COVID-19 Press Briefing

June 23, 2022
COVID-19 Response Team Update

Dr. Ashish Jha
State of the Pandemic & Science Update

Dr. Rochelle P. Walensky
Science & Safety Update

Dr. Anthony Fauci
COVID-19 Vaccines for Young Children and Infants

**Moderna COVID-19 Vaccine:**
- Primary series of two 25μg doses 4 weeks apart, for individuals 6 months through 5 years of age.

**Pfizer-BioNTech COVID-19 Vaccine:**
- Primary series of three 3μg doses; initial two doses administered 3 weeks apart; third dose administered at least 8 weeks after the second dose; for individuals 6 months through 4 years of age.

The effectiveness and safety data evaluated and analyzed by the FDA to support the EUA for these pediatric populations were generated in ongoing, randomized, blinded, placebo-controlled clinical trials.
Summary Data for Moderna COVID-19 Vaccine in Children 6 Months-5 Years of Age

- ~6,400 children and infants
- Immune responses in both age groups (6-23 months and 2-5 years) comparable to those of young adults vaccinated with a higher dose determined to be effective
Safety Data for Moderna COVID-19 Vaccine in Children 6 Months-5 Years of Age

- Reactogenicity (local and systemic):
  - Mostly mild to moderate
  - 15 fevers of > 40.0°C reported among vaccine recipients and 3 among placebo recipients
  - Any “severe” (prevents daily activities) or greater reaction reported in 7.7% of vaccinated vs. 4.1% of placebo group
  - Reactogenicity post-vaccine consistent with other recommended vaccines in this age group

- Serious adverse events:
  - One participant in vaccine group experienced fever and febrile seizure considered by FDA as possibly related to vaccination

- No myocarditis or MIS-C reported

Source: S. Oliver/CDC; R. Das/Moderna. ACIP Meeting June 17-18, 2022
Summary Data for Pfizer-BioNTech COVID-19 Vaccine in Children 6 Months-4 Years of Age

- ~4,500 children and infants
- Immune responses in both age groups (6-23 months and 2-4 years) comparable to those of young adults vaccinated with a higher dose determined to be effective

3 weeks

8 weeks
Safety Data for Pfizer-BioNTech COVID-19 Vaccine in Children 6 Months-4 Years of Age

- Reactogenicity (local and systemic):
  - Mostly mild to moderate
  - 6 fevers of > 40.0°C were reported among vaccine recipients and 1 among placebo recipients
  - Any “severe” (prevents daily activities) or greater reaction reported in 4.3% of vaccinated vs. 3.6% of placebo group

- Serious adverse events:
  - One vaccine recipient had fever and pain in extremity considered by FDA as potentially consistent with an unspecified viral infection

- No myocarditis or MIS-C reported

Source: S. Oliver/CDC; R. Das/Moderna. ACIP Meeting June 17-18, 2022
Bottom Line

- FDA’s evaluation and analysis of the safety, effectiveness and manufacturing data were rigorous and comprehensive to support EUA.

- Known and potential benefits outweigh the known and potential risks in the pediatric populations authorized for use for each vaccine.

- Prior to making the decision to authorize and recommend these vaccines, FDA’s and CDC’s independent advisory committees were consulted and voted in support of authorization and recommendation.
American Academy of Pediatrics
Applauds CDC Approval of Safe, Effective COVID-19 Vaccines for Children Ages 6 Months and Older

The AAP recommends COVID-19 vaccination for all children and adolescents 6 months of age and older who do not have contraindications using a vaccine authorized for use for their age.