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PUCILLO FAMILY PRACTICE P.A.



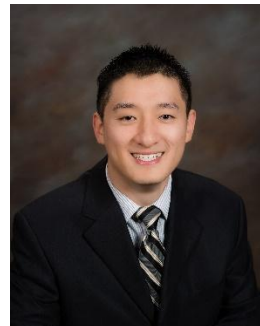
WELLNESS CENTER

Family Medicine & Bariatrics

PFP November: pediatric COVID vaccine, Omicron COVID variant



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November:

Happy holidays. We hope everyone had a wonderful Thanksgiving weekend.



November newsletter:

- COVID vaccine for kids 5-11 years
- Omicron COVID variants

Booster Vaccine For Kids 5-11 years (CDC, Nov 2021)

Authorized For	Pfizer-BioNTech	Moderna	J&J / Janssen
4 years and under	No	No	No
5-11 years old	Yes	No	No
12-17 years old	Yes	No	No
18 years and older	Yes	Yes	Yes

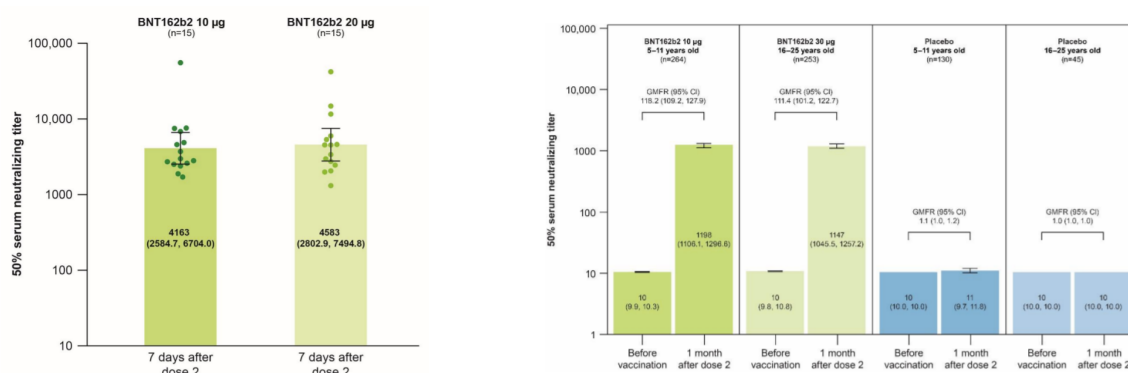
1. Pfizer COVID vaccine for children 5-11yo was approved by FDA on October 26, 2021, and by CDC on November 2, 2021
2. Dose will be $\frac{1}{3}$ of adult dose. 2 doses needed at 21 days apart.
3. Pfizer data shows 90.7% effective in preventing severe COVID-19 infection

Description	Current Adult/Adolescent Formulation (1170 and 450 packs)	Future Pediatric Formulation
	<i>Dilute Prior to Use</i>	<i>Dilute Prior to Use</i>
Age Group	12 years and older	5 to <12 years**
Vial Cap Color	PURPLE 	ORANGE 
Dose	30 mcg	10 mcg
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 doses per vial (after dilution)	10 doses per vial (after dilution)
Storage Conditions		
ULT 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

Pediatric COVID and Vaccine Questions

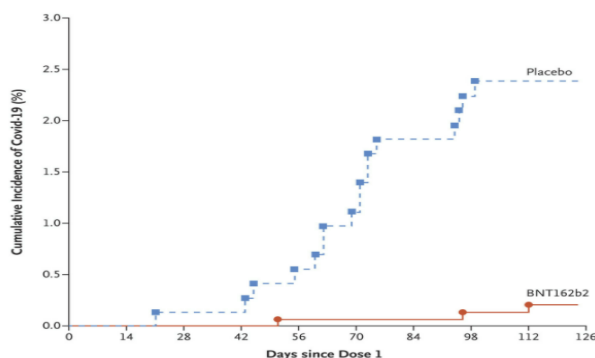
1. How was COVID vaccine studied in kids 5-11 years?

- Pfizer conducted study (*New England Journal of Medicine*, Nov 2021) <https://www.nejm.org/doi/full/10.1056/NEJMoa2116298>
- Phase 1 - **dose-finding study**. 48 children 5 to 11 years of age received 10 µg, 20 µg, or 30 µg of the Pfizer vaccine. 30µg had many cases of fever. 20 µg and 10 µg had similar responses. 10 µg was selected for further study
- Phase 2 & 3 - **randomized response study**. 2268 children were randomly assigned to receive the BNT162b2 vaccine (1517 children) or placebo (751 children). 1 month after the second dose of BNT162b2. Immunological response was compared to those in 16-to-25-year-olds trial of two 30-µg doses of Pfizer vaccine.
- Conclusion - A Covid-19 vaccination regimen consisting of two 10-µg doses of BNT162b2 administered 21 days apart was found to be safe, immunogenic, and efficacious in children 5 to 11 years of age



