COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers

Maine Immunization Program

COVID-19 Education Requirement

Introduction

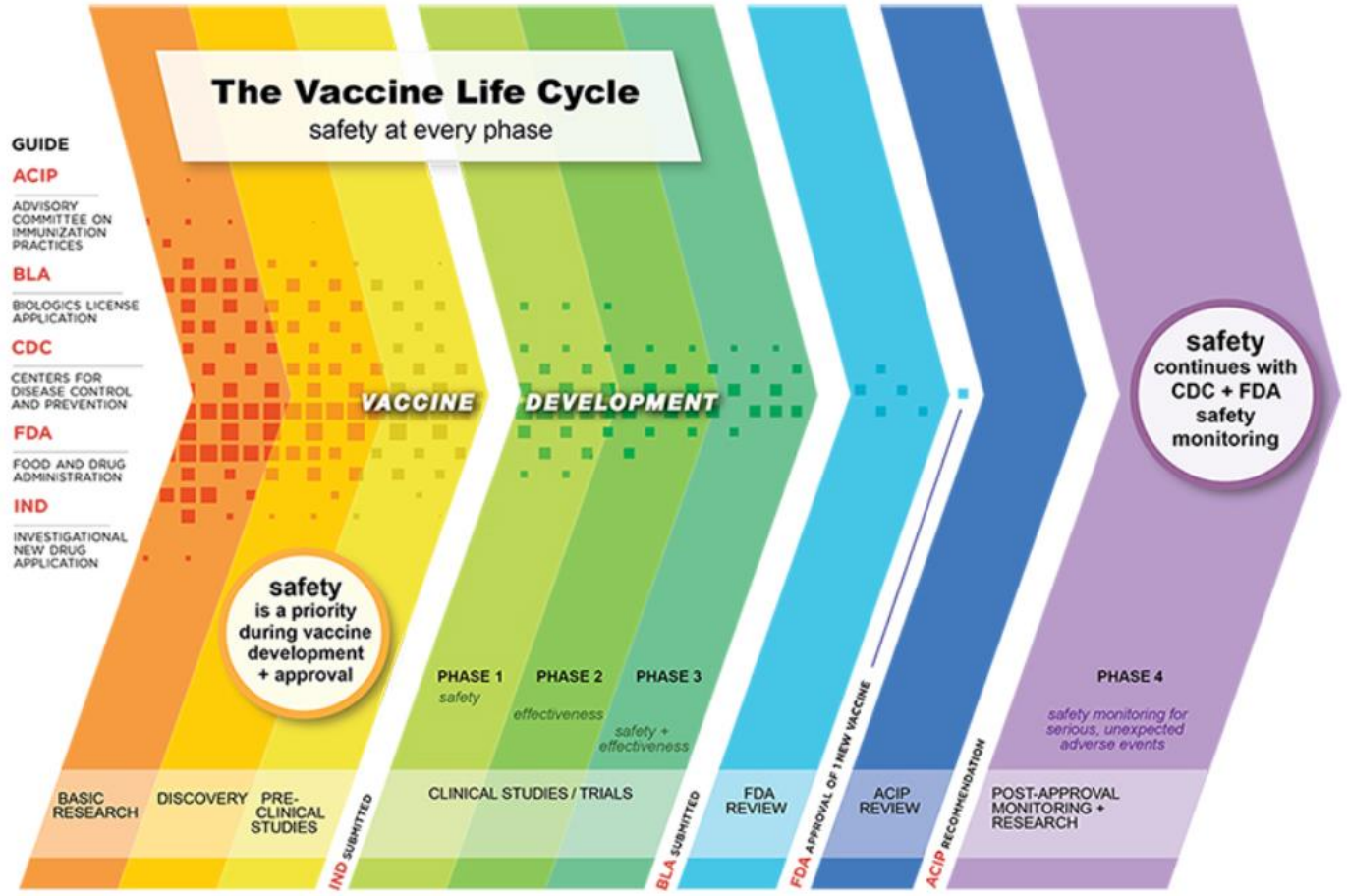
The objective of this module is to provide healthcare providers with information about COVID-19 vaccine Emergency Use Authorization and safety, as well as general information about vaccine storage, handling, administration, and reporting.

This overview is intended to assist healthcare providers in administering COVID-19 vaccines during the pandemic.

