

KPhA Checklist for KDHE COVID-19 Vaccine Site Visits

Vaccine Paperwork

- Has your staff changed recently? If so, report updates by emailing kdhe.covidenrollment@ks.gov to request a change to Sections A and B of your Program Provider Agreement
 - Any changes to Medical Director, Chief Executive Office, Vaccine Coordinator, and Backup Coordinator need to be reported
- Do you provide vaccine to other locations? If so:
 - Verify that the provider you're giving vaccine to is enrolled in the COVID-19 vaccine program – recommend keeping a copy of their Program Provider Agreement on file
 - Maintain a signed redistribution agreement with that site's information on file: <https://www.kansasvaccine.gov/DocumentCenter/View/180/CDC-COVID-19-Vaccine-Redistribution-Agreement-PDF?bidId=>
- Staff training documentation
 - APhA immunization certificate or equivalent for pharmacists
 - KPhA immunization certificate or equivalent for technicians
 - Vaccine related CE earned
 - Any other COVID-19 vaccine related education, such as vaccine specific education
- Standard operating procedure document (does not need to be vaccine specific, can be an immunization section in your pharmacy's SOP document)
 - Name and contact information for vaccine coordinator and backup
 - Staff roles and responsibilities
 - Storage and handling of vaccines, including receiving procedures
 - Procedures for monitoring expiration dates and what to do with expired/spoiled vaccines
 - Emergency procedures for vaccine storage failures and temperature excursions
- Vaccine inventory reported to Vaccines.gov on at least a weekly basis
- All vaccine records maintained for a minimum of 3 years
 - Temperature logs
 - Transfer logs/documentation
 - Billing records
 - Consent forms
 - Vaccine ordering records
 - Waste reports

Vaccine Storage

- Vaccine storage unit is not a dorm/cube style
 - pharmaceutical-grade unit preferred; household/commercial fridge standalone or household/commercial combo fridge/freezer (cannot use freezer for vaccine storage) is acceptable
- Digital data logger in every unit where vaccines are stored
 - Within calibration dates
 - Appropriate probe for vaccine storage used (propylene glycol vial preferred)
- Temperature logged manually daily – past month’s log available for review
 - Either min/max at the beginning of the workday or
 - Current temperature at start and end of workday
- Vaccines stored in original packaging
- Vaccines protected from light
- Vaccines are rotated on a first in, first out basis
- No expired vaccine stored with viable vaccine (store separately and label as DO NOT USE)
- “Do not disconnect” labels on fridge electrical outlet and circuit breaker
- No food stored in vaccine fridge!!!
- If other medications are in vaccine fridge, vaccines are stored separately and labeled as such
- Vaccine fridge maintained between 36°-46°
 - Any excursions outside this temperature addressed by calling manufacturer or state immediately
 - Excursion documentation maintained with temperature logs according to site policy
- If vaccines are transported (such as to a clinic location or due to unit failure)
 - Appropriate storage containers are used
 - Temperature conditions are monitored during storage
- Vaccinators are familiar with storage conditions for each vaccine product
 - How to determine correct expiration date
 - How long product can stay at room temperature
 - How long each product is viable after dilution or mixing (if that is required)

Vaccine Handling

- Vaccinators are familiar with how to mix or dilute each product
 - Recommend having current color copies or immediately visible CDC storage and handling documents available for each product – the summary document in these links is super helpful
 - Pfizer: <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/storage.html>
 - Moderna: <https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/storage.html>
 - Novavax: <https://www.cdc.gov/vaccines/covid-19/info-by-product/novavax/storage.html>
 - Janssen: <https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/storage.html>
- Vaccinators do not combine residuals from multiple vials to create a single dose
- If more than one product is being administered at a location, separate stations for preparation are used if possible
- If vaccines are pre-drawn (eg in prep for a clinic or busy day), individual syringes are labeled with name of vaccine, lot number, dose, exact beyond use date, and initials of the preparer

Vaccine Administration

- Vaccinators are familiar with each vaccine product, age requirement, primary series dose and booster dose (according to age and medical condition), and time between doses and boosters
- All vaccinees are screened for contraindications and precautions for the vaccine to be administered before the vaccine is administered
- Vaccinee name and date of birth and vaccine to be administered is verified with vaccinee prior to vaccine administration (eg “Jane Smith, 6/24/1968, getting Pfizer booster today, correct?”)
- EUA Patient Fact Sheet forms given to patients ahead of the vaccine (hard copy or electronic)
 - Recommend documenting form (hard copy or electronic) and that EUA was given on patient consent form/administration documentation
- COVID-19 Vaccine Record Card filled out and provided to patient after vaccine is administered
- Vaccine administration documented in pharmacy system within 24h of administration
- Vaccine recipients are never charged a fee for their COVID-19 vaccines, regardless of insurance coverage status or immigration status
- Vaccine recipients should be observed for 15-30 minutes following vaccine administration
- Moderate and severe adverse events are reported to VAERS

Vaccine waste

- Vaccine waste is minimized, but potential vaccine recipients should not be turned away for the sole reason of avoiding doses in a mixed or punctured vial not being used before the beyond-use date/time.
- Vaccine waste is reported to the immunization program within 72h of waste occurring
- Non-viable or wasted vaccine should be disposed of in sharps container

Recommended resources

- CDC Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>
 - o Several nice summary documents included at the top of this page – we recommend keeping active links to these summary documents handy or keeping up-to-date printed copies in your vaccination storage area
- CDC Vaccine Storage and Handling Toolkit: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>
- KDHE Abbreviated Provider Manual: <https://www.kansasvaccine.gov/DocumentCenter/View/333/KS-Vaccine-Abbreviated-Provider-Distribution-Manual-PDF?bidId=>
 - o Contains contact information for all KDHE Immunization resources

Contact information

- My regional consultant (non-urgent questions): _____
- KDHE on-call consultant (urgent questions, eg. vaccine fridge failure): 785-296-5592
- KSWebIZ Helpdesk: kdhe.immunizationregistry@ks.gov or 785-559-4227
- KPhA Immunization Consultant: Amanda Applegate – amanda@ksrx.org