10/08/2021

Pediatric COVID-19 Vaccination Operational Planning Information

Overview

Multiple vaccine manufacturers are currently developing COVID-19 vaccines for children <12 years old. An Emergency Use Authorization (EUA) application for the Pfizer-BioNTech COVID-19 Vaccine for children 5-11 years old has been submitted to the FDA and may receive authorization before other vaccines. This document outlines what is currently known and some assumptions to inform jurisdictional planning of a COVID-19 vaccination program for children <12 years old, pending FDA authorization and ACIP recommendations. Some details about the vaccination program are still pending and additional information will be forthcoming.

What is currently known about COVID-19 vaccines for children <12 years old

- There are approximately 28M children between the ages of 5-11 years old in the United States. The US government has procured enough vaccine to support vaccination of this population.
- The Pfizer-BioNTech COVID-19 Vaccine for 5–11-year-olds will be a new product with new packaging and a new national drug code (NDC). Current product for adults and adolescents should not be used in children.
- The new product configuration will be 10-dose vials, in packages of 10 vials (100 dose total) pending FDA authorization. The product can be stored for 10 weeks at 2-8°C. There will also be changes to the product shipper.
- COVID-19 pediatric vaccines will require diluent, and this will be provided with ancillary supplies which are configured specific to new vaccine packaging and appropriate for use in children.
- The new NDC will require additional coding and information technology accommodations, which are underway.
- The PREP Act has expanded scope of practice for pharmacists and pharmacy technicians nationwide to allow for provision of COVID-19 and influenza vaccinations to 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 regarding the COVID-19 vaccine program for children <12 years old

- FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) is scheduled to meet on Oct 26th. Jurisdictions should be ready to vaccinate children 5-11 years old shortly thereafter pending *FDA authorization and ACIP recommendations*.
- Ordering for pediatric vaccines will begin once FDA issues the EUA, and vaccine administration will begin once the CDC Director makes a recommendation based on the ACIP recommendations.
- Vaccine supply will be adequate to be delivered to thousands of sites within the first week following FDA authorization.
    - For the initial roll out, a large one-time bolus of pediatric product will be made available pro-rata for jurisdictions to order.
    - This will ensure that vaccine can be placed in thousands of locations nationwide making it easier for children to get vaccinated. These doses will remain in ordering caps for jurisdictions to order 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 site second dose needs through supply provided. There is no separate allocation for second doses.
  - The minimum order will be 300 doses in the first week and 100 doses in subsequent weeks.
- 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 for initial dose availability, with provider types likely varying across communities (e.g., pediatric clinics, federally qualified health centers [FQHC], pharmacies, rural health centers [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.
- Dashboards will be developed within the Tiberius application which will allow jurisdictions the ability to see their order thresholds, and optimally prioritize providers to receive initial shipments.

<u>Next steps</u>

- All jurisdictions should continue to promote enrollment of VFC providers as COVID-19 vaccine providers and identify priority pediatric vaccination sites and providers. Site selection in early stages of the program should also consider population access and provider readiness.
- CDC will release a Pediatric COVID-19 Vaccination Operational Planning Guide to help inform jurisdictional planning during the week of October 12th–15th. This guide will include additional details regarding COVID-19 vaccines for children <12 years old, key assumptions about the vaccine program, and strategies for jurisdictions to consider implementing, including school-located and community vaccination clinics.
- CDC will discuss this guide on partner calls during the week of October 12th–15th.