CLINICAL SERVICE GUIDE
EMERGENCY CHANGES / PFIZER and MODERNA
COVID-19 VACCINES

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Kentucky Public Health
Prevent. Promote. Protect.

VACCINATION FOCUS

- **PHASE 1 ROLL-OUT:**
- 1a: **Healthcare personnel** - Includes: outpatient care, hospitals, persons working in these facilities –paid and unpaid- who have potential for direct or indirect exposure to Covid-19 virus.
- 1a: **Long-term care facilities**
- 1b: **Essential Employees**
- 1c: **Persons 65 years and older, high-risk populations**

Pfizer BioNtech Vaccine - BNT 162b2®

- *2 doses, 21 days apart*
- *Primary efficacy analysis demonstrates BNT162b2 to be 95% effective against COVID-19 beginning 28 days after the first dose.*
- *Efficacy was consistent across age, gender, race and ethnicity demographics; observed efficacy in adults over 65 years of age was over 94%*
- *Data demonstrate vaccine was well tolerated across all populations with over 43,000 participants enrolled; no serious safety concerns observed. Well tolerated.*
- *Vaccines began shipping this week. First vaccinations occurred this week across hospitals in the state.*

www.Pfizer.com

Storage & Handling

Pfizer / BioNTech Vaccine

Primary Packaging (See Fig 1)

1. 2ml glass multi-dose vial (MDV)
2. MDV has 0.45ml FROZEN LIQUID drug product
3. 5 DOSES per vial after dilution

Secondary Packaging "Single Tray" (See Fig 2)

1. Single tray holds 195 vials
2. 975 doses per tray (smaller tray with 25 vials/125 doses is in development)

Tertiary Container: Thermal Shipper (See Fig 3)

1. Minimum 1 tray (975 doses) up to 5 trays (4,875 doses) stacked in "payload" carton
2. Payload carton submerged in dry ice pellets
3. Thermal shipper keeps Ultra Low Temperature (ULT) (-75 +/- 15C) up to 10 days if stored at 15C to 25C WITHOUT OPENING.
4. Thermal shippers are reusable and designed to be a temporary storage container, if replenishing dry ice.

BNT-1273 Administration Supplies

*****US Government has purchased ancillary supplies (syringes, needles, swabs) and will be distributed. Diluent will be included in the kit.*****

DILUENT SPECIFICATIONS:

1. Each THAWED vial should be diluted with **1.8ML of 0.9% Sodium Chloride Injection**.
2. OPTIMAL diluent vial is 2ML (0.9% Sodium Chloride Injection) depending on availability.

*****IMPORTANT: REGARDLESS OF VOLUME OF DILUENT VIAL, IT MUST BE USED FOR ONE TIME DILUTION - AFTER 1.8ML WITHDRAWN, DISCARD REMAINING*****

1. Diluent vial can be plastic or glass
2. 2ML saline is preferred to reduce waste, risk of over-dilution, and infection risk associated with excessive diluent reuse.

For DILUENT WITHDRAWAL & MIXING:

1. ONE 3ML syringe (optimal) or 5ML syringe to pull up 1.8ML of 0.9% Sodium Chloride Injection from each diluent vial.
2. ONE 21G or narrower needle should be used to withdraw the diluent.

For VACCINE ADMINISTRATION (INTRAMUSCULAR INJECTION)

1. FIVE 1ML syringes for each vaccine vial (1 syringe for each 0.3ML dose/patient)
2. FIVE 23G or 25G needles for intramuscular injection for each vaccine vial (Appropriate needle lengths: 5/8”, 1” and 1.5”

BNT-1273 Preparation / Administration

1. Remove a THAWED vial of vaccine from the refrigerator and allow it to come to room temperature. **If using a FROZEN vial, THAW for 30 minutes at room temperature.
2. Vials at ROOM TEMPERATURE must be diluted within 2 HOURS. **CANNOT REFREEZE VIALS**.
3. **Invert gently 10 times to mix**.
4. **DO NOT SHAKE.**
5. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab and withdraw 0.3ML of the vaccine.
6. Visually inspect each dose prior to administration. Diluted vaccine will be an OFF-WHITE suspension. Verify dose volume to be 0.3ML and confirm there are no particulates or discoloration.
7. Administer by IM injection into the DELTOID MUSCLE.
8. FIRST VISIT: 30mcg/0.3ML dose. SECOND VISIT: 30mcg/0.3ML dose administered 21 DAYS after first dose**. Vaccines MUST be the SAME; it is not interchangeable with other COVID-19 vaccines.**

