COVID-19 Series for Free & Charitable Clinics

November 11, 2021

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AT THE FOREFRONT UChicago Medicine

Vaccinate with Confidence

A National Strategy to Reinforce Confidence in COVID-19 Vaccines

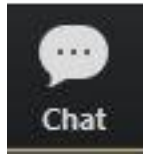
CDC's Strategy: **Empower Healthcare Personnel**: Promote confidence among healthcare personnel in their decisions to get vaccinated and recommend the vaccination to their patients.

Project Goal: Build and reinforce COVID-19 vaccine confidence among healthcare personnel in the safety net sector and, in turn, the patients they serve.

Partnerships: **The National Association of Free and Charitable Clinics** and **15 State Associations** and Federally Qualified Health Centers (FQHCs) in Puerto Rico and the U.S. Virgin Islands.

How: Provide tailored COVID-19 vaccine information to the free and charitable clinic sector through various channels and **give the FCC sector a direct line of communication to CDC**.

Reminders:

- Please use your first name and clinic name when you join the session
- Use the “chat” feature to ask questions 

- Please remember to mute your microphone 

- If you can’t connect audio via computer or you lose computer audio at anytime, you can call in to session at **(408) 638-0968, Meeting ID 932-6566-2201##**
- This activity has been approved for AMA PRA Category 1.25 Credit™ & Nursing CEUs

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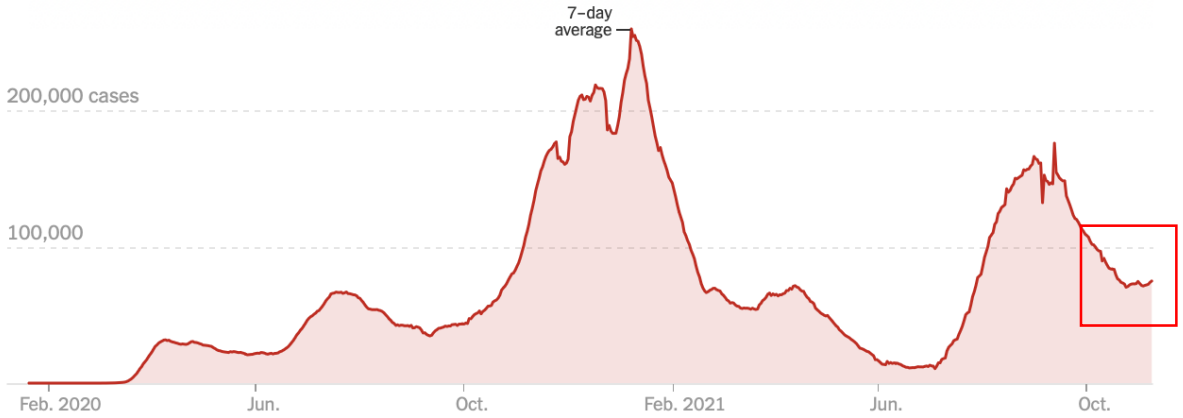
Disclosures

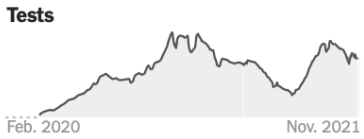
- We have no relevant financial interests to disclose.

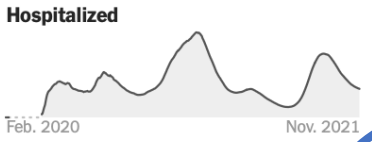
Coronavirus in the U.S.: Latest Map and Case Count

