

Science Advice for Newton Presbyterian Church

Article 2: What's next for vaccine development and distribution?

Intro: The purpose of this series is to provide timely information that is science-based for issues of concern for this community. It is based on vetted scientific and historical data. It is not meant to shape political and social views or offer medical advice, but to inform and help community members make informed decisions.

The latest on COVID-19 vaccines

Who's getting the vaccine?

In the US, we are following CDC guidelines for vaccine distribution. Massachusetts, like other states, is following the 3-phase approach according to CDC guidelines. Vaccines are being distributed to the states for administration. Phase 1 has begun for first responders, care givers and residents in long term care facilities. Phase 2 will begin in February 2021 and will cover patients in high-risk categories, staff in early education and K-12 institutions and adults over 65. The general population will be covered in Phase 3 which will begin in April 2021. It is possible to get the vaccine even if you are diagnosed with COVID-19. Patients may be screened by healthcare workers and be given warnings and precautions. People in all three phases also have the option not to receive the vaccine. However, some employers, such as health care facilities, can place restrictions on persons not taking the vaccines. At this time members of the military are not mandated to take the vaccine.

How will it be administered?

Vaccines against the COVID-19 virus, SARS-CoV-2, will be available at no cost to recipients. Phase 1 recipients can receive the vaccine at their workplaces and care facilities. CDC recommends that during the pandemic people wear a mask that covers their nose and mouth when in contact with others outside your household, when in healthcare facilities, and when receiving any vaccine, including a COVID-19 vaccine. The vaccines will be administered by clinicians and certified healthcare workers. Phase 2 and phase 3 recipients can receive the vaccine through pharmacies, clinicians, and health care providers.

Details on the vaccination plan are available through the State of Massachusetts website. <https://www.mass.gov/info-details/when-can-i-get-the-covid-19-vaccine>. CDC guidelines are available on their website for the nationwide policy. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>

What is being administered:

At this time Pfizer and Moderna vaccines are being administered to protect against COVID-19 infection and spreading of the disease. Patients that are already infected with COVID-19 can receive treatments of monoclonal antibody therapeutics to alleviate the disease. These treatments are

available by prescription. Vaccines are available at no cost to recipients but do not require a prescription currently. Be aware that infected persons can be re-infected and therefore are still eligible to receive the COVID-19 vaccines to prevent re-infection and spreading of the disease.

The Pfizer and Moderna vaccines both require two (2) inoculations 3 and 4 weeks apart respectively. Both injections must be taken and taken on schedule to have any effect. The first vaccine injection primes the immune system for a response to the spike protein of the SARS-CoV-2 Coronavirus. The second injection challenges the immune system and allows the body to protect against infection. Both vaccines target the SARS-CoV-2 Spike Protein which is part of the mechanism that allows the Coronavirus to penetrate the membranes of healthy cells. At this time recipients of the Pfizer vaccine have received both injections in the phase 1 distribution. No widespread serious adverse events have been reported.

Several vaccine candidates that require only a single injection are close to receiving an EUA authorization by the FDA. Monoclonal antibody therapeutics to treat COVID-19 are being developed to treat the disease in infected patients. They are specific to the SARS-CoV-2 Coronavirus. They are biologic molecules but not vaccines and are available by prescription.

How are people reacting to the vaccines?

Caregivers are reporting muscle soreness at the injection site in their upper arms and are experiencing some headaches. Vaccinations in caregivers and first responders are being staggered in case anyone reacts to the vaccine and cannot carry out their duties. Some side effects are expected after the second injection of the Pfizer and Moderna vaccines. Vaccine administration records and side effects are all being monitored closely by the CDC and FDA anywhere the vaccines are being administered. These are conditions of the Emergency Use Authorization (EUA).

What about influenza?

Public health authorities also recommend vaccination against influenza, a safe vaccine. People who are vaccinated against influenza would be able to avoid a situation called “the double whammy” in which a person susceptible to COVID-19 would also be made ill from Influenza as well. Therefore, influenza vaccination will reduce the spread of illness by removing a risk factor from the population. The Pfizer and Moderna vaccines have been found to be compatible with Influenza vaccines that are being administered during this flu season.

What’s next?

Although there are two vaccines being administered under EUA, there are more than 20 vaccines that are close to getting an EUA. The Food and Drug Administration (FDA) the National Institutes of Health (NIH) do not see this as a race. Even with an EUA, all recipients require careful monitoring. An EUA is conditional and can be revoked if significant side effects (adverse events) occur.