BNT162b2® – Pfizer/BioNTech® Vaccine CONSIDERATIONS

- Vaccination approved/recommended for persons 16 years of age and older. Advisory Committee on Immunization Practices (ACIP) states this is interim guidance and may be revised.
- Vaccine should be administered ALONE and 14-day minimum interval with other vaccines
- Vaccine should be administered without regard to prior COVID-19 infection. Defer vaccination if person is acutely ill.
- No current safety / efficacy data to support vaccinating persons who have received monoclonal antibodies or convalescent plasma…defer vaccination for 90 days to avoid treatment interference.
- No contraindications for persons with underlying medical conditions and who have no contraindication to vaccination
- Currently there are no recommendations for women who are Pregnant or Breastfeeding…shared clinical decision with MD or qualified medical provider
- Stagger vaccination….do not vaccinate your entire staff on the same day.
- IMMUNOCOMPROMISED and IMMUNOSUPPRESSIVE THERAPIES: Currently no safety data to support this high-risk group. Must discuss as follows: 1) Unknown vaccine safety in immunocompromised conditions 2) Potential for reduced immune response 3) Follow all current guidance to protect themselves against Covid-19 infection
- Continue to follow ALL recommended guidance regarding PPE, social distancing, large gatherings, etc.

Moderna mRNA-1273®

- *2 doses, 28 days apart*
- *94% effective*
- *Moderna filed for EUA on November 30. Awaiting FDA approval. Expected approval end of this week or weekend (December 17-20)*
- *Final information for EUA to follow*

Moderna® 2020

MODERNA mRNA 1273®

KEY POINTS

1. Flexible and adaptable supply chain
2. Use standard, existing vaccination infrastructure. Can be used in hospitals, doctor's offices, nursing homes, etc.
3. No dilution requirement.
4. Do not REFREEZE a thawed vial.
5. Protect vaccine from light.
6. Discard any PUNCTURED vial after 6 hours. Once opened (needle-punctured), store the vial at 2° to 25°C (36° to 77°F) for a maximum of 6 hours.)

Additional Considerations

- A Covid-19 EUA fact sheet should be given to recipients and caregivers (EUA fact sheets should come with vaccine supplies).
- Use caution with any persons with known history of vaccine reaction…consider vaccination at an emergency department or under direct physician supervision
- Consider monitoring all persons approximately 15 minutes after vaccination
- https://www.cdc.gov/vaccines/covid-19/info-by-manufacturer/Pfizer/clinicalconsiderations.html

VAERS

VACCINE ADVERSE EVENT REPORTING SYSTEM

ADVERSE EVENTS FOLLOWING VACCINATION

Adverse events have been reported following the administration of all vaccines. These events range from frequent, minor, local reactions to extremely rare, severe, systemic illness.

More complete information on adverse reaction to a specific vaccine may be found in the **ACIP** recommendations for each vaccine.

Events that occur after receipt of vaccine must be reported on the Vaccine Adverse Event Reporting System (**VAERS Form)** by the administering health provider. There are 2 ways on the https://vaers.hhs.gov/

1) Report Online via a secure site at https://vaers.hhs.gov/reportevent.html
2) Report using a PDF form. Forms and instructions at https://vaers.hhs.gov/uploadFile/index.jsp.

There is also a VAERS number: 1-800-822-7967

To ensure that the Kentucky Immunization Branch is aware of these events, please fax a copy to **502-564-4760.**

What should you do if you have a Vaccine reaction

1. Report the reaction to your Health Care Provider
2. Report the Reaction to Vaccine Adverse Event Reporting System (VAERS)

V-SAFE

- In addition to VAERS, there will be a mobile monitoring system called V-safe that will message the first receipts of vaccine and assess vaccine side effects. If they have adverse events, they will be referred to the Vaccine Adverse Event Reporting System. Furthermore , the VAERS team will be sending reports to the states on weekly basis through EPI-X instead of quarterly reporting any adverse events of the Covid-19 vaccine.
- https://www.cdc.gov/vsafe

Follow Up Information

PROVIDER ENROLLMENT SITE:

HTTPS://GOVSTATUS.EGOV.COM/KY-HEALTHCARE-GUIDANCE

VACCINE RECOMMENDATIONS

HTTPS://WWW.CDC.GOV/VACCINES/HCP/ACIP-RECS/VACC-SPECIFIC/COVID-19.HTML

EDUCATION & TRAINING SITE

HTTPS://WWW.CDC.GOV/VACCINES/ED/INDEX.HTML