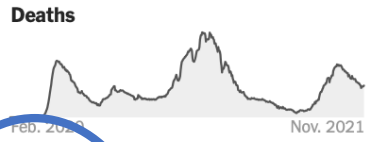
New reported cases

All time | Last 90 days



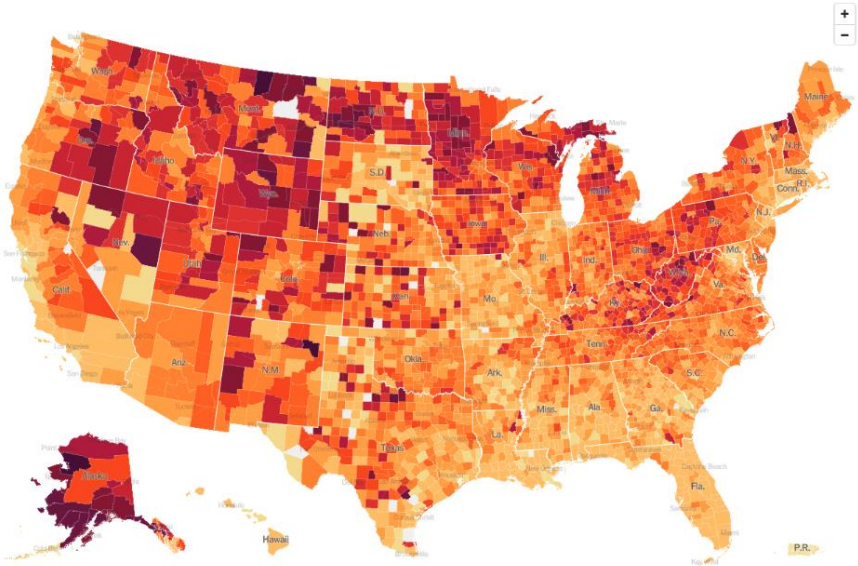




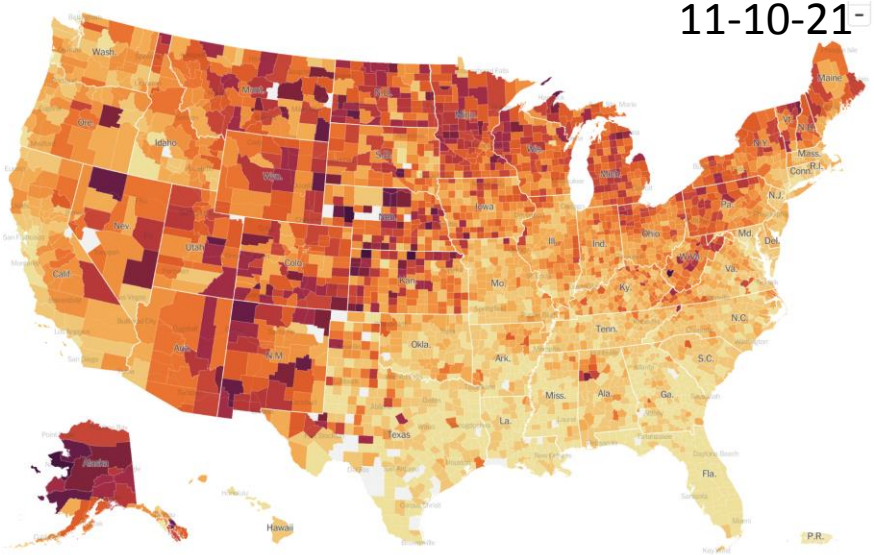


	DAILY AVG. ON NOV. 9	14-DAY CHANGE	TOTAL REPORTED
Cases	74,834	+6%	46,659,443
Tests	1,326,272	+10%	—
Hospitalized	46,287	−12%	—
Deaths	1,251	−11%	756,951

10-13-21

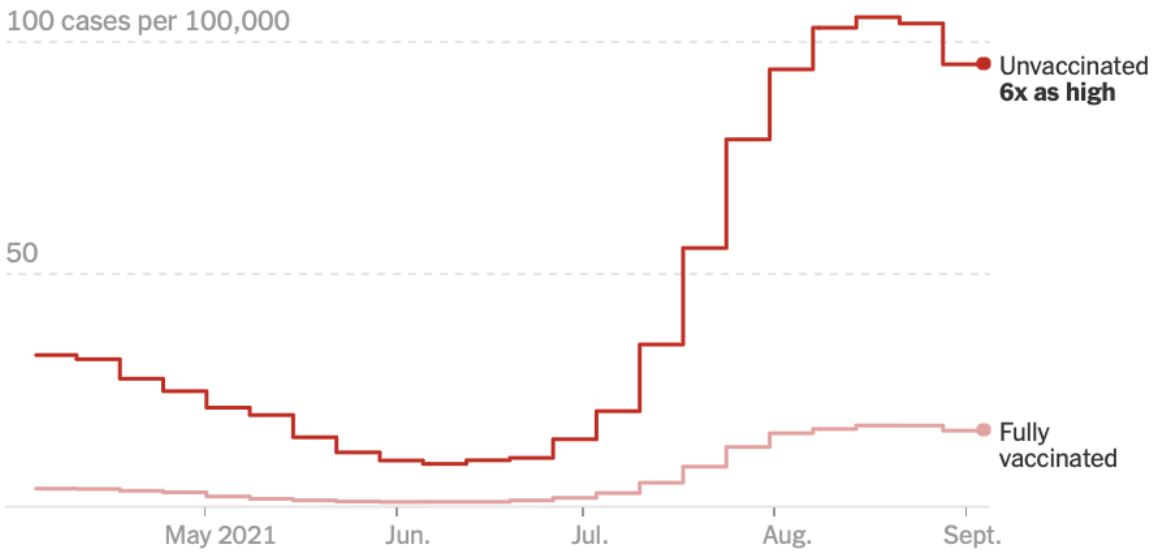


11-10-21



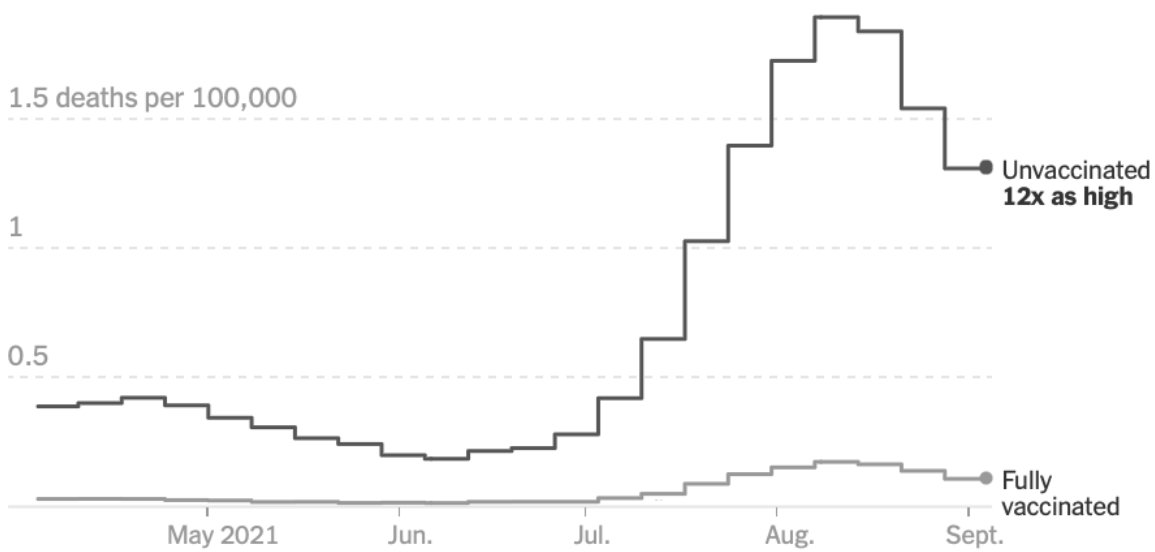
https://www.nytimes.com/interactive/2021/us/covid-cases.html?action=click&module=Top%20Stories&pgtype=Homepage

Average daily cases



▶ About this data

Average daily deaths



Vaccinations

	AT LEAST ONE DOSE	FULLY VACCINATED
All ages	68%	58%
12 and up	79%	68%
65 and up	98%	86%

How do COVID-19 Vaccine Boosters Compare?