A recent article in the New England Journal of Medicine describes the emergence of a variant of the spike protein D614G of the Coronavirus. This mutation has been linked to higher infection rates in MA, the US and worldwide. However, infections with this virus variant have not increased the severity of COVID-19 disease. Studies have shown that the new variant virus should be susceptible to the vaccines recently released by the FDA.

How do Vaccines get approved?

All vaccines require an advisory board review by the FDA before approval (licensure) or an EUA. A cold chain system needs to be developed to ensure that vaccines that are frozen (-20 or -80°C), cold liquid (2-8 °C) or freeze dried (lyophilized) are protected during processing and transport in a way that they do not experience temperature spikes that would inactivate the vaccines. Most pharmacies have the capability to store vaccines at -20°C but only larger medical facilities have -80°C Freezers that are expensive to maintain or depend on a supply of Liquid Nitrogen. Therefore, storage conditions and “cold chain” are critical. Since our supply chain and cold chain needs to be re-established, distribution would likely take place in large metropolitan facilities first. This can happen between 1-2 months after an EUA.

Once a vaccine is licensed, it can be labelled and marketed and shipped to pharmacies, medical facilities and healthcare providers. In a non-emergency situation, a review of clinical data can take 1-2 years after clinical trials are completed. That is because health authorities like the FDA need to ensure the benefits outweigh the risks based on lab tests and animal and human subject data. Risks can involve allergic reactions, systemic illnesses and other adverse events.

Vaccine Distribution

Outlying facilities and areas not on immediate threat may take longer due to distribution network issues and travel affected by weather conditions. Our first responders and healthcare workers can be vaccinated within 2 months to protect them from patient/facility borne illness. Supplies for the general public will take longer since the manufacturing process for biotech products is more complicated than it is for drugs. The general population can have access to a combination of vaccines no sooner than 2-3 months due to supply chain and transportation issues confounded by the pandemic.

Where do I go for more information:

Vaccine schedules and priorities are available through the State of Massachusetts and CDC websites. The FDA also has information on vaccines and therapeutics (drugs and biologic treatments) being developed and the approval process. Your clinician and pharmacy also have access to this information.

State of Massachusetts

<https://www.mass.gov/info-details/when-can-i-get-the-covid-19-vaccine>.

CDC guidelines are available on their website for the nationwide policy.

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>

Summary:

Public health officials recommend vaccination against influenza if patients can tolerate the vaccine and a combination of PPE and isolation this Winter. New vaccines are being developed against the Coronavirus spike protein G614 variant. Non-vaccine therapeutics are being developed to treat infected patients.

Phase 1 vaccine distribution is ongoing for first responders, caregivers and patients in long term care facilities. Phase 2 will begin in February and will cover high risk patients, adults over 65 and early education and K-12 staff. The general population will have access in April 2021 in Phase 3.

Meanwhile, observance of mask, PPE, handwashing, and social distancing measures are still needed for all of us to remain safe. The same measures that are being used to manage SARS-CoV-2 follow OSHA, NIH, and CDC protocols for reducing exposure to any chemical, radiation, and biohazard agent.

About the writer:



Richard Tharin, MS, RAC, is a scientist with The Cerneos Group, LLC. He provides scientific and regulatory advice to biotech, diagnostic and drug companies to develop innovative products to treat, diagnose, and mitigate exposure to infectious disease agents. He has more than 20 years in industry and government service with the FDA and NIH in development of vaccines and diagnostics. He has published articles on biodefense and infectious disease management.

Useful links and references

FDA website on COVID Vaccines

<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>

State of Massachusetts information on local vaccine distribution

<https://www.mass.gov/info-details/when-can-i-get-the-covid-19-vaccine>

CDC guidelines for the nationwide policy.

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>

Information on SARS-Cov-2 variant:

Baric, Ralph, S. Ph.D., *Clinical Implications of Basic Research - Emergence of a Highly Fit SARS-CoV-2 Variant. New England Journal of Medicine 383:27 December 31, 2020.*

<https://www.nejm.org/doi/full/10.1056/NEJMcibr2032888>

News on COVID-19

<http://cerneos.com/useful-links>

Future Articles:

Vaccines vs therapeutics - what are they when would you need them

Practical information masks and other PPE

COVID diagnostics – what you should know