COVID-19, Variants, and the Vaccine:

A Q&A Session with Medical Experts for Caregivers of Children with Disabilities

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University of Cincinnati Center for Excellence in Developmental Disabilities

Today's Agenda

- Welcome and Introductions
- Speakers' Presentations:
  - Dr. Patricia Manning-Courtney, MD
  - Dr. Robert Frenck, MD
  - Dr. Kara Ayers, PhD
  - Dr. Rena Sorensen, PhD
- Q&A
- Wrap Up

Dr. Patty Manning, MD

Chief of Staff

Developmental and Behavioral Pediatrician

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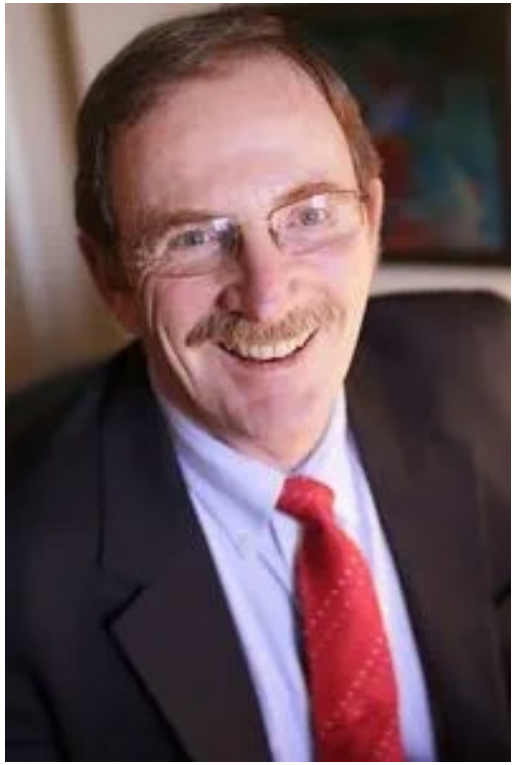
Dr. Robert Frenck, MD

Director, Vaccine Research Center

Infectious Diseases



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COVID-19 Updates

Robert W. Frenck, Jr., M.D.
Cincinnati Children's Hospital
Division of Infectious Diseases

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Human Coronavirus (HCoV)

- HCoVs are found worldwide.
- More common in winter and spring in temperate climates.
- Exposure is common in early childhood,
- By adulthood over 90% of people have had numerous HCoVs

COVID-19

- Novel coronavirus
- First detected in Wuhan China, Dec 2019
- Now present worldwide
- Named “SARS-CoV-2”
- Disease caused by virus named “coronavirus disease 2019” (“COVID-19”).

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COVID-19 Mode of Transmission

- Mostly direct person-to-person
  - Droplet spread
  - Possibly airborne
- Contact with contaminated surface

www.cdc.gov

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COVID-19 Definitions

- Infection
  - Able to detect organism in your body
- Disease
  - Infection with symptoms
- Moderate to Severe Disease
  - Hospitalization or worse

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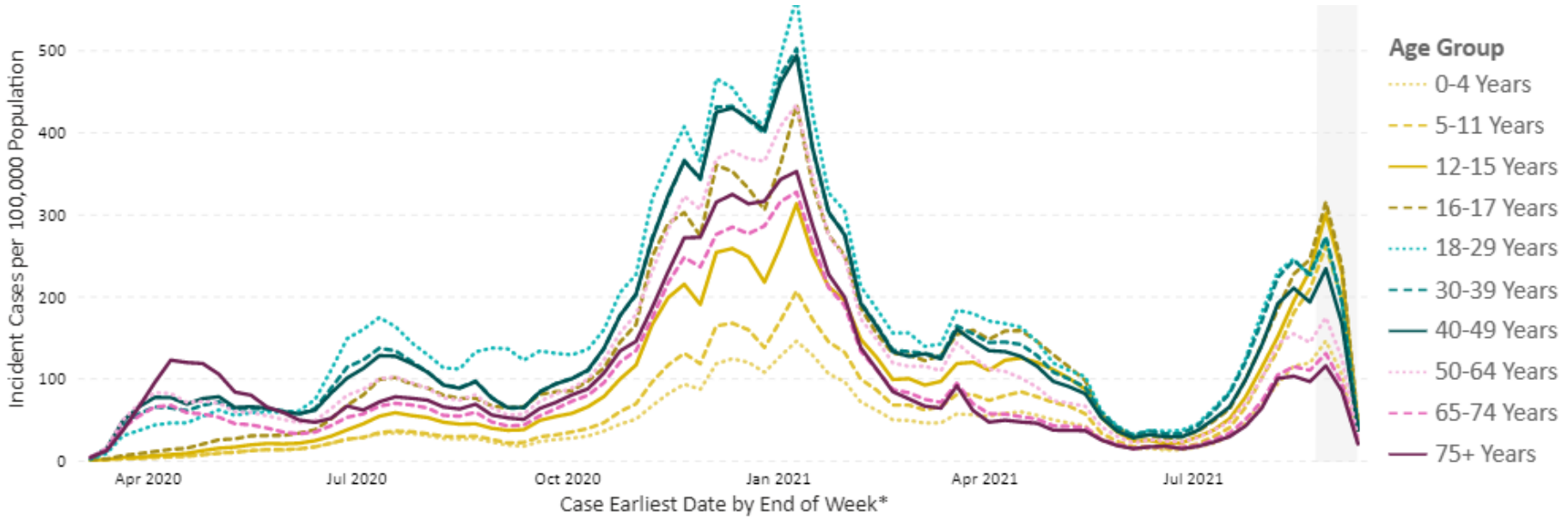
NIH News Release 29Jan21

