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Pfizer COVID-19 vaccine for 5-11 yo: What providers and staff need to know

Claire Boogaard MD, MPH, FAAP

General Pediatrician, Division of General and Community Medicine, Children's National Hospital

Bud Wiedermann, MD, MA

Division of Infectious Diseases, Children's National Hospital

Professor of Pediatrics, The George Washington University School of Medicine and Health Sciences

November 2, 2021

Objectives

- Update providers and staff on the current COVID-19 booster guidelines
- Summarize the findings from the Pfizer BioNTech COVID-19 vaccine trial for children 5-11 years
- Relate practical information to help begin vaccinating children 5-11 years
- Discuss vaccine access for children 5-11 years throughout the region

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Booster Vaccines:

MRNA Vaccines:

- booster dose for those who qualify (at least 6 months from dose 2):
 - people 65 years and older, residents in long-term care settings, and people 50-64 **should** receive a booster
 - people 18- 49 who are at high risk for severe COVID-19 due to certain underlying medical conditions **may** receive a booster
 - people aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting **may** receive a booster
- Can mix and match products
 - *people can self attest to their "high risk" nature

Johnson and Johnson's Janssen Vaccine:

- “Booster dose” for all who received 1st dose
- Booster/2nd dose can be J&J, Pfizer, Moderna (best if mRNA)

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Pfizer/BioNTech Pediatric COVID-19 Vaccine Trial in 5 – 11 yo Children: Update November 2, 2021

Bud Wiedermann, MD, MA

Division of Infectious Diseases, Children's National Hospital

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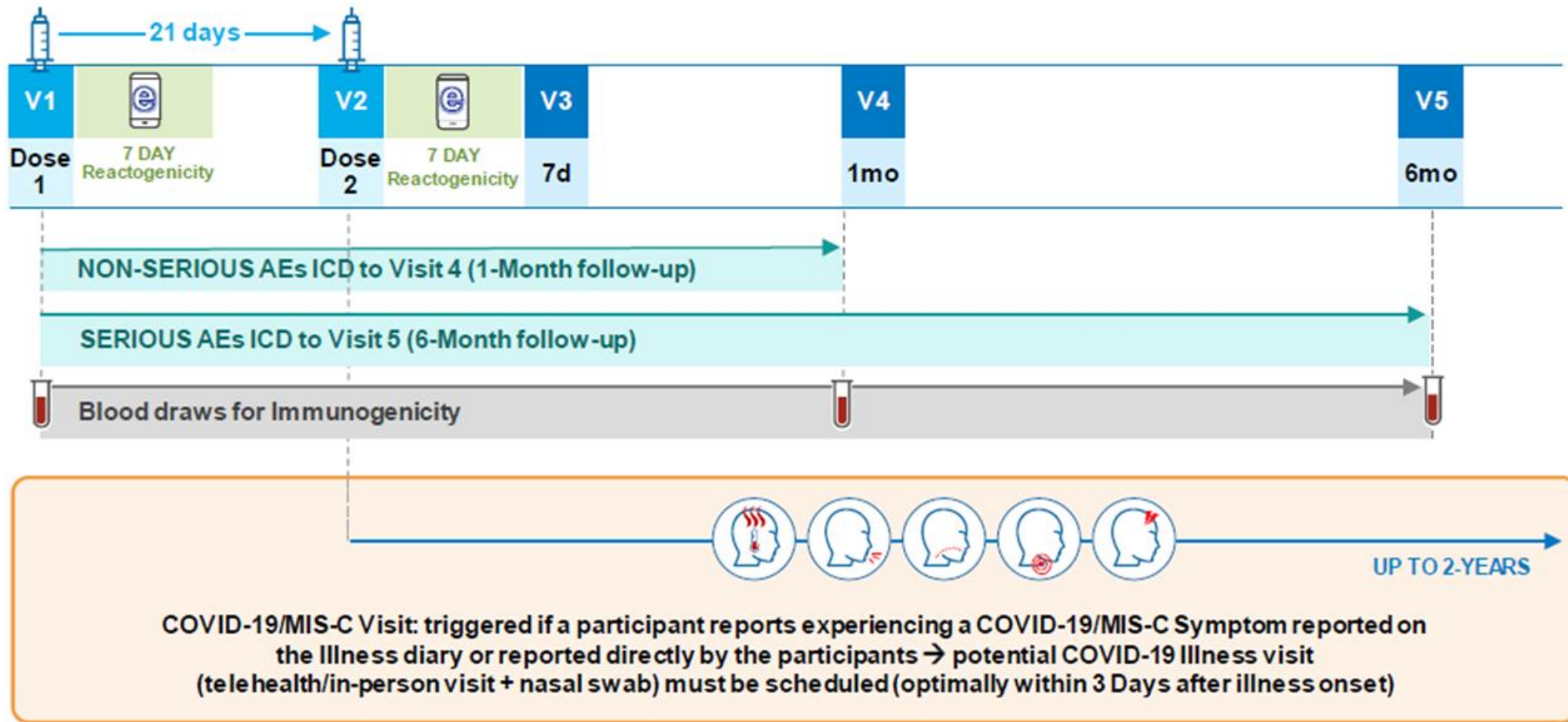
In the Interest of Transparency

