



Healthcare

COVID-19 Vaccination Program Planning

This resource serves as a reference for healthcare organizations seeking to evaluate risk exposures associated with COVID-19. The content is not intended to represent a comprehensive listing of all actions needed to address the subject matter, but rather is a means of initiating internal discussion and self-examination. Your organization and risks may be different from those addressed herein, and you may wish to modify the activities and questions noted herein to suit your individual organizational practice and patient needs. The information contained herein is not intended to establish any standard of care, or address the circumstances of any specific healthcare organization. It is not intended to serve as legal advice appropriate for any particular factual situations, or to provide an acknowledgement that any given factual situation is covered under any CNA insurance policy. The material presented is not intended to constitute a binding contract. These statements do not constitute a risk management directive from CNA. No organization or individual should act upon this information without appropriate professional advice, including advice of legal counsel, given after a thorough examination of the individual situation, encompassing a review of relevant facts, laws and regulations. CNA assumes no responsibility for the consequences of the use or nonuse of this information.

As the COVID-19 pandemic continues, an urgent focus has been placed on the development, distribution and administration of vaccines. In an effort to address the public health emergency and facilitate availability of COVID-19 vaccines, the U.S. Food & Drug Administration (FDA) has granted [Emergency Use Authorization \(EUA\)](#) to designated vaccine manufacturers. EUA facilitates the distribution and administration of the vaccines under an investigational status, as the FDA evaluates their safety and efficacy.

When implementing a vaccination program, comprehensive procurement, distribution, and administration protocols must be established and monitored for compliance through adaptation of a program tailored to the unique circumstances of individual healthcare organizations. Ensuring that vaccines are administered in appropriate settings with adequate patient safety and monitoring procedures remains a critical consideration. Pandemic response planning will require effective collaboration among various public

and private sector business partners, including public health emergency preparedness programs, state and local emergency management agencies, healthcare organizations and community vaccination providers. While many of these providers participate in seasonal influenza vaccination campaigns, additional planning and collaboration will be necessary in order to establish and realize a vaccination response designed to address a public health emergency such as COVID-19.

Healthcare organizations and community vaccination providers should take steps to implement a pandemic vaccine program, or evaluate their existing program in view of the unique circumstances and risks of the specific entity. This resource presents ideas that healthcare organizations may consider in identifying and mitigating their particular risks associated with the vaccination initiative, recognizing the following factors, among others.

Program Planning

- Establish a multi-disciplinary internal pandemic vaccination planning and coordination team with a wide array of expertise that includes members from clinical, leadership, risk management and legal teams.
- Delineate specific responsibilities for areas of implementation, including a delegated individual who is tasked with maintaining current situational awareness of regulatory changes, vaccination guidance updates, as well as vaccine availability and procurement data.
- Collaborate with external public and private sector business partners, including health departments, emergency management agencies, state/local/federal authorities, community vaccination providers and neighboring healthcare organizations to coordinate pandemic vaccination response plans.
- Evaluate the population to be served within your jurisdiction and the logistical requirements to facilitate access to the vaccine in collaboration with community partners and local emergency planning agencies and health departments.
- Monitor the phased approach to vaccine release and administration, as determined by state departments of public health, and incorporate guidance received into the response plan on an ongoing basis.
- Analyze plan implementation and take ongoing action to identify and incorporate operational improvements, when appropriate.

Vaccination Team Requirements and Training

- Educate team members on vaccine specifics, which may include, but not be limited to:
 - Patient selection criteria.
 - Contraindications for administration.
 - Potential adverse reactions.
 - Administration requirements, including mixing with diluent, appropriate needle size and anatomic administration sites.
 - Dosing requirements.
 - Storage and handling requirements, including transport.
 - Post-vaccination monitoring requirements.

- Documentation requirements to include:
 - Date and time of administration.
 - Vaccine administered.
 - Dosage and lot number.
 - Route and site of administration.
 - Post-vaccination monitoring information.
- Infection control procedures.
- Reporting of adverse events, as well as vaccine administration errors, to the VAERS system.
- Orient staff to partnership programs with external agencies for vaccinations of residents/patients.
- Establish backup plans for each staff specialty area to prevent potential interruption of activities because of illness or other unforeseen circumstances.
- Prepare and instruct team members on how to respond to potential adverse events, including anaphylaxis.

Storage and Handling

COVID-19 vaccine products have various requirements for storage and temperature maintenance, including ultra-cold storage, which should be understood and utilized in order to maintain product efficacy and maximize shelf life. Organizations should comply with the CDC "Vaccine Storage and Handling Toolkit" by implementing actions such as the following, among others:

- Maintain reliable storage and temperature monitoring equipment.
- Ensure accurate vaccine management inventory.
- Train staff on proper vaccine storage and handling procedures.
- Implement a preventive maintenance program to verify proper equipment operation and monitoring of temperature.
- Educate staff on cold chain procedures.
- Check and record storage unit minimum and maximum temperatures at the beginning of each workday.
- Verify the temperature on vaccine shipments as soon as they arrive and ensure immediate placement into properly maintained storage environment.

