Kentucky Public Health
Prevent. Promote. Protect.
Immunization Branch

Kentucky COVID-19 Vaccination Plan

Frequently Asked Questions

November 25, 2020

Contents

General COVID-19 Vaccine Information

Pfizer and its partner BioNTech announced that its first interim efficacy analysis has found its vaccine candidate is more than 95% effective. The study enrolled 43,538 participants and has not uncovered any serious safety concerns.

- FDA planned for soon after the required safety milestone is achieved.
- Clinical trial is going to continue through to final analysis at 164 confirmed cases in order to collect further data and characterize the vaccine candidate's performance against other study endpoints.
- Pfizer has submitted an Emergency Use Authorization (EUA) application as of 11/20/2020.

https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine

Moderna announced that its first interim efficacy analysis has found its vaccine candidate is 94.5% effective. The study enrolled over 30,000 participants and has not uncovered any serious safety concerns.

- Based on these interim safety and efficacy data, Moderna intends to submit for an Emergency Use Authorization (EUA) with the FDA in the coming weeks.
- Clinical trial is going to continue through to final analysis at 151 confirmed cases in order to collect further data and a median follow up of more than 2 months.
- By the end of 2020, Moderna expects to have approximately 20 million doses ready to ship in the U.S. and remains on track to manufacture 500 million to 1 billion doses globally in 2021.

https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy

Provider Enrollment

How can providers enroll to administer COVID-19 vaccine?

https://chfs.ky.gov/agencies/dph/covid19/CovidEnrollmentChecklist.pdf

https://redcap.link/COVID19VaccineProvider

Does every point of dispensing (POD) need a provider agreement, or can an organization have one provider agreement and host multiple PODs at different locations?

When an enrolled provider (e.g., local public clinic) takes vaccine offsite to a temporary location for a one-day vaccination clinic, it is not necessary to complete a provider agreement for that location. The provider named in Section B of the provider agreement should have indicated that a temporary/off-site setting would be used for vaccine administration.

Will VFC providers need to have a COVID-19 agreement signed as well as their VFC agreement or will the VFC agreement supersede a pandemic agreement?

Any provider receiving and administering COVID-19 vaccine will need to sign the COVID-19 agreement.

Can an organization with a provider agreement redistribute vaccine to a provider without an agreement?

The organization doing the redistribution may sign the provider agreement (Section A) and the redistribution agreement on behalf of all locations under its umbrella. Any location or site receiving redistributed vaccine from the organization must abide by all conditions of the provider agreement and submit a Section B form. If the organization is redistributing vaccine to a completely separate entity, the receiving entity must sign or be covered under a provider agreement (Section A).

How should Section B of the provider agreement be completed for a mass vaccinator that will be operating at a different site each day but receiving vaccine at a single location?

Section B is only required for the location where the vaccine will be received, and when a mobile vaccinator will hold multiple clinics at a single location. Transport records must be kept by the mobile vaccinator.

Inventory Management

Will providers be required to perform vaccine inventory reconciliations and, if so, how often?

Providers will be required to report vaccine inventory to VaccineFinder. During Phase 1A, inventory information must be reported daily.

How does my clinic enroll in vaccine finder?

Facilities will be "pre-registered" in VaccineFinder using the clinic information submitted on the Provider Enrollment. Once we process your enrollment form, we send that information to CDC. VaccineFinder will then send an email to the individual who completed the RedCap provider agreement, which will give directions on how to complete your provider profile in VaccineFinder. You will need to wait to do anything in VaccineFinder until you receive an email from them.

Is there a point of contact for vaccinefinder.org?

The point of contact for VaccineFinder is locatinghealth@healthmap.org. For information, please visit https://vaccinefinder.org/covid-provider-resources.

Vaccine Allocation and Supply

How will the vaccine be allocated to jurisdictions?

Allocations will be made based on population and how much vaccine is available from the manufacturers.

Who will define the subgroups of critical populations?

The Advisory Committee on Immunization Practices (ACIP) is considering four groups to possibly recommend COVID-19 vaccination for if supply is limited:

- Healthcare personnel (Learn who is included under the broad term "healthcare personnel".)
- Workers in essential and critical industries as defined by the Cybersecurity & Infrastructure Security Agency.
- People with certain underlying medical conditions
- Older adults

Since there will be a limited supply of vaccine initially, how is Kentucky using a phased approach to COVID-19 vaccination? What are the phases and who will get the vaccine first?

Each jurisdiction should plan for high-demand and low-demand scenarios and should be planning in terms of three phases.

- Phase 1: Potentially limited supply of COVID-19 vaccine doses available. Focus initial efforts on reaching the critical populations listed in Section 4: Critical Populations of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations.
- Phase 2: Large number of vaccine doses available. Focus on ensuring access to vaccine for members of Phase 1 critical populations who were not yet vaccinated as well as for the general population; expand provider network.
- Phase 3: Sufficient supply of vaccine doses for entire population (surplus of doses). Focus on ensuring equitable vaccination access across the entire population. Monitor vaccine uptake and coverage; reassess strategy to increase uptake in populations or communities with low coverage.