- I oversee this trial at CNH and have protected time to do so
- My salary is not dependent on whether the vaccine is authorized/approved
- The fancier diagrams in this presentation are Pfizer's (I don't have the time to make my own!)
- Data from Pfizer: <https://www.fda.gov/media/153513/download>
- Data from FDA: <https://www.fda.gov/media/153510/download>

Overview of 5-11 yo trial

- Phase 1 study in 48 children identified 10 mcg as optimal dose (vs 30 mcg in older people)
- Phase 2/3 trial is 2:1 randomization, 90 sites, 4 countries
- 1500 vaccine, 750 placebo
- Additional safety population of equivalent size added later
- Primary outcome non-inferior immune response 1 month post dose 2

Timeline of 5-11 yo Trial



Follow-up at Time of “Data Cutoff” for FDA VRBPAC 10/26/21

- Initial enrollment group n = 2268
 - Median follow-up time 2.3 months
 - Additional follow-up time to 3.3 months
- Safety expansion group n = 2379
 - Median follow-up time 2.4 weeks

Immunobridging and Efficacy Results

Immunobridging Compared to 16 – 25 yo in Prior Pfizer Study

- Subset with blood draws 1 month post dose 2
 - N = 322, compared to randomly selected 300 16-25 yo subjects
 - Specifically compared in those without evidence of SARS-CoV-2 infection prior to blood draw
 - N = 264 5-11 yo, N= 253 16-25 yo
- Neutralizing antibody against original strain (USA_WA1/2020)

Immunogenicity Results

	5-11 yo N = 264	16-25 yo N = 253
GMT (95% CI)	1197.6 (1106.1, 1296.6)	1146.5 (1045.5, 1257.2)
Seroresponse % (95% CI)	99.2 (97.3, 99.9)	99.2 (97.2, 99.9)

Vaccine Efficacy From 7 Days After Dose 2 in Children Without Evidence of Infection Prior to That Time

