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FAQs COVID-19 Vaccines
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This week Moderna and Pfizer released interim results from their ongoing COVID-19 vaccine trials showing results that the vaccines are about 95% effective at preventing COVID-19 infection. Both companies have also announced that they will be submitting emergency use authorization (EUA) requests to the FDA in the coming weeks. This is very optimistic news that can help us turn the tide in this pandemic! As your trusted pharmacy partner, we will continue to update you as we move through this dynamic time together.

Q: What is the efficacy of the COVID vaccines?

A: The Moderna experimental vaccine appears to be 94.5% effective after an interim analysis of its late-stage study. Pfizer just announced today that the primary efficacy analysis demonstrates the vaccine to be 95% effective against COVID-19 beginning 28 days after the first dose.
Pfizer reports efficacy is consistent across age, gender, race and ethnicity demographics; observed efficacy in adults over 65 years of age was over 94%.
Currently, four major drug companies have experimental coronavirus vaccines in late-stage clinical trials in the US. Both AstraZeneca and Johnson & Johnson have restarted their vaccine clinical trials in the US after earlier safety pauses.

Q: How can we ensure the vaccines that are being fast-tracked for emergency use authorization (EUA) are also safe?

A: Vaccines that get an EUA have the same safety measures as traditionally approved vaccines to ensure they are safe and effective. Vaccines are one of the most regulated drug and treatment processes in the US and have a rigorous process for approval. EUA goes through vetting by additional agencies that include the Data Safety Monitoring Board (DSMB), Vaccines and Biological products Advisory Committee (VRBAC) and Advisory Committee on Immunization Practices (ACIP). In addition, some states will review for safety with independent scientific workgroups.

Q: What is an Emergency Use Authorization (EUA)?

A: The United States FDA can make medications or treatments available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic. The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

Q: How do the Pfizer and Moderna COVID-19 vaccines work?

A: These vaccines are made with a brand-new technology using messenger RNA, or mRNA (ribonucleic acid). In simple terms they use a snippet of the genetic code of the coronavirus to train the body to recognize if the real virus comes along and trigger the immune system to produce antibodies without using actual bits of the virus. There is no coronavirus in the vaccine, and you cannot get COVID-19 from the vaccine.

Q: Are there any serious side effects reported with the vaccines?

A: No. At this time both companies have reported no serious side effects. Detailed safety data is expected to be reported by the companies over the next few weeks. The most common side effects reported are fatigue (4%) and headache at (2.0%).

Q: What are some key differences in the Pfizer and Moderna vaccines?

A: Pfizer: This vaccine is a preservative-free IM injection in a multi-dose vial that requires reconstitution with normal saline. This vaccine is fragile and requires ultra-cold frozen storage (-70 C). Pfizer has created special thermal shippers that will be available for temporary storage with dry ice. Refrigeration stability is 5 days. It requires 2 doses with 21 days between doses. EUA is expected at the end of November.
Moderna: This vaccine is a preservative free IM injection in a multi-dose vial that does not require reconstitution. It is more stable, which provides ease of shipping but requires traditional frozen storage (-20 C). It has refrigeration stability for 30 days. It requires 2 doses with 28 days between doses. EUA is expected in early December.

Q: Why might there be vaccine hesitancy and how can we address this?

A: One reason is that unfamiliar or new processes are psychologically perceived as riskier. As healthcare professionals, we will play a central role in encouraging COVID-19 vaccination to protect our front-line workers and residents. Educational campaigns and transparency about vaccine effectiveness and safety should be addressed before and during vaccine roll out. As your pharmacy partner, we will assist to continue to provide education and facts about the vaccines to booster the confidence around the safety and effectiveness. Remember, vaccines don't save lives: vaccinating people saves lives!

Q: How long does the vaccine protection last?

A: This is still unknown. Important questions such as how long protection lasts and whether people might need boosters is to be determined as studies are ongoing. The companies have not yet released detailed data on their study, and results have not been analyzed by independent experts. The information is rapidly evolving as we continue to learn more about the preventative vaccines

Q: I completed the survey to register for vaccine clinics … now what?

The Operation Warp Speed (OWS) team is engaged in the final stages of planning to distribute the vaccine. OWS is a full-scale military operation. They are managing a complex set of variables to ensure that the highest priority target populations receive the vaccine as quickly as possible. As a result, conditions and details are changing daily. Several members of our team are involved in the process at both the national and state level so that we are operating with the most up to date information possible. Our own OWS team is adapting our plans daily so that when vaccine is made available, we are prepared to execute quickly. As of today, it appears possible that distribution to the senior care community could begin at some point in December and will span into early 2021. Numerous factors will determine specifically when it will be available in our region of the country.