GENERAL COURSE INSTRUCTIONS:

Overview

Providers participating in the COVID-19 vaccine federal partner program are responsible for understanding and following all guidelines of the Centers for Disease Control and Prevention ("CDC") related to storage, handling and administration of the vaccines. This begins with ensuring that your pharmacy has well-defined and up to date policies and procedures for all components of vaccine administration. These courses do not replace routine training and education that have been defined in your pharmacy's policies and procedures ("SOPs") for general vaccine handling and administration. Completion and documentation of broad training for all applicable team members is the responsibility of each pharmacy.

COVID-19 Network Required Training

Introduction

Guidelines will continue to change throughout the next several months. Providers should monitor the COVID-19 Clinical Training and Resources for HCPs published by the CDC and check back frequently for updates.

Pre-Requisite Reading Assignment

Before completing the course exam, each learner must successfully complete the CDC's **"*COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers*** https://www2.cdc.gov/vaccines/ed/covid19/SHVA/index.asp

The course is an interactive, web-based immunization training course. It consists of a series of modules that address COVID-19 vaccine specific issues and guidance. The program also includes a thorough review of the Vaccine Adverse Events Reporting System (VAERS), Enhanced monitoring systems such as VSAFE, HCP and patient EUAs. The course also describes critical steps to take to safely protect the cold chain, ensure proper administration of vaccines and accurate documentation and retention of records.

Several sections include links to additional CDC resources, references and resource materials. This CDC course provides optional Continuing Education ("CE") credit and a downloadable certificate. Each participant can choose if they would like to receive the CE credit and follow the steps on the website to claim the credit.

All members of the pharmacy team involved in the vaccine administration process that are a part of the Health Mart Federal Partner Network must successfully complete the course in Health Mart University, including passing the HMU course exam and the one question evaluation to complete the required training. Please note, a score of 100% is required to pass the HMU Exam. Multiple attempts are possible.

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

The CDC course that was completed included these objectives

- Describe the Vaccine Safety, Development, and Emergency Use Authorization (EUA) mechanism to provide approval for COVID-19 vaccines.
- Describe the general storage and handling requirements for COVID-19 vaccines.
- Describe the general vaccine administration procedures for COVID-19 vaccines.
- Describe documentation and reporting procedures for adverse events associated with COVID-19 Vaccines.
- Locate current immunization resources to increase knowledge of team's role in program implementation for improved team performance.
- Implement disease detection and prevention health care services (e.g., smoking cessation, weight reduction, diabetes screening, blood pressure screening, immunization services) to prevent health problems and maintain health.

Introduction

This module recaps some of the key reminders of the information presented in the CDC's "**COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers**. As you review the points below, you are encouraged to revisit the CDC course, accessible at https://www2.cdc.gov/vaccines/ed/covid19/SHVA/index.asp for deeper learning. This summary is not intended to serve as a substitute for, nor replacement of, the required CDC trainings. You are responsible for ALL information presented in the original CDC trainings including, but not limited to, any updates or revisions that may occur following the availability of this training module and/or successful completion of this course. All staff members are responsible for staying up to date on newly released information and revisions to guidelines, program requirements and standards. Nothing in this training should be interpreted to supersede any law, regulation, statute, or requirement set forth by any federal, state, local, or reigning public health authority. When in question, contact the corresponding authority. If unavailable, professional judgement should be used.

Administering COVID-19 Vaccines During the Pandemic

As with other parts of daily life during the COVID-19 Pandemic new information and guidance are rapidly changing. It is important for all health care professionals to remain vigilant and constantly seek the most current guidance. For pharmacies administering vaccines during the pandemic, guidance from federal, state, tribal, local, and territorial health officials could affect practice. It is the pharmacy's responsibility to maintain awareness of and adherence to all official guidance.

Ensuring Vaccine Safety Throughout the Lifecycle

Before a vaccine is available for administration to patients, multiple organizations are in involved to ensure safety and effectiveness. This includes critical reviews by the FDA and ACIP. After the vaccine product is launched safety monitoring continues. Pharmacists will have responsibilities ~~in~~ monitoring for and reporting adverse events.

Visit the CDC website: Ensuring the Safety of COVID-19 Vaccines in the United States for a review of all tools and resources that are available to ensure the safety on the COVID-19 vaccines. Pharmacies have a responsibility to encourage patients to use the V-safe ^{SM} after Vaccination Health Checker application. Pharmacies are also responsible to report any vaccine administration errors, serious adverse events, regardless of the cause; cases of Multisystem Inflammatory Syndrome (MIS) and cases of COVID-19 that result in hospitalization or death using the Vaccine Adverse Event Reporting System (VAERS).