Initial Vaccine Administered	Pfizer BioNTech			moderna			Janssen Johnson & Johnson		
Initial Dose Regime	2			2			1		
Booster Shot Type	moderna	Pfizer BioNTech	Janssen Johnson & Johnson	Pfizer BioNTech	moderna	Janssen Johnson & Johnson	moderna	Pfizer BioNTech	Janssen Johnson & Johnson
Binding & Neutralizing Antibody Assays (*Geometric mean fold rise*)	17.3 x	14.9 x	6.2 x	9.7 x	7.9 x	4.7 x	56.1 x	32.8 x	4.6 x
Rank	1st	2nd	3rd	1st	2nd	3rd	1st	2nd	3rd

Atmar et al. doi: https://doi.org/10.1101/2021.10.10.21264827

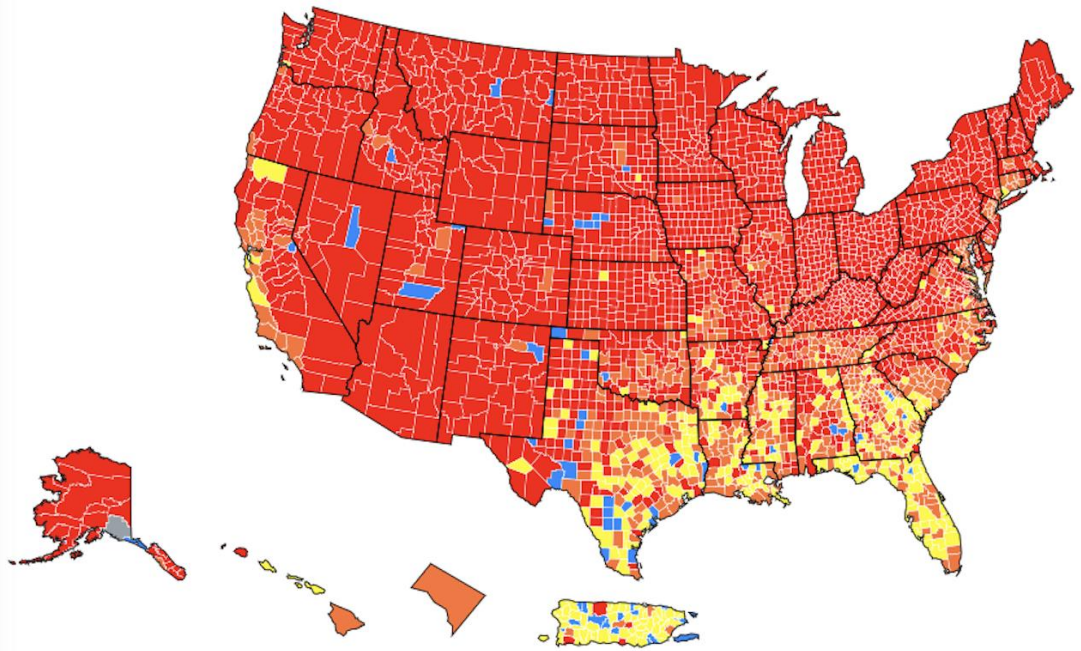
Pfizer-BioNTech expected to seek authorization for coronavirus booster for people 18 and older

- The request, which may be filed as soon as this week, is likely to win the backing of the Food and Drug Administration
  - *"In August, I thought it was extremely premature to offer boosters to everyone," partly because of a lack of data, said Jeanne Marrazzo, an infectious-diseases physician at the University of Alabama at Birmingham. "The idea of rolling out boosters, while we were trying to increase our primary vaccination rates and dealing with the crushing delta wave, I felt was tone deaf."*
  - *Now, Marrazzo said, additional data is showing that "durable immunity to the coronavirus is an elusive goal." She said she has treated several cases of breakthrough infections among the vaccinated and while the patients typically do not end up in the hospital, "It's not pretty. You don't want to get a breakthrough infection."*

https://www.washingtonpost.com/health/2021/11/08/pfizer-biontech-coronavirus-booster-authorization-18-and-older/

Level of Community Transmission of All Counties in US

CDC advises masking indoors in counties with substantial or high coronavirus spread



Community Transmission in US by County

	Total	Percent	% Change
High	2222	68.96%	-4.07%
Substantial	554	17.19%	0.22%
Moderate	364	11.3%	3.66%
Low	79	2.45%	0.25%

High Substantial Moderate Low No Data

cdc.gov

COVID Vaccine 5-11 Y/O

5-11 Years Old COVID-19 Vaccine

- Dose 10 mcg
- 2 dose series administered 3 weeks apart
- Can be used up to 12 hours after diluted

Use within 12 hours after dilution.

- Record the date and time of first vial puncture on the vial label.
- Store between 2°C to 25°C (35°F to 77°F).
- Discard any unused vaccine 12 hours after dilution.

