

**Reconnect & Rediscover:**  
A Convening Pediatric Experts  
and Advocates  
Oct. 2-4, 2021

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Pediatric Nurse Practitioners  
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Experts In pediatrics, Advocates for children. 1

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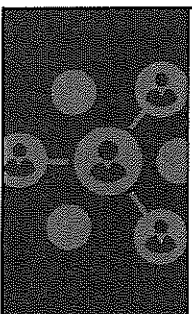
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**Is the COVID Vaccine Safe  
for My Child**

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**Disclosure**

- I am a participant in the Pfizer COVID vaccine trial and have ongoing surveillance

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## Learning Objectives

1. Review current EUA COVID-19 vaccine for children in the United States
2. Dispel common myths associated with the COVID-19 vaccine and how to counter the false information.
3. Address questions parents present with vaccinating their child with the COVID-19 vaccine
4. Review barriers associated with vaccinating children with the COVID-19 vaccine



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## Where are we now

Globally, as of September 22, 2021, there have been 229,373,963 confirmed cases of COVID-19, including 4,705,111 deaths, reported to WHO. As of September 20 2021, a total of 5,776,127,976 vaccine doses have been administered.

In United States of America, from January 3, 2020 to September 22, 2021, there have been 42,034,347 confirmed cases of COVID-19 with 671,728 deaths, reported to WHO. As of September 17, 2021, a total of 388,936,652 vaccine doses have been administered. <https://covid19.who.int/region/amro/country/us>

Good site CDC COVID data tracker:  
<https://covid.cdc.gov/covid-data-tracker/#demographics> to show numbers, demographics, cases/deaths by race and ethnicity, cases/deaths by age groups, cases/deaths by sex



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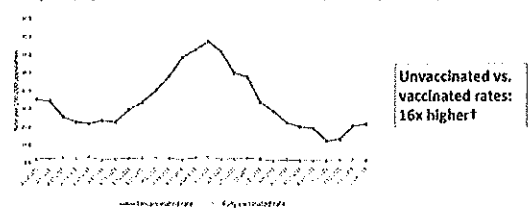
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Age-adjusted weekly COVID-19-associated hospitalization rates among adults ≥18 years, by week of admission\*—COVID-NET, January 24–July 17, 2021



\*Data are presented as weekly rates for hospitalizations based on the 14-day rolling average for total deaths and weekly data according to the Centers for Disease Control and Prevention (CDC) and are presented as the difference in rates between unvaccinated and vaccinated individuals.

†Percentages are based on the 14-day rolling average for total deaths and weekly data according to the Centers for Disease Control and Prevention (CDC) and are presented as the difference in rates between unvaccinated and vaccinated individuals.



<https://www.cdc.gov/vaccines/adp/meetings/downloads/slides-2021-08-30/01-COVID-Daley>

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## Children data as of September 16, 2021

- As of September 16, over 5.5 million children have tested positive for COVID-19 since the onset of the pandemic. Nearly 226,000 cases were added the previous week, the third highest number of child cases in a week since the pandemic began. After declining in early summer, child cases have increased exponentially, with over 925,000 cases in the past 4 weeks.
- For the week ending September 16, children were 25.7% of reported weekly COVID-19 cases (children, under age 18, make up 22.2% of the US population)
- Among the some 25 million US children between 12 and 17 years old, about 12.7 million have been vaccinated with at least one dose of vaccine, according to CDC data. (from September 15, 2021)
  - CDC. Demographic Trends of COVID-19 cases and deaths in the US reported to CDC. Retrieved August 6, 2021 from: <https://covid.cdc.gov/covid-data-tracker/#demographics>



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## Kids do get sick and die of COVID

- 4,403 MIS-C cause severe heart problems, vasculitis, blood clots, strokes,
- 37 deaths from MIS-C as of August 19, 2021
- About 40,000 hospitalizations from COVID-19 as of August 6, 2021
- Over 550 die from COVID as of September 23, 2021
- It is true that children do not get as many severe cases as older individuals but some do get severe infections
- We see more hospitalization than we do with influenza and double the number of deaths from COVID as what we have seen with influenza
- Can have prolonged COVID-like symptoms effects and do not immunologically close down the infection- causing brain fog, loss of taste/smell, ongoing symptoms
- When others not vaccinating may open door to variants and children at most risk because not able to get vaccine at all ages



