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COVID-19 Vaccine

Security, Storage, and Handling
Resource Guide

DISCLAIMER

The information contained in this resource guide is emerging and rapidly evolving and is subject to the professional judgment and interpretation of the practitioner due to the uniqueness of each medical facility's approach to the security, storage, and handling of vaccines and other drugs. ASHP provides this resource guide to help practitioners better understand current intelligence and guidance on the storage, handling, and security for the COVID-19 vaccines. ASHP has made reasonable efforts to ensure the accuracy and appropriateness of the information presented. However, given the evolving nature of the COVID-19 pandemic and distribution efforts in connection with the COVID-19 vaccines, any reader of this information is advised that ASHP is not responsible for the continued currency of the information, for any errors or omissions, and/or for any consequences arising from the use of the information in the resource guide in any and all practice settings. Any reader of this document is cautioned that ASHP makes no representation, guarantee, or warranty, express or implied, as to the accuracy and appropriateness of the information contained in this resource guide and will bear no responsibility or liability for the results or consequences of its uses.



The U.S. Food and Drug Administration (FDA) has issued an emergency use authorization (EUA) to permit the emergency use of both the Pfizer-BioNTech COVID-19 vaccine¹ and Moderna COVID-19 vaccine². Both of these vaccines require special storage and handling to ensure the vaccine is viable for use prior to the preparation of the vaccines for administration. During the course of this public health emergency, there is a compelling need to closely monitor scarce and essential life-saving resources such as the COVID-19 vaccines. As such, ensuring the proper receipt, storage, handling, and distribution processes of the vaccines is of utmost importance. As with any high-alert and high-value medication, there should be heightened security precautions to ensure the medication integrity, accuracy, and availability is dependable and trusted by patients and providers. There is an extreme societal need in ensuring that all possible doses of vaccines manufactured are utilized to vaccinate as many patients as possible and the integrity and security of the vaccines are critical components of this effort.

While the vaccine distribution process is an evolving one, this guide was compiled from the perspective of hospital and health-system pharmacy current COVID-19 vaccination efforts. This resource provides current intelligence and guidance on the storage, handling, and security for the COVID-19 vaccines. It incorporates information from the respective FDA EUA letters and Healthcare Provider Fact Sheets, as well as general best practices for cold chain storage and monitoring, management of the vaccines in preparation for administration, and safety and security measures for drugs prone to errors in mishandling (e.g., temperature excursions) or diversion.

This resource guide includes:

1. [General Security and Storage of COVID-19 Vaccine](#)
2. [Procurement of COVID-19 Vaccine](#)
3. [Pharmacy Security and Storage of COVID-19 Vaccine](#)
4. [Transport of COVID-19 Vaccine](#)
5. [Patient Care Area Security and Storage of COVID-19 Vaccine](#)
6. [Management of COVID-19 Vaccine Returns to Pharmacy](#)
7. [Community Pharmacy Considerations](#)

GENERAL COVID-19 VACCINE SECURITY AND STORAGE

It is imperative to establish policies and procedures that address all points of access, reflect a segregation of duties where there are overlapping processes for diversion risk, and ensure that the chain of custody and individual accountability are always maintained and verifiable. Additionally, with the specific storage requirements of the COVID-19 vaccine, organization assessment and necessary resources must be enabled to reduce risks to the product integrity.

