



COVID-19 Vaccine Updates

Saroj Rai, PhD, MPH

Senior Scientific Advisor | Office of Chief State Epidemiologist

DISCLAIMER

The information presented today is based on CDC's recent guidance and MAY change.

December 2, 2021

COVID-19 Vaccine Pediatrics



TEXAS
Health and Human
Services

Texas Department of State
Health Services

Federal Regulatory Authorization & Recommendation Timeline

FDA Review / Authorization

- October 29, 2021, the US FDA issued an EUA of Pfizer COVID-19 vaccine for active immunization of individuals 5-11 years of age

FDA: Food and Drug Administration EUA: Emergency Use Authorization

CDC (ACIP) Recommendation

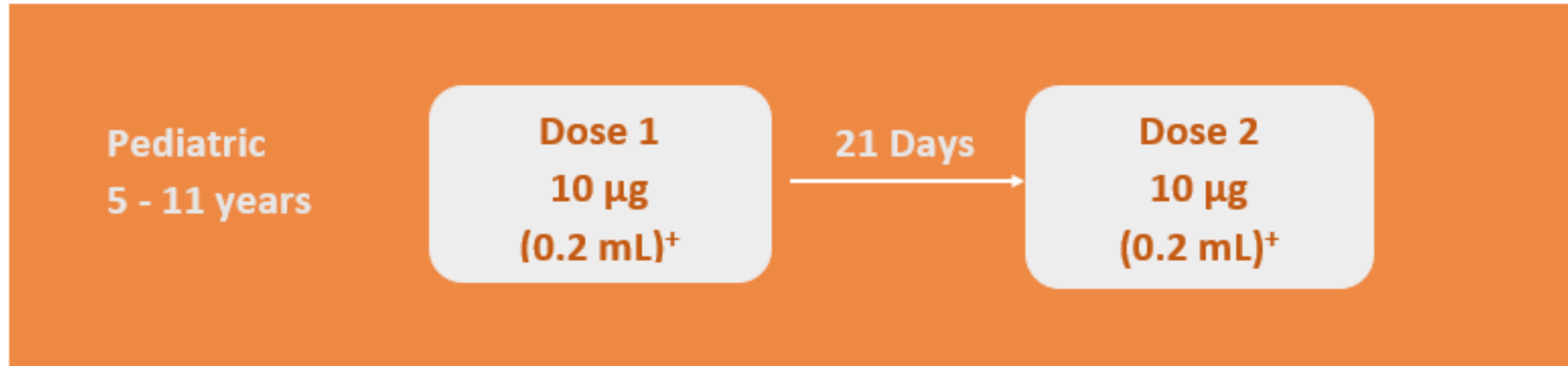
- November 2, 2021, ACIP issued an interim clinical recommendations for the vaccine for ages 5-11 years of age
- The same day, the CDC Director endorsed the ACIP recommendations allowing administration to began

ACIP: Advisory Committee on Immunization Practices

Began Vaccination

- **November 3, 2021, first day of vaccination of children ages 5-11 years of age**

Pfizer COVID-19 Pediatric (5-11 yrs) Vaccine (orange cap) Dosing & Schedule





⁺Different Vaccine Product

Only the 10-mcg tris-sucrose buffer formulation (orange cap) is authorized for use in children aged 5–11 years.



Pfizer COVID-19 Vaccine Formulations

Pfizer COVID-19 Vaccine	Pediatric Formulation (100 doses/pack)	Adolescent/Adult Formulation (1,170 doses/pack)
Age Group	5 to 11 years	12 years and older
Vial Cap Color	ORANGE 	PURPLE 
Dilution Needed	YES	YES
Dose (after dilution)	0.2 mL (10 mcg)	0.3 mL (30 mcg)
Total Doses per Vial (after dilution)	10 doses	6 doses

STORAGE OPTIONS		
Thermal Shipper	X	30 Days*
Ultra-Low Temperature Freezer	6 months	9 months
Freezer	X	2 weeks
Refrigerator	10 weeks	1 month
Room Temperature (after dilution)	12 hours	6 hours

*Dry ice replenishment every 5 days



Texas Department of State Health Services

as of 11/1/21

Additional Pediatric COVID-19 Vaccine Updates

Pfizer-BioNTech

- Ongoing clinical trial in children 2-4 years of age
 - Dose 3 mcg
 - Two-dose regimen 21 days apart
 - Tentative timeline for data readout end of the year with anticipated submission to the FDA 1Q22
- Ongoing clinical trial in infants 6 months – 2 years of age