Fact Sheet for Healthcare Providers Administering Vaccine

THE UNIVERSITY OF CHICAGO Department of Pediatrics Established 1930

PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL

Description	Current Formulation	Future Formulations
	Dilute Prior to Use	*Dilute Prior to Use*
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

Pfizer Pediatric Formulation Packaging

- Pediatric vials come packaged in cartons of 10 vials each
- Each vial contains 10 doses
- Vials come with a distinctive orange cap, orange striping on the label, and orange striping on the carton
- Diluent: Orders of Pfizer pediatric vaccine include ancillary kits that contain 10mL diluent vials
  - While these vials appear to contain sufficient diluent for multiple vials, they must only be used once
    - Diluent vials are a one-time-use item and should be discarded with the remaining content after each use

Note: the Adult/ Adolescent formulation (purple cap) should not be used to vaccinate children 5 through 11 years of age

Study Info

- Phase 2/3 study enrolled 3,109 vaccine recipients and 1528 placebo recipients
  - Cohort 1: 1,518 vaccine recipients and 750 placebo recipients, of whom 1,444 (95.1%) and 714 (95.2%), respectively, had at least 2 months of safety follow-up after completing a 2-dose primary series (data cutoff September 6, 2021) with a subset (322) followed for immunogenicity
  - Cohort 2: A second cohort of 1,591 vaccine recipients and 778 placebo recipients had a median duration of follow-up of 2.4 weeks post-Dose 2 at the time of data cutoff (October 8, 2021) followed only for safety data
- Participants were randomized 2:1 to receive two doses of 10 µg of vaccine or placebo (saline), 3 weeks apart

Table 5. Demographic and Baseline Characteristics, Phase 2/3, Participants 5-11 Years, Safety Population, Study C4591007 Cohort 1

Characteristic	C4591007 BNT162b2 10 µg (N[a]=1518) n[b] (%)	C4591007 Placebo (N[a]=750) n[b] (%)
Sex: Male	799 (52.6)	383 (51.1)
Sex: Female	719 (47.4)	367 (48.9)
Race: White	1204 (79.3)	586 (78.1)
Race: Black or African American	89 (5.9)	58 (7.7)
Race: American Indian or Alaska Native	12 (0.8)	3 (0.4)
Race: Asian	90 (5.9)	47 (6.3)
Race: Multiracial	109 (7.2)	49 (6.5)
Race: Not reported	9 (0.6)	7 (0.9)
Ethnicity: Hispanic or Latino	319 (21.0)	159 (21.2)
Ethnicity: Not Hispanic or Latino	1196 (78.8)	591 (78.8)
Age: Mean years (SD)	8.2 (1.93)	8.1 (1.97)
Age: Median (years)	8.0	8.0
Obese[c]: Yes	174 (11.5)	92 (12.3)
Obese[c]: No	1343 (88.5)	658 (87.7)
Baseline Evidence of Prior SARS-CoV-2 Infection: Negative[e]	1385 (91.2)	685 (91.3)
Baseline Evidence of Prior SARS-CoV-2 Infection: Positive[f]	133 (8.8)	65 (8.7)
Comorbidities[d]: Yes	312 (20.6)	152 (20.3)
Comorbidities[d]: No	1206 (79.4)	598 (79.7)
Country: Finland	158 (10.4)	81 (10.8)
Country: Poland	125 (8.2)	60 (8.0)
Country: Spain	162 (10.7)	78 (10.4)
Country: United States	1073 (70.7)	531 (70.8)

Abbreviations: BMI = body mass index; COVID-19 = coronavirus disease 2019; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein-binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Table 6. SARS-CoV-2 Neutralizing GMTs (NT50)[a] at 1 Month Post-Primary Series in Phase 2/3 BNT162b2 (10 µg) Recipients 5-11 Years of Age and Study C4591001 Phase 2/3 Cohort 1 BNT162b2 (30 µg) Recipients 16-25 Years of Age Without Evidence of SARS-CoV-2 Infection up to 1 Month After Dose 2, Evaluable Immunogenicity Population[b]

GMT (95% CI) 5-11 Years of Age Study C4591007 N[c] = 264	GMT (95% CI) 16-25 Years of Age Study C4591001 N[c] = 253	GMT Ratio (95% CI) (5-11 Years of Age / 16-25 Years of Age)[d]
1197.6 (1106.1, 1296.6)	1146.5 (1045.5, 1257.2)	1.04 (0.93, 1.18)

Table 7. Seroresponse Rates[a,b] at 1 Month Post-Primary Series in Phase 2/3 BNT162b2 (10 µg) Recipients 5-11 Years of Age and Study C4591001 Phase 2/3 Cohort 1 BNT162b2 (30 µg) Recipients 16-25 Years of Age[b] Without Evidence of SARS-CoV-2 Infection up to 1 Month After Dose 2, Evaluable Immunogenicity Population[c]

Seroresponse 5-11 Years of Age Study C4591007 %[d] (95% CI) N= 264	Seroresponse 16-25 Years of Age Study C4591001 %[d] (95% CI) N= 253	% Difference in Seroresponse Rate (Age Group 5-11 Years minus Age Group 16-25 Years)[e] (95% CI)
99.2 (97.3, 99.9)	99.2 (97.2, 99.9)	0 (-2.0, 2.2)

- No notable differences in GMTs or seroresponse rates were observed by age (i.e., 5-6 year-old vs. 7-8 year-old vs. 9-11 year-old), sex, race, ethnicity, obesity, or SARS-CoV-2 status.
- Small (10 patients) *in vitro* comparison for neutralization against delta variant vs reference USA-WA1/2020 strain documented similar neutralization