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## Variants

- A US government SARS-CoV-2 Interagency Group (SIG) developed a Variant Classification scheme that defines three classes of SARS-CoV-2 variants:
  - Variant of Interest
    - Alpha B.1.1.7-UK
    - Beta B.1.351-S Africa
    - Gamma P.1- Japan/Brazil
    - Delta B.1.617.2- India- spread through UK
  - Variant of High Consequence
- States that have lower vaccination rates has higher rates of COVID-19 variant disease



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## COVID vaccines adults and children 16/17

- December 9, 2020: Emergency Use Authorization Pfizer vaccine 16 years + (n=43,448) 52.4% after first dose (2 weeks) and 95% efficacy after second dose (7 days); FDA full approval on August 23, 2021: Comirnaty
- December 18, 2020: Emergency Use Authorization Moderna vaccine 18 years + (n=27,817) After first dose 80.2% protection after 2 weeks, 94.1% after 2 doses
- February 26, 2021: Emergency Use Authorization Johnson and Johnson 18 years+ (n=43,783)(n=19,302 in US), 72% protection against moderate to severe symptoms 28 days post vaccination in US (66% overall) and 85% effective in preventing severe disease across all regions studied
- August 20, 2021: Emergency Use Authorization: mRNA vaccine booster dose for moderately to severely compromised immune systems
- September 22, 2021: FDA booster for Pfizer vaccine recommended for certain populations



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## COVID vaccine for children under 16

- May 10, 2021: EUA: Pfizer-BioNTech COVID-19 Vaccine age 12-15 year old



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## Pfizer/BioNTech COVID-19 vaccine in children

- Pfizer/BioNTech randomized, placebo-controlled clinical trial; n=2,260 age 12-15 years of age; 1/2 received placebo. More than half of the participants were followed for safety for at least two months following the second dose.
  - Side effects similar as what have been seen with current EUA Pfizer vaccine.
  - Vaccine effectiveness: looked at 190 vaccinated 12-15 year olds compared with 170 of vaccinated 16-25 year olds. Cases of COVID-19 after 7 days of second vaccine was 0 in 1005 vaccinated individuals and 16 out of 978 of placebo individuals therefore 100% effectiveness in preventing COVID-19 virus in vaccinated individuals.
  - It is given same way and same dose as older individuals
- Started studying 5-11 year old in March 2021 and under age 5 started in April 2021
  - n=2,268, 1/3 dose (10 micrograms), similar side effects and effectiveness (awaiting disclosure of data)
- The Phase 1/2/3 study enrolled approximately 4,500 children 6 months to 11 years old in the United States, Finland, Poland and Spain at more than 90 clinical trial sites.
  - <https://www.pfizer.com/science/coronavirus/vaccine/additional-population-studies>



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## Other COVID-19 vaccines in children


**Original Title:** A Phase 2/3, Two-Part, Open-Label, Dose-Escalation, Age De-escalation and Randomized, Observer-Blind, Placebo-Controlled Expansion Study to Evaluate the Safety, Tolerability, Reactogenicity, and Effectiveness of mRNA-1273 SARS-CoV-2 Vaccine In Healthy Children 6 Months to Less Than 12 Years of Age

**Actual Study Start Date:** March 15, 2021

**Estimated Primary Completion Date:** June 15, 2021

**Estimated Study Completion Date:** June 15, 2021

Use: A Study to Evaluate Safety and Effectiveness of mRNA-1273 COVID-19 Vaccine in Healthy Children Between 6 Months of Age and Less Than 12 Years of Age. Retrieved from <https://clinicaltrials.gov/ct2/show/study/NCT04959596>




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## Common Myths with COVID19 vaccine




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### Myth #1: COVID-19 vaccine causes infertility

- Raised by Facebook post by Dr. Michael Yeadon and Dr. Wolfgang Wodarg claiming the vaccine could block a protein (syncytin-1) in formation of placenta and would make women infertile (Pfizer vaccine)
- Truth:
  - part of spike protein resembles a part of syncytin-1-not the whole protein
  - body's immune system (forming antibodies) unlikely to confuse the 2 proteins
  - If it did affect fertility might expect to see the COVID-19 infection doing same thing. COVID-19 symptoms has been shown more severe in pregnant women but not losing their pregnancy due to it
    - Full Fact. (2020). No evidence Pfizer COVID-19 vaccine affects women's fertility. Retrieved from <https://fullfact.org/health/vaccine-covid-fertility/>
- Video with Patsy Stinchfield  
[https://www.youtube.com/watch?v=cjVmqA\\_2884](https://www.youtube.com/watch?v=cjVmqA_2884)




