



THE WHITE HOUSE
WASHINGTON

COVID-19 Press Briefing

June 23, 2022





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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 25 μ g doses 4 weeks apart, for individuals 6 months through 5 years of age.

■ Pfizer-BioNTech COVID-19 Vaccine:

- Primary series of three 3 μ g 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



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

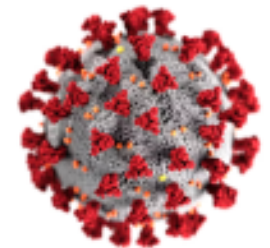
- **Reactogenicity (local and systemic):**
 - Mostly mild to moderate
 - 6 fevers of > 40.0°C were reported among vaccine recipients and 1 among placebo recipients
 - Any “severe” (prevents daily activities) or greater reaction reported in 4.3% of vaccinated vs. 3.6% of placebo group
- **Serious adverse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



June 18, 2022

DEDICATED TO THE HEALTH OF ALL CHILDREN™

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.**





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Q&A



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