

Pediatric COVID-19 Vaccination: 5 – 11 Year Olds

Indian Country COVID-19 ECHO Presentation

November 3, 2021

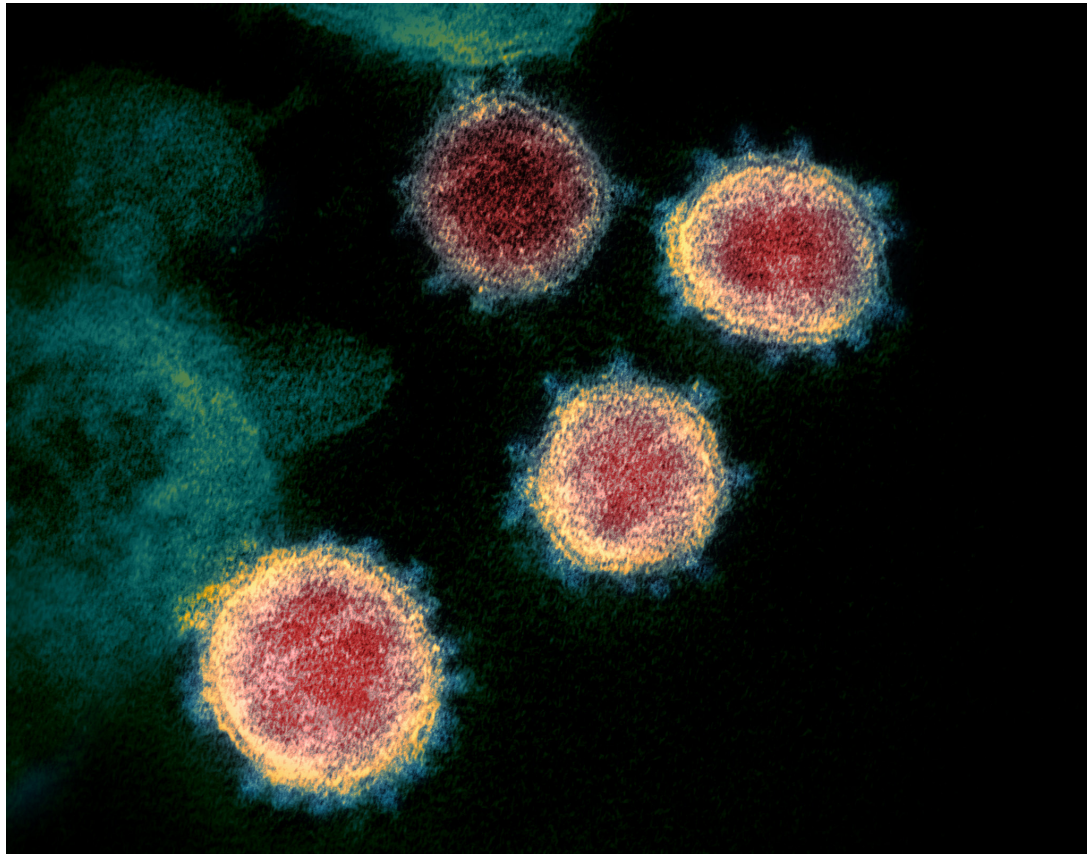
Harry J Brown, MD

USET Tribal Epidemiology Center

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Day 603 of the COVID-19 Pandemic



- EUA for Pfizer-BioNTech Covid-19 Vaccine for the age group 5 -11
- Summary of risks and benefits
- New pediatric formulation
- Time for questions

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Children and COVID-19

- 28.7 million children age 5 to 11 in the US
- 1.9 million reported cases of COVID-19
- >8300 hospitalizations; half had NO underlying disease
- 146 deaths attributed to COVID-19 (in the top 10 causes of death in this age group for the past year)
- MIS-C is an uncommon but serious post-COVID complication in this age group

[FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age | FDA](#)

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EUA for Pfizer-BioNTech COVID-19 Vaccine

- October 6, 2021 – BioNTech applied to the FDA for EUA of BNT162b2 for ages 5 – 11
- October 26 – VRBPAC recommended approval
- October 29 – FDA granted EUA for ages 5 – 11
- November 2 – ACIP recommended use of vaccine in ages 5 - 11

[FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age | FDA](#)

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Clinical Trial Results: Efficacy

- RCT involving 4637 children ages 5 – 11 (US, Finland, Poland, Spain)
- Randomized 2:1 – 3109 received vaccine, 1528 received placebo
- Compared immunogenicity to 16 – 25 yr old control group; results comparable in terms of levels of neutralizing antibody response
- Compared seroresponse rate: 99.2% (same as 16 – 25 yr olds)
- Observed vaccine efficacy against confirmed COVID-19 at least 7 days after the second dose was **90.7%**

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Clinical Trial Results: Safety

Side effects included:

- Injection site pain 71%
- Erythema 19%
- Swelling 15%
- Fatigue 39%
- Headache 28%
- Myalgia 12%
- Arthralgia 5%
- Fever 7%
- No cases of anaphylaxis, myocarditis, pericarditis, death
- Hypersensitivity:
 - Vaccine 0.92%
 - Placebo 0.53%

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Why Vaccinate this Age Group?