Administration and Monitoring

- Follow [CDC guidelines](#) for vaccine screening, administration and monitoring.
- Confirm and document that candidates for vaccination have no known [contraindications](#).
- Document vaccine administration in the healthcare information record system within 24 hours of administration.
- Report data to the relevant system for the jurisdiction (i.e. [Immunization Information System – IIS](#)) as soon as possible, and no later than 72 hours after administration.
- Conduct the informed consent process and document it appropriately
- Verify patient monitoring in compliance with manufacturer specific and [CDC guidelines](#).
- Be prepared to manage possible [allergic reactions](#) such as [anaphylaxis](#).
- Establish a reporting structure to advise organizational leadership and risk management of any potential adverse events or complaints related to administration.

Multiple Dose Reminders

As multiple dose requirements may vary by manufacturer, organizations should develop a subsequent dose reminder program. Such a program may include, without limitation, the following:

- A system to document the manufacturer of first and subsequent doses administered, as vaccine products are not interchangeable.
- Follow-up dose appointment scheduling, as appropriate.
- Provision of COVID-19 vaccination report cards to recipients, including a request that they bring the card to their subsequent dose appointment(s).
- Completion of the COVID-19 vaccination report cards with accurate vaccine information to include:
 - Vaccine manufacturer.
 - Lot number.
 - Date of first dose administration.
 - Subsequent dose date(s).
- Multiple, redundant reminder methods such as encouraging recipients to add appointments or reminders to their electronic calendars; conducting reminder calls; and initiating automated patient calls, email messages and text messages such as [VaxText](#), among others.

Infection Control

- Select a vaccination location that permits physical distancing between individuals who are in line to receive the vaccine in conformity with the guidelines issued by the Centers For Disease Control and Prevention (CDC).
- Provide designated appointment times to vaccine recipients, while prohibiting “walk-in” appointments.
- Consider the creation of dedicated vaccination areas or specified hours for those at higher or severe risk associated with COVID-19.
- Implement strategies to manage patient flow and limit crowding or long lines by setting up unidirectional signage.
- Limit the overall number of individuals permitted in vaccination and monitoring areas.
- Select a vaccination location that permits proper distancing in post-vaccination monitoring areas.

Informed Consent

Prior to administering the vaccine, the informed consent process is conducted and properly documented.

- Share the manufacturer’s [Fact Sheet for Recipients and Caregivers](#).
- Inform the patient of all required information in the informed consent process, which typically includes, but may not be limited to:
 - EUA status of vaccine.
 - Known and potential benefits and risks, as well as notation of the extent to which risks and benefits are not known.
 - Option to accept or refuse the vaccine and the risks associated with refusal.
 - Any available alternatives.
- Obtain the patient’s written informed consent.
- Maintain the content of the discussion, materials provided to the patient, and the signed consent form in the healthcare information record.

Adverse Event Reporting

Per the [CDC COVID-19 Vaccination Program Provider Agreement](#), healthcare providers are required to report the following to [The Vaccine Adverse Event Reporting System \(VAERS\)](#) :

- Vaccine administration errors, whether associated with an adverse event (AE) or not.
- Serious AEs (even if it is not clear whether they are associated with the vaccine).
- Multisystem inflammatory syndrome (MIS) in children or adults.
- Cases of COVID-19 that result in hospitalization or death.

Providers also are encouraged to report to VAERS any additionally significant AEs following vaccination, even if it is not clear that they are caused by the vaccination.

As the COVID-19 pandemic continues, healthcare personnel and organizations provide the frontline services for patient care and vaccine administration. A well-planned pandemic vaccination program will help facilitate proper vaccine storage, administration, monitoring and support throughout this ongoing public health emergency. During this uniquely challenging time, CNA Healthcare stands ready to assist our customers in helping to address current and evolving demands. The strategies presented herein are provided for consideration and evaluation, through adaptation to your unique environment of care, including consultation with retained professionals, and designed to help mitigate risk exposures.

Resources

The following list of resources is provided to facilitate ongoing updates as the pandemic environment evolves:

American Dental Association

- [COVID-19 Vaccine Information and Resources](#)

American Hospital Association

- [COVID-19 Vaccines and Therapeutics](#)

American Medical Association

- [COVID-19 & Vaccine Development](#)

American Nurses Association

- [COVID-19 Resource Center](#)

American Pharmacists Association

- [APhA COVID-19 Resources: Know the Facts](#)

Centers for Disease Control and Prevention (CDC)

- [Advisory Committee on Immunization Practices \(ACIP\) – COVID-19 Vaccine Recommendations](#)
- [Clinical Considerations for COVID-19 Vaccination](#)
- [Guidance for Planning Vaccination Clinics Held at Satellite, Temporary or Off-Site Locations](#)
- [Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the US](#)

- [Vaccines & Immunizations Resource Page](#)
- [COVID Vaccination Toolkits](#)
- [U.S. COVID-19 Vaccine Product Information](#)
- [Vaccine Administration and Storage and Handling Resource Guide](#)

Centers for Medicare and Medicaid Services

- [COVID-19 Vaccine Policies & Guidance](#)

CNA Resources

- [Employer COVID-19 Vaccination Policies – Some Risks and Considerations](#)

Immunization Action Coalition

- [COVID-19 Resource Page](#)

LeadingAge

- [COVID-19 Vaccination Information and Resources](#)

U.S. Food and Drug Administration (FDA)

- [COVID-19 Vaccine Resource Page](#)
- [Emergency Use Authorization – Vaccines](#)

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