional FDA approval process.

There is a general misconception that "fast tracking" a drug under EUA means cutting corners in terms of safety. This is simply not the case. "Fast tracking" has little to do with the actual trials, and more to do with producing the vaccine. While many vaccines wait for FDA approval before production begins, pharmaceutical companies have already begun production of COVID-19 vaccine candidates to ensure there is not a significant delay between FDA authorization and the first administered doses of a vaccine.

Are there other vaccine candidates in the works?
There are currently five large-scale Phase 3 clinical trials that are underway or being planned in the U.S., which include tens of thousands of patients. In fact, one of these current trials is being done at our own Tufts Medical Center, which is enrolling 800 high-risk patients in a COVID-19 study with the experimental vaccine from Astrazeneca.

What are the next steps in the federal process?
The next step in the process is for the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to hold a public, live-streamed hearing to discuss the safety and efficacy data associated with the Phase 3 clinical trials of the Pfizer and Moderna vaccine candidates.

VRBPAC is made up of 17 external experts, including Tufts Children's Hospital Chief of Pediatric Infectious Disease Dr. Cody Meissner. Collectively, they will make a recommendation to the FDA regarding issuing an emergency use authorization. The FDA then determines if it will in fact issue an emergency use authorization, typically following the recommendation of the VRBPAC.

The VRBPAC meeting regarding the Pfizer vaccine candidate is scheduled for December 10, and the VRBPAC meeting regarding the Moderna vaccine candidate is scheduled for December 17. The FDA has indicated that these meetings will be livestreamed on the agency's YouTube, Facebook, and Twitter pages, as well as webcast on the FDA website. There is no clear answer how quickly emergency use authorization will come after the VRBPAC meetings. It could occur as soon as within 24 hours. .

What are the next steps for Wellforce?
While we do not know exactly when and how many doses of the vaccine we will receive, teams at Wellforce have been preparing for the safe receipt, storage and distribution of the vaccine for several months and Wellforce leaders will continue to develop a methodical and

thoughtful plan to appropriately distribute the initial rounds of vaccinations that we receive to our employees, following CDC and Massachusetts DPH guidance.

Because the vaccine will receive an emergency use authorization, no one will be mandated to be vaccinated. However, **if a COVID-19 vaccine is authorized by the FDA, and supported by CDC and Massachusetts DPH, the clinical leaders of Wellforce HIGHLY recommend that every health care worker who is identified as an appropriate candidate to receive the vaccine does so.**

The bottom line

At Wellforce, we all share a common goal to provide outstanding care in a safe and compassionate environment during this very difficult time for patients, families and staff. It is important for health care providers and the public to be educated about a vaccine to make their own informed decisions. Health care workers are also trusted resources to share relevant, accurate and timely information about vaccines, prevention measures and available treatments with patients in accordance with federal and state guidelines and mandates.

We will continue to provide staff and the public with regular updates, as well as appropriate, accurate information to share to ensure all health care employees and patients across the system receive standardized information and guidance, as appropriate.

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