COVID-19 Vaccine FAQ

Question: What are the differences in technology development between the vaccine candidates?

Answer: There are several platforms being used to develop the COVID-19 vaccine candidates. They are briefly explained here.

DNA – Protects against disease by injecting genetic plasmid containing the DNA sequence encoding the coronavirus antigen so cells directly produce the antigen, causing a protective immunological response. These vaccines have the advantage of ease of development and production.

mRNA – Fragments of messenger RNA (mRNA) encoding for production of the coronavirus antigen are inserted into human cells to stimulate production of the antigen, creating an immune response against the pathogen. This is a new type of vaccine and is the platform for the Pfizer/BioNTech and Moderna vaccines.

Replicating Vector – Virus vectors shuttle fragments of viral RNA into human cells, where they are presented to the immune system, triggering an immune response. This method is used in development of HIV/AIDS vaccines.

Nonreplicating Vector – Based on recombinant viral vectors that are sufficient to induce host immune responses but cannot replicate inside host cells.

Protein-based – Vaccine made from small proteins or peptides that contain epitopes that are then presented to and recognized by T-cells as target antigens and generate an immune response.

Inactivated – Vaccine consists of virus particles that are grown in culture and then killed so they lose disease-producing capacity.

Live attenuated – Unlike inactivated vaccines, the particles, bacteria, or other pathogens are still alive but are in a weakened state.

Additional Resources:

Centers for Disease Control and Prevention (CDC) COVID-19 Website: https://www.cdc.gov/coronavirus/2019-ncov/your-health/index.html

ASHP Vaccine Candidate Tracking Table: https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/Coronavirus/docs/Vaccine-candidate-tracking-table.ashx

CDC Understanding and Explaining mRNA COVID-19 Vaccines: https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html

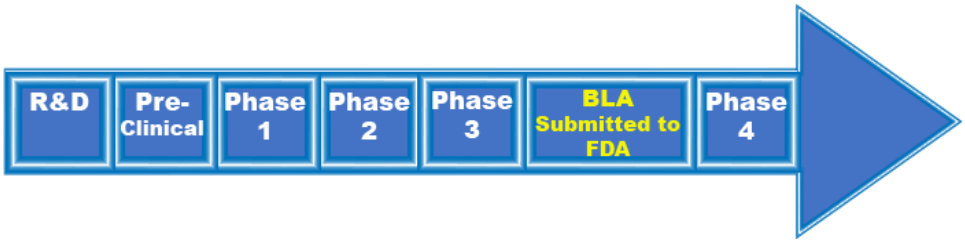
Updated 12/11/2020

Question: What are the various regulatory review pathways that the FDA can consider in order to release a vaccine (BLA, EUA, Expanded Access)?

Answer: The regulatory approval pathways are summarized below. The FDA will rely on the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to make recommendations based on its evaluation of safety, efficacy, and appropriate use data available for the COVID-19 vaccine candidates.

Biologics License Application (BLA):

Once preclinical and clinical development programs have been successfully completed, companies submit a BLA to the FDA. A BLA is a comprehensive submission that includes preclinical and clinical data and information, as well as details of the manufacturing process and facility(ies). The BLA is the official request for permission to introduce a biologic product, including a vaccine, into interstate commerce.



Emergency Use Authorization (EUA):

During a public health emergency, if certain criteria are met, manufacturers may submit a request for EUA to FDA to facilitate the availability and use of their vaccine for the duration of the emergency.

Under an EUA, the FDA Commissioner may allow an unapproved drug, unlicensed vaccine, or uncleared device to be used in a public health emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused when there are no adequate, approved, and available alternatives.

The EUA process is different than an FDA approval or clearance. With each EUA decision, FDA weighs known and potential benefits of product against known and potential risks.

- EUAs helped speed access to COVID-19 diagnostic tests, N95 respirators, remdesivir, and several monoclonal antibodies.
- COVID-19 vaccines: FDA prefers Phase 3 studies be completed. Granting an EUA sooner could impair determination of efficacy and safety.

Expanded Access:

The FDA Expanded Access (Compassionate Use) program allows investigational drugs, biologics, or medical devices that have not yet been approved or cleared by FDA to be used for a patient with an immediately life-threatening condition or serious disease for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

Currently, expanded access is one pathway for use of COVID-19 convalescent plasma for patients with serious or immediately life-threatening COVID-19 disease who are not eligible for or who are unable to participate in randomized clinical trials.

Additional Resources:

- Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19
- FDA BLA Resources
- FDA EUA Guidance: https://www.fda.gov/media/97321/download
- FDA Vaccines and Related Biological Products Advisory Committee https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committee

Question: What are the storage and handling considerations for the leading vaccine candidates?

Answer: Due to their formulations, the two leading vaccine candidates in the U.S. must be stored at extremely low temperatures. The other vaccine candidates appear to be stable at normal refrigerated temperatures (2-8°C).

