COVID-19 Vaccination for Young People

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Safety Concerns

Is the vaccine safe for children? Will the vaccine make my child sick?

COVID-19 vaccines are <u>safe and effective</u> as documented by the Centers for Disease Control and Prevention (CDC). Currently, the only COVID-19 vaccine authorized for individuals aged 12 years and older is the <u>Pfizer-BioNTech</u> vaccine. A small number of people may experience allergic reactions to the vaccine. Children should not get vaccinated if they have had a serious or an immediate <u>allergic reaction</u> to any ingredient in the vaccine or after getting the first dose of the vaccine, according to the CDC. Parents can also find answers to <u>frequently asked questions</u> about the COVID-19 vaccines from the American Academy of Pediatrics.

What approval does the vaccine hold from the FDA?

On December 11, 2020, the U.S. Food and Drug Administration (FDA) authorized the Pfizer-BioNTech COVID-19 vaccine for emergency use to prevent COVID-19 for individuals 16 years of age and older. On May 10, 2021, FDA expanded the EUA for the Pfizer-BioNTech COVID-19 vaccine to include adolescents aged 12 to 15 years. FDA reviews clinical testing, safety, and effectiveness data before granting emergency use authorization (EUA); the same safety protocols the FDA usually use. The EUA process does not affect safety protocols and allows the FDA to speed up manufacturing and administrative processes to make medical products, such as vaccines, available faster during public health emergencies, such as the COVID-19 pandemic.

Will the vaccine make children sick with COVID-19?

No. None of the COVID-19 vaccines authorized for use in the United States contain the live virus that causes COVID-19. This means the vaccine cannot make anyone sick with COVID-19, according to the CDC.

Will the vaccine make children sick with MIS-C?

Multisystem Inflammatory Syndrome in Children (MIS-C) is a rare condition without a known cause. However, many children with MIS-C had the virus that causes COVID-19 or had been around someone with COVID-19, according to the CDC. Because the Pfizer-BioNTech COVID-19 vaccine does not contain the live virus that causes COVID-19, it cannot give anyone MIS-C. CDC continues to study MIS-C to learn more about the condition and how to prevent it.

Will the vaccine make children sick with myocarditis?

CDC is monitoring rare cases of mild inflammation of the heart — called myocarditis and pericarditis — to determine if they are related to COVID-19 vaccination. There is no indication at this time that these cases are caused by COVID-19 vaccine. Experts, including the <u>American Academy of Pediatrics</u> and <u>CDC</u>, continue to recommend COVID-19 vaccination for everyone 12 years of age and older because the known and potential benefits of COVID-19 vaccination outweigh the known and potential risks, including the possible risk of myocarditis and pericarditis.

Myocarditis is a rare condition in children and adolescents¹ that is often induced by viruses² ³ ⁴ and more regularly affects males.⁵ Reports of myocarditis following COVID-19 vaccination have not differed from what's expected in this age group, according to the CDC. According to the CDC, the relatively few cases of myocarditis and pericarditis reported to date occurred predominately in male adolescents and young adults aged 16 years and older, though most patients who received care responded well to medicine and rest and quickly felt better. While rare, CDC advises everyone to look out for the following symptoms of myocarditis and pericarditis: chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart. Individuals who experience these symptoms within a week after COVID-19 vaccination should seek medical care and report their side effects to their health care provider(s) for entry into the Vaccine Adverse Events Reporting System (VAERS).

Are there any side effects associated with the vaccine?

There may be side effects of the vaccine, which may be more intense after the second shot in a two-shot series. These side effects are normal signs that the body is building protection against the virus. According to the CDC, <u>common side effects</u> include pain, redness, or swelling at the injection site; tiredness; headache; muscle pain; chills; fever; and nausea. These symptoms are often similar to flu-like symptoms and often resolve within a few days with supportive care such as fluids, pain reliever, and rest.

Why should children get the vaccine if they've already had COVID-19?

¹ Vasudeva et al., 2021: https://doi.org/10.1016/j.amjcard.2021.03.019

² Canter & Simpson, 2014: https://doi.org/10.1161/CIRCULATIONAHA.113.001372

³ Foerster & Canter, 2011: https://doi.org/10.1016/j.ppedcard.2011.02.010

⁴ Levine, Klugman, & Teach, 2010: https://doi.org/10.1097/MOP.0b013e32833924d2

⁵ Fairweather, Cooper, Jr., & Blauwet, 2013: https://dx.doi.org/10.1016/j.cpcardiol.2012.07.003

Getting COVID-19 may offer some protection from getting it again, known as "natural immunity." Reinfection with the coronavirus is uncommon in the months after initial infection but may increase with time, according to the CDC, especially for individuals with mild or asymptomatic disease (no symptoms),^{6 7} who are the majority of children with COVID-19.^{8 9} COVID-19 vaccination is a safer way to build immunity without having to experience sickness and the chance of severe illness.