Clinical Efficacy

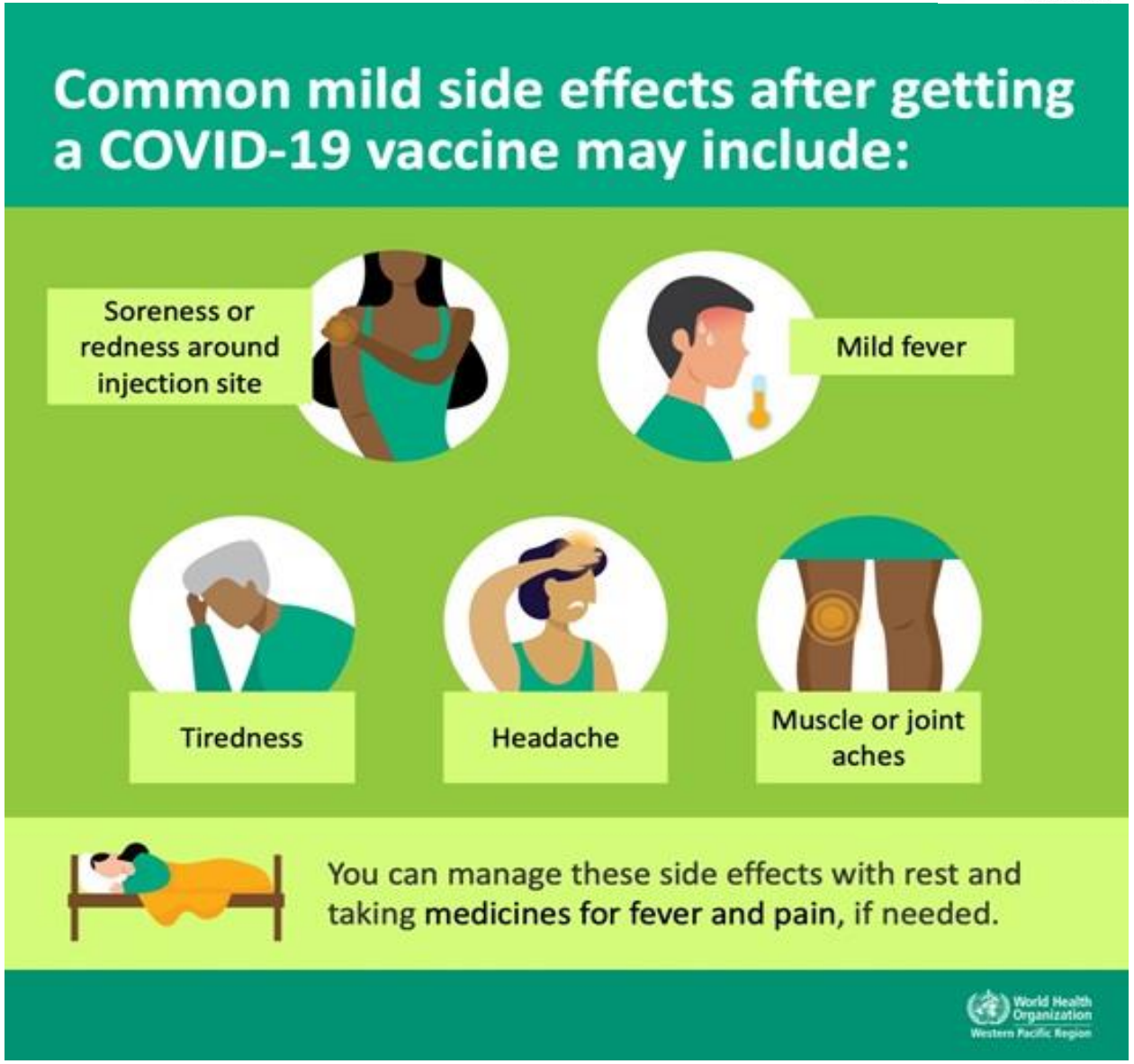
- In participants 5-11 years of age without evidence of SARS-CoV-2 infection prior to Dose 2, the observed VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 90.7% (95% CI: 67.4%, 98.3%)
  - 3 COVID-19 cases in the Pfizer group compared to 16 in the placebo group

Safety

- Reactogenicity assessments included solicited injection site reactions and systemic adverse events
  - The occurrence of lymphadenopathy (<1%), and myocarditis/pericarditis, anaphylaxis, Bell's palsy, appendicitis, pregnancy exposures and outcomes, and MIS-C cases (no cases)

