The following information is provided by the Rhode Island Department of Health:

Pfizer-BioNTech COVID-19 Vaccine for Adolescents Age 12-15 | Topline Messages

Key messages

- The Pfizer-BioNTech COVID-19 vaccine is safe for adolescents age 12 and older.
- The Pfizer-BioNTech vaccine showed 100% effectiveness in preventing COVID-19 infection with symptoms among adolescents age 12-15 enrolled in a clinical trial.
- Adolescents age 12 and older who have gotten other vaccinations should wait until 14 days have passed to get the Pfizer-BioNTech COVID-19 vaccine.
- Vaccination is one of the best ways to protect adolescents both in school and out.

Safety

- The Pfizer-BioNTech COVID-19 vaccine is safe for adolescents age 12-15.
 - The Pfizer-BioNTech COVID-19 vaccine is now authorized for use under an <u>Emergency Use</u>
 <u>Authorization (EUA)</u> for active immunization to prevent COVID-19 in people age 12 and older.
 - On March 31, 2021, Pfizer-BioNTech <u>announced positive results</u> from its Phase 3 COVID-19 vaccine study in adolescents age 12-15. The clinical trial included more than 2,200 participants age 12-15 without prior evidence of SARS-CoV-2 infection (the virus that causes COVID-19).
- Adolescents age 12-15 experience similar post-vaccination symptoms as compared to older people.
 - Clinical trial participants tolerated the vaccine well: Post-vaccination symptoms (side effects)
 were generally consistent with those observed in participants age 16 to 25 from previous
 trials.
 - Post-vaccination symptoms of the Pfizer-BioNTech COVID-19 vaccine include pain in the arm where someone got the shot as well as tiredness, headache, chills, muscle pain, fever, and joint pain. These should go away within a few days. Some people do not have any symptoms after getting vaccinated.
 - With the exception of pain at the injection site, more adolescents reported these post-vaccination symptoms after the second dose than after the first dose.
 - Post-vaccination symptoms are normal and show that the body is building protection.
 - If post-vaccination symptoms do not go away after a few days, people should contact a healthcare provider.
 - All participants in the clinical trial will continue to be monitored for long-term protection and safety for an additional two years after their second dose.
- Adolescents age 12 and older who have gotten any other vaccine should wait until 14 days have passed to get the COVID-19 vaccine.
 - This includes <u>immunizations</u> recommended for adolescents age 12-15 such as influenza (flu); tetanus, diphtheria, and acellular pertussis (Tdap); human papillomavirus (HPV); and other diseases.

- Certain groups should not get the Pfizer-BioNTech COVID-19 vaccines.
 - Anyone who has had a <u>severe allergic reaction</u> (anaphylaxis) or an immediate allergic reaction to any ingredient in an mRNA COVID-19 vaccine should not get the Pfizer-BioNTech COVID-19 vaccine.
 - An immediate allergic reaction means a reaction within four hours of getting vaccinated, and includes symptoms like hives, swelling, or wheezing (respiratory distress).
 - Anyone who has had a severe allergic reaction (anaphylaxis) or an immediate allergic reaction after getting the first dose of vaccine should not get the Pfizer-BioNTech COVID-19 vaccine.
 - Anyone who has a concern about allergic reactions should talk to a medical provider.

Effectiveness

- Clinical trial data suggest the Pfizer-BioNTech COVID-19 vaccine is highly effective for adolescents age 12-15.
 - o In the <u>clinical trial</u>, the Pfizer-BioNTech vaccine demonstrated 100% effectiveness in preventing COVID-19 infection with symptoms and led to a strong immune response among more than 2,200 participants age 12-15 without prior evidence of SARS-CoV-2 infection.
 - In the trial, there were 16 cases of COVID-19 among 978 adolescents who did not get vaccinated and 0 cases among the 1,005 vaccinated study participants.
 - Vaccination demonstrated strong immune response in a subset of adolescents one month after getting the second dose of vaccine.
- The Pfizer-BioNTech vaccine is highly effective against variants of SARS-CoV-2, the virus that causes COVID-19.
 - Studies based on real-world use of the vaccine suggest that the vaccine can prevent severe
 outcomes such as pneumonia and death caused be the B.1.1.7 <u>variant</u> first identified in the
 United Kingdom as well as B.1.351, the variant first identified in South Africa.

Importance

- Vaccination is key to protecting adolescents both in school and out.
 - Adolescents account for a growing proportion of COVID-19 cases in Rhode Island and nationally.
 - A small percentage of adolescents infected with COVID-19 can develop a <u>serious</u> inflammatory condition, MIS-C, in the two to six weeks after COVID-19 infection.

The following information is all from the Rhode Island Department of Health and is also posted on their website: https://covid.ri.gov/vaccination/covid-19-vaccine-faqs#kids

COVID-19 Vaccine for Adolescents Age 12-15 | FAQs

Is the COVID-19 vaccine safe for adolescents age 12-15?

Yes. The United States (US) Food and Drug Administration (FDA) has <u>authorized the Pfizer-BioNTech</u> <u>COVID-19 vaccine</u> for use in adolescents age 12 and older. A large clinical trial that included more than 2,200 adolescents age 12-15 showed that adolescents in this age group tolerated the vaccine well. The adolescents in the trial experienced mild post-vaccination symptoms (side effects) similar to the symptoms people age 16-25 had experienced in earlier studies.