The Pfizer/BioNTech vaccine must be stored at -70°C and will last for up to 5 days at refrigerated temperatures (2-8°C). Thermal shippers can be room temperature for 10 days (some sources indicate 15 days) if they are replenished with dry ice. Prior to administration, the vaccine must be thawed (thawed vaccine must be used within 5 days) and then reconstituted with diluent (reconstituted vaccine must be used within 6 hours).

The Moderna vaccine must be stored at -20°C and can be stored for up to 6 months. The vaccine will be stable at refrigerated temperatures of 2-8°C for 30 days. All doses in a vial must be administered within 6 hours after vial puncture.

Additional Resources:

The CDC's Vaccine Storage and Handling Toolkit
https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

Question: What are possible initial reactions from the COVID-19 vaccine?

Answer: Some minor effects are expected as your body responds to the COVID vaccine. Common reported symptoms include pain at the injection site, fever, fatigue, and headaches, and are worse after the second dose. Other symptoms can include muscle and joint pain, cough, lethargy, and shortness of breath.

Additional Resources:

CDC COVID-19 Site - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html.

Question: What should I do if I or a patient experiences an adverse event from the vaccine?

Answer: Monitoring for safety signals of the COVID-19 vaccines after their approval and/or authorization is an important responsibility of the vaccinating workforce. In addition, it is an expectation outlined in the CDC COVID-19 Vaccination Program Provider Agreement. An "adverse event following immunization" is an adverse health problem or condition that happens after vaccination. To continuously monitor the safety of the new COVID-19 vaccines, the CDC will be leveraging existing vaccine safety monitoring infrastructure, including the Vaccine Adverse Event Reporting System (VAERS), Vaccine Safety Datalink, and Clinical Immunization Safety Assessment Project. Healthcare organizations often have internal safety reporting systems as well. Healthcare providers are required by law to report to VAERS when any adverse event listed in the VAERS Table of Reportable Events Following Vaccination occurs within the specified timeframe and when an adverse event listed by the vaccine manufacturer as a contraindication to future doses of the vaccine occurs.

Additional Resources:

CDC COVID-19 Vaccination Program Provider Agreement:
https://scdhec.gov/sites/default/files/media/document/COVID19-Vaccination_Program_Provider_Agreement_and_Profile_Form.pdf

Vaccine Adverse Event Reporting System: https://vaers.hhs.gov/index.html

Vaccine Safety Datalink: https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html

Clinical Immunization Safety Assessment Project:
https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/

VAERS Table of Reportable Events Following Vaccination:
https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

Question: Will it be mandatory for nurses, pharmacists, and other healthcare workers to receive the vaccine?

Answer: Vaccination mandates are generally controlled by employers as a condition of employment. For example, hospitals often require employees to obtain an influenza or hepatitis B vaccine. Employers may allow for exemptions, such as medical contraindication. Although a vaccine mandate is possible for healthcare workers, most employers are making vaccination voluntary until more efficacy and safety information is available.

According to the best and most current evidence outlined by the CDC and the Advisory Committee on Immunization Practices (ACIP), effective protection of the public health requires that all individuals receive immunizations against vaccine-preventable diseases (VPDs). ANA and ASHP strongly recommend that registered nurses and pharmacists be vaccinated against VPDs, including COVID-19, to protect themselves, their patients, and their communities. However, we recognize that, as trained healthcare professionals, nurses and pharmacists expect a well-established efficacy and safety profile in order to

make an informed decision. We do not believe health care professionals should be retaliated against if they choose not to be vaccinated. In addition, COVID-19 vaccines authorized by the FDA through an EUA carry additional allowances to accept or refuse the product that will factor into mandatory vaccination policies.

Question: How can I help stop the spread of COVID-19 vaccine misinformation?

Answer: As trusted healthcare professionals, patients will look to nurses and pharmacists for reliable information about the COVID-19 vaccines. Demand for the vaccine will increase as the public gains confidence in its safety and efficacy. The immunizing and healthcare professional community will play an important role in gaining that confidence. Address patient concerns and hesitancy with transparency, accuracy, and empathy. Resources and campaigns are being developed to support nurses and pharmacists in promoting patient willingness to be vaccinated. The CDC Vaccinate with Confidence program will deploy products and tools aimed at reinforcing trust, empowering healthcare providers, and engaging communities and individuals.

Additional Resources:

CDC Vaccinate with Confidence program: https://www.cdc.gov/vaccines/partners/vaccinate-with-confidence.html

About the American Nurses Association (ANA)

The American Nurses Association (ANA) is the premier organization representing the interests of the nation's 4.2 million registered nurses. ANA advances the nursing profession by fostering high standards of nursing practice, promoting a safe and ethical work environment, bolstering the health and wellness of nurses, and advocating on health care issues that affect nurses and the public. ANA is at the forefront of improving the quality of health care for all. For more information, visit www.nursingworld.org

About the American Society of Health-System Pharmacists (ASHP)

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's over 55,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. Visit ASHP online at www.ashp.org. Access our COVID-19 Resource Center at https://www.ashp.org/COVID-19.