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### Myth #2: There is a microchip in the vaccine

- Myth started by comments Bill & Melinda Gates Foundation about a digital certificate of vaccine records
- Also there is no antibiotics, blood products, preservatives like thimerosal, gluten, egg proteins, pork proteins in any COVID-19 vaccine in use in the US



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### Myth #3: Vaccine will alter my child's DNA

- Pfizer/Moderna vaccine uses lipid nanoparticles to slip a single strand of genetic material called messenger RNA (mRNA) into our cells.
- J&J vaccine uses double-stranded DNA inserted into a common, but inert virus called an adenovirus. This DNA also contains the instructions for building the spike protein. Once inside the cell, these instructions are read and translated into mRNA.
- It enters onto a cell's cytoplasm and joins about 200,000 other pieces of mRNA (gives instructions to make spike proteins against the COVID virus)
- mRNA chains last only a couple days and are excreted
  - <https://www.chop.edu/centers-programs/vaccine-education-center/video/can-mrna-vaccines-alter-a-persons-dna>



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### Myth #4: Vaccine has a live virus.

- None in the current or planned COVID-19 vaccines for the US
- The current EUA and approved vaccines for use in the United States are not live
- Pfizer & Moderna are mRNA
- Johnson and Johnson are non-replicating vector vaccines
- You CANNOT get sick with COVID-19 from the vaccine



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### Myth 4: mRNA is brand new technology

- Been around since 1990s
- Has been studied previously for Influenza, Zika, rabies, and cytomegalovirus (CMV)
- Cancer research has used mRNA to trigger immune response against specific cancer cells such as stem cell transplant



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### Questions parents may have about having their child get the vaccine



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### #1: Is the vaccine safe for my child?

- As of mid September over 388 million doses of the COVID-19 vaccine have been given to the general population, 12.7 million of those were children age 12-18 years of age with at least one dose of vaccine

Video with Stacy Buchanan, Immunization SIG Secretary

- <https://youtu.be/OQRDFYe79i8>

Video by CDC

- Video: <https://youtu.be/7bBmQaX2k4w>



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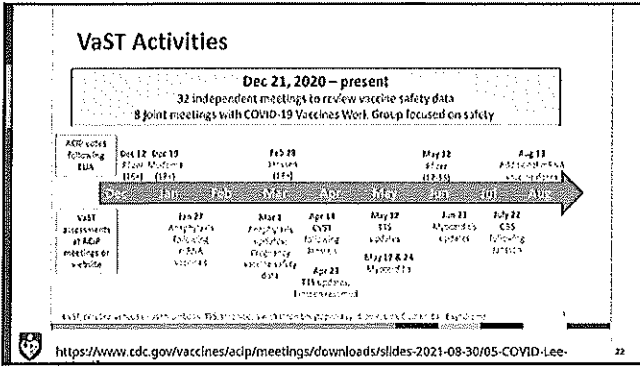
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### #2. I believe COVID Vaccines were rushed into the market.

- Operation Warp Speed
- After EUA continued to be closely observed by FDA, ACIP, Mayo clinical vaccine experts, and researchers around the world
- Systems in place to help recognize adverse effects of the vaccine: VAERS, Vaccine Safety Datalink, V-safe and V-safe COVID-19 pregnancy registry, Clinical Immunization Safety Assessment Project, Medicare/Medicaid, Biologics effectiveness and safety system, sentinel initiative

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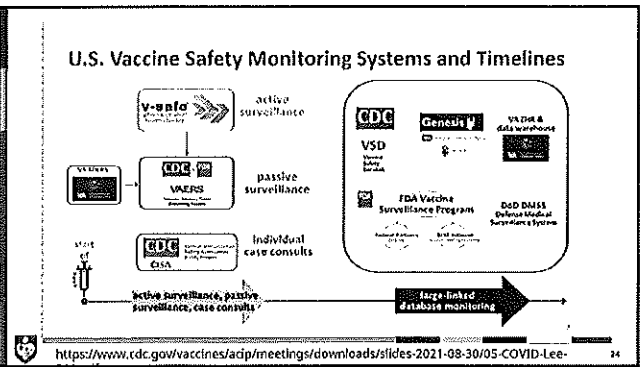
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### #3: Were COVID-19 vaccines developed using fetal tissues?