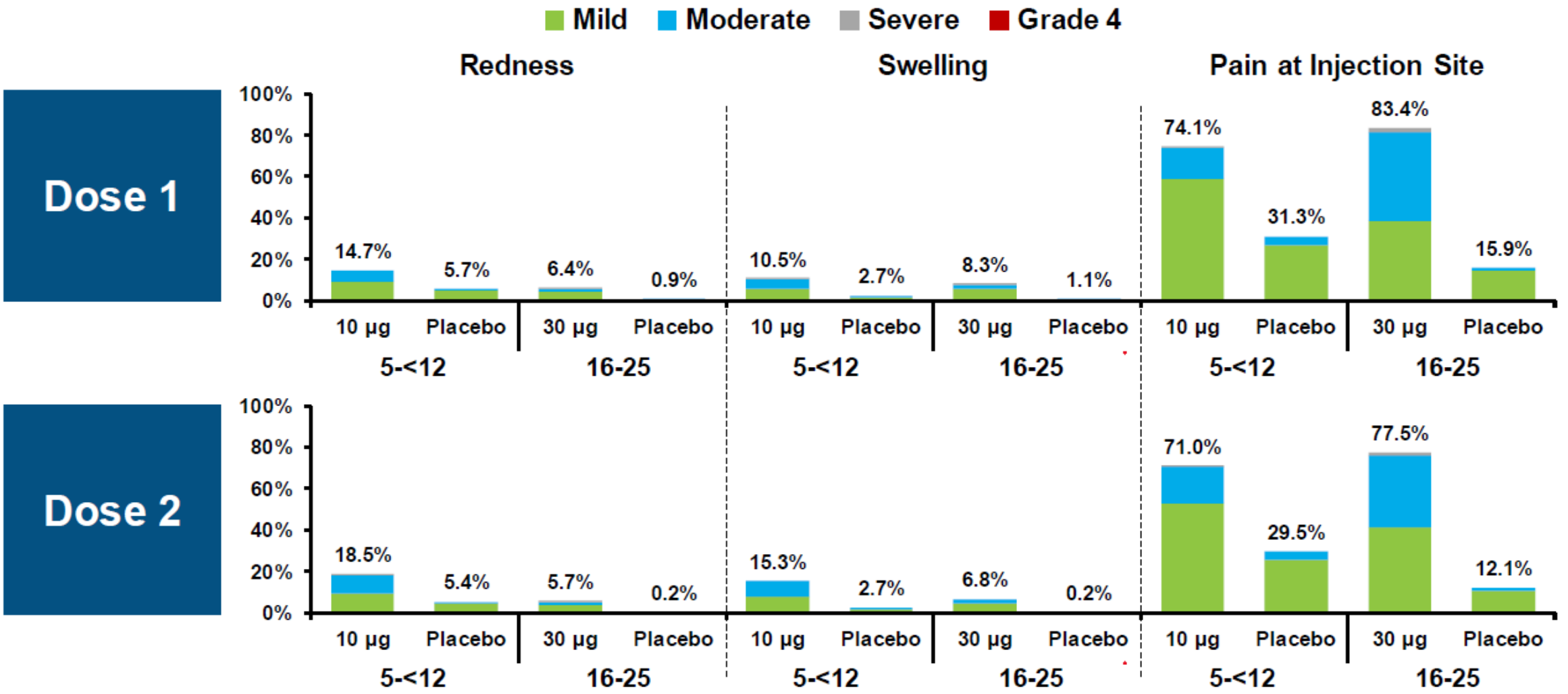
Common Vaccine Side Effects Similar to Adult Vaccine

Symptoms last for less than 48-72 hours and generally less severe than adults



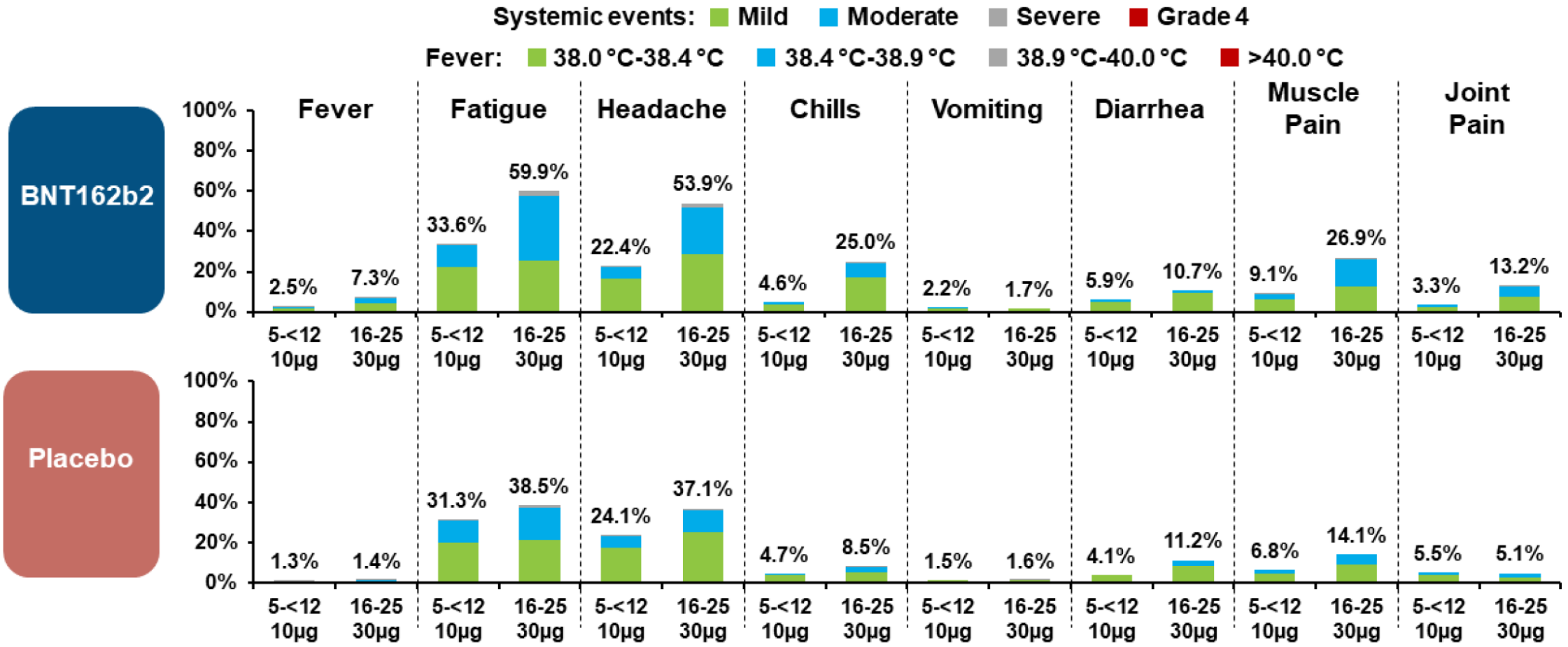
https://www.who.int/westernpacific/emergencies/covid-19/information-vaccines/covid-19-vaccine-side-effects-aefis-and-safety