- Storage, security, and surveillance of COVID-19 vaccines requires a coordinated approach that includes strict internal controls such as facility controls (e.g., camera surveillance), physical access controls (e.g., locks or biometric access technology, limited or restricted access areas), and frequent inventory checks and surveillance to allow discrepancies to be discovered in a timely manner. Key elements of COVID-19 vaccine storage and security include the following:
 - » COVID-19 vaccines are stored in a locked and secure location (e.g., automated dispensing devices; safe, locked freezer or refrigerator) at all times unless in the direct physical control of an authorized individual. When implementing or assessing facility and physical access controls, the security and safety of healthcare workers (HCWs) are taken into consideration.
 - » There is a defined process to ensure that only authorized individuals have access to the COVID-19 vaccine. Access to COVID-19 vaccine storage areas is limited or restricted to authorized personnel. There is a complete assessment of all HCWs with access privileges to ensure that only those permitted have access (i.e., currently employed, temporary employees, or licensed independent practitioners with privileges), and removal of access privileges occurs immediately upon separation.
 - » There are policies and procedures regarding vaccine access, including restrictions through assignment, key controls, and the use of passwords. For automated dispensing devices, biometric identification with a user ID is preferred over passwords. Storage freezers or refrigerators that are not automated dispensing devices are secured with an electronic lock that requires a user-specific biometric identification, code, or badge swipe. Access is recorded and retrievable for surveillance.
 - » Where traditional key lock security and manual inventory systems are used, there is a procedure to track keys, secure keys after hours, replace lost keys, and change locks. Any HCW authorized to have access to or prescribe COVID-19 vaccine will be able to provide appropriate photo identification upon request.
 - » The physical plant/building security should provide for monitoring of secure locations (e.g., video surveillance and recording), particularly in high-volume storage areas at risk for theft and diversion, such as the main pharmacy vault, inventory storage location, and packaging areas.
 - » Camera surveillance should be considered (1) within pharmacies when feasible; (2) in locations where there is high risk for diversion; (3) in locations where electronic or biometric access is not available; (4) in remote locations; and (5) to assist with an active diversion investigation.
 - » When delivering COVID-19 vaccine, restocking, or managing returns there should be a witness or other verification process to ensure accurate quantities and proper storage capacity and capability with a dedicated emergency power source and temperature alarm.

- Refrigerator and freezers utilize continuous-monitoring temperature alarm system technology to monitor temperatures and temperatures are manually verified at least twice daily.
- Organizational assessment is made and documented for the provision of redundancies in power supply as well as capital equipment (e.g., additional cubic footage for storage in the event of an emergency) to ensure all COVID-19 vaccine can be stored in the event of emergencies.
- In the event of wasting of COVID-19 vaccine, there should be an independent witness and documentation. Procedures should define what constitutes complete and timely documentation of waste, including any additional reporting to agencies that wasting of COVID-19 vaccine has occurred.
- For significant diversions or temperature excursions, a quality-improvement review is initiated by filing an incident report with your facility's error reporting system to trigger an investigation to determine a root cause and recommendations to prevent future occurrences. Proactive, systematic analyses of COVID-19 vaccine processes are conducted, such as a failure mode and effects analysis, to identify risk points and take action to improve diversion prevention practices.

PROCUREMENT OF COVID-19 VACCINE

Under Operation Warp Speed, the goal is to distribute millions of safe COVID-19 vaccines as quickly as possible. In order to do this, there must be effective communication, collaboration, and coordination with government agencies, public health organizations, regulatory agencies, and health departments. Administration sites, such as hospitals and health systems, will need to communicate with the state as well as manufacturers to order and receive COVID-19 vaccines.

- Ensure there is a standard point-of-contact and process to coordinate ordering and receiving the COVID-19 vaccine.
- COVID-19 vaccines received are recorded on a perpetual inventory log, and accessible only to those authorized to procure the vaccine or manage vaccine inventory.
- Two authorized individuals count and check in COVID-19 vaccine received and confirm that the order, invoice, and product-received documentation match. The process is overseen by a licensed pharmacist.
- Conduct visual inspection of containers and temperature monitoring sensors to identify obvious signs of tampering and/or temperature excursions that may have occurred in transit.
- If there are no issues with the shipment, unpack vaccines and place them in the appropriate, properly functioning cold storage unit. If there are discrepancies with the packing slip or the monitor indicates a possible temperature excursion, document the monitor reading and then segregate and mark the vaccine as "Do Not Use," but still place the vaccine in a properly functioning cold storage unit. Report the event to your organizational leadership, state department of health, and file an incident report with your facility's error reporting system to trigger an investigation to determine root cause. Do not use or discard the vaccine until the department of health/manufacturer verifies the integrity of the vaccine.
- All COVID-19 vaccines are procured from the pharmacy. If other departments or individuals are authorized to procure the COVID-19 vaccine, there are checks and balances established to ensure the same policies and procedures are consistently followed throughout the organization.

- There are COVID-19 vaccine procurement and/or purchasing safeguards in place that prohibit ordering of COVID-19 vaccine by those not authorized by the organization. COVID-19 vaccines may only be ordered by authorized individuals.
- There is a process to investigate and remedy discrepancies when COVID-19 vaccines are received in the pharmacy from the wholesaler or other distributor.

PHARMACY SECURITY AND STORAGE OF COVID-19 VACCINE

Policies and procedures should be established that address all points of access, reflect a segregation of duties where there are overlapping processes for diversion risk, and ensure the chain of custody and individual accountability are always maintained and verifiable. Additionally, proper storage and handling is an important element to ensure vaccine integrity, and these special conditions need to be integrated into the overall accountability and security management of COVID-19 vaccine inventory policies and procedures.