Serious Adverse Events are defined as:

1. Death;
2. A life-threatening AE;
3. Inpatient hospitalization or prolongation of existing hospitalization;
4. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
5. A congenital anomaly/birth defect;
6. An important medical event that may not result in death, be life-threatening, or require hospitalization, but may be considered serious when, based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

VAERS REPORTING

VAERS reports are submitted online: https://vaers.hhs.gov/uploadFile/index.jsp. The website has two options for submitting reports. Submissions can be made directly online in an interactive webform or by completing a fillable PDF that can be downloaded from the site, completing the information and uploading the form to the website. Pharmacies must keep a copy of all reports submitted to VAERS for a minimum of 3 years. To do this, you may email a copy of the interactive online webform to yourself at the end of the session or save a copy of the completed fillable PDF.

Please note that the webform will time out and erase all data within 20 minutes.

V-safe ^{SM} After Vaccination Health Checker

The government created a smartphone application called v-safe [sm] to connect with patients receiving the COVID-19 vaccines for important reminders and health checks. The app also is used as an additional vaccine safety monitoring tool. Pharmacies will be required to recommend v-safe[sm] participation to all vaccine recipients. Information about the application is available https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html Professional recommendations are required. Recipient participation is not required.

Emergency Use Authorization

An Emergency Use Authorization (EUA) may be issued by the FDA to allow access to critical medical products that may help during a public health emergency. EUAs are issued based upon specific criteria:

- 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.

EUA Fact Sheet for Health Care Providers

An EUA for Health Care Providers is similar to a package insert. Each product specific EUA contains:

- COVID-19 disease description
- Dosage and administration information
- Storage and handling instructions
- Dose preparation and administration information
- Requirements for use of vaccine under EUA
- Information to provide to vaccine recipients/caregivers
- 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

HCP Conditions of Use

Health Care providers have three requirements, or conditions of use when using a product under an EUA. The conditions of use for Health Care providers include:

- 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 Recipients

The recipient EUA is a product specific fact sheet that must be given to that patient prior to administration. It is similar to a Vaccine Information Statement (VIS) for licensed products. The EUA Fact Sheet for Recipients provides 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

Pharmacies are responsible for maintaining the cold chain and managing expiration and beyond use dates to avoid spoiled or wasted products. The EUA for Health Care providers or manufacturer websites provide information about storage and handling requirements and expiration and beyond use date information.

Potency is reduced every time a vaccine is exposed to improper conditions. This includes exposure to heat, cold or light at any step in the cold chain. Once lost, potency cannot be restored. Liquid vaccines that contain an adjuvant can permanently lose potency when exposed to freezing temperatures. Extreme care must be taken to ensure that a refrigerated vaccine is never frozen, even temporarily, Vaccine appearance is not a reliable indicator that vaccines have been stored in inappropriate conditions. Inactivated vaccines, even when exposed to freezing temperatures, may not appear frozen giving no indication of reduced or lost potency.

Managing Temperature Excursions

Maintaining the cold chain is critical to protect the COVID-19 vaccines. If a temperature excursion occurs, contact the manufacturer with complete details to receive recommendations for how to handle.

Safe administration

All pharmacies are required to follow standard immunization practices and SOPs that have been developed for any immunization delivered in the pharmacy. These include proper training and certification of individuals providing immunizations and well-defined policies for all other general operations.

When administering vaccines during a pandemic, it is critical to practice infection control practices that have been recommended by officials. Basic requirements for healthcare facilities include:

- physical distancing processes
- respiratory and hand hygiene
- surface decontamination