Incidence of COVID-19 in US by Age



COVID Data Tracker; CDC.gov, Sept 10, 2021

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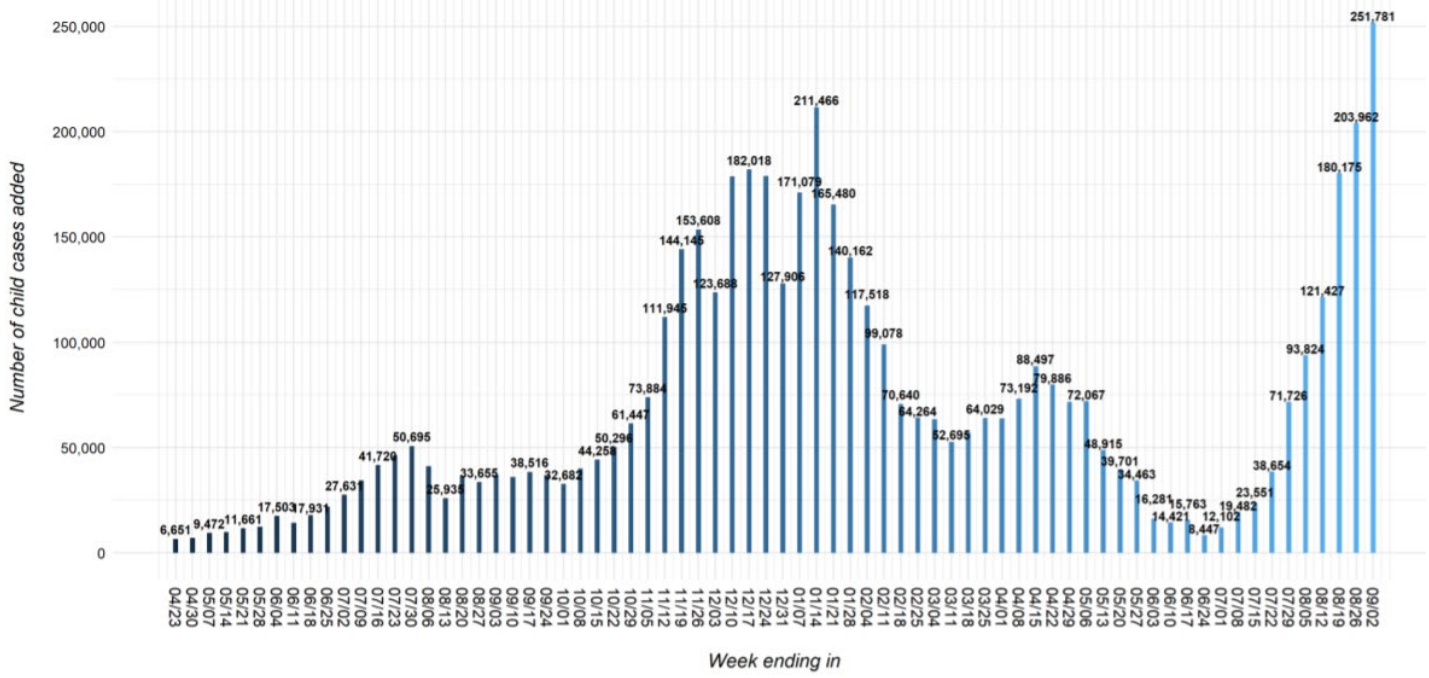
Number of Pediatric COVID-19 Cases in US per Week



CDC and AAP/Children's Hospital Association. https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/

Downloaded Sept 10, 2021

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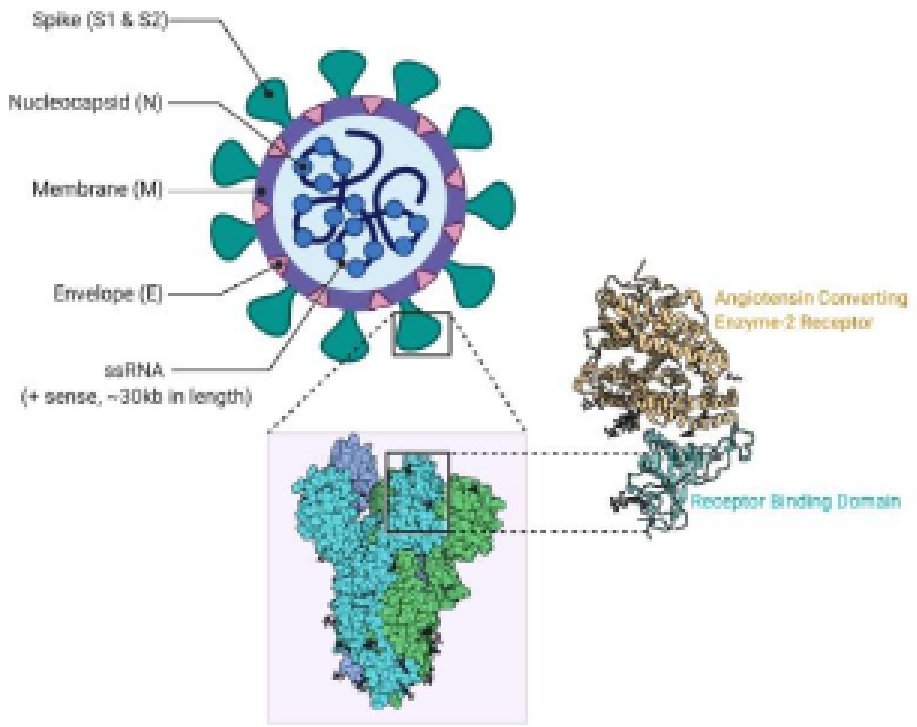
SARS-CoV2 Structure



SARS- CoV 2 Structure. Contributed by Rohan Bir Singh, MD; Made with Biorender.com. From: Features, Evaluation and Treatment Coronavirus (COVID-19). http://creativecommons.org/licenses/by/4.0/

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COVID-19 Vaccine Candidates

Platform	Developer	Current Status
Nucleic Acid	Pfizer	EUA Approved
	Moderna	EUA Approved
Viral Vector	Janssen	EUA Approved
	Astra Zeneca	Finished Phase 3
Protein Subunit	Novavax	Phase 3 Done
	Sanofi	Phase 3 Pending