Local Reaction



https://www.fda.gov/media/153513/download

Systemic Reactions



https://www.fda.gov/media/153513/download

Myocarditis/Pericarditis

- Study not powered to determine rate in 5-11 year olds
- Turn to educated guessing by looking at data in 12-17 y/o
  - Medical chart-confirmed myocarditis and pericarditis in VAERS is highest in males 12-17 years of age
    - ~71.5 cases/million second doses among males age 16-17 years and 42.6 cases/million second doses among males age 12-15 years)
  - In an FDA analysis of the Optum healthcare claims database, the estimated excess risk of myocarditis/pericarditis approached 200 cases/million fully vaccinated males 16-17 years of age and 180 cases/million fully vaccinated males 12-15 years of age
  - Short-term follow-up shows resolution of symptoms with conservative management nearly all by 5 days
  - Information is not yet available about potential long-term sequelae

Is it Worth Doing?

- To answer the question, CDC and FDA generated various scenarios to try and attempt to estimate the impact of vaccination on the population and the risk of serious complications from the vaccine
  - Scenario 1 with COVID-19 incidence as of September 11, 2021
  - Scenario 2 with COVID-19 incidence close to the recent peak of the Delta variant surge at the end of August 2021
  - Scenario 3 with COVID-19 incidence close to the lowest recorded incidence in June 2021
  - Scenario 4 with the same COVID-19 incidence as Scenario 1 and an assumption of 90% vaccine efficacy against cases and 100% efficacy against hospitalizations
  - Scenario 5 with a 3x multiple of the death rate to more closely match the cumulative death rate for 5-11 years old seen in CDC Data Tracker
  - Scenario 6 with the same COVID-19 incidence and assumed vaccine efficacy as Scenario 1 but 50% of the myocarditis cases as Scenario 1.
- The estimates for excess myocarditis/pericarditis among fully vaccinated individuals assumed the highest rates (i.e., Optum dataset)

Model-Predicted Benefit-Risk Outcomes of Scenarios 1-6 per One Million Fully Vaccinated Children 5-11 Years Old

	Benefits				Risks			
Sex	Prevented COVID-19 Cases	Prevented COVID-19 Hospitalizations	Prevented COVID-19 ICU Admissions	Prevented COVID-19 Deaths	Excess Myocarditis Cases	Excess Myocarditis Hospitalizations	Excess Myocarditis ICU Admissions	Excess Myocarditis Deaths
Males & Females								
Scenario 1	45,773	192	62	1	106	58	34	0
Scenario 2	54,345	250	80	1	106	58	34	0
Scenario 3	2,639	21	7	0	106	58	34	0
Scenario 4	58,851	241	77	1	106	58	34	0
Scenario 5	45,773	192	62	3	106	58	34	0
Scenario 6	45,773	192	62	1	53	29	17	0

adult

A study of hospitalized patients with symptoms similar to COVID-19* found...

Unvaccinated people with a previous infection were

5x

more likely to have a positive COVID-19 test compared to vaccinated people†

*COVID-19-like illness hospitalizations 90–179 days after prior infection or full vaccination
†Received two doses of an mRNA vaccine and no previous infection

Get vaccinated **as soon as possible**

bit.ly/MMWR7044e1

MMWR

Bottom Line

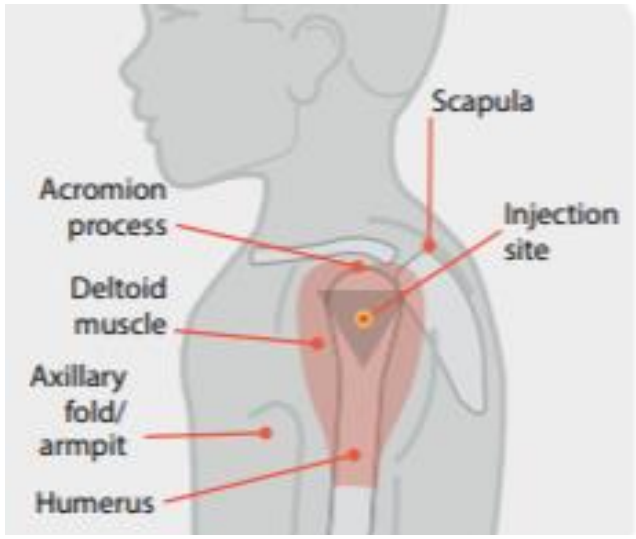
- 28 million children age 5-11 years live in the US
  - 42% have gotten COVID based on antibody screening
    - Much fewer have appeared for testing
  - 8,000 hospitalized
  - 100 deaths
  - 4-8% with long haulers syndrome from COVID
- The virus is never going away, but new treatments could appear
- Vaccine seems safe and highly effective but we don't know yet about rare side effects
  - Myocarditis in the older age group is very rare 1/8,000-1/20,000 doses and full recovery is generally the rule, likely lower rates will be seen in 5-11 year olds
    - For comparison, SARS-CoV-2 infection causes myocarditis/pericarditis in about 1% of children and recovery is much longer
- Vaccination makes good clinical sense for where we are at in the pandemic and perhaps even beyond depending on how side effects evolve

