Updated Pediatric COVID-19 Vaccination Operational Planning Guide — Information for the COVID-19 Vaccine for Children 6 Months–4 Years Old

Overview

In October 2021, CDC released the first Pediatric Operational Planning Guide outlining key aspects of a COVID-19 vaccination program for children younger than 12 years. At the beginning of November 2021, COVID-19 vaccine for children ages 5–11 years was authorized by the Food and Drug Administration (FDA) and subsequently recommended by the Advisory Committee on Immunization Practices (ACIP) and CDC. Currently, the Pfizer-BioNTech two-dose series remains the only recommended COVID-19 vaccine for children ages 5–11 years.

Pfizer-BioNTech and Moderna are conducting clinical trials and data collection for COVID-19 vaccines for children ages 6 months through 4 years (henceforth referred to as ages 6m–4 years). Pfizer-BioNTech has begun submitting data to FDA for an Emergency Use Authorization (EUA) application for a vaccine for children ages 6m–4 years. Data were submitted for two doses of what is anticipated to be a three-dose series. This operational planning guide includes details about the anticipated Pfizer-BioNTech product and may be updated as other manufacturers submit applications for FDA review. This guide is intended to inform planning in all current COVID-19 vaccine programs and channels (referred to as jurisdictions for the remainder of this document) for distribution of vaccine for children ages 6m–4 years, should it receive FDA EUA and CDC recommendation. Additional information will be released as it becomes available.

FACTS

- There are approximately 18 million children ages 6 months through 4 years in the United States. The U.S. government has procured enough vaccine to support vaccination of this population, pending FDA EUA and CDC recommendation. FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) is scheduled to meet on February 15, 2022. ACIP is anticipated to meet within several days of VRBPAC; the meeting will be posted here once scheduled: https://www.cdc.gov/vaccines/acip/index.html.
- The current products for adults, adolescents, and children ages 5–11 years should NOT be used in children ages 6m–4 years.
- The Pfizer-BioNTech vaccine for 6m–4-year-olds ships at -80°C, like all current Pfizer COVID-19 vaccines, and has a similar product configuration to the 5–11-year-old vaccine, but with a different color cap (maroon), different dose (3 micrograms/0.2mL), different amount of diluent added (2.2mL), and a new national drug code (NDC). Please see accompanying CDC document "Pfizer-BioNTech COVID-19 Vaccine Products" for more details. The new NDC will require additional coding and information technology accommodations, which are underway. The packaging configuration for vaccine product for children ages 6m–4 years is expected to be 10-dose vials in cartons of 10 vials each (100 doses total) with a minimum order quantity of 100 doses. The diluent will be provided with ancillary supplies to support 100 doses per kit.

- The PREP Act and the PREP Act Declaration issued by the Secretary of the Department of Health and Human Services authorize and provide liability protections to licensed providers and others identified in the declaration to administer COVID-19 vaccines authorized by FDA, including COVID-19 vaccines authorized for administration to children. This authorization preempts state requirements that would otherwise prohibit, or effectively prohibit, these providers from administering the vaccine. The PREP Act Declaration authorizes certain providers listed in the Declaration to administer vaccines regardless of state requirements. For example, the Declaration authorizes pharmacists, pharmacy interns and pharmacy technicians nationwide to order and/or administer COVID-19 vaccines, influenza vaccines, and other vaccines authorized by FDA and recommended by CDC for children ≥3 years old (Please see: https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf).

ASSUMPTIONS

- As of late January 2022, approximately two-thirds of Vaccines For Children (VFC) program providers were enrolled COVID-19 vaccine providers. Children ages 5–11 years have also received COVID-19 vaccine at other sites, including pharmacies, where approximately one-third of vaccinated children ages 5–11 years received their COVID-19 vaccine. While many pharmacies are planning for a COVID-19 vaccination program for children under 5 years, their ability to vaccinate these children may be limited for various reasons (e.g., PREP Act Declaration authorizations). For the 6m–4 years age group, encouraging VFC providers to enroll as COVID-19 vaccine providers and enrolled providers to administer the COVID-19 vaccine becomes even more critical to ensure access to COVID-19 vaccine as well as all other routine vaccines.
- Continued coordination through the jurisdiction will be needed for the Indian Health Services (IHS), Tribal and Urban Indian Health Programs, and Health Resources and Services Administration (HRSA) programs, which will continue to have directly-allocated vaccine supply at the same time as the jurisdictions.
- Similar to the COVID-19 vaccine rollout for 5–11-year-olds, jurisdictions should plan their ordering strategy now and identify priority locations to vaccinate children ages 6m–4 years.
- Shipment of Pfizer-BioNTech COVID-19 vaccine for ages 6m–4 years is planned to begin once FDA issues the EUA. However, vaccine administration can only begin following the CDC recommendation.
- Doses being supplied under this rollout will be made available under thresholds rather than allocations. This means that ordered doses will be replenished with each new threshold.
- Currently, planning is for a sequenced rollout involving an initial total of approximately 10 million doses. This will be split into two separate thresholds, with five million doses each. The first threshold of five million doses will make up Sequence 1a and Sequence 1b. The second threshold of five million will be Sequence 2. There will be continued supply in addition to the initial 10 million doses following Sequence 2.