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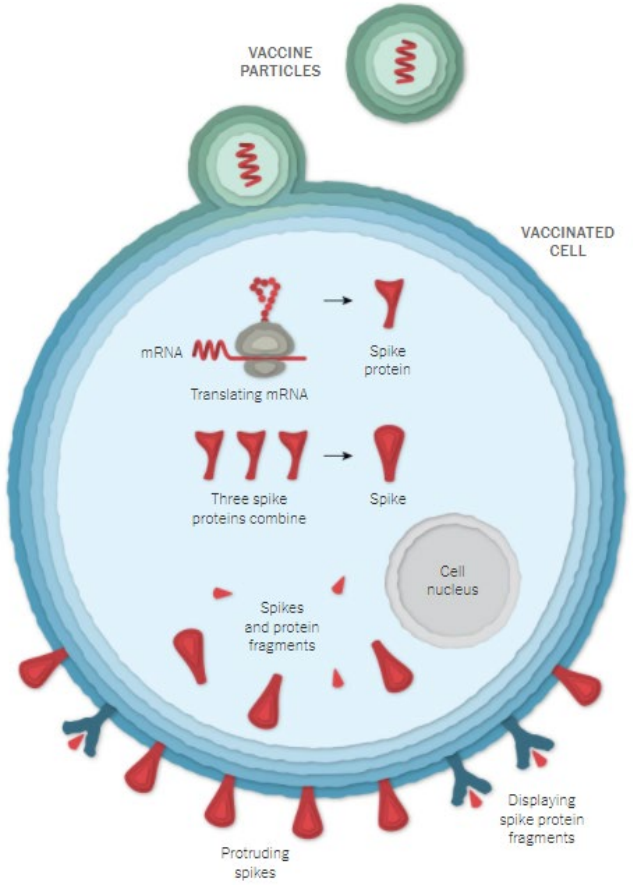
COVID-19, mRNA Vaccine Entering Cell



NY Times: https://nytimes.com/interactive/2020/health/moderna-covid-19-vaccine.html

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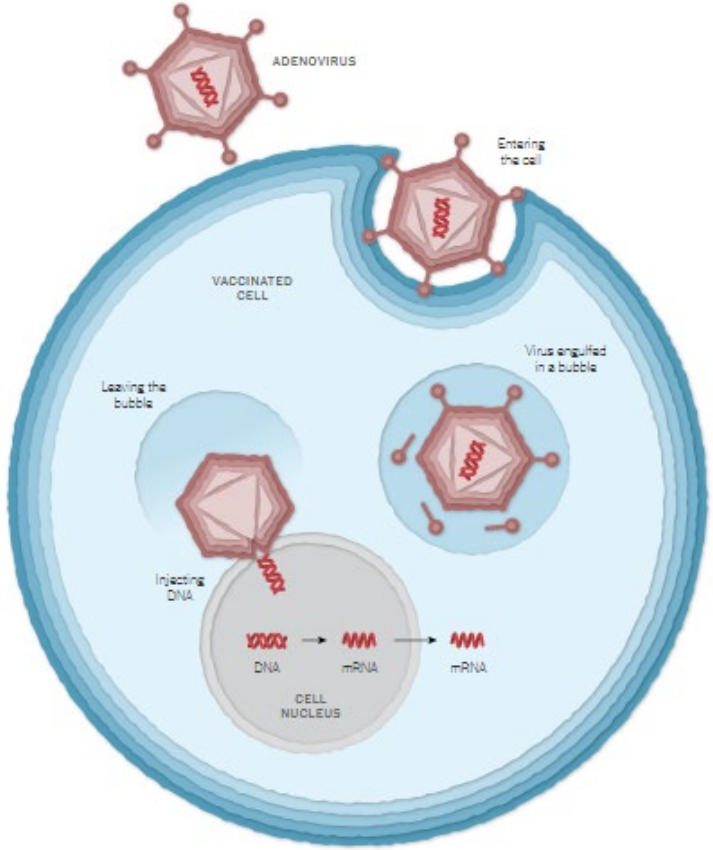
Adenoviral Vectored Vaccine Entering Cell



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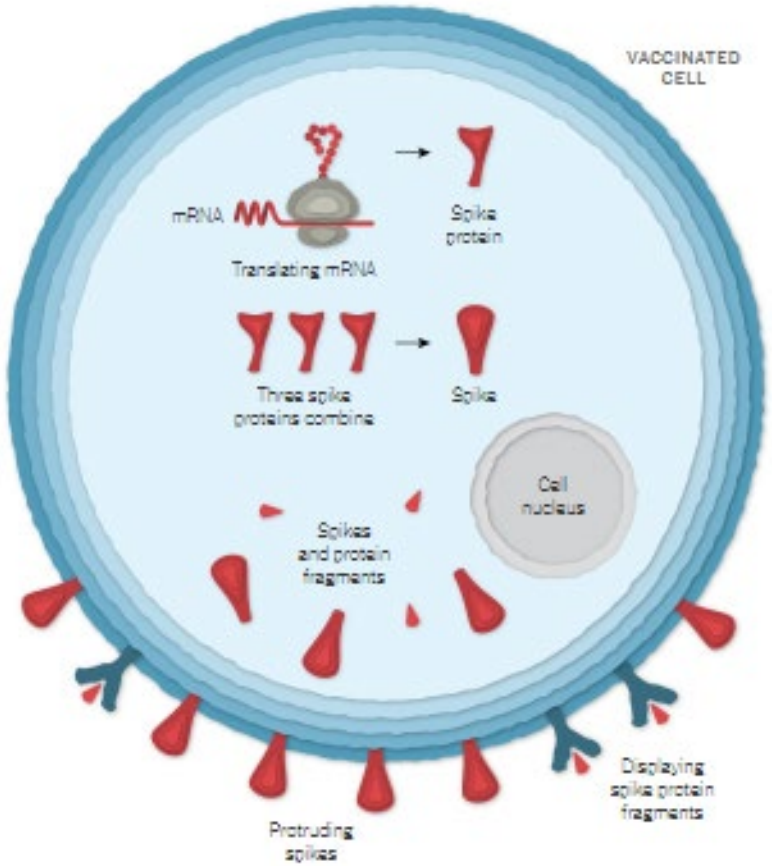
Building the Spike Protein in Our Cells



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Emergency Use Authorization (EUA)

- In cases of a declared medical emergency, the FDA may allow the use of medical products still being tested
- Vaccines used through an EUA is almost like going to a doctor's office to get a vaccine
- Fact sheets containing information on product safety, available alternative products are required.
- We still collect information about any side effects

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mRNA Vaccine Trials in Teens, Results

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Pfizer COVID-19 Vx Trial for 12-15 Year Olds

- 2260 adolescents 12-15 yrs old randomized 1:1 vaccine to placebo
- 2 doses 3 weeks apart, 30 ug dose
- Blood collected baseline and 1 month after 2nd dose
- Local and systemic reactogenicity collected for 7 days after each dose
- SAEs and unsolicited AEs collected for 6 months after dose 1.
- Immunogenicity safety and efficacy compared with 16–25 year-olds
- Participant asked to contact site if had COVID-like illness