This training module will be continually reassessed and updated based on the evolving epidemiology of COVID-19 as well as when new vaccines are introduced in the United States.

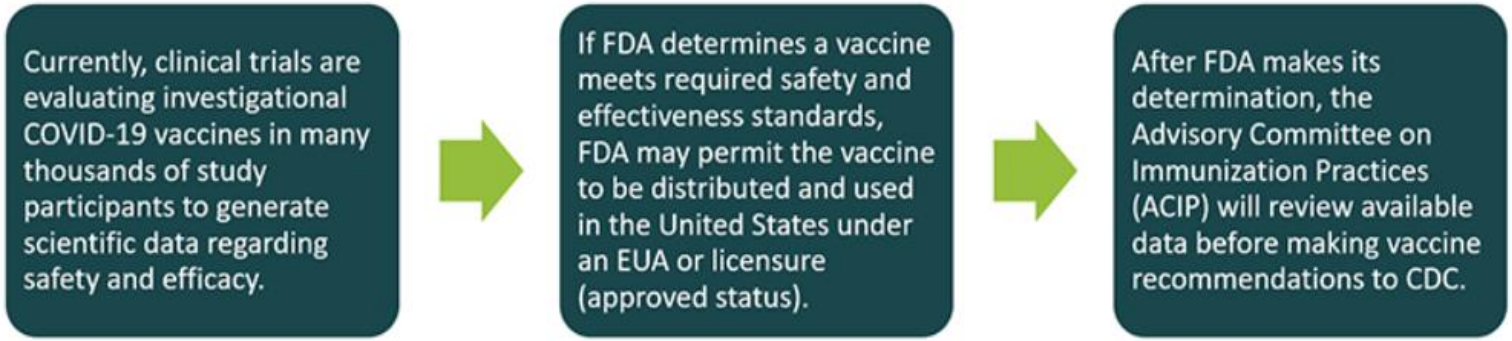
Vaccine Safety, Development, and Emergency Use Authorization (EUA)

The Vaccine Life Cycle: Safety at Every Phase



Vaccine Safety, Development, and Emergency Use Authorization (EUA)

COVID-19 Vaccine Safety and Development



Ensuring the Safety of COVID-19 Vaccines in the United States

COVID-19 Vaccine Safety and Development

After a COVID-19 vaccine is authorized or approved for use, CDC, FDA, and other federal partners will use multiple existing, robust systems and data sources to conduct ongoing safety monitoring.

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

The national system that collects reports of adverse events that happen after vaccination. Reports can be submitted from healthcare providers, vaccine manufacturers, and the public. Reports of adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns are followed up with specific studies.

VAERS: https://vaers/hhs/gov/

Federal Safety Monitoring Systems and Data Sources

Vaccine Safety, Development, and Emergency Use Authorization (EUA)

Enhanced COVID-19 Vaccine Safety Monitoring

CDC is also working to expand COVID-19 vaccine safety surveillance through new systems and additional information sources as well as by scaling up existing safety monitoring systems. This will give CDC and FDA the ability to evaluate vaccine safety and make sure COVID-19 vaccines are as safe as possible.

v-safe

A new voluntary, smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins for COVID-19 vaccine recipients. V-safe allows participants to report any side effects after COVID-19 vaccination to CDC in almost real time. It also gives them a convenient reminder to get their second COVID-19 vaccine dose if they need one.

National Healthcare Safety Network (NHSN)

An acute-care and long-term care facility monitoring system that will promote reporting to VAERS.

Ensuring the Safety of COVID-19 Vaccines in the United States

How an Emergency Use Authorization (EUA) Works

An EUA may be issued by the FDA to allow access to critical medical products that may help during a public health emergency. An EUA is different from approval/licensure.

The following criteria must be met for an EUA to be issued:

- The product will be used for a serious or life-threatening disease or condition.
- Based on the totality of scientific evidence available, it is reasonable to believe the product may be effective.
- The known and potential benefits of the product outweigh the known and potential risks of the product.
- There is no adequate FDA-approved alternative available.

FDA Information on EUAs

FDA Guidance on EUA for Vaccines to Prevent COVID-19

FDA Video, "What is an EUA?"

What does an EUA Mean for Healthcare Providers?

An EUA means that a COVID-19 vaccines has been authorized for use. The scope authorized use is specified in the EUA Fact Sheet for Healthcare Providers (similar to a package insert for licensed vaccines).