Dispensing of the COVID-19 Vaccine

- A perpetual inventory is maintained, and a blind-count process is used when adding or removing COVID-19 vaccine from a pharmacy inventory location.
- Access to inventory is limited, with controls to identify who accessed the inventory, when the inventory was accessed, and what changes were made to the inventory; access provides a readily accessible audit trail.
- To minimize diversion through drug product alteration or tampering, drug products are inspected for alteration or tampering, and any potential discrepancy is investigated for possible diversion.
- Delivery and restocking of COVID-19 vaccines in point-of-dispensing (POD) and patient care locations require auditable verification of delivery and receipt.
- Returns from the patient care areas have an auditable verification of return. Returns are inspected for integrity.

Monitoring of COVID-19 Vaccine Inventory

- Controls are in place to monitor pharmacy inventories for discrepancies. COVID-19 vaccine inventory should be manually inventoried by two rotating, licensed, or otherwise authorized pharmacy personnel (e.g., pharmacy technicians) daily. The inventory count should include expired or otherwise unusable COVID-19 vaccine awaiting disposal or transfer to designated location/agency, and appropriate storage conditions. A proper handoff with clear instructions to pharmacy team members should take place after shift changes to ensure clearly communicated transitions between rotating staff.
- Assessment of risk for storage areas should be completed, and when determined a high-volume or high-risk area, more frequent verification audits should be considered to prevent or minimize inventory count discrepancies and minimize the time window for discovery of the discrepancy. At least one of those conducting the inventory is a licensed pharmacist.
- COVID-19 vaccine counts managed by automated dispensing devices or done manually are verified by a blind count each time a refrigerator or freezer is accessed.

- Inventory verification is conducted for COVID-19 vaccine managed by automated dispensing devices by two authorized HCWs if a blind count has not been performed within one week. COVID-19 vaccine not managed by automated dispensing devices are manually inventoried by two authorized HCWs at the beginning and end of every shift when the area is open for services.
- Documents used to procure or prescribe COVID-19 vaccine are secured and monitored with the same diligence as above-mentioned procedures to prevent theft or loss.

Pharmacy Storage of COVID-19 Vaccine

The Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine both have unique and specific storage requirements that are described in the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) for each manufacturers' vaccine. Additionally the Centers for Disease Control and Prevention (CDC) provides information on each vaccine.

- [FDA FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE \(VACCINATION PROVIDERS\)](#) (Pfizer-BioNTech)
- [CDC Product Information — Pfizer-BioNTech COVID-19 Vaccine](#)
- [FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING](#) (Moderna)
- [CDC Product Information — Moderna COVID-19 Vaccine](#)

Storage procedures must be employed to ensure maximum shelf-life capacity and minimize deterioration and waste of a constrained supply of COVID-19 vaccine.^{3,4}

- Cold chain storage and handling requirements for COVID-19 vaccines vary in temperature from refrigerated (2°C to 8°C) to frozen (-15°C to -25°C) to ultra-cold (-60°C to -80°C). Systems should be in place that allow for tracking and documentation of storage conditions throughout the cold chain. The use of medical-grade cold storage equipment to ensure appropriate storage of drug products is highly recommended.
- A process must be in place to ensure that COVID-19 vaccines are being stored at appropriate temperatures within the required temperature range including recording systems to log and track temperatures. Vaccine storage areas should maintain product temperature between the limits defined on the product label.
- Organizations should have processes in place to identify maintenance responsibilities and disposition of medications from a refrigerator or freezer that has deviated from the specified temperature range. Storage should be orderly and provide for segregation of approved, quarantined, or rejected drug product. It is important to sequester vaccine that has experienced a temperature excursion and properly label this potentially compromised vaccine (e.g., DO NOT USE") while still keeping this vaccine supply stored under the proper storage conditions until such time a final disposition is determined by the manufacturer whether or not the product can still be used.
- Organizations should conduct regular maintenance checks that can be divided into daily, weekly, monthly, and periodic actions (e.g., check if freezer doors are closed and seals intact; defrost; clean motor and coils).

- To ensure a reliable cold chain, it is imperative to have staff well trained in proper vaccine storage and handling practices, reliable storage and temperature monitoring equipment, and accurate vaccine inventory management.