Frenck et al. NEJM 27May 2021

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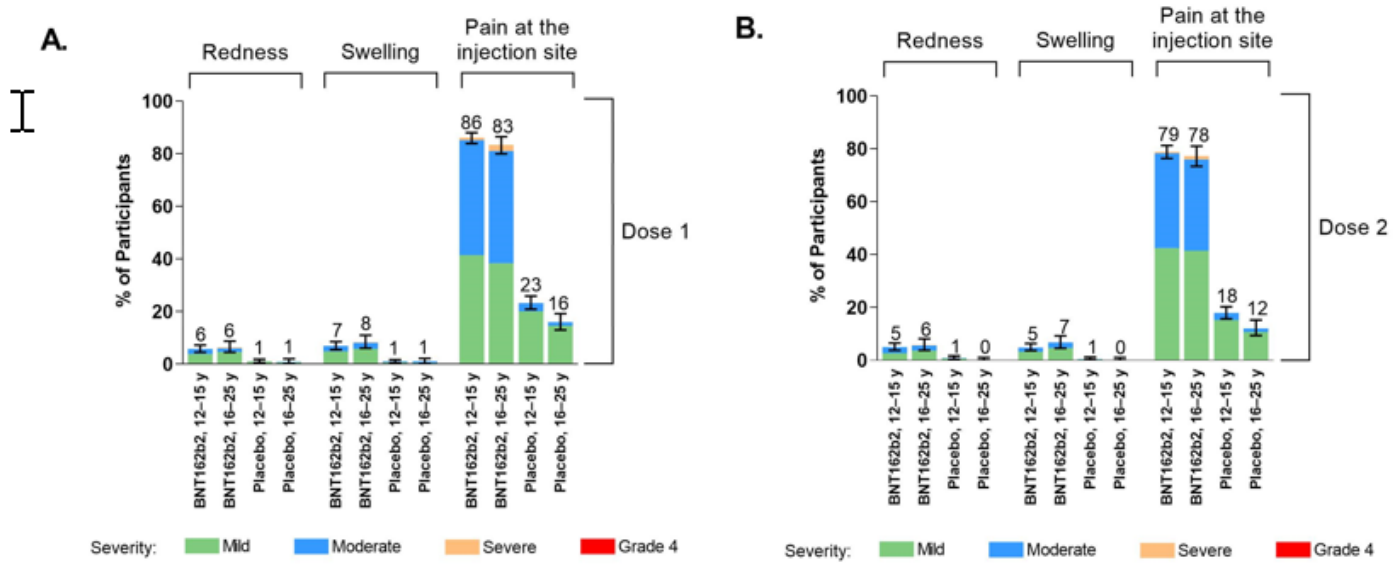
Pfizer COVID-19 Vaccine, Local AEs, 12-15 yr old vs 16-25 yr old



Frenck et al. NEJM 27May 2021

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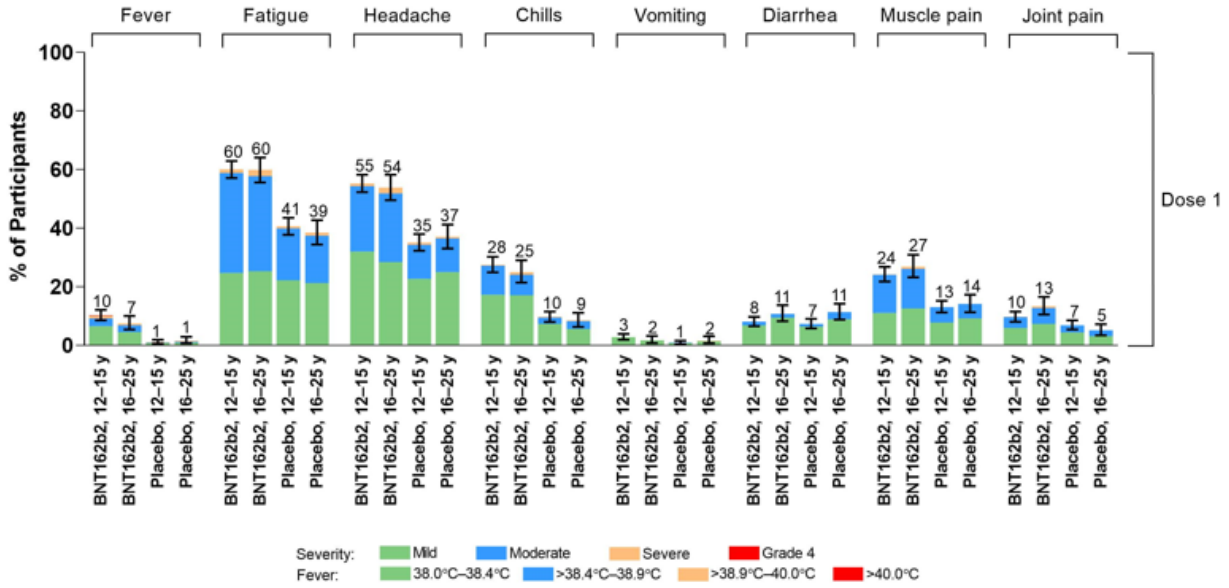
Pfizer COVID-19 Vaccine, Systemic AEs, 12-15 yr old vs 16-25 yr old, Dose 1