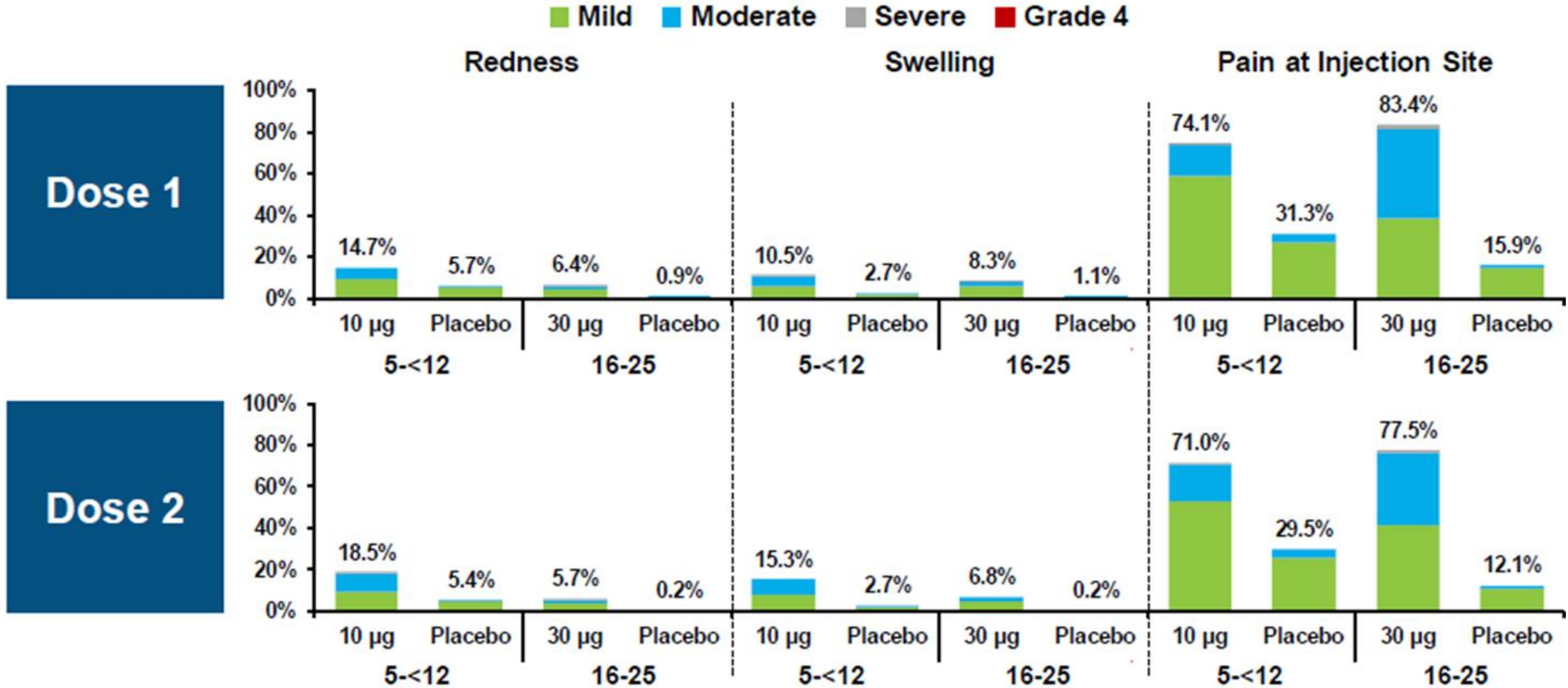
- 3 children in vaccine group were infected, 16 in placebo group; VE = 90.7% (67.7, 98.3)
 - No severe COVID-19, no MIS-C
- Total surveillance time 1000 person-years
- Not primary endpoint, but 21 total cases previously calculated to provide better accuracy
- Stay tuned

Other Efficacy Caveats

- Most infections occurred July – August 2021 (Delta)
- None severe, no hospitalizations
- All cases except 1 were in US (Spain)
- No assessment for asymptomatic infection or for transmission