- No mRNA COVID-19 vaccines used fetal cell cultures
- 2 non-replicating viral vectors vaccines has used legally aborted fetus from around 1972 and 1985 that have been used in development of other vaccines such as rubella, hepatitis A, and varivax
  - Great presentation from Dr. Paul Offit from CHOP on this issue: <https://www.chop.edu/centers-programs/vaccine-education-center/video/are-fetal-cells-used-make-vaccines>



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### #4. Are there long term side effects from the vaccine?

- Historically, vaccine monitoring has shown that if side effects are going to happen, they tend to happen within six weeks of a vaccine dose.
- For this reason, the Food and Drug Administration made sure each of the authorized COVID-19 vaccines was studied for at least eight weeks after the final dose.
- Millions of people have received COVID-19 vaccines, and ongoing surveillance to look at adverse effects.



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### #5. Can my child get COVID-9 vaccine along with other vaccines?

- All vaccines may be given together
- Initially was separated by 14 days as caution only. We know other vaccines that are given together work well and do not need to be separated.
- Further delaying of other vaccines may increase risk of disease
- Video with Christina Cwynar- Immunization SIG co-chair: <https://youtu.be/YcTfj2jD6qg>



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### #6. Does my child need the COVID-19 vaccine if they have already had COVID?

- The protection that someone gains from having COVID-19 will vary from person to person, and we also don't know how long natural immunity might last
- If have no symptoms or mild may get vaccine after quarantine period
- If received convalescent or monoclonal antibodies should wait 90 days
- If had MIS-C should wait 90 days and also clinical recovery including normal cardiac function
- Any COVID disease after vaccination should be reported

Video with Dana DeShon- Immunization SIG chair:  
<https://www.youtube.com/watch?v=pRDoOfO96Lo>



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### #7. Will getting a COVID-19 vaccine cause my child to test positive for COVID-19 on a viral test

- None of the authorized and recommended COVID-19 vaccines cause you to test positive on viral antigen/PCR tests, which are used to see if you have a current infection.
- If your body develops an immune response to vaccination, which is the goal, you may test positive on some antibody tests. Antibody tests indicate you had a previous infection and that you may have some level of protection against the virus.



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### #8. Should my pregnant teenage daughter get the vaccine?

- Pregnant women are at increase risk of severe illness from COVID-19
- Recent reports have shown that pregnant women who got mRNA vaccines, mainly during their third trimester, passed antibodies to their fetuses. These antibodies could help protect the babies after birth
  - CDC. COVID-19 Vaccines While Pregnant or Breastfeeding. Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html>
- Pfizer trial: 23 participants became pregnant during the trial (12 vaccine, 11 placebo) No unsolicited adverse events, including spontaneous abortion, occurred
  - CDC and IDSA (2020). Pfizer-BioNTech COVID-19 vaccine. Retrieved from <https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/Pfizer-BioNTech-COVID-19-Vaccine/>
- Moderna trial: Thirteen pregnancies were reported through December 2, 2020 (6 vaccine, 7 placebo). Unsolicited AEs related to pregnancy include a case of spontaneous abortion and a case of elective abortion, both in the placebo group
  - CDC and IDSA. (2020). Moderna COVID-19 vaccine. Retrieved from <https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/moderna-covid-19-vaccine/#Safety>



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**#9. Will the vaccine affect my daughter's menstrual cycle?**

- Your menstrual cycle cannot be affected by being near someone who received a COVID-19 vaccine or getting the vaccine.
- Many things can affect menstrual cycles, including stress, changes in your schedule, problems with sleep, and changes in diet or exercise. Infections may also affect menstrual cycles.



