FAQs For Vaccinations and Adolescents

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How does the COVID-19 vaccine work?

The COVID-19 vaccine works similarly to other vaccines your child has had. Germs such as SARS-CoV-2, the virus that causes COVID-19, invade and multiply inside the body. The vaccine stops this by helping the immune system make special proteins call antibodies to fight the virus. After vaccination, your child has less of a chance of getting COVID-19. And if they do get infected with the virus, they may not be as sick as they would without the vaccine.

What are the types of vaccines?

Three different vaccines were given emergency use authorization by the U.S. Food and Drug Administration (FDA) so far. Two require two doses (Pfizer and Moderna), and one involves a single shot (Johnson & Johnson).

Distribution of the one-shot vaccine was temporarily paused to look for possible ties to rare but serious blood clots reported during the vaccine's safety monitoring process. The FDA lifted the pause when data confirmed the chance of developing the rare clots with the vaccine is extremely low, but continues to monitor the risk.

The COVID-19 vaccines that require two doses are both messenger ribonucleic acid (mRNA) vaccines. The other was developed as a "viral vector" vaccine. They all have the same result — protecting people from COVID-19—but their delivery systems are a bit different.

How RNA and viral vector vaccines different?

COVID-19 mRNA vaccines carry instructions to our cells to produce harmless pieces of "spike" protein found on SARS-CoV-2. This triggers an immune system response that the body remembers if the virus ever invades.

Although this technology has been studied for decades, widespread use of mRNA vaccines is new. They don't use the live coronavirus that causes COVID-19. The mRNA in the vaccine gets into the cells where the shot is given. Then it gives the cells instructions on how to create a piece of protein that is found on the virus that causes COVID-19.

Once the protein is created, your immune system identifies it as a foreign molecule. body. The immune process starts, making antibodies that attach to the protein. These antibodies then protect you from getting COVID-19.

Viral vector vaccines, like the mRNA vaccines, also give instructions to your immune cells. Instead of carrying the instructions to your cells on a fat bubble, as with the mRNA vaccine, they are carried in a harmless virus (not the coronavirus that causes COVID-19).

The same process happens as with the mRNA vaccine—the cells create the protein that's found on the virus that causes COVID-19, the immune system makes antibodies to fight it, and you're protected from getting COVID-19.

How do we know COVID-19 vaccines are safe for kids?

Before getting FDA authorization, clinical trials showed COVID-19 vaccines to be remarkably safe and effective for adults and teens age 16 and up. Trials for each of the vaccines involved tens of thousands of volunteers.

Based on clinical trial results for younger adolescents, one of the vaccine makers has now asked the FDA to extend emergency use authorization for children as young as age 12. And clinical trials are starting for children as young as six months old.

The vaccines continue to be monitored very closely. In fact, the Centers for Disease Control and Prevention (CDC) say that COVID-19 vaccines will have “the most intensive safety monitoring in U.S. history."

What is the safety testing that has been done on COVID-19 vaccines? How do we know it is safe long-term?

The safety follow-up for COVID-19 vaccines is essentially the same that it is for all vaccine trials. The expectation for the adult phase 3 trials is 2 years of safety follow-up - longer than for most vaccines during development. It is impossible to know the very long-term safety profile of vaccines that have only been in humans for about 6 months. That said, no vaccines licensed have been found to have an unexpected long-term safety problem that was found only years or decades after introduction.

What vaccine safety surveillance programs are in place?

The US has a robust vaccine safety monitoring system that has been in place and operating for decades through the CDC and FDA. There is expanded monitoring for COVID-19 vaccine, including a new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines called V-SAFE. V-SAFE uses text messaging and web surveys from CDC to check in with vaccine recipients following COVID-19 vaccination, including second vaccine dose reminders if needed, and telephone follow up to anyone who reports medically significant adverse events. Healthcare providers should encourage patients to opt in for the V-SAFE program.

How effective are the vaccines?

Research shows that all of the COVID-19 vaccines are highly effective at stopping people from getting COVID-19. The vaccines also help prevent serious illness, hospitalization, and death in those who get COVID- 19.

Scientists don't know how long immunity from the vaccine will protect people. This will become clearer in the future.