Are there any known delayed side effects that will occur months or even years after receiving the vaccine?

Research into long-term side effects from the vaccine is ongoing. CDC, FDA, and public health experts across the country continuously monitor COVID-19 vaccines for <u>safety</u> and will identify any long-term side effects, if they emerge. <u>According to the CDC</u>, serious side effects that could cause a long-term health problem are extremely unlikely following any vaccination, including the COVID-19 vaccine.

What do I do if my child has allergies?

If your child is allergic to any of the ingredients in the vaccine, discuss vaccination with your child's health care provider. Children should not get vaccinated if they have had a serious allergic reaction or an immediate allergic reaction to any ingredient in the vaccine or after getting the first dose, according to the CDC. You can find the <u>full list of ingredients</u> in the FDA fact sheet for the Pfizer-BioNTech COVID-19 vaccine.

What do I do if my child has an underlying health condition?

Discuss with a health care provider your child's potential for getting sick from COVID-19 and considerations for vaccination. Children with certain medical conditions may be at increased risk for severe illness, according to the CDC, and may benefit from the protection offered by the vaccine.

Should teens with autoimmune conditions get the vaccine?

Children with autoimmune conditions may receive the COVID-19 vaccine. According to the CDC, no data are currently available on the safety of COVID-19 vaccines for people with autoimmune conditions.

Will the vaccine have an impact on children's development?

There is currently no evidence that the COVID-19 vaccine will cause adverse impacts for children's physical or neurological development. The FDA, CDC, and other public health

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⁶ Ibarrondo et al., 2021: https://doi.org/10.1056/NEJMc2025179

⁷ Poland, Ovsyannikova, & Kennedy, 2020: https://doi.org/10.1016/S0140-6736(20)32137-1

⁸ Castagnoli et al., 2020: https://doi.org/10.1001/jamapediatrics.2020.1467

⁹ Ludvigsson, 2020: https://doi.org/10.1111/apa.15270

scientists continue to study the side effects of the COVID-19 vaccines and will report any findings on future side effects as they become available.

Does the vaccine affect fertility in women?

There is currently no evidence that any vaccines, including COVID-19 vaccines, <u>affect fertility</u>, <u>according to the CDC</u>. FDA, CDC, and other public health scientists are studying COVID-19 vaccines and will report any findings on future side effects as they become available.

Does the vaccine cause heavier periods in teens? How does the vaccine impact menstrual cycles for teens?

This is not yet known. There have been some reported cases of menstrual irregularities following COVID-19 vaccination, for example, in the United Kingdom. Teens and others should report this side effect to their health care providers or the <u>Vaccine Adverse Events</u> <u>Reporting System</u> (VAERS). There is some evidence that people who menstruate and were confirmed to have COVID-19 experienced menstrual cycle changes, such as decreased volume and prolonged cycle, the but nothing has been reported related to the COVID-19 vaccines and the clinical trial data does not include any information on menstrual changes. Researchers are currently studying this issue to learn more. Of note, no participant in the clinical trials for the COVID-19 vaccines reported changes to their menstrual cycle after receiving the vaccine.

Where do I go if I have questions about the vaccine?

If you have questions about the vaccine, speak with your child's health care provider or visit the CDC website. CDC provides answers to <u>frequently asked questions about the COVID-19</u> vaccines.

Vaccine Impacts

I've heard that children don't get sick from COVID. Why should they get vaccinated?

While children are less susceptible to COVID-19 than adults¹² and more likely to have asymptomatic or mild disease,¹³ ¹⁴ their risk of contracting and transmitting the virus is not zero. In particular, there is some evidence that COVID-19 cases in children have increased following the emergence of new variants of the virus.¹⁵ ¹⁶ Research also shows children, especially older

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¹⁰ Merchant, 2021: https://www.bmj.com/content/373/bmj.n958/rr-2