Preparing For Rollout

- Ensure staff are equipped and trained to respond to possible severe allergic reactions like with all vaccine administration
- Consider co-administration of COVID-19 vaccines with influenza and other childhood vaccines, when indicated
- Consider offering COVID-19, influenza, or other routine vaccines, to additional eligible persons (e.g., siblings, family members, community members) when vaccinating kids
- Consider second dose timing when scheduling clinics
- Make sure staff understand the difference between purple and orange tops vials so the right formulation and dose given to each person

Quick Training Resources

- ***You call the shots***
  - Vaccine administration module
    - (Pediatric IM admin slides 72-74):
    - https://www2.cdc.gov/vaccines/ed/vaxadmin/va/index.html
  - Comfort and restraint techniques
    - (3yo and over @ 3:14)
    - https://www.youtube.com/watch?v=r1dGpTCgerE
  - Intramuscular (IM) Injection: Sites
    - (3yo and over @ 2:22)
    - https://www.youtube.com/watch?v=PqSuCPnPeYE



CDPH slide

TIPS & TRICKS

TO HELP YOU AND YOUR CHILD GET THROUGH THE NEEDLESTICK

PROTECT PROTECT PROTECT PROTECT PROTECT

CHICAGO ✶ CHICAGO ✶ CHICAGO ✶ CHICAGO ✶ CHICAGO ✶

BEFORE

CDPH

Make a plan.

Talk to your child about getting the vaccine.

- Tell younger children on the same day as the vaccine.
- Give older children more time to ask questions. Talk with them about a plan for the vaccine so they feel in control.

CDPH Chicago Department of Public Health

RUSH

Ann & Robert H. Lurie Children's Hospital of Chicago

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Comer Children's

THE UNIVERSITY OF CHICAGO Department of Pediatrics Established 1930

https://www.chicago.gov/city/en/sites/covid19-vaccine/home/for-youth.html

CDPH slide

CDPH Provider Ed Videos

- 11/1 (6:17) **NEW Vaccine News You Can Use**
  - https://www.dropbox.com/s/36o1sf930o6w6rc/Dr.%20F%20102921_video%201.mp4?dl=0
- 11/1 (2:01) **NEW Parent-friendly answers: what does COVID in kids look like and why vax 5-11 now?**
  - https://www.dropbox.com/s/ahpt4e7subycpz5/Dr.%20F%20102921_COVID%20in%20kids.mp4?dl=0
- 11/1 (1:45) **NEW Epi data to answer why 5-11 now?**
  - https://www.dropbox.com/s/m3s51r5ug0hc0l5/Dr.%20F%20102921_5-11yo.mp4?dl=0
- 11/1 (5:12) **NEW Parent-friendly facts for the COVID Vaccine Ambassador**
  - https://www.dropbox.com/s/o6c37nqorb0seox/Dr.%20F%20102921_vaccine%20Ambassador.mp4?dl=0
- 11/1 (Coming soon) Short Parent Vax Convo Training

https://www.chicago.gov/city/en/sites/covid19-vaccine/home/facilities.html

More training

- Videos and infographics here: Vaccine Administration Resource Library | CDC
  - Includes information Vaccine administration e-learn with CE for pharmacists, infographics for identifying injection sites + short video demonstration injection and holding children.
- Epidemiology and Prevention of Vaccine-Preventable Diseases at Pinkbook: Vaccine Administration | CDC includes strategies to decrease anxiety and procedural pain.
- COVID-19 vaccine webinar series includes a recorded, short webinar Administering More than 1 Vaccine on the Same Day: Clinical Considerations and a webinar on Clinical Considerations: Vaccinating Adolescents at COVID-19 Vaccine Webinar Series | CDC
  - A version for younger children should be posted soon
- All COVID-19 clinical materials are here: COVID-19 Vaccination Clinical and Professional Resources | CDC

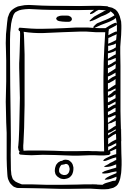
HFS Billing info

- All HFS Coronavirus (COVID-19) Updates: https://www2.illinois.gov/hfs/Pages/coronavirus.aspx
- HFS' COVID-19 Fee Schedule uses Medicare rates: https://www2.illinois.gov/hfs/SiteCollectionDocuments/COVID19FeeScheduleAdd0004AEffective10042021Final.pdf
- Information on billing Federal HRSA for COVID-19 Testing, Treatment, and Vaccine Administration for the Uninsured: https://www.hrsa.gov/coviduninsuredclaim

I-VAC
ILLINOIS VACCINATES AGAINST COVID-19

Foundational Training

Learning Collaboratives



Technical Assistance

Toolkit & Outreach Materials

Website: https://illinoisaap.org/covid19-immunization-campaign/

Jennie Pinkwater - **jpinkwater@illinoisaap.com**
Kathy Sanabria - **ksanabria@illinoisaap.com**
Stephanie Atella - **satella@illinoisaap.com**

Questions?

Thank you!

Next Session: Thursday, December 9th,12-1:15pm CST

Resources & recording of the session

https://www.echo-chicago.org/resources/covid19/

This project was funded in part by a cooperative agreement with the Centers for Disease Control and Prevention grant number 1 NU50CK000588-01-00. The Centers for Disease Control and Prevention is an agency within the Department of Health and Human Services (HHS). The contents of this resource center do not necessarily represent the policy of CDC or HHS and should not be considered an endorsement by the Federal Government.

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Health is on the way.™