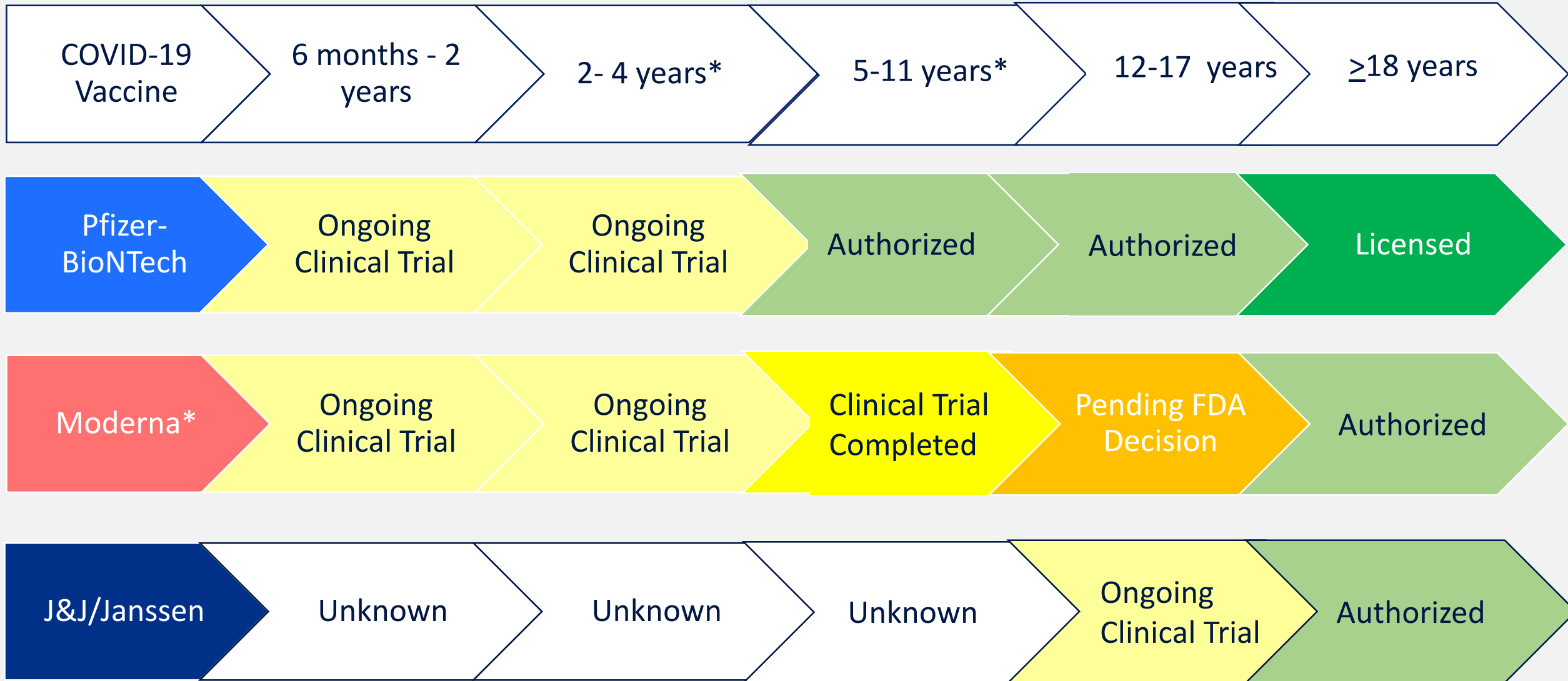
Moderna

- FDA decision pending on the request for an EUA expansion for ages 12-17 years of age
 - October 31, 2021, the FDA informed the company that it needs additional time (~January 2022) to evaluate the submission
- Clinical study completed in children 6 – 11 years of age
 - FDA submission on hold pending decision on 12-17 years of age
- Ongoing clinical trial in children younger than 6 years of age

J&J/Janssen

- Ongoing clinical trials in 12-17 years of age

Summary of Pediatric COVID-19 Vaccine Age Authorization in the U.S.



*Moderna age groups: 2- 5 years & 6-11 years of age

COVID-19 Vaccine Boosters



TEXAS
Health and Human
Services

Texas Department of State
Health Services

Rolling COVID-19 Vaccine Booster Recommendations

November 29, 2021

Everyone ≥ 18 years should get a booster dose
 6 months post 2nd shot of Pfizer or Moderna vaccine
 2 months post single dose of J&J vaccine
 Mix-and Match

November 19, 2021

Pfizer & Moderna COVID-19 Booster
 ≥ 50 Yrs
 + certain populations
 6 months post 2nd dose

J&J COVID-19 Booster
 ≥ 18 Yrs
 2 months post 1st dose

Immunocompromised ≥ 18 yrs
 Booster dose (4th dose mRNA)
 6 months post 3rd dose

Mix-and-Match

October 21, 2021

Pfizer & Moderna COVID-19 Booster
 ≥ 65 Yrs
 + certain populations
 6 months post 2nd dose