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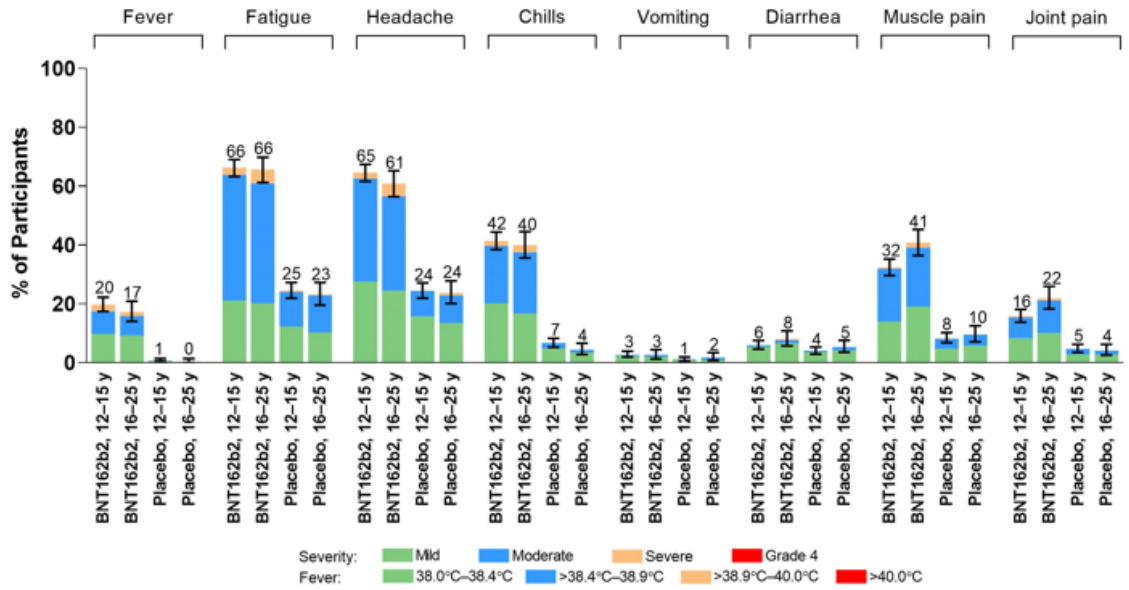
Pfizer COVID-19 Vaccine, Systemic AEs, 12-15 yr old vs 16-25 yr old, Dose 2



Frenck et al. NEJM 27May 2021

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Geometric mean ratio of 50% neutralizing titers 1 mo after dose 2, 12–15 vs 16–25 years of age

Assay	BNT162b2				12–15/16–25 years of age	
	12–15 years of age		16–25 years of age			
	n	GMT (95% CI)†	n	GMT (95% CI)†	GMR (95% CI)†	Met noninferiority objective‡
SARS-CoV-2 neutralization assay (NT50)	190	1239.5 (1095.5, 1402.5)	170	705.1 (621.4, 800.2)	1.76 (1.47, 2.10)	Yes

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Frenck et al. NEJM 27May 2021

Pfizer COVID-19 Vaccine Efficacy, 12–15 years of age

Efficacy endpoint	SARS-CoV-2 infection status	BNT162b2		Placebo		VE (95% CI[§])
		n1* (N)	Surveillance time† (n2‡)	n1* (N)	Surveillance time† (n2‡)	
First COVID-19 occurrence from 7 days after dose 2	Without evidence of infection prior to 7 days after dose 2	0 (1005)	0.154 (1001)	16 (978)	0.147 (972)	100.0% (75.3, 100.0)
First COVID-19 occurrence from 7 days after dose 2	With or without evidence of infection prior to 7 days after dose 2	0 (1119)	0.170 (1109)	18 (1110)	0.163 (1094)	100.0% (78.1, 100.0)

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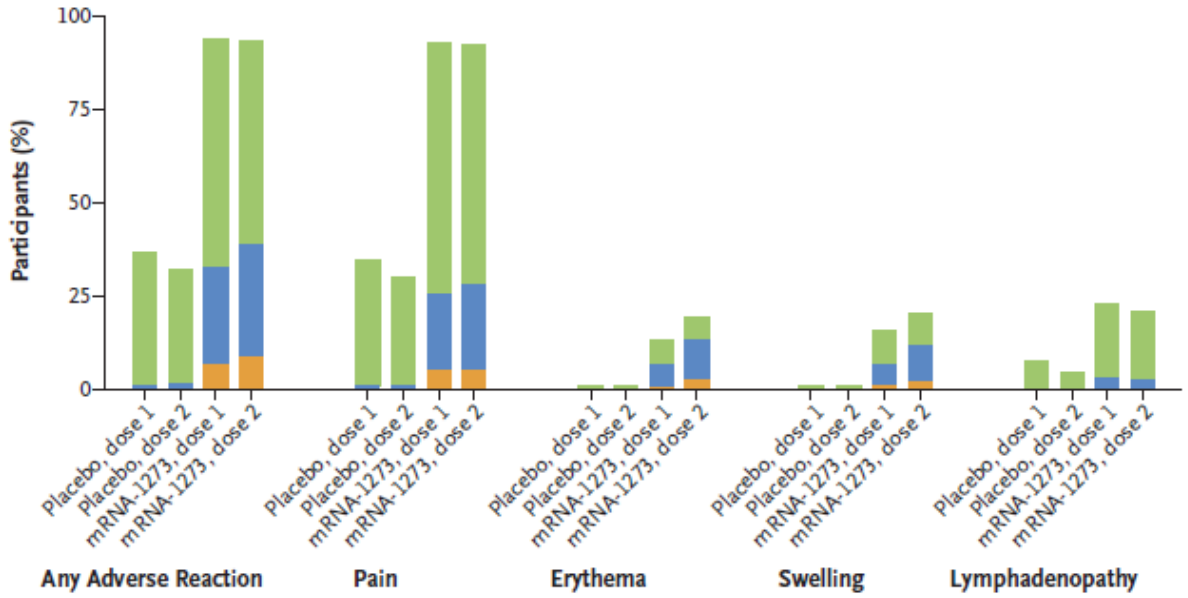
Frenck et al. NEJM 27May 2021

Moderna, TeenCove Study (12-<18 yrs old)

- 3732 participants, 2:1 randomization (vaccine:placebo)
- Receive 2 doses of vaccine (100 ug dose) 28 days apart
- Nasal swab collected prior to each vaccine and if have COVID-like symptoms
- Blood collected at baseline and 28 days after 2nd vaccine
- Local and systemic adverse reactions collected for 7 days after each dose
- SAEs and unsolicited AEs collected for 6 months after dose 1.

Local AE's in Adolescents After 1st of 2nd Dose mRNA-1273 Vaccine vs. Placebo.



