Pediatric COVID-19 Vaccination Operational Planning Guide

Overview

Multiple vaccine manufacturers are currently developing COVID-19 vaccines for children younger than 12 years old. This Operational Planning Guide outlines key aspects of a COVID-19 vaccination program for children younger than 12 years old and was designed to inform jurisdictional planning under the assumption of FDA authorization and CDC recommendations of at least one COVID-19 vaccine product for children of this age. An Emergency Use Authorization (EUA) application for the Pfizer-BioNTech vaccine for children 5-11 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. While some details about the pediatric COVID-19 vaccination program are still pending, this guide aims to inform planning based on current facts and planning assumptions and introduces strategies for consideration. Given jurisdictions' extensive experience implementing a COVID-19 vaccination program for adults and adolescents, this guide will mainly focus on key differences between that program and one designed to vaccinate children younger than 12 years old. Additional information will be released as it becomes available.

FACTS

- There are approximately 28 million children between the ages of 5-11 years old in the United States. The U.S. government has procured enough vaccine to support vaccination of this population.
- The Pfizer-BioNTech vaccine for 5–11-year-olds will be a new product configuration with new packaging, new preparation, and a new national drug code (NDC). The current product for adults and adolescents should not be used in children.
- The packaging configuration will be 10-dose vials in cartons of 10 vials each (100 doses total) pending FDA authorization. The product will be delivered in a newly updated product shipper at -80°C. Once the product arrives at the provider site, it can be stored for up to 10 weeks at 2 to 8°C and 6 months at ultracold temperatures of -90 to -60°C.
- Based on information current as of October 14th, it is anticipated that once a vial is opened, doses must be used within 6 hours.
- COVID-19 pediatric vaccines will require diluent. The diluent will be provided with ancillary supplies which are configured specifically for use in children. NOTE – reconstitution of the product for use on 5–11-year-olds uses a different volume of diluent than the adult formulation.
- The new NDC will require additional coding and information technology accommodations, which are underway.
- 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, 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)

- The months of November and December have multiple holidays. This should be considered in site selection and planning

ASSUMPTIONS

- FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) is scheduled to meet on October 26th. The CDC's Advisory Committee on Immunization Practices (ACIP) is scheduled to meet on November 2nd and 3rd, 2021. Jurisdictions should be ready to vaccinate children 5–11 years old shortly thereafter, pending FDA authorization and CDC recommendations.
- To ensure efficient rollout of vaccine supply, jurisdictions should plan their ordering strategy now and identify the priority locations and sequence of activating these priority locations during the initial weeks of the pediatric vaccination efforts.
- Shipment for pediatric vaccines can begin once FDA issues the EUA, and vaccine administration can begin once the CDC Director makes a recommendation.
    - For the initial roll out, a large, one-time bolus of pediatric product will be made available pro-rata for jurisdictions to pre-order.
        - Pre-orders will occur in three waves beginning October 20th. Jurisdictions will have 48 hours to enter orders for each wave.
        - Wave 1: Order cap will be raised October 20th
        - Wave 2: Order cap will be raised again on October 22nd
        - Wave 3: Order cap will be raised again on October 24th. This will be the final order cap raise of the initial launch period, and standard order cap cycles will begin the first full week of the launch.
        - Pre-ordering through these waves will allow for a manageable and equitable launch for this new vaccine
    - This bolus of supply will ensure that vaccine can be placed in many locations nationwide, making it easier for children to get vaccinated. These doses will remain in ordering caps for jurisdictions to order as needed. Second dose planning is the responsibility of the jurisdiction and should be considered as part of the initial order.
    - Depending on the jurisdiction's roll-out plan, the entire allocation may not need to be ordered the first week. Any unordered doses will remain allocated to the jurisdictions to order in the future as needed.
    - After this initial bolus, a weekly supply will be made available to help sustain the network and support site specific needs as vaccine is administered.

    - Jurisdictions and providers should continue to manage sites' second dose needs through supply provided. There is no separate allocation for second doses.
    - The minimum order will be 300 doses for program launch and 100 doses in subsequent weeks. Jurisdictions should account for these minimum order quantities when identifying the initial sequence of provider site activation for receipt of pediatric COVID-19 vaccine.
- Not all COVID-19 vaccination sites will need to receive pediatric vaccines. Vaccination providers that are most likely to vaccinate pediatric populations should be prioritized, with provider types likely varying across communities (e.g., pediatric clinics, federally qualified health centers [FQHC], pharmacies, rural health clinics [RHC]).
- Pharmacies participating in the Federal Retail Pharmacy Program (FRPP) will be able to order vaccine to select pharmacy locations, increasing the number of locations children may go to get vaccinated.
- Pharmacies will be asked to select locations within their network that can best manage supply and that are ready to administer vaccine to pediatric populations.
- Most jurisdictions have enrolled the majority of Vaccines for Children (VFC) providers as COVID-19 vaccination providers.
- Dashboards will be developed within the Tiberius application that will allow jurisdictions the ability to see 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 offering COVID-19 pediatric vaccines. Thus, it is critical that all providers report pediatric vaccine supply to VaccineFinder 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.
- To support increased logistics needed to push out large number of pediatric doses during the first week, no orders for Pfizer adult vaccine shipments (1170 product configuration) will be distributed during the pediatric product launch. This will be temporary and last for the first few days (exact dates to be determined based on timing of FDA authorization).