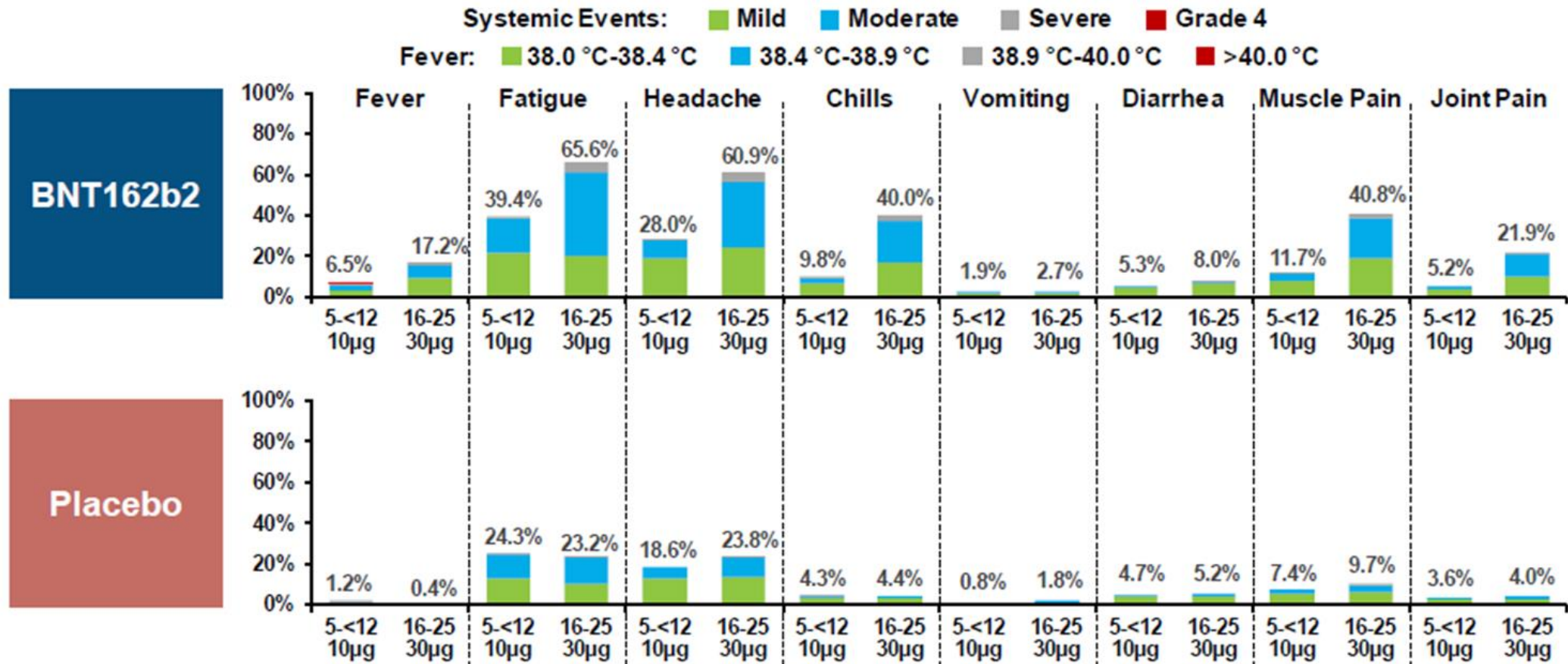
Safety Results

Local Reactions Within 7 Days After Each Dose



Redness and swelling severity definition: Mild=>2-5cm, Moderate=>5-10 cm; Severe=>10 cm; Grade 4= necrosis
 Pain at injection site severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
 Dose 1: 5-<12yrs N=2260; 16-25 yrs N=1064 Dose 2: 5-<12 yrs N=2242 16-25 yrs N=984

Systemic Events Within 7 Days After Dose 2



Fatigue, headache, chills, muscle pain, joint pain severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
 Vomiting severity definition: Mild=1-2 time in 24h; Moderate=>2times in 24h; Severe=Requires IV hydration; Grade 4=ER visit or hospitalization
 Diarrhea severity definition: Mild=2-3 times in 24h; Moderate=4-5 times in 24h; Severe=6 or more times in 24h; Grade 4=ER visit or hospitalization
 Dose 2: 5-<12 yrs N=2242 16-25 yrs N=984

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Unsolicited Adverse Events (AE)

- Lymphadenopathy most common
 - 19 in vaccine and 4 in placebo groups
- 1 child withdrew from study due to fever 2 d after dose 1 and worsening neutropenia (Hx benign transient neutropenia)

Adverse Events of Special Interest (AESI)

- Hypersensitivity (rash, dermatitis)
 - 23 in vaccine group, 8 in placebo group
- Angioedema (includes hives)
 - 7 in vaccine group, 4 in placebo group
- 1 case of HSP 21 days after dose 1
- Chest pain 6 in each group, all felt to be noncardiac, all resolved without intervention

Serious Adverse Events (SAEs)

- Arthropod bite, knee infection, traumatic bone fractures
 - All considered unrelated to vaccination
- No myocarditis/pericarditis, anaphylaxis, deaths

Pharmacovigilance Planned

- Anaphylaxis, myocarditis/pericarditis
- Vaccine-associated enhanced disease
- Other planned observational studies
 - Surveillance for all AESIs
 - Natural history of myocarditis/pericarditis (also 5-year cohort study for long-term sequelae)