For healthcare providers, conditions of use require:

- Providing the recipient/caregiver the Fact Sheet for Recipients (similar to a vaccine information statement [VIS] for licensed vaccines), which communicates vaccine benefits and risks to the recipient, via hard copy or electronic means
- Reporting vaccine administration data to CDC
- Reporting vaccine administration errors and specified adverse events to VAERS

EUA Fact Sheet for Healthcare Providers

Each vaccine-specific EUA Fact Sheet for Healthcare Providers will provide the following information:

- COVID-19 disease description
- Dosage and administration information
- Storage and handling instructions
- Dose preparation and administration information
- Requirements for use of vaccine under EUA
- Risks and benefits, including common adverse events (AEs)
- Any approved available alternatives for preventing COVID-19
- Reporting requirements, including reporting AEs to VAERS
- Additional resources

EUA Fact Sheet for Recipients

Each vaccine-specific EUA Fact Sheet for Recipients will provide the following information:

- Basic information on COVID-19, symptoms, and what to discuss with a healthcare provider before vaccination
- Who should and should not receive the vaccine
- That recipients have the choice to receive the vaccine
- Dosage and vaccine series information
- Risks and benefits of the vaccine, including common side effects
- Information on reporting side effects to VAERS
- An explanation of what an EUA is and why it is issued
- Any approved available alternatives for preventing COVID-19
- Additional resources

Storage and Handling

Proper vaccine storage and handling practices play a very important role in protecting individuals and communities from vaccine-preventable diseases.

Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease.

For specific, detailed storage and handling protocols for individual vaccine products, always refer to the manufacturer's product information or contact the manufacturer directly.

For CDC's storage and handling recommendations and best practices, go to CDC's *Vaccine Storage and Handling Toolkit*.

If you are new to storage and handling and would like to take an online training, go to *You Call the Shots*, Vaccine Storage and Handling module.

Expiration and Beyond Use Date (BUD)

Determining when a vaccine or diluent expires is a critical step in proper storage and handling. Understanding vaccine expiration dates can help save your practice time and money.

All vaccine have expiration dates, and some routinely recommended vaccines have a beyond use date (BUD), which is calculated based on the date the vial is first punctured and the storage information in the package insert.

For COVID-19 vaccines:

- The expiration date may change for some vaccines as more stability data becomes available
- The EUA Fact Sheets for Healthcare Providers or manufacturer websites will provide more information about expiration dates and BUDs.

COVID-19 Vaccine Temperature Excursion

A temperature excursion is any temperature reading that is outside the recommended range for vaccine storage as defined by the manufacturer's package insert or EUA Fact Sheet for Healthcare Providers.

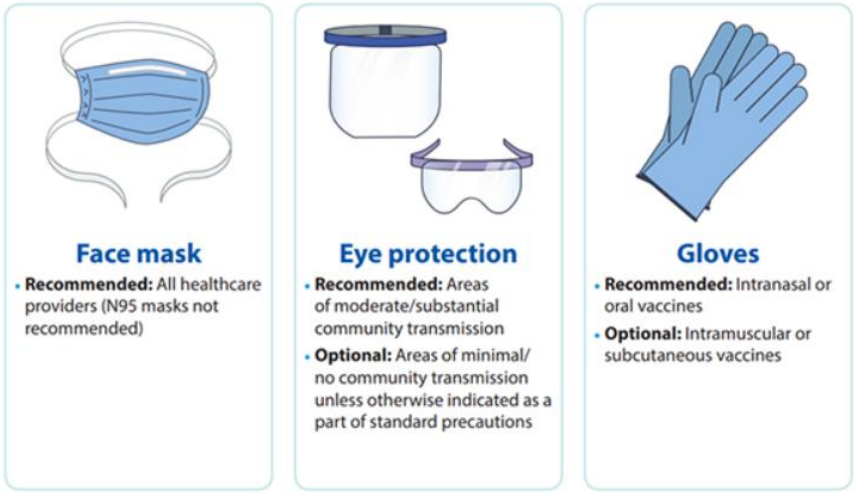
Identify temperature excursions quickly and take immediate action to correct them.

For COVID-19 vaccines, contact the vaccine manufacturer or the Maine Immunization Program if you experience temperature excursions.

Personal Protective Equipment

The COVID-19 pandemic underscores the importance of implementing infection prevention practices, including physical distancing, respiratory and hand hygiene, surface decontamination, and source control, while in a healthcare facility.