PROJECTED LAUNCH PLAN – CONSIDERATIONS FOR JURISDICTIONS

To enhance readiness to launch the pediatric COVID-19 vaccination program and begin administering vaccine to children immediately following the FDA authorization and CDC recommendations, jurisdictions should identify providers that will receive the doses of pediatric vaccine in weeks one and two of program launch.

Similar to other COVID-19 program launches (adolescents, additional doses, booster), the first weeks of launch will likely require sites to be ready to vaccinate a larger volume of children who may present once the program launches. The public will be directed to use www.vaccines.gov to help people find providers offering pediatric vaccine. 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 risking wastage. The goal is to allow for the most equitable access and efficient reach of the target pediatric age groups in these initial weeks when demand is higher.

Considerations for week 1 include:

- Clinic location and access to population (population density, rural access, access in communities that may be disproportionally impacted by COVID-19)
- Ability to handle 300 dose product configurations or has plans in place for redistribution
- Vaccination capacity/throughput to meet community demand
- Once open, doses in vials should be used within 6 hours. Clinics should consider vial size (10-doses) and 6-hour timeframe when scheduling children for vaccination, especially early in the program to minimize waste and optimize use of supply.
- Sites understand the U.S. Government will not offer second dose management of vaccine in ordering processes. Sites should manage their inventory to assure availability of second doses in their supply chain. Keep in mind, those receiving vaccine shortly after EUA may schedule second doses during November holidays.
- Overall site readiness (staffing, training, scheduling capabilities)

Considerations following initial rollout include:

- Ability to handle at least 100 dose product configurations or has plans in place for redistribution.
- Sites ordering more than 100 doses will find 10 packs consolidated into single shippers
- All other criteria same as week 1

PEDIATRIC READINESS CHECKLIST

Main Theme	Key activities for readiness and response
Supply and Ordering Readiness	❑ Review CDC and manufacturer materials regarding product configuration, shipping, storage, dosing, intervals, and adverse event profiles as they become available. ❑ Determine which provider locations will receive initial vaccine supply, balancing equitable access with vaccinating 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. Consider November holidays when selecting initial sites as second doses may be due during a holiday week. ❑ A list of providers, and sequence of provider activation, for the first week of vaccine deliveries should be finalized on the week of Oct 19th. CDC will be requesting information on initial sites early to facilitate validation and delivery of initial orders.

	❑ Be ready to submit pre-orders beginning October 20th.
	❑ Continue to optimally use vaccine supply.
	  ❑ Order additional supply responsibly to avoid accumulation of unadministered inventory.
	  ❑ Understand vaccine wastage, and while seeking to minimize vaccine loss, ensure that no vaccination opportunity is missed.
	❑ Continue to manage and accurately report on-hand product inventory to track near-expiry and redistribution.
	❑ Track trends in vaccine administration and adjust ordering patterns accordingly.

Provider Readiness	❑ Enrolling an adequate network of providers:
	  ❑ Review the adequacy of the provider network to ensure equitable access across all pediatric populations.
	  ❑ Facilitate enrollment of VFC providers who can become COVID-19 vaccination providers, with a focus on promoting equitable access by filling a geographic gap in communities that are disproportionally impacted by COVID-19, particularly those with a high social vulnerability index.
	  ❑ Reach out to tribal nations within the respective areas for involvement in planning efforts.
	  ❑ Consider offering school-located vaccination clinics, especially in areas with limited access to providers (e.g., rural or frontier areas).
	  ❑ Review CDC's Considerations for Planning School-Located Vaccination Clinics.
	  ❑ Consider identifying schools or school districts that routinely provide school-located influenza vaccination or that were successful in providing COVID-19 vaccination to adolescents and consider implementing those clinics for 5–11-year-old children.
	  ❑ 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).

	❑ Consider that November and December have multiple holidays when selecting sites. ❑ Preparing enrolled providers to receive pediatric COVID-19 vaccine: ❑ Develop a plan to identify when additional sites may be needed to increase vaccination capacity of 5-11-year-olds especially during the initial weeks of the vaccine program or when community level willingness to get vaccinated is high. ❑ Disseminate training and communication materials to providers. ❑ Remind enrolled providers to make immunization information system changes as needed to allow for pediatric populations. ❑ Remind enrolled providers to prepare scheduling systems and bolster capacity for 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. ❑ Ensure providers are prepared to co-administer COVID-19, influenza, and other childhood vaccines, when appropriate. ❑ 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., pharmacies, school-located and other temporary vaccination clinics, FQHCs, rural health clinics) may be needed to further increase equitable access and ensure vaccine equity. ❑ To help ensure equitable access, pharmacy locations selected should include those that help fill geographic gaps in vaccine providers or will be open during holidays

	when most other provider locations are closed or have decreased hours (e.g., Thanksgiving).
Information Technology Systems, Reporting and Monitoring	❑ Ensure electronic systems, including immunization information systems (IIS), 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 5–11-year-olds. ❑ Understand existing data on parent 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 (e.g., pediatric clinics, schools, pharmacies), and anticipated timing of when parents would be interested in children being vaccinated relative to issuance of EUA or Biologics License Application (BLA). Share these data with jurisdictions and partners to help shape messages. ❑ Develop communications products for providers, pharmacies, and 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] State Chapters) to help mobilize providers and messaging to families. ❑ Engage and educate partners and trusted messengers as soon as possible (e.g., healthcare providers, community leaders, school administrators, faith leaders and faith-based organizations).