TRANSPORT OF COVID-19 VACCINE

Due to the unique storage and handling requirements for the COVID-19 vaccines and the intrinsic risk of temperature excursions as well as the risk of diversion, two authorized HCW verification process should be implemented for any transfer of vaccine from one storage location to another. Considerations must be made for (a) non-pharmacy staff obtaining COVID-19 vaccine in limited volumes from the pharmacy, (b) pharmacy personnel replenishment of PODs and patient care areas (considerations need to include low and high volume replenishments), and (c) bulk COVID-19 vaccine transportation to PODs and patient care areas.

- Procedures exist to ensure the chain of custody and proper storage condition are maintained for transfer or transport of COVID-19 vaccine (e.g., from a central distribution hub).
- Procedures define the controls and documentation required when COVID-19 vaccines are transferred between pharmacies.
- All COVID-19 vaccine procurement paperwork is reviewed for completion and filed according to applicable laws and regulations.
- The pharmacist-in-charge has oversight and authority to ensure proper procurement controls are being utilized in patient-care areas under common control.
- Procedures are in place to ensure COVID-19 vaccines are stored appropriately to prevent any waste. Recommend implementing a double-check by authorized personnel, one of whom should be a pharmacist.

PATIENT CARE AREA SECURITY AND STORAGE OF COVID-19 VACCINE

Policies and procedures should be established that address all points of access, reflect a segregation of duties where there are overlapping processes for diversion risk, and ensure the chain of custody and individual accountability are always maintained and verifiable. Additionally, proper storage and handling is an important element to ensure vaccine integrity, and these special conditions need to be integrated into the overall accountability and security management of COVID-19 vaccine inventory policies and procedures.

- Verification of a perpetual inventory should be conducted on a regular basis with the frequency consistent with the controls to limit the time frame for discovery. It is important to identify inventory discrepancies in a timely manner so the reason for the discrepancy can be more easily investigated.

- Inventory verification is conducted for COVID-19 vaccine managed by automated dispensing devices by two authorized HCWs if a blind count has not been performed within one week. COVID-19 vaccine not managed by automated dispensing devices are manually inventoried by two authorized HCWs at the beginning and end of every shift when the area is open for services.
- Injectable drugs often have overfill in the vial. This overfill is variable from product to product and is determined by the technique and syringe/needle utilized by the HCW. The use of overfill from a vial must follow best practice technique and should be accounted for to ensure accuracy in medication administered and to prevent diversion. Considerations for management of overfill of the COVID-19 vaccines include:
 - » Establish organizational procedures on management of overfill.
 - » Conduct continuous quality improvement on procedures and among health professionals preparing and drawing doses of vaccine to determine any variances in expected outcomes.
 - » Document overfill doses administered on a daily basis.
- Nursing management integrates routine auditing and surveillance activities into core daily, weekly, or monthly responsibilities, including staff education regarding signs of diversion and diversion-reporting procedures; review of nursing removal, return, and wasting records; development, implementation, and monitoring of procedures for transactions; and investigation and reporting of suspected diversion in accordance with organization procedures.
- The organization should identify high-risk areas (e.g., areas with limited traffic in off-hours) and include an assessment of risk for diversion (e.g., known diversion points), ease of detection (e.g., high-volume locations, level of oversight and controls, state of awareness of patients), and probability of harm (e.g., potential to impact the quality of care). Automation and technology should be utilized in high-risk areas to facilitate security controls and surveillance. High-risk areas should be defined by the organization, but include areas where the same provider is prescribing, obtaining, preparing, and administering the medication.
- Pharmacy is immediately notified of and supports the reconciliation investigation when an unresolvable discrepancy is discovered, and an authorized pharmacist is responsible for overseeing the investigation of the discrepancy, even when a technician assists with these duties.
- Organizations should proactively assess their COVID-19 related medication and vaccine policies, procedures, and practices to the ASHP Guidelines on Preventing Medication Errors in Hospitals.⁵ Additional precautions should include:
 - » Ensure two healthcare professionals confirm product when being removed from bulk storage; either from the pharmacy bulk storage or at the point of care storage.
 - » Consider having different locations and/or different days of the week for administration for the different COVID-19 vaccines.
 - » Consider having each vaccinator or individual drawing up doses have the first five patients' doses checked by a second healthcare professional for each day (e.g. to ensure the “muscle memory” of the different dose milliliter requirements for each vaccine does not create an error).

