Legislative Budget Committee

Phil Griffin | December 1, 2020
COVID-19 Vaccine Update

Where are we at today?

- There has not been authorization or approval of a vaccine to prevent COVID-19. In recent weeks, several vaccines have published press releases about their successful trials.

- Pfizer and Moderna have submitted for Emergency Use Authorization from the FDA.

- FDA expected to act on Pfizer 12/10 and Moderna 12/17
1. Food & Drug Administration sets rigorous standards for COVID-19 vaccine testing in humans

2. Clinical trials in a small group of volunteers to determine safety

3. Safety and effectiveness of a slightly larger study group

4. Researches safety and effectiveness of vaccine on very large trial group against control groups

5. Clinical trials complete by medical & research professionals

6. FDA reviews scientific data and other information

7. FDA makes a determination to approve vaccine or not

8. Advisory Committee on Immunization Practices (ACIP) reviews clinical trial data

9. ACIP makes a recommendation to CDC on vaccine and who should receive it

10. CDC makes vaccine available

11. Kansas’s vaccine distribution plan engaged

COVID-19 Vaccine Approval Process
COVID-19 Organizational Structure and Partner Involvement

**Internal Planning Committee**
- Project Leads Liaison
- Immunization/Tuberculosis Clinical Section Chief
- Public Health Emergency Preparedness Program Specialist
- Immunization Information System (IIS) Manager
- Immunization Clinical Field Services Manager
- Vaccine Coordinator
- Immunization Outreach Coordinator
- Emergency Management
- Director
- Deputy Director of Public Affairs
- GIS Database Administrators
- Adult Vaccine Coordinator
- Local Health Department Representatives
- Kansas Hospital Association
- Community Care Network of Kansas

**External Planning Committee**
- Alliance for Kansans with Developmental Disabilities
- Children's Cabinet and Trust Fund
- Community Care Network of Kansas
- InterHab
- Kansas African American Affairs Commission
- Kansas Area Agency on Aging
- Kansas Association of Local Health Departments
- Kansas Commission for the Deaf and Hard of Hearing
- Kansas Commission on Disability Concerns
- Kansas Department of Education
- Kansas Department on Aging and Disabilities
- Kansas Emergency Management
- Kansas Governor’s Office
- Kansas Health Foundation
- Kansas Highway Patrol
- Kansas Hispanic & Latino American Affairs Commission
- Kansas Hospital Association
- Kansas Medical Society
- Kansas Pharmacist Association
- Kansas State Nurses Association
- Mid America Regional Council
- Native American Affairs Commission
- United Methodists Health Ministry Fund
COVID-19 Vaccine Update

Phased Approach to COVID-19 Vaccination

- It is anticipated that the COVID-19 vaccine will initially be available in very limited doses but will scale up in production rapidly.
Current Broad Distribution Order

Phase 1A: (Expecting first delivery around mid-December)
- High Risk Healthcare Workers (ED, ICU staff)
- State of Kansas Continuity of Operations
- Federally Qualified Health Centers/Safety Net Clinics
- Pharmacists (Will be vaccinating LTCFs)
- Department of Corrections Staff (COVID-19 Medical Units)
- First Responders – Fire and EMS

Between Phase 1A/Phase 1B:
- Long Term Care Facility residents
- Local Health Department Staff
- Other First Responders

Phase 1B:
- Remaining unvaccinated people from groups above
- Those at most risk for severe illness/death from COVID-19

Phase 2: (estimated Spring)
- Essential Workers

Phase 3: (estimated Summer)
- General Public
COVID-19 Vaccine Update

Vaccine Allocation, Ordering, Distribution and Inventory Management

- Goal is to vaccinate all willing Kansans as vaccine is available
- Challenges of vaccine distribution
  - Unclear timeline and quantity
  - Most vaccine candidates require a 2-dose series which are not interchangeable
  - Usage of different storage and cold chain management for different vaccine candidates
    - Refrigeration (2 to 8 degree Celsius)
    - Standard Freezing (-15 to -25 degree Celsius)
    - Ultra Cold Freezing (-80 degree Celsius)
  - Multiple vaccinating partners some of which are new relationships
  - Varied dosing vial sizes with some much larger than usual
COVID-19 Vaccine Update

Vaccine Storage

- Thermal shipping container must be opened and inspected upon receipt
- Initial inspection must be completed in less than 10 minutes
- The thermal shipping container can only be opened twice per day for 3 minutes during each opening

Option 1
Placed in ultra-cold temperature freezer

Option 2
Maximize use of thermal shipping container

Option 3
One-time re-ice of thermal shipping container

Option 4
Immediately placed in refrigerator

If the thermal shipping container will be used for storage, it must be re-iced within 24 hours of initial inspection and then every 5 days thereafter. Up to 3 re-icings are authorized.

Vaccine Thawing

Minimum shipper quantity: 1 tray (195 vials, 975 doses)
Maximum shipper quantity: 5 trays (975 vials, 4875 doses)

If removed directly from ultra-cold temperatures, thaw vial at room temperature 30 minutes to 2 hours before dilution.

Once vaccine is thawed, it must be diluted within 2 hours; if unable to dilute within 2 hours, store at 2°–8°C.

Must use diluted vaccine within 6 hours (discard any unused, diluted vaccine after 6 hours).
COVID-19 Vaccine Update

COVID-19 Vaccine Safety Monitoring

• As with other vaccines, it will be imperative to monitor for any expected or unknown adverse events that occur after an individual receives the COVID-19 vaccine. This monitoring will happen by using VAERS and any other system indicated by the CDC and/or FDA

• Vaccine Adverse Event Reporting System (VAERS) was developed to:
  • Detect new, unusual, or rare vaccine adverse events
  • Monitor increases in known adverse events
  • Identify potential patient risk factors for particular types of adverse events
  • Assess the safety of newly licensed vaccines
  • Determine and address possible reporting clusters (e.g., suspected localized [temporally or geographically] or product-/batch-/lot-specific adverse event reporting);
  • Recognize persistent safe-use problems and administration errors
  • Provide a national safety monitoring system that extends to the entire general population for response to public health emergencies, such as a large-scale pandemic influenza vaccination program.
Thank You/Questions