Kashif A. NEJM. August 11, 2021 DOI: 10.1056/NEJMoa2109522

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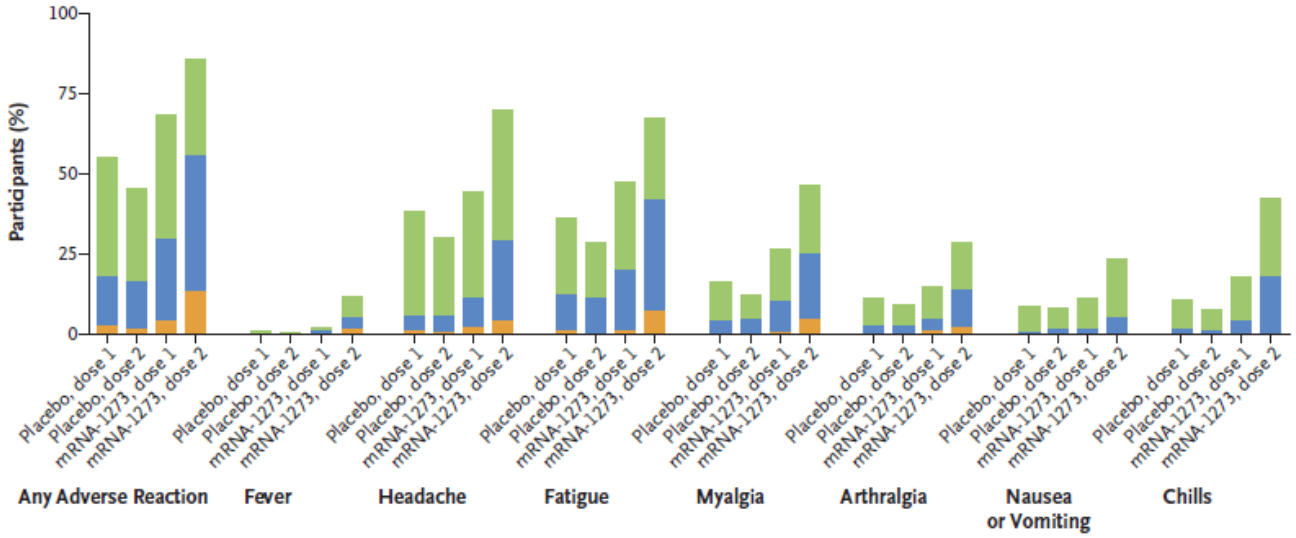
Systemic AE's in Adolescents After 1st of 2nd Dose mRNA-1273 Vaccine vs Placebo



Kashif A. NEJM. August 11, 2021 DOI: 10.1056/NEJMoa2109522

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Immunogenicity of mRNA-1273 in Adolescents and Young Adults

Age Group	Participants	Serologic Response†	Difference in Serologic Response, 12 to 17 Yr vs. 18 to 25 Yr‡	Geometric Mean 50% Pseudovirus Neutralizing Antibody Titer (95% CI)§	Geometric Mean Titer Ratio (95% CI), 12 to 17 Yr vs. 18 to 25 Yr
	no.	*no. of participants/total no. (%; 95% CI)*	*percentage points (95% CI)*		
12 to 17 yr	340	336/340 (98.8; 97.0 to 99.7)	0.2 (–1.8 to 2.4)	1401.7 (1276.3 to 1539.4)	1.08 (0.94 to 1.24)
18 to 25 yr	296	292/296 (98.6; 96.6 to 99.6)	—	1301.3 (1177.0 to 1438.8)	—

Kashif A. NEJM. August 11, 2021 DOI: 10.1056/NEJMoa2109522

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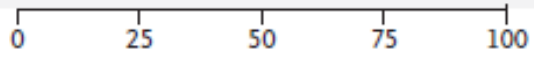
Vaccine Efficacy of mRNA-1273 in Adolescents

Efficacy End Point	Placebo	mRNA-1273	Vaccine Efficacy (95% CI)
	no. of participants with event		*percent*
Covid-19 14 days after second dose, PP	4	0	100.0 (28.9 to NE)
Covid-19 (secondary case definition) 14 days after second dose, PP	7	1	93.3 (47.9 to 99.9)
Covid-19 (secondary case definition) 14 days after first dose, mITT1	13	2	92.7 (67.8 to 99.2)
SARS-CoV-2 infection 14 days after second dose, PP	23	22	55.7 (16.8 to 76.4)
SARS-CoV-2 infection 14 days after first dose, mITT1	42	27	69.8 (49.9 to 82.1)
Asymptomatic SARS-CoV-2 infection 14 days after second dose, PP	16	21	39.2 (−24.7 to 69.7)
Asymptomatic SARS-CoV-2 infection 14 days after first dose, mITT1	29	25	59.5 (28.4 to 77.3)



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Kashif A. NEJM. August 11, 2021 DOI: 10.1056/NEJMoa2109522

Post-EUA Reported AEs

- Myocarditis
  - Annual background incidence about 20 per 100,000
  - 204 reports of myocarditis/pericarditis in Ontario, Canada after COVID-19 vaccine
  - 79.1 % occurred within 7 days of vaccine administration
  - 79.9% occurred in males
  - 69.6% occurred following second dose
  - Pfizer vaccine 37.4 per million doses administered following second dose
  - Moderna vaccine was 263.2 per million following the as second dose.

mRNA Vaccine Design, Pre-Teen

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Pfizer Pediatric COVID-19 Vaccine Trial

- Three age ranges (5 yrs - <12 yrs; 2 yrs - <5 yrs; 6 mo - < 24 mos)
- Part 1, dose finding, open label (10ug, 20ug, 30 ug to be evaluated)
- Part 2, placebo controlled, expanded cohort
  - Randomized 2:1 (vaccine:placebo) using optimal dose from Part 1
  - 2250 (5-11 yrs), 1125 (2-4 yrs) and 1125 (6-24 mo)
- Outcome measures
  - Safety and tolerability
  - Immunobridging within each age group to 16-25 year age group in Phase 3
  - Efficacy (if sufficient cases)

ClinTrials.gov

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Moderna KidCove

- Three age ranges (6 yrs - < 12 yrs; 2 yrs - < 6 yrs; 6 mo - < 2 yrs)
- Part 1, dose finding, open label (25 ug, 50 ug, 100 ug dose)
- Part 2, placebo controlled, expanded cohort (Phase 2/3)
  - 3:1, vaccine:placebo using optimal dose from Part 1
  - 1700 (6- <12), 2000 (2- <6 yr) and 2000 (6-24 mo)
- Outcome measures
  - Safety and tolerability
  - Immunobridging within each age group to 16-25 year age group in Phase 3
  - Efficacy (if sufficient cases)