Threshold 1 — Five million total doses (split between Sequence 1a and Sequence 1b)
- o Sequence 1a — As part of the total, two million doses will be made available pro-rata for jurisdictions and federal entities, including HRSA, to pre-order. The initial threshold of two million will be posted in Tiberius on February 7, 2022. Preordering will occur from 9:00 AM on February 7 up to 9:00 AM on February 11 . Federal pharmacy partners will not be able to order vaccine at this time.
    - Jurisdictions should begin to prioritize which sites would be first to receive doses based on various considerations (e.g., vaccinating children at highest risk for severe COVID-19 disease; ensuring vaccine equity; feasibility of sites efficiently implementing the vaccine program).
    - **All providers/facilities that order in Sequence 1a must be able to receive vaccine shipment on Monday February 21, which is Presidents' Day and a federal holiday**.
    - All jurisdictions should submit a least one order during this time to ensure all jurisdictions receive shipments of vaccine as product launches.
- o Sequence 1b — At approximately noon on February 17, Threshold 1 will be expanded by three million doses for ordering across all channels. Two million doses will be added to existing jurisdiction and federal entity thresholds (for a total threshold of 4 million doses across jurisdiction and federal entity awardees, including those in sequence 1a) and 1 million doses will be made available to the federal pharmacy partners at this time.
    - Orders received by the 9:00 AM cutoff on Friday, February 18 will be expected to begin delivering on Tuesday, February 22 and continue over the following days, depending on order volume.
    - **An additional one-time afternoon cutoff will occur at 2:00 PM on Friday, February 18.** Orders placed between 9:00 AM and 2:00 PM are expected to begin delivery starting Wednesday, February 23, but earlier delivery is possible.

Threshold 2 — Five million doses
- o Sequence 2 — Tentatively on February 25, or approximately one week after the CDC recommendation, thresholds will be refreshed for jurisdictions, federal entities, and pharmacy partners. As a reminder, this is a threshold top-off and not an allocation.
- o Providers will be responsible for managing second and potentially third doses (depending on the FDA authorization and CDC recommendation). However, the U.S. Government has sufficient product to ensure adequate supply for expected needs. Jurisdictions and clinicians should ensure that no vaccination opportunity is missed. Additional information on weekly thresholds after Sequence 2 will be forthcoming.

- Additional information regarding timing of delivery of vaccine shipments for each sequence will be shared in the coming days.

- Dashboards will be developed within the Tiberius application that will enable jurisdictions to view their order thresholds and optimally prioritize providers to receive initial shipments.
- The public will be directed to use www.vaccines.gov to help find providers who are offering COVID-19 pediatric vaccines. Thus, it is critical to strongly encourage all sites to turn on their public display so that their location may be displayed on www.vaccines.gov.
- The U.S. government and the manufacturer will be providing additional training to prepare providers to administer vaccine to younger children; providers and locations will all need to be trained.
- Vaccine administrations will be reported to the public on CDC COVID Data Tracker.

PROJECTED LAUNCH PLAN – CONSIDERATIONS FOR JURISDICTIONS

To enhance readiness to launch the 6m–4 years COVID-19 vaccination program and begin administering vaccine to children ages 6m–4 years immediately following the FDA authorization and CDC recommendation, jurisdictions should identify providers who will receive the initial doses of pediatric vaccine.

Similar to other COVID-19 vaccination program launches, including for other pediatric age groups, the first weeks of launch will require sites to be ready to meet the initial demand. Jurisdictions should create a distribution plan in coordination with local health departments and other partners, and carefully determine which sites will receive initial vaccine product, incorporating the considerations listed below. Jurisdictions will need to determine the sites to receive initial supplies of vaccine, balancing making vaccine accessible to all, especially where vaccine demand is expected to be high. While avoiding distributing inventory across too many sites and seeking to minimize vaccine loss, jurisdictions and clinicians should ensure that no vaccination opportunity is missed. The goal is an efficient rollout resulting in equitable vaccine access for the 6m–4 years age group in these initial weeks when demand is likely to be higher.

Considerations for selecting sites to receive the initial doses include vaccination sites:
- Location and access to a range of populations (e.g., urban and rural, access in communities that may be disproportionally impacted by COVID-19).
- Ability to handle 100-dose product configurations, depending on whether the jurisdiction has plans in place for redistribution.
- Vaccination capacity/throughput to meet community demand.
- Ability to use all 10 doses within 12 hours once a vial is opened. Sites should consider currently configured vial size (10-dose vials) in planning and one-day timeframe when scheduling children for vaccination, especially early in the program, to optimize use of supply.
- Ability to manage inventory to ensure availability of subsequent doses in their supply chain. The U.S. Government will not offer subsequent dose management of vaccine in ordering processes.
- Overall readiness (e.g., staffing, training, scheduling capabilities).