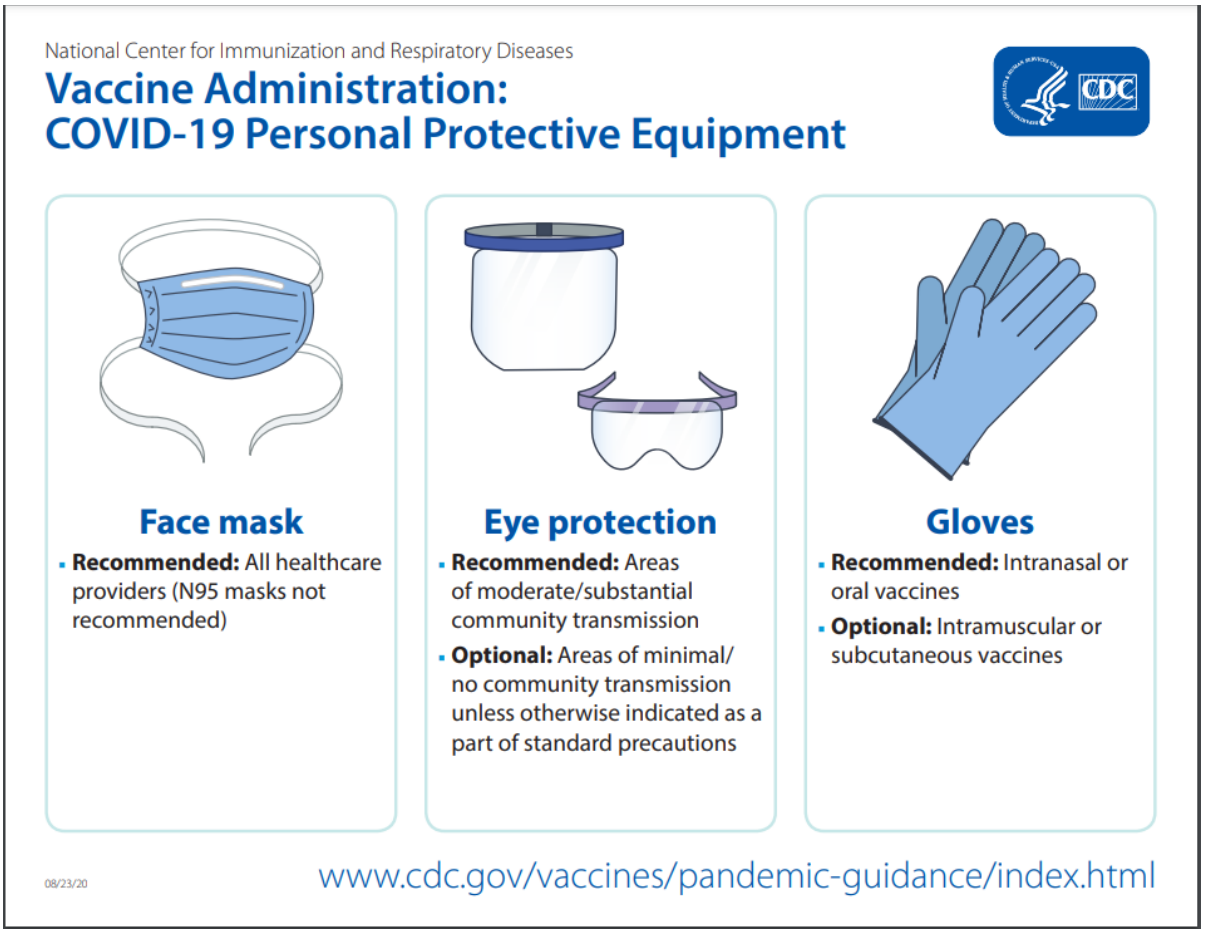
- source control

The CDC has also issued Interim Guidance for Routine and Influenza Immunization Services during the COVID-19 Pandemic. This resource contains multiple topics to ensure safety throughout the process. It describes steps that pharmacies can take, including the use of barriers during workflows.

Personal Protective Equipment (PPE)

When delivering immunizations, staff members must have the correct PPE. General recommendations include face masks for all healthcare workers. N95 masks are currently not recommended per the CDC. Eye protection may be recommended depending upon the level of transmission in the community. Gloves are also optional when administering intramuscular or subcutaneous vaccines. Gloves should be used when administering intranasal or oral vaccines.

The specific guidance is found here: https://www.cdc.gov/vaccines/hcp/admin/downloads/COVID-19-vaccine-administration-PPE-508.pdf



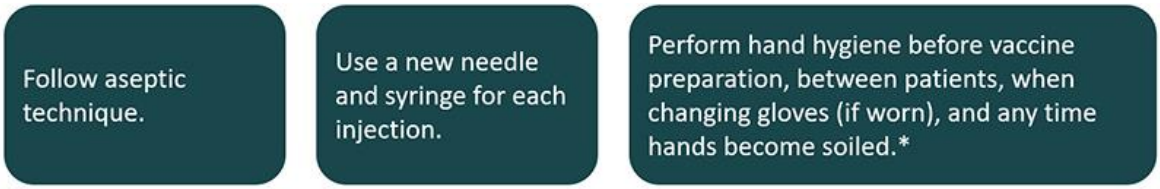
Vaccine Administration

Proper Vaccine administration is critical for every vaccine. Providers are expected to follow all policies and procedures.

Key resources to review are included in the training, including the CDC's Injection Safety Website and the vaccine administration website

COVID-19 Vaccine Administration Guidelines

COVID-19 vaccines are administered by the intramuscular (IM) route. There are three key components defined by the CDC to ensure safety and effectiveness:



*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.

Vaccination Schedule Maintenance

COVID-19 vaccines are not interchangeable, and some products require a series, more than one administration on a specific schedule. Patients must know which vaccine they received and when they need to return for an appointment. Follow-up appointments must be confirmed at the time of the first dose.

COVID-19 Vaccination Documentation

Administration related requirements

Pharmacists must ensure each of the following when administering COVID-19 vaccines to patients:

- Provide the EUA Fact Sheet for Recipients to the caregiver or patient prior to administration
- Provide 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 (IIS).

Adverse Event Reporting Requirements

Healthcare providers are required to report the following to VAERS:

Other reporting may be required to the CDC through the Federal Partner Point of Contact.

- 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.