ClinTrials.gov

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COVID-19 Vaccination in Adolescents

- As of July 31, 2021, of 12–17 year olds in the US
  - 42.4% of had received at least 1 dose of a COVID-19 vaccine
  - 31.9% have received both doses
  - If received 1 dose, 87% received both doses
- Hospitalization rate for unvaccinated 12-17 year olds 10x rate of vaccinated teens

Havers FP, MMWR. 2021;70:851–7.
Murthy BP. MMWR 2021;70:1206–1213

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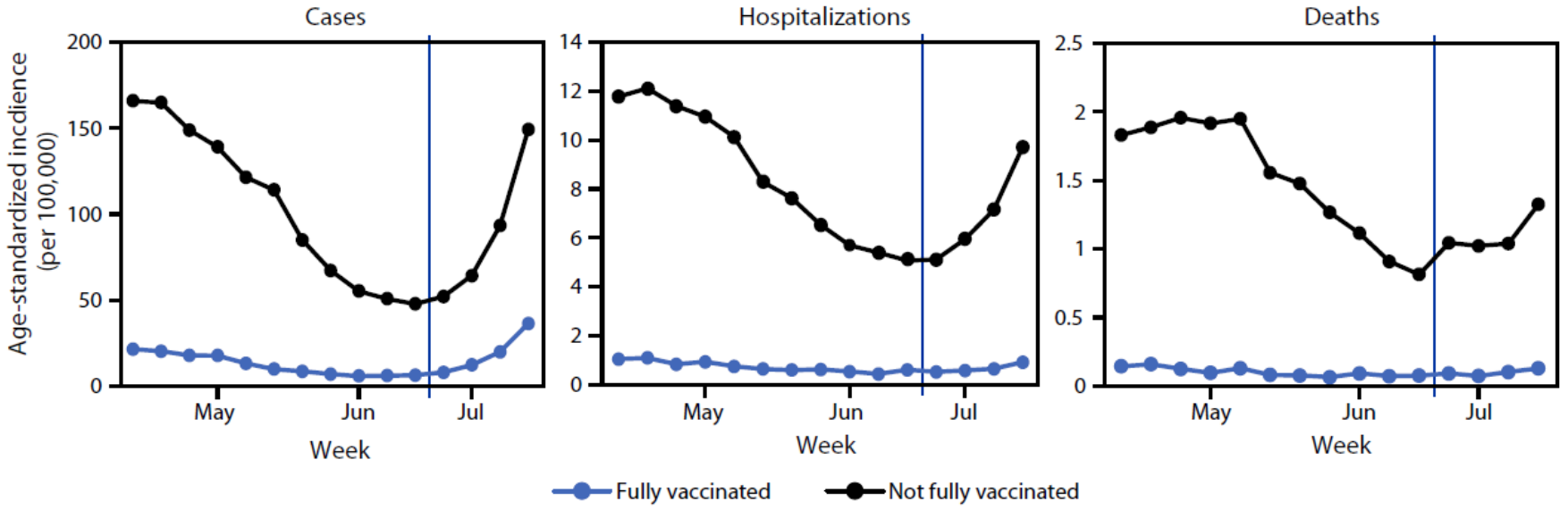
COVID-19 cases, hospitalizations and deaths in US by vaccination status



MMWR. September 10, 2021

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COVID-19 “Untruths”

- COVID-19 vaccines **DO NOT**
  - Make you infertile
  - Modify your DNA
  - Cause you to test positive on PCR tests
  - Give you COVID
  - Protect against flu (or vice versa)

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Dr. Kara Ayers, PhD

Associate Director, University of Cincinnati Center for Excellence in Developmental Disabilities

Assistant Professor

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Impact of COVID-19 on our Disability Community

Kara Ayers, PhD

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COVID's disproportionate impact on disability community

- Increased risk of hospitalization and death connected to many underlyling conditions., including intelectual and developmental disability.
- Negative sentiment from some that people at high risk should "just stay home".

Ayers family

Managing risk

- Masking even when others are not
- Outdoor events when possible
- Setting boundaries around contact with unvaccinated people
- Balancing risk is family-centered
    - High risk family members may be parents, children, or extended family.

Accessibility of mitigation strategies

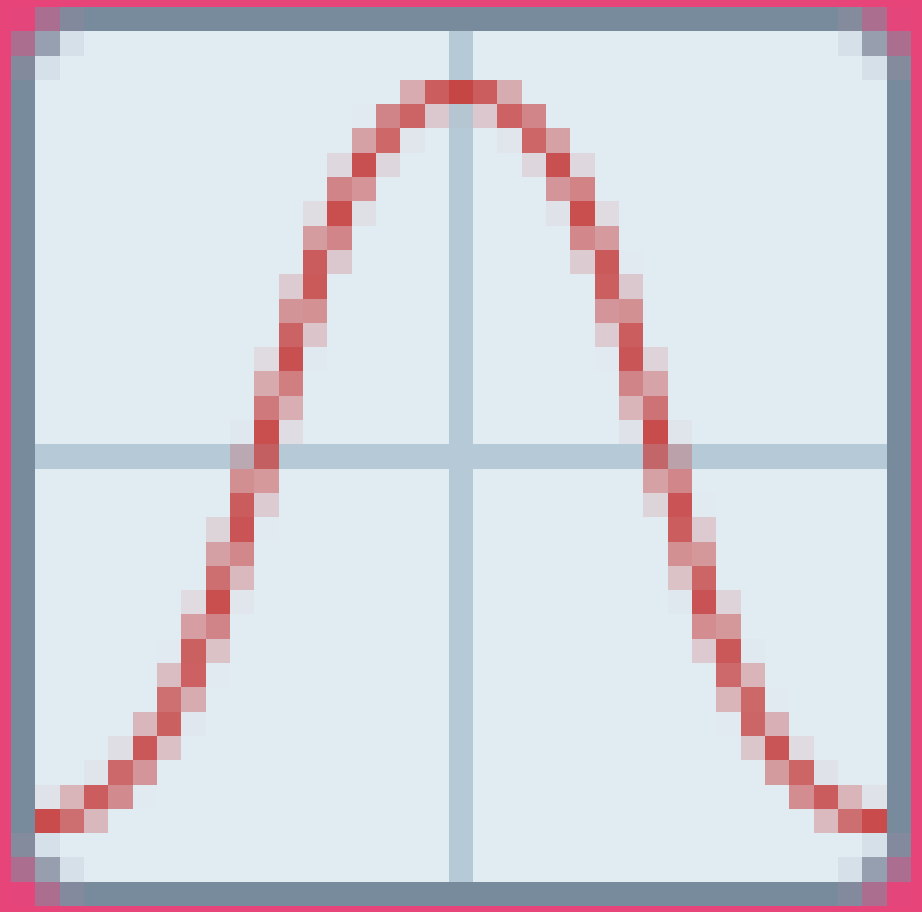
- Upgraded our masks to follow recommendations
- Lanyards and headband attachments to keep masks clean and on face
- Hand washing options must be within reach to all

