BROADCAST-What is Emergency Use Authorization and How Does It Ensure Safe Vaccines?

The phrase “emergency use authorization” is becoming part of our talk about COVID-19 vaccines that are awaiting final government approval for distribution. But, what constitutes emergency use?

Sandy Salverson, vice president of Pharmacy Services for OSF HealthCare says the Emergency Use Authorization process was developed for situations in which the country doesn’t have existing drug therapies to support treatment that’s needed quickly and on a large scale. The process was first used in 2009 during the H1N1 flu season.

“One of the drugs that we know today as Tamiflu, at that time had no approval for infants and H1N1 was really impacting our kiddo population (Pediatrics) and so they (the Food and Drug Administration (FDA)) went through and evaluated the evidence that they had on efficacy and safety and opted to implement an emergency use authorization at that time.” (:26)

The Food and Drug Administration can make a judgement that it’s worth releasing something for use without the typical timeline for a new vaccine or drug.

The process Salverson describes involves making sure there’s enough research to support use of a treatment or vaccine.

“They weigh out what is the benefit (to address) what is occurring right now in the moment and what data we have, and does that outweigh the risk of not acting at all. That is done looking at all of the efficacy and safety data that we have available and then assessing the situation we have at hand.” (:23)

The FDA uses an independent review team of career scientists to check the science and ensure research results are valid. The Advisory Committee on Immunization Practices (ACIP), a part of the Centers for Disease Control and Prevention also sets immunization guidelines and makes recommendations on dosage and the need for a booster shot.

Both vaccines under review for EUA, one from Pfizer and the other from Moderna, require two doses separated by several weeks. With limited supplies, Salverson says the CDC gives additional recommendations for priority distribution based on several factors.

“Who is getting ill, who has the highest risk of dying from COVID, who has the highest risk of experiencing a long hospital stay or health burden from the disease and those are decisions that influence how the nation chooses to prioritize who gets the vaccine first.” (:21)

The CDC’s advisory committee recommended the very first group of Americans to get vaccinated should be frontline health care workers and residents of long term care facilities.

The FDA not only has the power to grant Emergency Use Authorization, it can also revoke an EUA. That happened recently with hydroxychloroquine and chloroquine to treat COVID-19. Salverson says the FDA reviewed *new* data including a large, randomized clinical trial in hospitalized patients.

“It didn’t really look like it made a large impact on the disease itself. There was also some concerns about how it interacted with other drugs that we used to treat conditions like pneumonia, and the combination of efficacy and safety is what really removed that EUA for COVID-19.” (:22)

The two leading vaccines from Pfizer and Moderna that are being evaluated for EUA use new technology called messenger RNA. Unlike other vaccines, the new approach gives the immune system a preview of what the real virus looks like without causing disease. This preview gives the immune system time to design antibodies that can neutralize the real virus if the individual is ever infected.

“There are other vaccines in Operation Warp Speed or the pipeline that may not have that same approach but that doesn’t mean they won’t be (effective), it’s just a different way to approach it and we’re thinking that this messenger RNA will be faster and more specific to the virus.” (:22)

Salverson says the FDA criteria for EUA explicitly outlines vaccines cannot pose a risk that would put someone in the hospital or cause serious side effects. The process also includes evaluating manufacturing safety and the ability to produce enough vaccine to significantly prevent the spread of the virus.

The Food and Drug Administration will consider Emergency Use Authorization for Pfizer’s coronavirus vaccine candidate on Dec. 10 and Moderna’s vaccine candidate on Dec. 17. Distribution is expected to begin the next day if EUA is granted.