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**#10. Is my child at risk of getting a blood clot after the vaccine?**

- Johnson & Johnson vaccine has a warning for rare incidence increase risk of thrombosis with thrombocytopenia syndrome (TTS)
- Most reports are of younger women age 18-49 with a rate risk of 7 per million (as of July, 2021 15 reports- median age 37 years with symptoms beginning between 6-15 days of vaccination)
- Reports in men and older women have been reported in a rate of 0.9 per million risk stratification.
- Johnson & Johnson vaccine is currently unavailable at this time (August 2021) for anyone under the age of 18
- As of July 26 there has been 2 reports to VAERS TTS after giving more than 328 million doses of mRNA vaccine (with only Moderna)



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**#11 Do children need to be vaccinated in order for the world to reach herd immunity against SARS-CoV-2?**

- Children under the age of 15 account for 26% of the global population. Successfully vaccinating children will contribute to protection against COVID-19.



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## #12. Will my child get heart problems from the vaccine?

- Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the outer lining of the heart. In both cases, the body's immune system causes inflammation in response to an infection or some other trigger.
- Symptoms:
  - Chest pain
  - Shortness of breath
  - Feelings of having a fast-beating, fluttering, or pounding heart
- Confirmed cases have occurred:
  - Mostly in male adolescents and young adults age 16 years or older
  - More often after getting the second dose than after the first dose of one of these two mRNA COVID-19 vaccines
  - Typically within several days after COVID-19 vaccination

The known and potential benefits of COVID-19 vaccination outweigh the known and potential risks, including the possible risk of myocarditis or pericarditis. Also, most patients with myocarditis and pericarditis who received care responded well to treatment and rest and quickly felt better.

CDC continues to recommend COVID-19 vaccination for everyone 12 years of age and older, given the risk of COVID-19 illness and related, possibly severe complications, such as long-term health problems, hospitalization, and even death.



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## Risk of myocarditis following SARS-CoV-2 infection is described in several recent studies

- Patients with SARS-CoV-2 infection had 16-18 times higher risk for myocarditis compared with patients without SARS-CoV-2; risk varied by age and sex
  - Retrospective cohort using administrative data from >800 U.S. hospitals<sup>1</sup> in a large national study from Israel<sup>2</sup>
- Risk of myocarditis in individuals post-SARS-CoV-2 infection was 6-34 times higher compared to those who received mRNA vaccine
  - Administrative dataset analysis of 48 large healthcare organizations in the U.S.<sup>3</sup>
  - Retrospective cohort using EHR data from 42 U.S. healthcare systems<sup>4</sup>

<sup>1</sup> Friedman & Benayahu, et al., Association between COVID-19 and Myocarditis Using Hospital-Based Administrative Data. Publication, CDC authors. *MedRxiv*. Safety of the mRNA COVID-19 Vaccines in Hospital Settings. August 24, 2021

<sup>2</sup> Shapira et al., Risk of Myocarditis from COVID-19 Infection in People Under Age 35: A Population-Based Analysis. *medRxiv*. Preprint July 2021

<sup>3</sup> Rosenblum et al., Occurrence of Myocarditis, Pericarditis, and Myocardial Injury in Children and Young Adults after COVID-19 Vaccination compared to SARS-CoV-2 Infection. *medRxiv*. Preprint August 2021

<https://www.cdc.gov/vaccines/adcp/meetings/downloads/slides-2021-08-30/06-COVID-Rosenblum-508.pdf>



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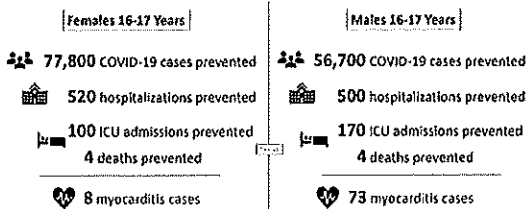
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## Estimated COVID-19 cases prevented vs. myocarditis cases for every million Pfizer-BioNTech COVID-19 vaccinations over 120 days



Cases included based on week of July 11 to 15. Hospitalizations, ICU admissions and deaths based on data for weeks of July 19 to 23. Based on CDC forecasts. <sup>19</sup>



<https://www.cdc.gov/vaccines/adcp/meetings/downloads/slides-2021-08-30/06-COVID-Rosenblum-508.pdf>

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#13. Is there a risk of allergy from the vaccine?

- **Anaphylaxis after COVID-19 vaccination is rare** and has occurred in approximately 2 to 5 people per million vaccinated in the United States.
- Severe allergic reactions, including anaphylaxis, can occur after any vaccination.
- If this occurs, vaccination providers can effectively and immediately treat the reaction
- If anaphylaxis occurred then the person would not receive further doses of that vaccine



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#14. Is there a risk of Guillain-Barre' Syndrome (GBS)?