Community inclusion

- Can be improved or made more difficult with COVID-19 mitigation strategies
- Disability rights to access remain intact during pandemic.
- Staring and negative public interactions can be hard for re-entry

Safe re-entry

- Staring can feel new and more intense
- Keeping COVID-safe aspects of life that have worked for us
  - curbside pick-up
  - reservations
- Keeping in touch with healthcare teams (catch-up if needed)



Peaks and Valleys of COVID

- Ups and downs of school with COVID
  - Learning Aid in Ohio
  - Department of Ed guidance on IEP (10/5/21)
- Uncertainty around winter but hopeful

Ohio COVID-19 Disability Advisory Committee has addressed

Accessibility of vaccine sites

Masking and quarantine policies for school districts

Direct Support Professional Shortages

Vaccine mandates

What else?

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@ThinkEquitable

Let's connect

Dr. Rena Sorensen, PhD

Behavior Support Team

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Keeping Your Child Safe in a Pandemic

Rena Sorensen, PhD

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Our Tool-kit for Safety

- Masking
- Social Distancing
- Handwashing
- Vaccines

- For more in-depth information on teaching these strategies: https://youtu.be/nLHRoitYiyM

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Teach and Build Tolerance for Wearing Masks

- Teaching tolerance for masks is a process, not an event
  - Find a comfortable mask.
  - Identify a reinforcer – use until wear is consistent, then fade
  - Start small and gradually increase the amount of time required/tolerated.
  - Teach proper donning/doffing
  - Teach where to place a mask when removed
  - Make mask wearing part of a routine
- Teaching tools: Social Stories, Videos, Modeling, and Practice-practice-practice!

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Social Distancing

- Try to stay at least 6 feet (about 2 arms' lengths) from other people who are not from your household in both indoor and outdoor spaces
- **How to teach**:
  - Start out with a social story specific to the where the individual needs to practice the skill.
  - Review the rules prior to entering the environment.
  - Develop a simple cues such as stickers for where to stand or sit.
  - Introduce the cues. Teach what they mean and practice using them. Continue to teach and practice until they become a natural part of the routine.
  - Reinforce use of the skill frequently when teaching and intermittently to maintain.
- **Be consistent.** If the cue is used only some of the time, it will lose effectiveness.

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Handwashing

- Develop routines around handwashing – teach when to wash
  - Upon arriving home (or to the classroom)
  - Before food prep, before and after meals
  - Before and after cleaning
  - Before touching your face, mouth, nose
  - After restroom, blowing nose, coughing, sneezing, etc.
  - After using shared items, touching surfaces

- Teach handwashing skill using visual cues, social stories and a song or other auditory cues to help increase the washing time to 20 seconds.
- Increase the use of hand sanitizer in appropriate instances.
  - CDC recommends hand sanitizer that is at least 60% alcohol
  - https://www.cdc.gov/handwashing/hand-sanitizer-use.html
- Teach to cough/sneeze into elbow. Practice this skill and use social stories to explain the reasons.

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Considerations for the COVID-19 Vaccine

- Most individuals will cope the same way they have for their other vaccines.
- Older individuals may be more aware of a vaccine associated with COVID-19 and this may make them more willing to get the vaccine or it may increase worry due to information they have heard from others or read online.
- Monitor access to misinformation and discuss concerns.
- Anyone above age 7 who is struggling to cope with vaccines may benefit treatment to help increase coping with needle-based procedures.

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Tips to Prepare Your Child for a Vaccine

- **Be honest:**
  - It is ok to say shots can feel like a little pinch.
  - Remind them that it is fast and will not hurt for long.
  - If your child is bothered by the word “shot”, call it a “vaccine” or “medicine in the arm.”
- **Focus on staying healthy:**
  - Remind your child that immunizations help protect them from getting sick.
  - It can be helpful to describe it as medicine that puts a little army of fighters in your body to help protect them from illness.
- **Teach:** Use a social story to show what to expect
- **Consider incentives:**
  - Some parents provide an incentive when done, such as going to the park or planning for something fun. This may only be needed for individuals with increased anxiety about vaccinations.

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Tips for Supporting During the Vaccine

- **Bring distractions:**
  - Bring comfort items, a favorite activity or music to help distract and keep them calm.
- **Give appropriate choices:**
  - Which arm?
  - Count to 3 or just do it?
- **Sit up:**
  - Often it is helpful to request that your child sit up instead of lie down.
- **Be a calm and supportive model:**
  - Children cope better when parents remain calm, positive and supportive.
- **Help your child use coping strategies** (breathing, counting, singing, squeezing a stress ball).

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Emotional Support Strategies

- Some individuals will not overcome the anticipatory anxiety to feel ready. They will need to be supported and doing the vaccine quickly while providing emotional support may be the best option.
  - Make sure they know they are not in trouble, and nobody is angry
  - Use the least number of people necessary to hold
  - Establish one communicator to the child to provide information and emotional support
  - All others stay quiet and calm
  - Praise the individual at completion
- Provide choices and support following the vaccine:
  - Allow them to choose an appropriate spot to wait for 15-minutes.
  - Allow them to choose an activity to do while waiting.
  - Praise their success in getting the vaccine, even if they needed to be held, to build confidence for next time.

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Support is Available

Preplanning and support for individuals who need the COVID vaccine but struggle with needle-based procedures is available at Cincinnati Children's Hospital:

Call 513-636-6989 to discuss support needs

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Q&A Session

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Wrap-Up

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