

COVID-19 Vaccine for Children 6 Months–4 Years Old Preliminary Considerations for Pediatric Planning

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 old. At the beginning of November, COVID-19 vaccine for children ages 5–11 years old was authorized by FDA and recommended by the Advisory Committee on Immunization Practices (ACIP) and subsequently the CDC Director. Currently, the Pfizer-BioNTech two-dose series remains the only recommended COVID-19 vaccine for this age group.

Pfizer and Moderna are conducting clinical trials and data collection for children 6 months through 4 years old (henceforth referred to as 6m–4 years old or under 5 years old). An Emergency Use Authorization (EUA) application for the Pfizer-BioNTech vaccine for children 6m-4 years old has been submitted to the FDA and may receive authorization before other vaccines. Therefore, this guidance will include details about the anticipated Pfizer-BioNTech product and may be updated as other manufacturers submit applications for FDA review. This preliminary planning guide is intended to inform jurisdictional, federal partner, and pharmacy planning for distribution of vaccine for children 6m-4 years old should it receive Emergency Use Authorization (EUA). Additional operational planning guidance will be released as it becomes available.

FACTS

- There are approximately 18 million children 6 months through 4 years old in the United States. The U.S. government has procured enough vaccine to support vaccination of this population, pending FDA EUA and CDC recommendations.
- The current products for adults, adolescents, and children ages 5–11 years old should NOT be used in children under 5 years old.
- Any potential products currently in clinical trials would likely have configurations and storage and handling requirements similar to the other mRNA COVID-19 vaccine products in use.
- The Pfizer-BioNTech vaccine for 6m–4-year-olds has a similar product configuration to the 5–11-year-old pediatric vaccine, but with a different color cap, different dose, a new national drug code (NDC), and potentially a different schedule. The packaging configuration for vaccine product for children 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.
 - A new NDC will be used for any product with an under 5 years old indication and so will require additional coding and information technology accommodations, which are underway.
- The Pfizer-BioNTech COVID-19 vaccine for 6m–4 years old children will require diluent. The diluent will be provided with ancillary supplies to support 100 doses per kit.
- Once open, doses in vials must be used within 12 hours.

- 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, the 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) providers are enrolled COVID-19 vaccine providers. There have been other sites at which adults, adolescents, and even children 5–11 years old can receive vaccine, including pharmacies, where approximately 35-40% of vaccinated children 5–11 years old receive their COVID-19 vaccine. While pharmacies are planning for the under 5 years old age group, their ability to vaccinate these children may be limited. For the 6m–4 years old age group, encouraging VFC providers to enroll as COVID-19 vaccine providers and enrolled providers to administer the vaccine becomes even more critical to ensure access to potential COVID-19 vaccines as well as all other routine immunizations.
- 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 jurisdictions do.
- 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 6m–4 years old.
- 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 . 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 pediatric 6m–4 years old COVID-19 vaccination program and begin administering vaccine to children immediately following the FDA authorization and CDC recommendations, jurisdictions should identify providers who will receive the doses of pediatric vaccine initially.

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 and carefully determine which sites will receive product, incorporating the considerations listed below. The public will be directed to use www.vaccines.gov to help find providers offering pediatric vaccine. Jurisdictions will need to continue determining 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 risking higher vaccine wastage. The goal is an efficient rollout resulting in equitable vaccine access for the 6m–4 years old 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' include vaccination sites':

- Location and access to a range of populations (e.g., urban and rural, access in communities that may be disproportionately impacted by COVID-19).
- Ability to handle 100-dose product configurations or 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 minimize waste and optimize use of supply.
- Ability to manage their 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 |
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| <p>Supply and Ordering Readiness</p> | <ul style="list-style-type: none"> <input type="checkbox"/> 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. <input type="checkbox"/> 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. <input type="checkbox"/> Review CDC and manufacturer materials regarding product configuration, shipping, storage, dosing, dosing intervals, and adverse event profiles as they become available. <input type="checkbox"/> Optimize vaccine use <ul style="list-style-type: none"> <input type="checkbox"/> Order additional supply responsibly to avoid accumulation of unadministered inventory. <input type="checkbox"/> Understand vaccine wastage and, while seeking to minimize vaccine loss, ensure that no vaccination opportunity is missed. <input type="checkbox"/> Manage and accurately report on-hand product inventory to track near-expiry and redistribution. |
| <p>Provider Readiness</p> | <ul style="list-style-type: none"> <input type="checkbox"/> Enroll an adequate network of providers to ensure equitable access across all pediatric populations: <ul style="list-style-type: none"> <input type="checkbox"/> 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 disproportionately impacted by COVID-19. This is especially important for children <3 years old, who generally will not be vaccinated in pharmacies but rather in primary care clinics. <input type="checkbox"/> Reach out to tribal nations within the respective areas for involvement in planning efforts. <input type="checkbox"/> 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). <input type="checkbox"/> Prepare enrolled providers to receive pediatric COVID-19 vaccine: |

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| | <ul style="list-style-type: none"> <input type="checkbox"/> Develop a plan to identify when additional sites may be needed to increase vaccination capacity for the 6m–4 years old age group, especially during the initial weeks of the vaccination program when community level willingness to get vaccinated may be elevated. Limiting wastage from a 10-dose vial will be important. <input type="checkbox"/> Disseminate training and communication materials to providers. <input type="checkbox"/> Remind enrolled providers to make immunization information system (IIS) changes as needed to allow for pediatric populations. <input type="checkbox"/> Remind enrolled providers to prepare scheduling systems and bolster capacity for call center and website, as needed, to handle additional volume. <input type="checkbox"/> 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. <input type="checkbox"/> 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. <input type="checkbox"/> Encourage providers to consider offering the vaccine for children 6m–4 years old who are not their patients and to turn on their public display so that their location may be displayed on www.vaccines.gov. <input type="checkbox"/> 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). <input type="checkbox"/> 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. <input type="checkbox"/> Routinely evaluate the adequacy of the provider network, identifying gaps and whether additional vaccination locations (e.g., VFC providers, public health departments, temporary vaccination clinics, FQHCs, rural health clinics) may be needed to further increase equitable access and ensure vaccine equity. |
| <p>Information Technology Systems,</p> | <ul style="list-style-type: none"> <input type="checkbox"/> Ensure electronic systems, including IISs, are prepared to report and track pediatric vaccine administration. |

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| <p>Reporting and Monitoring</p> | <ul style="list-style-type: none"> <input type="checkbox"/> 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. <input type="checkbox"/> Leverage Tiberius dashboards to help plan for an appropriate network of pediatric providers that ensures access by all children. <input type="checkbox"/> Once the vaccination program begins, continue to leverage Tiberius dashboards to monitor the program. |
| <p>Communications</p> | <ul style="list-style-type: none"> <input type="checkbox"/> Create a communication plan that outlines strategies, audiences, and products that will be used to promote COVID-19 vaccination of 6m–4-year-olds. <input type="checkbox"/> Understand existing data on parent/guardian knowledge, attitudes, and perceptions regarding 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 jurisdictions and partners to help shape messages. <input type="checkbox"/> 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. <input type="checkbox"/> Leverage partnerships (e.g., American Academy of Pediatrics [AAP] State Chapters) to help mobilize providers and promote vaccination messaging to families. <input type="checkbox"/> 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. |