What I Would Tell Parents of 5-11 yo

- In general, all 3 COVID-19 vaccines authorized/approved in US far surpassed our hopes for safety and efficacy
- Benefits clearly outweigh risks for individual children, compared to risks from SARS-CoV-2 infection itself in healthy children
 - Applies to children who have been infected in past: uncertain how long immunity lasts after infection and no antibody test currently can tell us if someone is immune
- The only way vaccine might not be a good choice is if COVID-19 won't circulate in coming months

Parent advice continued

- If vaccine in short supply can prioritize
 - Children with risk factors for complications of COVID-19*
 - Children with contacts at high risk

*Note that 1/3 of children hospitalized with COVID-19 have no risk factors

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Vaccine Formulation and Administration

Description	<i>Dilute Before Use</i>	<i>Do Not Dilute</i>	<i>Dilute Before Use</i>
	Storage Conditions		
Ultra-Low-Temperature (ULT) Freezer [-90°C to -60°C (-130°F to -76°F)]	9 months [†]		6 months [†]
Freezer [-25°C to -15°C (-13°F to 5°F)]	2 weeks		DO NOT STORE
Refrigerator [2°C to 8°C (35°F to 46°F)]	1 month		10 weeks
Room Temperature [8°C to 25°C (46°F to 77°F)]	2 hours prior to dilution (including any thaw time)		12 hours prior to dilution
After First Puncture [2°C to 25°C (35°F to 77°F)]	Discard after 6 hours		Discard after 12 hours

Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in this Fact Sheet supersedes the number of hours printed on vial labels and cartons.

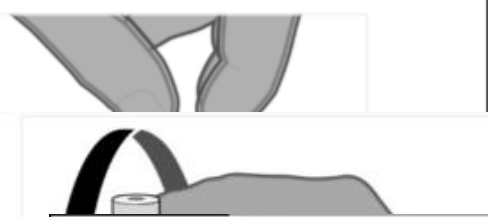
Dilution and Preparation Instructions

Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and Label with Orange Border - DILUTION

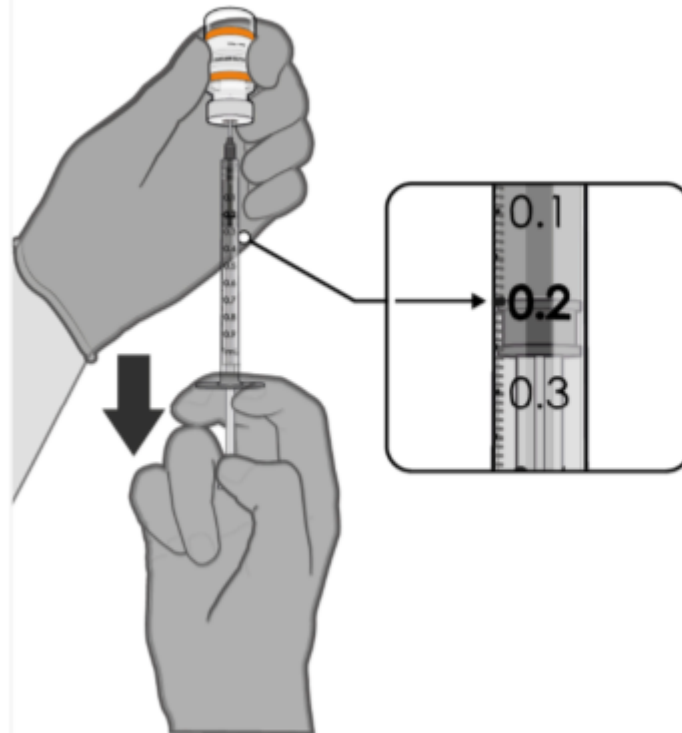


Add 1.0 mL of diluent to the vial.

Pull back



Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and Label with Orange Border - WITHDRAWAL OF INDIVIDUAL 0.2 mL DOSES



Use within 12 hours

Withdraw 0.2 mL dose of vaccine.

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle.
- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
- Administer immediately.