¹¹ Li et al., 2021: https://doi.org/10.1016/j.rbmo.2020.09.020

¹² Viner et al., 2020: https://doi.org/10.1001/jamapediatrics.2020.4573

¹³ Castagnoli et al., 2020: https://doi.org/10.1001/jamapediatrics.2020.1467

¹⁴ Ludvigsson, 2020: https://doi.org/10.1111/apa.15270

¹⁵ Mensah et al., 2021: <u>https://doi.org/10.1016/j.jinf.2021.02.022</u>

¹⁶ BMJ, 2020: https://doi.org/10.1136/bmj.m4944

adolescents, can transmit the virus at least as well as adults. ¹⁷ ¹⁸ ¹⁹ ²⁰ As such, additional cases and exposures among children may increase the risk of infection and more serious COVID-19 disease in adults, especially household members. ²¹ ²² ²³ ²⁴ ²⁵ Moreover, exposure to other infected children may lead to the loss of in-person learning and other activities due to quarantine or isolation. ²⁶ ²⁷ Vaccination reduces children's chances of contracting the virus and transmitting the virus to others, ²⁸ ²⁹ ³⁰ and allows for exception from some mitigation efforts that can disrupt their lives, including isolation, quarantine, physical distancing, and wearing a mask.

What does it mean for children to be "fully vaccinated"?

<u>According to the CDC</u>, a child aged 12 years and older is fully vaccinated two weeks after the second dose of a two-dose vaccine series.

Why won't kids benefit from herd immunity if more adults are vaccinated?

Herd immunity is when most of a population is immune to an infectious disease, thereby protecting those who are not immune to the disease. Researchers have estimated herd immunity for COVID-19 to be about 70%. ^{31 32} 2019 Census data shows 22.2% of Illinois residents are under age 18 years. Nearly every adult in Illinois would need to be vaccinated to reach the herd immunity threshold without vaccinating children. Vaccine is available for all adults in the state, but some will choose not to be vaccinated. It may also be harder to reach herd immunity because of virus variants ³⁴ spreading across the state that appear to be more transmissible ^{35 36 37} and more deadly ^{38 39 40} and experts are still learning how long immunity will last following

¹⁷ Heald-Sargent et al., 2020: https://doi.org/10.1001/jamapediatrics.2020.3651

¹⁸ Madera et al., 2020: https://doi.org/10.1038/s41598-021-81934-w

¹⁹ Park et al., 2020: https://dx.doi.org/10.3201/eid2610.201315

²⁰ Yonker et al., 2020: https://doi.org/10.1016/j.jpeds.2020.08.037

²¹ Grijalva et al., 2020: http://dx.doi.org/10.15585/mmwr.mm6944e1

²² Koh et al., 2020: https://doi.org/10.1371/journal.pone.0240205

²³ Laws et al., 2020: https://doi.org/10.1542/peds.2020-027268

²⁴ Laxminarayan et al., 2020: https://doi.org/10.1126/science.abd7672

²⁵ Madewell et al., 2020: https://doi.org/10.1001/jamanetworkopen.2020.31756

²⁶ Artherstone et al., 2020: http://dx.doi.org/10.15585/mmwr.mm7004e4

²⁷ Siegel et al., 2020: http://dx.doi.org/10.15585/mmwr.mm7011a3

²⁸ Levine-Tiefenrbun et al., 2021: https://doi.org/10.1038/s41591-021-01316-7

²⁹ Petter et al., 2021: https://doi.org/10.1101/2021.02.08.21251329

³⁰ Lipsitch & Kahn, 2020: https://doi.org/10.1101/2021.02.25.21252415

³¹ Fontanet & Cauchemez, 2020: https://doi.org/10.1038/s41577-020-00451-5

³² Randolph & Barreiro, 2020: https://doi.org/10.1016/j.immuni.2020.04.012

³³ Aschwaden, 2021: https://doi.org/10.1038/d41586-021-00728-2

³⁴ Sette & Crotty, 2021: https://dx.doi.org/10.1016/j.cell.2021.01.007

³⁵ Davies et al., 2021: https://doi.org/10.1126/science.abg3055

³⁶ Graham et al., 2021: https://doi.org/10.1016/S2468-2667(21)00055-4

³⁷ Washington et al., 2021: https://doi.org/10.1016/j.cell.2021.03.052

³⁸ Challen et al., 2021: https://doi.org/10.1136/bmj.n579

³⁹ Davies et al., 2021: https://doi.org/10.1126/science.abg3055

⁴⁰ Grint et al., 2021: https://doi.org/10.2807/1560-7917.ES.2021.26.11.2100256

vaccination. 41 42 As herd immunity becomes harder to reach, children should seek vaccination for protection from the virus.

What would vaccination mean for children's activities?