As of now, adolescents age 12-15 are eligible for the Pfizer-BioNTech vaccine only. The Moderna and Johnson & Johnson (Janssen) COVID-19 vaccines are authorized for people age 18 and older only.

Is the COVID-19 vaccine effective for adolescents age 12-15?

In a large <u>clinical trial</u>, the Pfizer-BioNTech vaccine demonstrated 100% effectiveness in preventing COVID-19 infection with symptoms and led to strong immune responses among more than 2,200 participants age 12-15 without earlier evidence of COVID-19. In the trial, there were 16 cases of COVID-19 among 978 adolescents in the group that did not get vaccinated and 0 cases among the 1,005 vaccinated study participants.

How was the COVID-19 vaccine made and approved so fast?

The COVID-19 vaccines are being held to the same standards as other vaccines to make sure they are safe. No steps involving safety have been **skip**ped.

There are some reasons why the COVID-19 vaccines became available much faster than a typical vaccine. Importantly, there has been much collaboration across the scientific community to develop a vaccine. This is a global pandemic. As a result, a lot of time and resources from across the globe have gone into developing several COVID-19 vaccines.

Further, researchers had a head start on vaccine development because of research already done on similar coronaviruses. This includes the viruses that caused Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). Also, the government began producing doses of certain COVID-19 vaccines when they reached Phase 3 trials. This way, when these vaccines were determined to be safe and effective, people could get them immediately.

Does my child need to wait to get the COVID-19 vaccine if they have gotten other immunizations recently?

Yes. People who have gotten any other vaccine should wait until 14 days have passed to get the COVID-19 vaccine. This includes <u>immunizations</u> for influenza (flu); tetanus, diphtheria, and acellular pertussis (Tdap); human papillomavirus (HPV); and other diseases.

Will my child have post-vaccination symptoms (side effects) from getting the COVID-19 vaccine?

It is common to have symptoms after getting the COVID-19 vaccine. In a large clinical trial, participants age 12-15 experienced symptoms similar to those observed in participants age 16-25 from earlier studies. All participants in the clinical trial will continue to be monitored for long-term protection and safety for an additional two years after their second dose.

<u>Post-vaccination symptoms</u> of the Pfizer-BioNTech COVID-19 vaccine include pain in the arm where someone got the shot as well as tiredness, headache, chills, muscle pain, fever, and joint pain. These should go away within a few days. With the exception of pain at the injection site, more adolescents reported these post-vaccination symptoms after the second dose than after the first dose.

Some people do not have any symptoms after getting vaccinated. Symptoms are normal and show that the body is building protection. If symptoms do not go away after a few days, people should contact a healthcare provider.

Do adolescents need to follow a different schedule for COVID-19 vaccination?

No. Adolescents age 12 and older should follow the standard two-dose schedule for the Pfizer-BioNTech vaccine. They should get the second dose of vaccine 21 days after getting the first dose.

Will a parent/guardian need to accompany an adolescent age 12-15 when they get vaccinated or will online consent be enough?

Adolescents age 12 to 15 should be accompanied by a parent, legal guardian, or other individual age 16 or older when getting a COVID-19 vaccination at any State-sponsored, mass vaccination clinic (while not required by law, this is highly preferred). Also, when registering either in advance or on-site, consent must be granted by a parent or legal guardian.

Will the State get consent first from a parent or guardian?

Yes. A parent or guardian will need to give consent first on www.vaccinateRl.org or before vaccination on site.

Adolescents age 12-15 cannot get a vaccine appointment without consent from a parent or guardian.

If an adolescent age 12-15 signs up for a vaccination appointment through www.vaccinateRI.org and consents for "Self," but their parent/guardian is present at the vaccination event, do they need to reregister?

No. As long as a parent/guardian consents to vaccination on the adolescent's behalf before the adolescent is vaccinated, they do not need to re-register. Registration is not a legally significant part of the vaccination process.

Can a parent/guardian provide consent for an adolescent age 12-15 over the phone?

No. There would be no way to verify parenthood or guardianship, and there would be no written or recorded proof of consent.

Does someone under age 16 who is married need consent from a parent/guardian?

According to Rhode Island state statute, any person of the age of 16 or over **or married** may consent to routine, emergency, medical, or surgical care. A minor parent or guardian may consent to the treatment of his or her child.

Can an adolescent age 12-15 get vaccinated at any type of vaccination clinic?

Yes, adolescents age 12-15 can get a COVID-19 vaccine appointment at a State-run, regional or local, or select pharmacy as long as the clinic offers the Pfizer-BioNTech vaccine.

Only the Pfizer-BioNTech vaccine is authorized for adolescents age 12 and older. The Moderna and Johnson & Johnson (Janssen) vaccines are authorized for people age 18 and older.

Can adolescents age 12-15 get a COVID-19 vaccine appointment on site?

Yes, but adolescents age 12-15 must have a parent or guardian with them to give consent for vaccination.

Adolescents age 12 to 15 should be accompanied by a parent, legal guardian, or other individual age 16 years or older when getting a COVID-19 vaccination at any State-sponsored, mass vaccination clinic (while not required by law, this is highly preferred). Also, when registering either in advance or on-site, consent must be granted by a parent or legal guardian.