J&J COVID-19 Booster
 ≥ 18 Yrs
 2 months post 1st dose

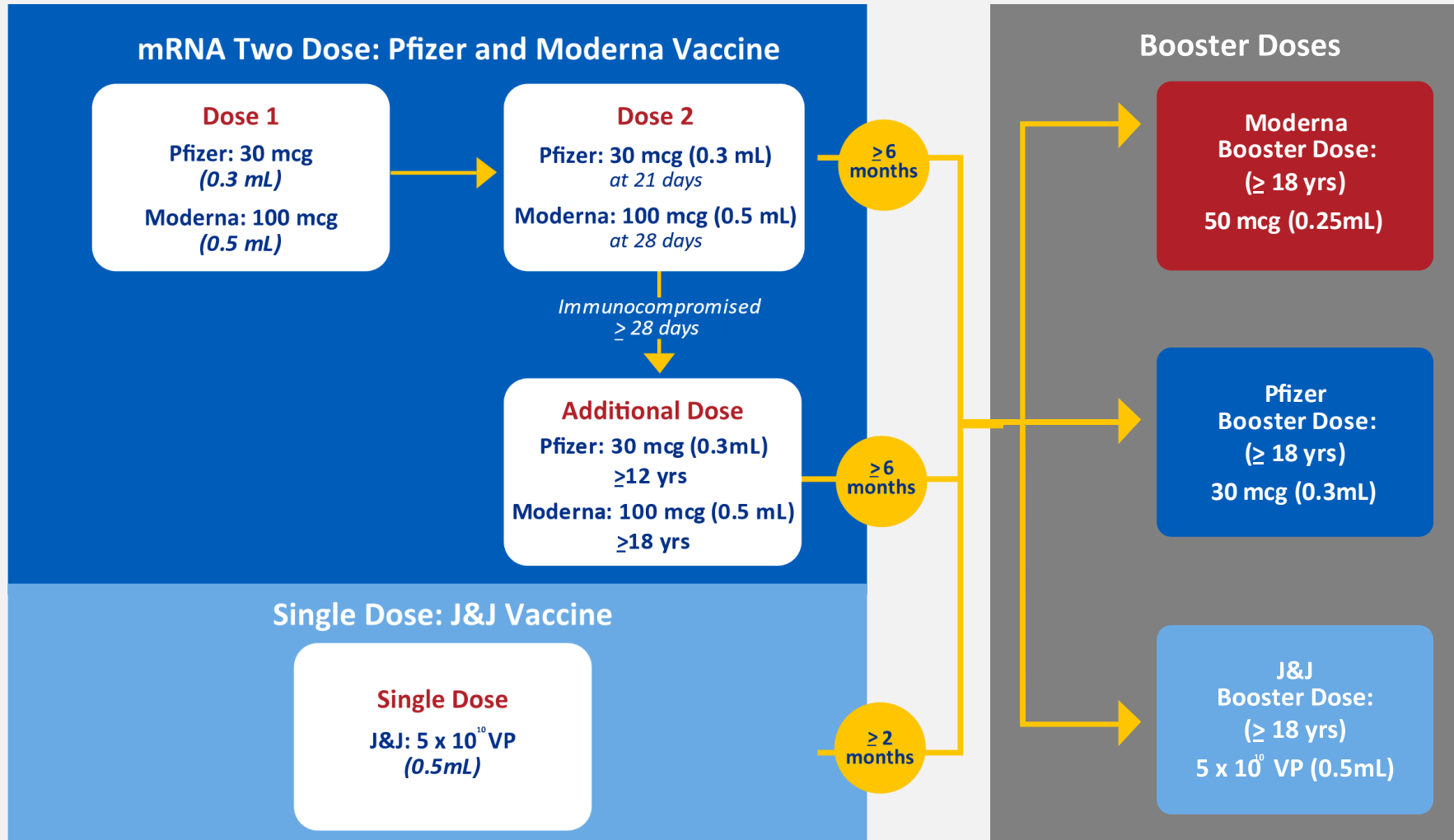
Immunocompromised ≥ 18 yrs
 Booster dose (4th dose mRNA)
 6 months post 3rd dose

Mix-and-Match

September 24, 2021

Pfizer COVID-19 Booster
 ≥ 65 Yrs
 + certain populations
 6 months post 2nd dose

COVID-19 Vaccine Recommendations With Additional and Booster Doses



COVID-19 Vaccine Boosters

- November 29, 2021, in response to the Omicron variant, United Kingdom recommended boosters to all individuals 18 years and older at a **reduced minimum of 3 months** post completion of the primary series.
- November 30, 2021, Pfizer has submitted a request to the FDA to expand the booster dose to all individuals 16 years and older.



DISCLAIMER

The information presented today is based on CDC's recent guidance and MAY change.

December 2, 2021

Thank you!



dshs.texas.gov/coronavirus

Follow TexasDSHS on [Twitter](#) , [Facebook](#) , [YouTube](#) and [Instagram](#) or visit www.dshs.texas.gov