Children who are fully vaccinated can engage in more normal, in-person activities. For example:

- Children who are fully vaccinated will be able to attend school for in-person learning with fewer episodes and periods of quarantine for close contacts at school.
- Children who are fully vaccinated can remove their masks and relax physical distancing in all outdoor settings and most indoor settings, according to the CDC.
- Children who are fully vaccinated may resume domestic and international travel without needing to test before departure or self-quarantine upon arrival, according to the CDC.
- Children who are fully vaccinated may skip routine testing for COVID-19, according to the CDC. This applies to screening testing for sports that involve sustained close contacts with others as recommended in the sports safety guidelines from the Illinois Department of Public Health (IDPH).

Do children have to keep wearing a mask after they're vaccinated?

Children who are fully vaccinated may remove their mask and relax physical distancing in all outdoor settings and most indoor settings, according to the CDC.

However, at school, when inside, children who are fully vaccinated should continue wearing a well-fitted mask and maintaining physical distancing at least through the remainder of the 2020-2021 school year, according to the CDC. This is because most students won't be fully vaccinated by the end of the 2020-2021 school year, especially children younger than 12 years old, who are not yet eligible for vaccination. Districts and schools will also need to time to adjust their systems and policies to change mask requirements for students and staff. While the state continues to make progress on those fronts, mitigation measures will continue in schools to protect individuals at increased risk for severe COVID-19 disease or who live with a household member at increased risk for severe COVID-19 disease. For more information on COVID-19 mitigation efforts for the 2020-2021 school year, see the revised public health guidance for schools jointly issued by the Illinois State Board of Education (ISBE) and IDPH. The Governor's Executive Order 2021-10 requires individuals in schools and educational institutions to continue following this guidance.

Children who are fully vaccinated may resume sports-related activities without wearing masks or maintaining physical distance from others for any sport, both indoors and outdoors, except where required by federal, state, local, tribal, or territorial laws, rules, and regulations, including local business and workplace guidance. For more information, review the <u>IDPH sports guidelines</u>.

Is the possibility of transmission after vaccination the same for children as it is for adults?

⁴¹ Dagan et al., 2021: https://doi.org/10.1056/NEJMoa2101765

⁴² Xie et al., 2021: https://doi.org/10.1038/s41591-021-01270-4

Vaccination may reduce the amount of virus in an infected person's body, thereby making them less likely to spread the virus⁴³ ⁴⁴ ⁴⁵ if later infected. There is not currently data to suggest this would be different for children. Researchers will continue to study this question as vaccine trials continue.

Will children have to show proof of vaccination like adults?

Some venues and organizations that serve children (e.g., summer camps, sports leagues, etc.) may require proof of vaccination to participate. The vaccinated individual and/or a parent or guardian will generally be required to consent to disclosing vaccination status. There is currently no state requirement for individuals, including children, to show proof of vaccination to gain access to any location or venue, but other entities may choose to require proof of vaccination separate from state requirements.

Is the vaccine going to be required for my children to go back to school in person?

There is currently no state requirement for students to receive the COVID-19 vaccine. Please check with your child's school about any school-specific requirements.

Are vaccinated children required to quarantine if exposed to COVID-19?

Children who are fully vaccinated with no symptoms of COVID-19 do not need to quarantine; be restricted from school, athletics, or other extracurricular activities; or be tested for COVID-19 following an exposure to someone with suspected or confirmed COVID-19, according to the CDC. Fully vaccinated children should monitor for symptoms of COVID-19 for 14 days following an exposure and, if symptoms begin, should isolate from others, and contact their health care provider.

Are vaccinated children required to be tested for COVID-19 to attend school or participate in other activities?

Children who are fully vaccinated with no symptoms of COVID-19 and no known exposure to someone with suspected or confirmed COVID-19 do not need to be tested for COVID-19 in screening programs, according to the CDC.

Do I need to keep my vaccinated children separate from my other kids at home?

No. Fully vaccinated children can interact with household members who are not vaccinated, and can do so without a mask or physical distancing, according to the CDC.

⁴³ Marks et al., 2021: https://doi.org/10.1016/S1473-3099(20)30985-3

⁴⁴ Cevike et al., 2020: https://doi.org/10.1016/S2666-5247(20)30172-5

⁴⁵ Walsh et al., 2020: https://doi.org/10.1016/j.jinf.2020.10.009

⁴⁶ Levine-Tiefenrbun et al., 2021: https://doi.org/10.1038/s41591-021-01316-7

⁴⁷ Petter et al., 2021: https://doi.org/10.1101/2021.02.08.21251329

⁴⁸ Lipsitch & Kahn, 2020: https://doi.org/10.1101/2021.02.25.21252415

Vaccine Administration

Do minors need permission from a parent or guardian to get vaccinated?