- VAERS reported 143 preliminary reports of GBS in VAERS as of July 30 with J&J vaccine after >13 million doses given
- Occurred mostly in men > 50 years of age around 2 weeks after vaccination.
- To date (August 22,2021) there have been no reported cases of GBS in mRNA vaccine



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#15. I heard COVID-19 vaccine causes death.

- Over 388 M doses of vaccine given as of September 22, 2021
- VAERS reported 6,490 reports of death (since August 2, 2021)
- FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it is unclear whether the vaccine was the cause
- Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem.
- Reviews so far, including death certificates, autopsy, and medical records has not established a causal link to COVID-19 vaccines except case of rare event of TTS with J&J vaccine which has caused deaths. (since August 2, 2021)



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#16. What are the side effects of the vaccine?

- pain at the injection site
  - fatigue
  - headaches
  - muscle and joint pain
  - fever.
- Side effects are usually mild and should only last 1-2 days



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#17. If my child has an adverse reaction should my child get the second shot?

- Child **SHOULD NOT** get second vaccine if has anaphylactic reaction needing epinephrine or has to go to the hospital for care.
- Child **SHOULD NOT** get the second dose if they had an immediate allergic reaction that happened within 4 hours of getting vaccinated with symptoms such as hives, swelling, and wheezing (respiratory distress)
- **Special consideration** if developed myocarditis or pericarditis after the first dose
- If you got a red, painful, itchy rash within hours to days after the vaccine you **SHOULD** get the next vaccine
- If you had a fever, muscle fatigue, headache, joint pain, sore arm you **SHOULD** get the booster dose



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#18. Does my child need 3 doses of the vaccine to be protected?

- On August 12, 2021 FDA modified the Emergency Use Authorizations (EUAs) for Pfizer-BioNTech COVID-19 vaccine and Moderna
  - On September 22, 2021 FDA and on 24<sup>th</sup> from CDC recommended Pfizer vaccine 6 month booster for:
    - Individuals 65 years of age and older and residents in long-term care settings should receive booster
    - Individuals 50-64 years of age with underlying medical conditions should receive booster
    - Individuals 18 through 49 years of age at high risk of severe COVID-19 may receive booster
    - Individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19 may receive booster
- No recommendation yet for booster dose for Moderna or J&J recipients (as of September 24, 2021)



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## Why vaccinate?

- Safest to protect from very contagious disease, including death
- Ability to visit high risk people such as grandparents, those with chronic diseases
- Hang out with friends safely
- Continue participating in sports
- Less likely the need to wear a face mask
- Less likely the need to quarantine if expose to COVID-19
- Protect family, friends, others at school and activities



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## More Tips for Counseling Patients

### 1. Consider the AIMS principle

- **A = Announce** → Announce vaccination will happen and assume that patient families are ready to vaccinate. Start with a statement - do not imply a question.
- **I = Inquire** → If the patient is hesitant or refuses, seek to understand their concerns. Use active listening and open-ended questions to help you understand the patient's point of view and feelings.
- **M = Mirror** → Make sure the patient knows you understand them by repeating what they said and asking if that was the intended meaning. This demonstrates that you understand their concerns and how they feel.
- **S = Secure** → Our goal is to end every conversation by securing trust. The way we respond will determine whether we build that trust or not.



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## More Tips for Counseling Patients

2. Use easy-to-understand language, especially when describing potential risks or side effects.



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## More Tips for Counseling Patients

3. Be prepared to offer comfort-measures for injections – soothing music, conversational distractions, topical cooling or a numbing agent.

PedsCE: PREVENTING IMMUNIZATION ASSOCIATED PAIN: EDUCATIONAL PRESENTATION FOR PRACTITIONERS AND BEDSIDE STAFF

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## Go forward and vaccinate!!

- Please vaccinate yourself...be the example
- Recommend to parents to vaccinate themselves to protect their unvaccinated ineligible children
- All eligible children should get the vaccine as soon as possible
- Know resources and know what new myths are being created by anti-vax world ([info@stronger.org](mailto:info@stronger.org)) [nfo@stronger.org](mailto:nfo@stronger.org)
- CDC: COVID-19 Vaccinations: A Resource for Parents
- NAPNAP site- type COVID in search engine
- CHOP- Dr. Offit
- Vaccinate Your Family
- ACIP



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