PEDIATRIC READINESS CHECKLIST	
Main Theme	**Key activities for readiness and response**
Supply and Ordering Readiness	❑ Determine which provider locations will receive initial vaccine supply, balancing equitable access with vaccination capacity and consideration of initial demand. Also ensure that an expanded set of providers will be able to provide equitable and convenient access to all children. ❑ Finalize a list of providers and sequence of provider activation for the first week of vaccine deliveries. CDC will be requesting information on initial sites early to facilitate validation and delivery of initial orders. ❑ Review CDC and manufacturer materials regarding product configuration, shipping, storage, dosing, dosing intervals, and adverse event profiles as they become available. ❑ Optimize vaccine use by ordering additional supply responsibly to balance unwanted accumulation of inventory and wastage while also ensuring no vaccination opportunity is missed. ❑ Manage and accurately report on-hand product inventory to track near-expiry and redistribution.

Provider Readiness	❑ Enroll an adequate network of providers to ensure equitable access across all pediatric populations:
	    ❑ Identify VFC providers who are not yet COVID-19 vaccination providers and facilitate their enrollment, especially providers who can fill a geographic gap in access and providers who care for children from racial and ethnic minority or other communities that may be disproportionally impacted by COVID-19. This is especially important for children <3 years, who generally will not be vaccinated in pharmacies but rather in primary care clinics.
	    ❑ Reach out to tribal nations within the respective areas for involvement in planning efforts.
	    ❑ Identify and facilitate enrollment of providers who frequently care for children with disabilities or special healthcare needs (e.g., children's hospitals, pediatric subspecialty clinics).
	❑ Prepare enrolled providers to receive pediatric COVID-19 vaccine:
	    ❑ Develop a plan to identify when additional sites may be needed to increase vaccination capacity for the 6m–4 years age group, especially during the initial weeks of the vaccination program when demand may be high.

	❑ Disseminate training and communication materials (e.g., preferred anatomical sites of vaccination in this age group) to providers, especially those who do not routinely care for this age group. ❑ Remind enrolled providers to make immunization information system (IIS) changes as needed to allow for the 6m–4 years age group. ❑ Remind enrolled providers to prepare scheduling systems and bolster capacity for their call center and website, as needed, to handle additional volume. ❑ Ensure providers or other on-location staff are equipped and trained to respond to possible severe allergic reactions, like anaphylaxis, especially in the very young age groups where equipment and medication dosing may be different. ❑ Ensure providers are prepared to recommend and co-administer COVID-19, influenza, and other childhood vaccines to ensure children are up-to-date on recommended vaccines. ❑ Encourage providers to consider offering the vaccine for children ages 6m–4 years who are not their patients and to turn on their public display so that their location may be displayed on [www.vaccines.gov.](www.vaccines.gov) ❑ Encourage providers to consider offering COVID-19, influenza, or other routine vaccines, as feasible, to additional eligible persons (e.g., siblings, family members, community members). ❑ Reinforce that providers are required to report certain adverse events following COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS) and support providers in encouraging parents or guardians to enroll their children in v-safe. ❑ Routinely evaluate the adequacy of the provider network, identifying gaps and whether additional vaccination locations (e.g., VFC providers, local public health departments, temporary vaccination clinics, FQHCs, rural health clinics) may be needed to further increase equitable access and ensure vaccine equity. ❑ Encourage providers who are not offering COVID-19 vaccination to refer their patients to nearby vaccination providers.
Information Technology Systems, Reporting and Monitoring	❑ Ensure electronic systems, including IISs, are prepared to report and track pediatric vaccine administration. ❑ Remember that the Special Project Provider (COVID-19 Providers) label is required for COVID-19 vaccine ordering. Inclusion of this flag on the provider record indicates that the jurisdiction has

	signed the agreement with the provider to receive COVID-19 vaccines. ❑ Leverage Tiberius dashboards to help plan for an appropriate network of pediatric providers that ensures access by all children. ❑ Once the vaccination program begins, continue to leverage Tiberius dashboards to monitor the program.
Communications	❑ Create a communication plan that outlines strategies, audiences, and products that will be used to promote COVID-19 vaccination of 6m–4-year-olds. ❑ Understand existing data on parent/guardian knowledge, attitudes, and perceptions regarding COVID-19 vaccination (including co-administration with influenza and routine childhood vaccines) in terms of demand, provider types, and locations where vaccination would be preferred, and anticipate timing of when parents/guardians would be interested in getting children vaccinated. Share these data with local jurisdictions and partners to help shape messages. ❑ Develop communications products for providers, pharmacies, and the public; align with federal messaging (e.g., How to Talk with Parents about COVID-19 Vaccination) and ensure communication materials are culturally and linguistically appropriate. ❑ Leverage partnerships (e.g., American Academy of Pediatrics [AAP] Chapters) to help mobilize providers and promote vaccination messaging to families. ❑ Engage and educate partners and trusted messengers (e.g., healthcare providers, community leaders, early childhood care and education providers, school administrators, faith leaders and faith-based organizations) as soon as possible.