MANAGEMENT OF COVID-19 VACCINE RETURNS TO PHARMACY STORAGE

The pharmacy department and organization will develop procedures for returns to the pharmacy storage. These situations may arise if there is a physical plant emergency, such as power outage or flooding. Additionally, if PODs and patient care areas are utilized in an alternating model for days dedicated to different COVID-19 vaccines there may be the need to return product to the centralized pharmacy storage location. Considerations should include:

- A witnessed count should occur with removal of COVID-19 vaccine from ancillary storage area.
- The same policies and procedures required for re-stocking of area for transport of COVID-19 vaccine back to the pharmacy department should be utilized for returns.
- There should be validation and integrity of storage conditions by two HCWs if return of COVID-19 vaccine to pharmacy is due to a physical plant issue.
- Returned vaccine is assessed for re-stocking in pharmacy, added to perpetual inventory as needed, and managed subsequently per organization's policy for the vaccine.
- Procedures should be developed to ensure first in-first out for any useable returned product due to the unique storage requirements of the COVID-19 vaccine.

COMMUNITY PHARMACY CONSIDERATIONS

Hospital and health-system owned community pharmacies might also be engaged in the procurement, storage, and administration of the COVID-19 vaccines. The guidance provided in this resource can and should be generally applicable to the community pharmacy setting. Additional considerations include:

- Security measures, such as camera surveillance throughout the pharmacy, are imperative to deter and monitor for suspected theft and provide an avenue for discrepancies to be resolved in a timely manner.
- Badge reader or biometric access should be required for access to all COVID-19 vaccine storage areas.
- Community pharmacies should consider having auditing systems in place to track and validate inventory adjustments performed by staff.
- Personnel should keep a complete and accurate written or electronic perpetual inventory record for the receipt and dispensing of all COVID-19 vaccines. The perpetual inventory should be updated each time a COVID-19 vaccine shipment is received and should be verified by two employees, one of whom needs to be a licensed provider. Furthermore, the same sign-off process in the perpetual inventory log should occur with each fill of a COVID-19 vaccine, when possible.
- If providing vaccination directly to patients off site, the pharmacy staff should ensure the chain of custody from preparation to delivery or administration to the patient and wasting, including procedures that validate that the chain of custody has been maintained.

REFERENCES:

1. [FDA FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE \(VACCINATION PROVIDERS\)](#) (Pfizer-BioNTech) (accessed Jan. 6, 2021)
2. [FDA FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE \(VACCINATION PROVIDERS\)](#) (Moderna) (accessed Jan. 6, 2021)
3. Risks and mitigation strategies for the storage and transportation of finished drug products (chapter 1079). In: The United States Pharmacopeia, 43 rev., and the National Formulary, 38 ed. Rockville, MD: The United States Pharmacopeial Convention; 2021. Accessed January 4, 2021. https://online.uspnf.com/uspnf/document/1_GUID-5EE764A5-0531-405E-9475-5D0D11E0921C_4_en-US
4. Centers for Disease Control and Prevention Vaccine Storage and Handling Toolkit; <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html> (accessed Jan. 6, 2021)
5. Cohen MR, Smetzer JL, Vaida AJ. guidelines on preventing medication errors in hospitals: Advancing medication safety to the next level, American Journal of Health-System Pharmacy, Volume 75, Issue 19, 1 October 2018, Pages 1444-1445, <https://doi.org/10.2146/ajhp180283>

ADDITIONAL RESOURCES:

ASHP Resources:

1. [ASHP Guidelines on Preventing Diversion of Controlled Substances](#)
2. [ASHP Guidelines on Preventing Medication Errors in Hospitals](#)
3. [ASHP Guidelines on the Pharmacist's Role in Immunization](#)
4. [ASHP Guidelines on the Safe Use of Automated Dispensing Devices](#)
5. [ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals](#)
6. [ASHP Principles for COVID-19 Vaccine Distribution, Allocation, and Mass Immunization](#)
7. [ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control](#)

Other Resources:

1. [COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations](#). U.S. Department of Health and Human Services Centers for Disease Control and Prevention (CDC). Published October 29, 2020. Accessed on Jan. 5, 2021.
2. [Operation Warp Speed Distribution Process](#). U.S. Department of Health and Human Services (HHS). Accessed on Jan. 5, 2021.
3. [Refrigerator/Freezer - Medication Temperature Logs](#). The Joint Commission. The Joint Commission. Published June 3, 2020. Accessed Jan. 5, 2021.

Last updated: January 7, 2021