Will vaccine be available for children and adolescents in the initial phase?

At first, COVID-19 vaccines may not be authorized, approved, or recommended for children.

Vaccine Distribution

How many vaccine doses will each shipment contain in the initial phase?

The minimum order size and increment for centrally distributed vaccines will be 100 doses for Moderna and 975 doses for Pfizer per order; though early in the response, some ultra-cold

(60°C to -80°C) vaccine, if authorized for use or approved, may be shipped directly from the manufacturer in larger quantities.

How will jurisdictions or providers know they'll receive the same vaccine for both doses? Should jurisdictions or providers hold back stock for second doses to ensure they have a matching product?

In the early phases when vaccine is limited, the second dose will be held at the federal level to ensure availability of a matching dose to complete the vaccine series. Neither jurisdictions nor providers should hold vaccine for a second dose, especially in the first month.

Ancillary Kits/Supplies

What supplies will be provided with COVID-19 vaccine?

Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in VTrckS. Each kit will contain supplies to administer 975 doses of Pfizer vaccine or 100 doses of Moderna vaccine, including 105 needles, 105 syringes, 210 alcohol prep pads, four surgical masks and two face shields (per kit) for vaccinators, and 100 COVID-19 vaccination record cards for vaccine recipients.

Vaccine Storage and Handling

Will there be different storage and handling requirements for COVID-19 vaccine?

Yes, the Pfizer vaccine requires ultra-cold storage conditions. CDC is working on ways to support ultra-cold chain vaccine storage and handling needs.

Will there be additional funding for jurisdictions to purchase ultra-cold storage units?

Because CDC does not recommend jurisdictions invest in ultra-cold storage units at this time, there will be no additional funding available.

What are the on-site storage requirements and warm-up protocols for the Pfizer vaccine that must be stored at ultracold temperatures?

CDC anticipates jurisdictions will receive direct shipment to the vaccination provider site on a real-time, day-to-day basis. Currently, the Pfizer vaccine candidate requires storage at -60°C to -80°C or at 2–8°C for up to 5 days (i.e., 120 hours). Thawing: 3 hours at 2° to 8°C or 30 min at room temperature. Post-dilution in use period is 6 hours. However, stability testing is still ongoing and storage temperatures may change.

Will ultra-cold vaccine need to be stored on site or can it be transported on the day vaccine is being administered?

We do not recommend transporting the Pfizer vaccine at ultra-cold temperatures. However, the vaccine can be kept for 5 days (120 hours) between 2 and 8°C.

Additional Information:

Storage for Ultra-cold Pfizer vaccine:

- Vaccine will be shipped from the manufacturer in coolers that are packed with dry ice.
- This vaccine requires ultra-cold storage (-60° to -80° C) or storage at 2-8° C for up to 5 days (120 hours). Once reconstituted, the vaccine can be at room temperature for up to 6 hours.

Storage for Moderna Vaccine:

- Freezer: -25° to -15°C for 6 months.
- Refrigerator: 2° to 8° C for up to 30 days. Do NOT freeze.
- Room Temperature: up to 12 hours.
- Discard any punctured vial after 6 hours

Emergency Use Authorization (EUA) Fact Sheets

What is the difference between an EUA, an EUA Fact Sheet for Healthcare Providers and an EUA Fact Sheet for Patients?

During a public health emergency, the FDA can use its Emergency Use Authorization (EUA) authority to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives. The term "EUA" can refer either to the legal authority itself or to the regulatory status of a medical product, such as COVID-19 vaccine. When the FDA authorizes emergency use of a medical product such as the COVID-19 vaccine, an EUA Fact Sheet for Healthcare Providers gives instructions regarding administration of the vaccine and other important details. The EUA Fact Sheet for Recipients supplies information to the person receiving the vaccine regarding important details of the vaccine.

COVID-19 Vaccine Prep & Administration

Supplies Required to Prepare for Pfizer Vaccine:

- 1 Vial Pfizer BioNtech COVID-19 Vaccine
- 1 Vial 0.9% Sodium Chloride Injection (at least 2 mL)
- 1 diluent syringe/needle (3 mL or 5 mL syringe/21 G needle recommended)
- 5 dosing syringes/needles (1 mL syringe/ IM injection needle)
- Other ancillary materiels such as alcohol swabs, gloves, PPE

Pfizer Dilution Steps:

Remove thawed vial from refrigerator and allow it to reach room temperature

- For frozen vial, thaw for 30 min at room temperature
- Vials at room temperature must be diluted within 2 hours
    - Invert gently 10 times to mix

- DO NOT SHAKE

Preparing Pfizer Vaccine Dose:

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of vaccine
- Administer immediately

Pfizer Vaccine Administration:

- Visually inspect dose inside syringe, diluted vaccine will be an off-white suspension.
- Verify final dosing volume of 0.3 mL and there are no particulates and discoloration.
- Administer intramuscularly in the deltoid muscle
    - 0.3 mL dose at 1st visit
    - 21 day waiting period between doses
    - 0.3 mL dose at 2nd visit
    - 2nd dose MUST be Pfizer, it is NOT interchangeable with other vaccines

Administration for Moderna Vaccine:

- No dilution required
- Draw 0.5 mL
- Inject intramuscularly

Will there be guidance for mass vaccination clinics?