Yes. In Illinois, the age of consent is 18 years. The Consent by Minors to Health Care Services Act (410 ILCS 210) contains exceptions to parental consent in specific, limited circumstances for those aged 14-17 years. Children younger than 14 years of age need consent from a parent or guardian to receive the COVID-19 vaccine. In many cases, the provider of the vaccine will also require a parent or guardian to accompany a minor child for vaccination or sign a consent form before administering vaccine to a minor, especially those unaccompanied by a parent or guardian. Local health departments or local jurisdictions who are administering vaccinations to minors without a parent or guardian should consult with their local state's attorney's office with questions or concerns.

Can minors register themselves for the vaccine? If so, what documentation is needed?

When doing so, minors, in accordance with all requirements under state law, should arrive at the vaccination appointment with their parent or guardian or with a consent form signed by their parent or guardian, photo identification (e.g., school ID, etc.), and, if covered by Medicaid or commercial insurance, an insurance card. Please note that different vaccination sites may have their own requirements that minors and families should follow. The COVID-19 vaccine is free to everyone, with or without insurance, and available to everyone in Illinois, including individuals who are undocumented. Vaccine providers may not ask any individual to provide documentation regarding their immigration status.

Does it matter which vaccine my child gets?

Yes. Currently, only the Pfizer-BioNTech vaccine is approved for use in children as young as 12 years old.

Where can I get a vaccine for my children?

Children can receive vaccine at any site that has Pfizer-BioNTech vaccine available. Available sites include local health departments, pharmacies, hospitals and clinics, mass vaccination sites, and other community settings. Find the nearest vaccination site at https://coronavirus.illinois.gov/s/vaccination-location.

Is the vaccine sequence the same for children as for adults? Why?

Yes. Children will receive two doses of the <u>Pfizer-BioNTech COVID-19 vaccine</u> spaced three weeks (21 days) apart, the same as for adults. Two doses are required for the Pfizer COVID-19 vaccine to produce a stronger immune response, ⁴⁹ as was shown in the clinical trials.⁵⁰

⁴⁹ Livingston, 2021: https://doi.org/10.1001/jama.2021.1375

⁵⁰ Polack et al., 2020: https://doi.org/10.1056/NEJMoa2034577

How does the COVID-19 vaccine interact with the normal schedule of childhood vaccines?

According to the CDC, COVID-19 vaccine series should routinely be administered separate from other vaccines, with at least 14 days before or after administration of any other vaccine. However, COVID-19 and other vaccines may be administered within a shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration or to avoid barriers to or delays in COVID-19 vaccination.

When will children younger than 12 be able to get vaccinated?

On May 12, 2021, <u>CDC recommended</u> that the Pfizer-BioNTech COVID-19 vaccine be used in adolescents as young as 12 years old, following FDA <u>expansion of the emergency use</u> <u>authorization</u> for that age group on May 10, 2021. A COVID-19 vaccine for children younger than 12 years is not yet available. Researchers must first conduct clinical trials with younger children to determine if the vaccines are safe and effective. These <u>trials</u> are currently underway. This document will be updated when additional information is available regarding vaccinations in children younger than 12 years of age.

Other

How diverse was the trial group?

<u>According to the CDC</u>, clinical trials for the Pfizer-BioNTech vaccine included people from the following racial, ethnic, age, and sex categories:

Race

81.9% White

9.8% African American

4.4% Asian

<3% other races/ethnicities

<1% Native Hawaiian or Other Pacific Islander

<1% American Indian or Alaska Native

Ethnicity

73.2% Not Hispanic or Latino 26.2% Hispanic of Latino

<1% Not Reported

Sex

50.6% male

49.4% female

Age

57.9% 16 to 55 years 41.8% 55 years and older 21.4% 65 years and older 4.3% 75 years and older

A total of 283 individuals aged 16 and 17 years old were included among the 37,586 participants in the phase 2/3 trial, of whom 138 received the vaccine and 145 received the placebo, according to the FDA.

How long was the vaccine studied on 16-18-year-olds?

This age group was included in phase 2/3 of the clinical trials for the Pfizer-BioNTech vaccine, which took place between July 27, 2020, and November 14, 2020.⁵¹

⁵¹ Polack et al., 2020: https://doi.org/10.1056/NEJMoa2034577