5-11yo Vaccine Ordering and Distribution

- All clinics must register with CDC as vaccine administration site (vaccines.gov)
- Vaccines can be ordered through local departments of health
- CNH's hub and spoke model to Primary Care and specialty clinics:
 - COVID-19 vaccine should be ordered through pharmacy using the COVID-19 Vaccine Request and Transfer Form. Forms should be completed and sent 2-3 business days prior to delivery to PharmacyPurchasing@childrensnational.org
- Children's National expecting delivery today!

5-11yo Vaccine Documentation and Reporting

- Important to keep log of vaccinator training
- Order in your vaccine in your EMR immediately upon administration
 - EMR links to local immunizations registries (required within 24 hours of administration)
- Waste must be recorded and reported back to DC Health

Adverse Reactions need to be reported in [VAERS.hhs.gov](https://vaers.hhs.gov)

Vaccine Billing

Patient	Vaccine name	CPT code
12y+	Pfizer COVID19 vaccine admin 1st dose ADM SARSCV2 30MGC/0.3ml 1st	0001A
12y+	Pfizer COVID19 vaccine admin 2nd dose ADM SARSCV2 30MGC/0.3ml 2nd	0002A
12yo+ immunocompromised	Pfizer COVID19 vaccine admin 3rd dose ADM SARSCV2 30MGC/0.3ml 3rd	0003A
18yo+ high risk or 65y+	Pfizer COVID19 vaccine admin booster ADM SARSCV2 30MGC/0.3ml BST	0004A
5-11yo	Pfizer COVID19 vaccine admin 1st dose ADM SARSCV2 10MGC TRS-SUCR 1	0071A
5-11yo	Pfizer COVID19 vaccine admin 2nd dose ADM SARSCV2 10MGC TRS-SUCR 2	0072A

Vaccine answers to FAQ

- How far apart can the vaccine for 5-11yo be?
 - The two doses are 21 days apart (19-42 days at best, but can always get the second)
- Who is contraindicated to getting the vaccine?
 - Those with known history of anaphylaxis to any component of the vaccine (i.e. miralax)
 - Allergy is on call and accepting consults
- Would my immunocompromised 5-11yo patients get a 3rd dose like those >12yo?
 - Not yet authorized, but may have low response
- What happens if a child has his/her 12th birthday between shot 1 and 2?
 - Dose 1 would be 10mcg
 - Dose 2 would be 30 mcg
- Are we still offering vaccines to all eligible patients (including those older than 11y)?
 - Yes, we are offering vaccine to all patients 5 and older and their eligible family members at each encounter

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Where can our patients get the vaccine?

- CNH Delivery points:
 - 14 Primary Care locations scattered throughout the region
 - Mobile Unit partnering with Children's School Services (elementary school nurses) East of the River to deliver routine, flu, and COVID19 vaccine
 - Select ambulatory specialty clinics at main hospital
 - Endocrine, heme/once, cardiology, nephrology, dialysis, SI, pulmonary, GI
 - Allergy vaccine challenge clinic
 - Inpatient 7days/week
 - Walgreens in hospital lobby 7 days/week (40/day weekdays, 20/day on weekends)
- Vaccine only clinics: **initially Invite only**, prioritizing most vulnerable to severe COVID-19 infection
 - SZ, Prince George's County, and RIC COVID-19 vaccine clinics (up to 150/day, M-F)
 - Run two mass vaccine events for invited patients targeted at the most vulnerable to infection (based on medical condition and zip code)
 - THEARC: Saturday, November 13 and December 4
 - Children's National Prince George's County, MD: Saturday, November 20 and December 11

Community Outreach

- Working with CHAI to engage schools, parents, families, community orgs
 - DCPS and DC Public Charter School Board town hall
- DCHA town hall to parents
- CNH Town Hall for parents/families later this winter
- Education on website, social media, print/digital media

Summary

- Boosters now available for individuals 6 months after mRNA vaccine dose #2 or 2 months after J&J vaccine dose #1
- COVID-19 Pfizer vaccine is safe and effective at protecting against COVID-19 infection
- Risks outweigh benefits in communities with circulating disease
- CDC ACIP should decide tonight and we will begin vaccinating tomorrow morning
- Teams should prepare with training staff, gathering supplies, and learning the data to share as patient educators
- Want to be more involved or have ideas? Contact cboogaar@childrensnational.org

Thank You!



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