2. How effective was COVID vaccine?

- Efficacy was 90.7% at preventing COVID



Efficacy End Point	SARS-CoV-2 Infection Status	BNT162b2		Placebo		Vaccine Efficacy (95% CI)
		No. of participants with event (total no.)	Surveillance time (no. at risk) 1000 person-yr	No. of participants with event (total no.)	Surveillance time (no. at risk) 1000 person-yr	
Covid-19 ≥7 days after second dose	Without evidence of previous infection	3 (1305)	0.322 (1273)	16 (663)	0.159 (637)	90.7 (67.7–98.3)
Covid-19 ≥7 days after second dose	With or without evidence of previous infection	3 (1450)	0.353 (1398)	16 (736)	0.176 (704)	90.7 (67.4–98.3)

3. What are side effects of the COVID vaccine for kids 5-11 years?

- Mild-to-moderate injection-site reaction, fever, fatigue and headache
- Injection-site pain - 71 to 74%
- Fever - 8.3%
- Other symptoms - severe fatigue - 0.9%, lymphadenopathy - 0.9%, headache (0.3%), chills (0.1%), muscle pain (0.1%)
- No cases of myocarditis, pericarditis, hypersensitivity, or anaphylaxis reported in recipients

4. Are COVID symptoms mild for kids?

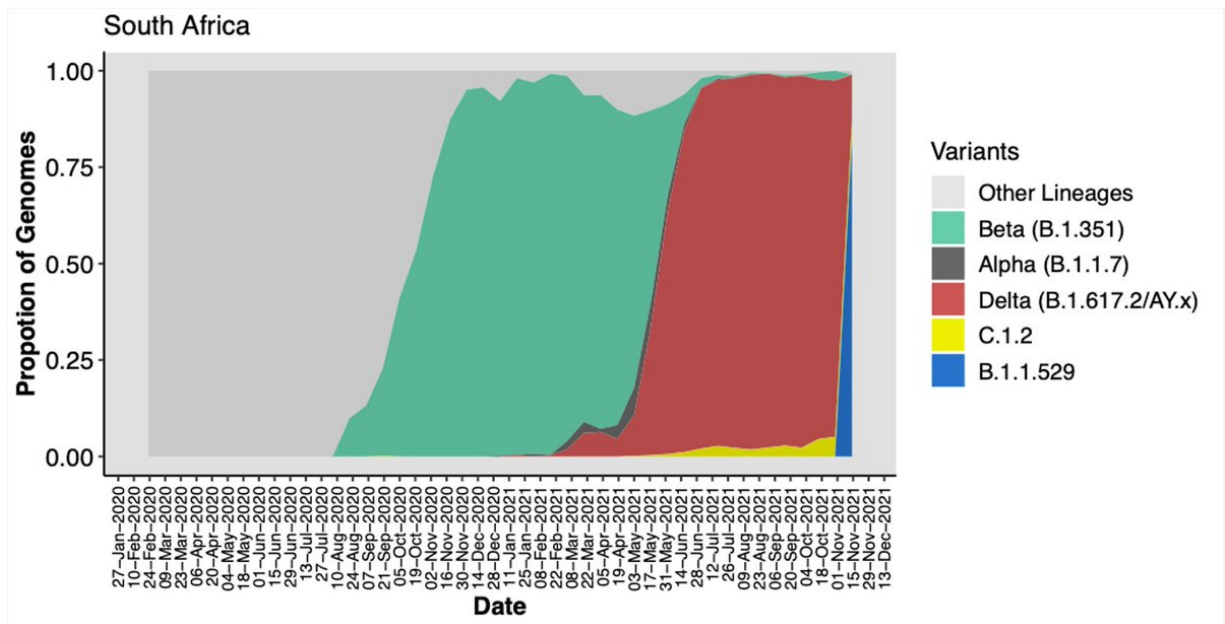
- As of 11/25/2021, 6,767,762 total child COVID-19 cases reported. This represented 16.9% of total COVID cases. (*American Academy of Pediatric, Nov 2021*)
- Many have no symptoms. Some experience mild symptoms such as low-grade fever, fatigue, and cough. Some children have had severe symptoms requiring hospitalization. Few will develop a dangerous complication of COVID called MIS-C (multisystem inflammatory syndrome in children).

5. What is MIS-C in kids?

- multisystem inflammatory syndrome
- symptoms include - fever lasting more than a couple of days, rash, "bloodshot eyes"(redness of the white part of the eye), stomachache, vomiting and/or diarrhea, a large/swollen lymph node in the neck, neck pain, red, cracked lips, a tongue that is redder than usual and looks like a strawberry, swollen hands and/or feet, irritability and/or unusual sleepiness or weakness.
- As of Nov 25th 2021, 5,526 cases have been identified. 0.082% of all pediatric COVID cases.

Omicron COVID Variant

- On November 26, 2021, WHO has identified **B1.1.529**, **Omicron COVID variant**, a variant of concern
- This variant originated in South Africa and had spread rapidly in the region in the past 2 weeks (**Blue**)
- What we know
 - the virus has >30 mutations in the spike protein. It is believed these mutations will make the virus more transmissible.
 - 16 countries have confirmed cases
- What we don't know
 - the severity of the virus
 - whether if current vaccines will work in preventing the virus



We continue to wish you all the best. Please feel free to contact us if you have any questions.

Sincerely,
Staff at Pucillo Family Practice