TEXAS MEDICAL CENTER

A Comprehensive Approach To Vaccine Preparedness

Across the Texas Medical Center, providers are continuing to treat COVID-19 while making plans to administer a vaccine. Currently, there are two vaccine candidates that have submitted data to the U.S. Food and Drug Administration (FDA) and requested emergency use approval (EUA).

Reports indicate that these vaccines, developed by Pfizer and Moderna, achieved greater than **90%** efficacy with no serious safety concerns.

Clinical leaders across the TMC are optimistic about the preliminary safety and efficacy reports and will continue to follow the progress of clinical trials, regulatory reviews and clinical data carefully.

It is possible that the FDA will grant authorization for emergency use of the Pfizer COVID-19 vaccine as early as the second week in December. Initially, vaccine supply is expected to be limited. TMC health care institutions are prepared to distribute any supply received in accordance with city, county and state/federal guidelines.

TMC health care organizations also are developing long-term plans for a comprehensive effort to support region-wide vaccination across many months. This process includes:

PREPAREDNESS

- Monitoring the regulatory process, data and next steps to ensure clinical teams understand FDA-approved vaccines and necessary infrastructure for administering each product safely and effectively
- Maintaining close contact with city, county and state/federal officials to assure that vaccination strategies are coordinated and address key public health priorities
- Developing distribution strategies for the first wave of available vaccines. Given the limited number of vaccines expected to be available as manufacturing ramps up, all providers are initially focusing on frontline healthcare workers performing essential functions within the region

NECESSARY STORAGE AND DISTRIBUTION STRATEGIES

- At least one of the early vaccine candidates requires ultra-cold storage. Hospitals are surveying their available storage space and ensuring that equipment needs are met
- Both vaccine candidates currently under FDA review require at least two doses; hospitals are considering strategies to support full compliance with vaccine protocols
- Early distribution to frontline healthcare workers will provide hospitals with important insights on how to effectively manage a wide-scale vaccination effort

CONTINUED FOCUS ON NON-VACCINE PREVENTION METHODS

- Full distribution of the vaccine across the greater Houston area could take many months and clinical experts are urging continued vigilance
- Masking, physical distancing, hand washing and other measures will remain critical as rolling vaccines occur and the medical community continues to learn more about the longevity and effectiveness of the immunization effort

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Vaccine FAQ

What vaccines will be available?

Currently, multiple vaccine candidates are going through clinical trials (the scientific process by which a vaccine is tested for effectiveness and safety) and regulatory review. At this time, two vaccine candidates, produced by Pfizer and Moderna, are likely to be the first FDA-approved vaccines under emergency use authorization. Pfizer's vaccine could be approved as early as the second week in December.

Will they be FDA approved?

YES. Though several steps have been taken to streamline the process and reduce regulatory obstacles, the underlying approval process remains the same. It is possible that early vaccines will be approved as Emergency Use Authorization (EUA) immunizations. EUA occurs if there's evidence that strongly suggests that patients have benefited from a treatment or test and the treatment is safe, but not all typical regulatory steps have yet been completed.

The FDA, drug producers and independent physicians and researchers will monitor and track a wide variety of data once the vaccine is available to continue to learn about the vaccine's safety and effectiveness.

Will they be safe?

The FDA approval process, even in an EUA situation, prioritizes health and safety. During phase 3 clinical trials, both the Pfizer and Moderna vaccines showed better than 90% effectiveness with no serious adverse safety concerns.

In addition, individual TMC hospitals will have their researchers and physicians review the data to ensure that the vaccine meets hospital safety standards.

When are vaccines likely to be available?

It is not yet clear when the first vaccines may be available. Pfizer submitted for EUA on Friday, November 20, and FDA is planning to meet on Thursday, December 10.

If the Pfizer vaccine is approved as early as the second week in December, we understand that it will be distributed by the company, in collaboration with the state and federal government, shortly thereafter.

How were they made available so quickly? I thought it would take a long time to manufacture the vaccines.

Due the unprecedented need created by the COVID-19 pandemic, the FDA and manufacturers, in some instances supported by government investment, took the unusual step of creating manufacturing capacity before drugs were fully approved.

How many vaccines will be sent to Houston?

It is not clear; early estimates are that the United States is likely to receive approximately 6.4 million initial doses of the Pfizer vaccine. We do not yet have information on how many will be sent to the greater Houston area.

Who decides which hospitals and doctors' offices get the vaccines?

Over the past several weeks, hospitals and clinics have been enrolling to become approved vaccine distribution sites.

Texas will receive its allocation from the federal government, and Texas will distribute across providers. During the first phase, the majority of vaccine doses will likely be offered in a hospital setting.

Who will get the first vaccines?

Based on the recommendations of the state's Expert Vaccine Allocation Panel, the initial priority will likely be frontline healthcare workers and highly vulnerable populations such as skilled nursing and assisted living facility residents.

We are awaiting additional guidance, but most hospitals are preparing internal distribution strategies for the first phase. This includes developing equitable allocation strategies and prioritizing the administration of the vaccine based on the risk of exposure to COVID-19. For example, employees and physicians in COVID-19 ICUs will likely be in the first group of individuals eligible to be vaccinated at most hospitals.

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If the first vaccines go to healthcare workers, when will the general population get the vaccines?

This is difficult to answer at this time based on a number of factors: the production schedule for the vaccines, the need to vaccinate highly vulnerable populations (i.e., people with pre-existing conditions, congregate senior-care settings, individuals over 65, etc.) and a distribution strategy for a drug that requires ultra-cold storage and a two-dose regimen.

Will vulnerable populations (elderly, immune compromised, obese, etc.) be given priority?

The initial priority will likely be frontline healthcare workers. The state's Expert Vaccine Allocation Panel will likely also prioritize vulnerable populations, but we are waiting for more guidance on how to implement this strategy on a practical level.

Will children be able to get the vaccine?

Children under the age of 14 are unlikely to be vaccinated in the early months of availability. None of the clinical trials has included children.

Will there be a choice in which vaccine a person receives?

NO.

Where will I be able to be vaccinated if I am not a frontline healthcare worker?

This is still being determined.

Will the vaccine be required?

NO. Additionally, until adequate supply is available, it cannot be required. Based on currently available data on safety and efficacy, the clinical community is likely to recommend widespread vaccination.

How long will it likely take to vaccinate our whole community?

We do not have that information at this time.

What might be different about this vaccine from the flu vaccine?

It is important to realize that the two vaccines currently under FDA review require two doses. When vaccinated, follow your clinician's instructions to schedule your second dose in the recommended timeframe. Another difference is that a leading vaccine candidate requires ultra-cold storage, which limits the facilities where vaccinations may be administered.

Why is a second dose required?

The clinical trials showed that a two-dose model was most effective in preventing the spread of COVID-19.

How long will immunity last?

We don't know yet; the medical community and vaccine producers will continue to study efficacy and immunity levels to better understand the long-term vaccination strategy.

When can we stop wearing masks, physical distancing, hand washing, etc.?

Masking, physical distancing, hand washing and other safety measures will remain critical as vaccines are administered in phases and the medical community continues to learn more about the longevity and effectiveness of the immunization effort.