How long does it take for the vaccines to create immunity?

It takes around 2 weeks after getting the second dose of the mRNA vaccines for your body to build up an immunity to the virus that causes COVID-19. For the one-dose vaccine, building up immunity takes 2 to 4 weeks.

Do mRNA vaccines change your DNA?

No, the mRNA actually doesn't interact with your DNA at all. DNA is your genetic material and it's stored in the nucleus of a cell. The mRNA in the vaccines doesn't get into the nucleus. And once your immune cells have used the instructions, they break down the mRNA and discard it.

Which vaccine should my child get?

Currently, one of the two-dose vaccines (Pfizer) is approved for adolescents 12 years and older. Anyone who is 18 or older should get whichever vaccine is available to them first. This is especially important now with the rise in cases caused by the variant strains of the virus, which seem to be more contagious and continue to spread at alarming rates here in the US and globally.

What about side effects of the vaccine?

Some people don't have any side effects at all. But for those who are 12 or older, the most common side effects that have been reported include:

- Pain, redness, and swelling where the injection was given
- Fever
- Chills
- Headache
- Fatigue
- Nausea
- Pain in the muscles

While also rare, some people have had serious allergic reactions to the COVID-19 vaccine. This is why you'll need to wait for 15 to 30 minutes after you have a vaccination. If you happen to be one of the few people who has an allergic reaction, there are medications to quickly treat it.

As for long-term side effects, the CDC says this is unlikely. We have years of research and monitoring on other vaccinations that show side effects almost always happen within six weeks of getting a vaccine.

Is it safe to get a vaccine if I'm pregnant or breastfeeding?

Right now, there's no evidence that getting a COVID-19 vaccine causes any safety concerns for pregnant or breastfeeding women. The American College of Obstetricians and Gynecologists (ACOG) recommends that pregnant and breastfeeding women should be offered the vaccine when they're eligible.

Were fetal cells used in the COVID-19 vaccine's development?

None of the vaccines contain fetal cells. All of the vaccines have used fetal cell lines at some point, but there is a difference between fetal cells and fetal cell lines.

Fetal cell lines have been grown in labs since the 1960s. These cells have multiplied, creating generations of fetal cell lines. This means that the cells we have today no longer contain fetal tissue. Several religious groups and bioethics institutes have issued statements and guidance

about the COVID-19 vaccines. The Charlotte Lozier Institute (https://lozierinstitute.org/) has information available for those who want to learn more about this topic.

What is the current status of COVID-19 vaccine research in children and adolescents?

To date, Pfizer-BioNTech has started testing its COVID-19 vaccine in children younger than 12, has completed a study in 12-15 year olds and has been granted EUA by the FDA for this age category on May 10, 2021. Their current FDA EUA for adults (ages 16 and older) was approved in December 2020.

Moderna has started a clinical trial to test its COVID-19 vaccine in children under 12, including babies as young as six months and is expecting to enroll 6,750 healthy children in the US and Canada. The company is also conducting a separate clinical trial testing the vaccine in 3,000 children ages 12 to 17.

Janssen and Astra Zeneca also have plans to study their vaccines in younger age groups. We anticipate that these studies including younger children will begin soon (perhaps over the next couple of months).

Do we need to worry about an increase in MIS-C in kids receiving COVID-19 vaccine?

One of the reasons to perform vaccine trials in children is to make sure that they do not have any side effects that are pediatric-specific. Since there are also cases of MIS-A, in young adults, if MIS were to be a problem, we may see it in the larger adult trials. We have not, to date. There is no known biomarker to predict an immune response that leads to MIS-C. It is also possible that protection from COVID-19 by vaccination will also protect against its sequelae, including MIS-C.

If your child has been diagnosed with MIS-C or MIS-A in the past, they must be cleared by a healthcare provider before receiving any COVID-19 vaccine.

What are your sources?

https://www.healthychildren.org/English/health-issues/conditions/COVID-19/Pages/The-Science-Behind-the-COVID-19-Vaccine-Parent-FAQs.aspx

https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/covid-19-vaccine-for-children/about-the-covid-19-vaccine-frequently-asked-questions/