Ensure staff has the correct PPE before administering vaccines.



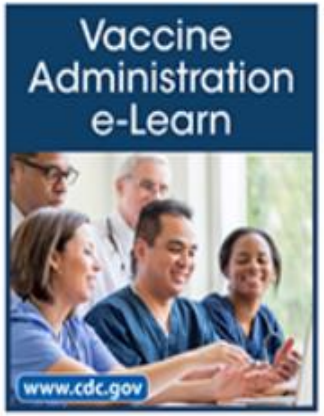
Interim Guidance for Routine and Influenza Immunization Services during the COVID-19 Pandemic

General Vaccine Administration Information

Proper vaccine administration is critical to ensure that vaccination is safe and effective.

Always check the expiration date of the vaccine and diluent before preparing vaccine. Expired vaccine and diluent should never be administered.

If you are new to vaccine administration and would like to take an online training, go to *You Call the Shots,* Vaccine Administration module.



Check the expiration date using the 2D barcode on the vaccine carton/vial or vaccine manufacturer's website.

You Call the Shots, Vaccine Administration Module

CDC's Vaccine Administration web page

Vaccine Preparation

Prepare vaccines in a clean, designated medication area away from where the patient is being vaccinated and away from any potentially contaminated items.

- This is to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment.

CDC recommends that providers draw up vaccines only at the time of administration.

CDC's Injection Safety website

CDC's *Epidemiology and Prevention of Vaccine Preventable Diseases*, "Vaccine Administration" chapter

Vaccine Administration

Healthcare providers should be knowledgeable of safe injection practices and site identification.

Intramuscular (IM) injection is the recommended route for COVID-19 vaccines.

To ensure vaccines are safe and effective:

- Follow aseptic technique.
- Use a new needle and syringe for each injection.
- Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.*

*Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.

COVID-19 Vaccination Schedule

COVID-19 vaccine products are not interchangeable. The same product must be used for each dose in the vaccine series.

To get the best protection, if a second dose of vaccine is required, patients need to know:

- Which vaccine product they received
- When to schedule their next appointment to receive the second dose

Reminder Systems and Strategies for Increasing Adult Vaccination Rates

Documentation and Reporting Adverse Events

COVID-19 Vaccination Documentation

Always provide the recipient/caregiver with a personal vaccination card that includes the name of vaccine administered, the date of administration, and the name/location of the administering clinic.

Provide the recipient/caregiver the EUA Fact Sheet for Recipients and v-safe information and encourage them to participate in v-safe for active safety monitoring.

Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine in the patient's medical record and/or immunization information system (ImmPact).

COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration, and use their best efforts to report administration data to the relevant system for the jurisdiction (ImmPact) as soon as practicable and no later than 72 hours after administration.

Documentation and Reporting Adverse Events

Reporting to the Vaccine Adverse Event Reporting System (VAERS)

Healthcare providers are required to report the following to VAERS:

- Vaccine administration errors (whether associated with an adverse event [AE] or not)
- Serious AEs (irrespective of attribution to vaccination)
- Multisystem inflammatory syndrome (MIS) in children (if vaccine is authorized for use in children) or adults
- Cases of COVID-19 that result in hospitalization or death after the recipient has received COVID-19 vaccine

Healthcare providers are also encouraged to report any clinically significant AEs that occur after vaccine administration.

Adverse events should be reported even if the cause of the AE is uncertain.

Healthcare providers should report any additional AEs and adhere to any revised safety reporting requirements per the FDA conditions of authorized vaccine use posted on FDA's website throughout the duration of the EUA.

VAERS website

COVID-19 Vaccine Education Credit

This completes the Maine Immunization Program COVID-19 Vaccine Education Requirement.

To receive credit for this training you MUST email C19Education.MECDC@maine.gov the following information:

- First/Last Name
- Organization Name
- Site Location Name
- Site Location Address
- VFC PIN (if known)
- Immunization Role (Vaccine Coordinator, Pharmacist, Administrative Staff, etc.)

At a minimum, we must receive a completed education email from the Primary Vaccine Coordinator listed on your COVID-19 Program Provider Agreement. However, secondary coordinators and vaccine administration staff are encouraged to participate as well.

As always, thank you for your efforts preparing for COVID-19 vaccine distribution and administration.