- Usually a mild disease; risk of hospitalization much lower than adults
- Estimates of asymptomatic cases 15 to 50%
- However, some have serious outcomes
 - MIS-C
 - Long COVID
 - 36-fold increase in incidence of myocarditis in <16 yrs of age
- Effect on schooling and other activities
- Decrease transmission to older, more vulnerable individuals

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What Are the Risks?

- Anaphylaxis: 6.1 cases per million doses administered
- Myocarditis/Pericarditis
 - Higher than expected rates in males under age 40
 - Higher than expected rates in young females, but much less than males
 - 72 – 200 cases per million fully vaccinated 16 – 17 yr old males
 - 43 – 180 cases per million fully vaccinated 12 – 15 yr old males

Boehmer TK, Kompaniyets L, Lavery AM, et al. Association Between COVID-19 and Myocarditis Using Hospital-Based Administrative Data — United States, March 2020–January 2021. MMWR Morb Mortal Wkly Rep 2021;70:1228–1232. DOI: <http://dx.doi.org/10.15585/mmwr.mm7035e5>

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Risk – Benefit Analysis

FDA modelled 6 scenarios based on different variables

- Benefit varies according to incidence of COVID-19
- In all but the lowest incidence scenario, the benefit of decreased hospitalization and death from COVID-19 outweighed the risk of hospitalization from myocarditis
- Hospitalization from COVID-19 not necessarily equivalent to hospitalization from myocarditis
- Benefit to society not evaluated
- FDA and CDC concluded that BENEFITS > RISKS

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New Pediatric Formulation



- Lower dose: 10 mcg (adult dose is 30 mcg)
- Comes in 10 dose vials
- Can be kept at room temperature for up to 12 hours after dilution
- New buffer – tromethamine (Tris, THAM)
- Replaces phosphate/NaCl/KCl buffer
- Allows for storage in refrigerator (2 to 8 C) for up to 10 weeks
- No preservative, latex-free stopper

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Formulation for Pfizer-BioNTech COVID-19 Vaccines

	Formulation for ≥12-year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)
Age group	12 years and older	5-11 years
Vial cap color		
Dose (mRNA concentration)		
Injection volume	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	1.3 mL
Amount of Diluent* Needed per vial	1.8 mL	1.3 mL
Doses per Vial	6 (after dilution)	10 (after dilution)

*Diluent: 0.9% sterile Sodium Chloride Injection, USP (non-bacteriostatic; DO NOT USE OTHER DILUENTS)

Modified from <https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf>

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Formulation and Dosing for Pfizer-BioNTech COVID-19 Vaccines

	Formulation for ≥ 12 -year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)
Storage conditions		
Ultralow temperature freezer (-90°C to -60°C)	9 months	6 months
Freezer (-25°C to -15°C)	2 weeks	N/A
Refrigerator (2°C to 8°C)	1 month	10 weeks

Modified from <https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf>

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Dosing for Pfizer-BioNTech COVID-19 Vaccines

	Formulation for ≥12-year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)
Number of doses	2	2
Interval	3 weeks (21 days)	3 weeks (21 days)
Additional primary dose	Moderate and severe immunocompromise	Not recommended
Booster dose	Not recommended 12–17 years	Not recommended
	Recommended for certain groups ≥18 years*	

*Individuals 65 years and older or individuals ages 18 years and older who live in long-term care settings, have underlying medical conditions, or who work or live in high risk settings. Mbaeyi S, Oliver SE, Collins JP, et al. The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines — United States, 2021. MMWR Morb Mortal Wkly Rep. ePub: 29 October 2021



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Key Points

- Pfizer-BioNTech vaccine shown to be safe and effective in the 5 – 11 year old age group
- Risk-benefit analysis seems to favor benefit
- Vaccine dose and formulation for this age group is different from the dose and formulation for age 12 and above
- Vaccinating this age group has positive individual and public health implications

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Thank You for Your Time and Attention!

Harry J Brown, MD
Medical Epidemiologist
USET Tribal Epidemiology Center

hbrown@usetinc.org

615-467-1547

615-917-7526

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