Yes. CDC has updated guidance for satellite, temporary, and off-site clinics and it is available at https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html.

What are the PPE requirements when administering vaccines during the COVID-19 pandemic?

CDC has issued "Interim Guidance for Immunization Services during the COVID-19 Pandemic" to help immunization providers in a variety of clinical settings plan for safe vaccine administration during the COVID-19 pandemic (see https://www.cdc.gov/vaccines/pandemic-guidance/index.html). For information on PPE for healthcare workers, see https://www.cdc.gov/coronavirus/2019ncov/hcp/using-ppe.html.

Does CDC recommend an observation period after vaccination?

The Advisory Committee on Immunization Practices (ACIP) currently recommends that providers should consider observing vaccine recipients for 15 minutes after receipt of a vaccine.

Is social distancing necessary when an individual receives their second dose of vaccine?

CDC recommends following the "Vaccination Guidance during a Pandemic" for all routine vaccination as well as for planning for COVID-19 vaccination clinics (see https://www.cdc.gov/vaccines/pandemicguidance/index.html).

Billing, Costs and Reimbursement

Who will pay for COVID-19 vaccine? Can it be ordered privately?

COVID-19 vaccine will be procured and distributed by the federal government at no cost to enrolled COVID19 vaccination providers

Can a client be turned away if they owe a previous balance to the provider?

COVID-19 vaccine is being provided at no cost to participating vaccine providers and should be provided regardless of ability to pay.

Will providers be able to charge a COVID-19 vaccine administration fee?

Providers can bill for an office visit when administering COVID-19 vaccine if the visit meets the criteria for office visit coding under a recipient's plan. However, participating vaccine providers must administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay COVID-19 vaccine administration fees or coverage status, as stated in the CDC Provider Agreement. Vaccine providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient. Vaccine providers may not seek any reimbursement, including through balance billing, from the vaccine recipient. For uninsured patients, the vaccine provider can seek reimbursement for an administration fee from the HRSA Provider Relief Fund. https://www.hrsa.gov/CovidUninsuredClaim

Pharmacies and Long-term Care Facilities

For independent pharmacies, can the pharmacists sign the CDC provider agreement even though they do not have prescribing authority?

Yes, pharmacists may sign the provider agreement. Per the PREP Act.

Is CDC considering using private contractors, such as pharmacy chains, as PODs in future phases?

In Phase 2, once we have adequate supply of COVID-19 vaccine(s) to support broader vaccination efforts. The U.S. Department of Health and Human Services is partnering with CVS and Walgreens to offer on-site COVID-19 vaccination services for nursing homes and assisted living facilities residents once they are recommended to receive vaccine. The Pharmacy Partnership for Long-term Care (LTC) Program provides end-to-end management of the COVID-19 vaccination process, including cold-chain management, on-site vaccinations, and fulfillment of reporting requirements, to facilitate safe vaccination of this prioritized patient population, while reducing burden on facilities and jurisdictional health departments.

Second-dose Reminders

What assistance will jurisdictions receive to ensure the same vaccine is administered for the first and second doses? How will the type of vaccine and intervals between doses be tracked?

COVID-19 vaccination record cards will be provided as part of vaccine ancillary kits. In addition to recording information in the Kentucky Immunization Registry (KYIR) and/or Electronic Health Record (EHR), vaccination providers are required to complete these cards with accurate vaccine information (i.e., vaccine manufacturer, lot number, date of first dose administration, and second dose due date), and give them to each vaccine recipient who receives vaccine to ensure a basic vaccination record is provided. Several of the vaccines in clinical trials will require 2 doses, separated by 21(Pfizer) or 28(Moderna) days. Vaccination providers will provide the completed vaccination each vaccine recipient to ensure a basic vaccination record is provided and to keep the card in case the KYIR or other system is not available when they return for their second dose.

Vaccine Safety Monitoring

CDC will use established and new systems to monitor vaccine safety:

- V-SAFE, a new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines. V-SAFE will use text messaging and web surveys to check in with vaccine recipients and will also provide telephone follow up to anyone who reports medically important adverse events.
- The Vaccine Adverse Event Reporting System (VAERS), an early warning system, co-managed by CDC and FDA, which monitors for potential vaccine safety problems; anyone can report possible vaccine side effects to VAERS.
- The Vaccine Safety Datalink (VSD), a collaboration between CDC and nine healthcare organizations that conducts vaccine safety monitoring and research.
  The Clinical Immunization Safety Assessment (CISA) Project, a partnership between CDC and several medical centers that provides expert consultation and conducts clinical research on vaccine-associated health risks.