Addressing Concerns About COVID-19 Vaccine Side Effects

The Issue

Concerns about side effects of COVID-19 vaccines are one of the largest contributors to vaccine hesitancy. People are concerned about short-term side effects, serious adverse events, possible long-term adverse effects, and rumored effects with no basis in fact.

Sound Bites

- Some people who receive COVID-19 vaccines experience predictable mild side effects. This is normal and means the vaccines are working to create an immune response.
- Some people have no side effects from COVID-19 vaccination. Vaccination protects you from severe COVID-19 infection, whether or not you experience side effects.
- Common side effects are pain, redness, and swelling in the arm where the shot was administered, as well as tiredness, headache, muscle pain, chills, fever, and nausea throughout the rest of the body.
- Side effects after COVID-19 vaccination may affect your ability to do daily activities, but they should go away in a few days.
- For vaccines that require two doses in the primary series, side effects may be more intense after the second shot than the first shot.
- Adverse effects that could cause a long-term health problem are extremely unusual following any vaccination, including COVID-19 vaccination. If adverse effects occur, they generally happen within 6 weeks of receiving a vaccine dose.
- None of the COVID-19 vaccines contain the live virus that causes COVID-19, so a COVID-19 vaccine cannot make anyone sick with the disease.
- COVID-19 vaccines do not change or interact with a person's DNA in any way.
- V-safe (https://vsafe.cdc.gov) is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccine. Through **v-safe,** you can quickly tell the Centers for Disease Control and Prevention (CDC) if you have any side effects after getting a COVID-19 vaccine. (Providers should inform vaccine recipients of this app.)

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Questions for Exploring Patient Concerns

- What have you heard about possible side effects of COVID-19 vaccines? (If this is not the patient's first COVID-19 vaccination, what reaction, if any, did that person get after the previous vaccination?)
- What is your understanding of [possible side effect/adverse event]?
- What is your biggest concern about [possible side effect/adverse event]?
- What would make you less concerned about [possible side effect/adverse event]?
- What if I told you…. *(Provide information or suggest possible actions that would alleviate the stated concern. For example, if the person is concerned about blood clots, explain why an mRNA vaccine would be a safer choice.)*

What We Know

When discussing the safety of COVID-19 vaccines, the CDC differentiates between *side effects* (representing predictable vaccine reactogenicity) and *adverse events* (health problems that occur after vaccination).[1] Although adverse events may be caused by a vaccine, they also may be caused by a coincidental event not related to a vaccine.

Predictable Common Short-Term Side Effects. Common side effects of COVID-19 vaccines include injection-site reactions (e.g., pain, redness, swelling on the arm where the shot was given) and systemic reactions (e.g., tiredness, headache, muscle pain, chills, fever, nausea).[2] For vaccines that require two doses in the primary series (e.g., mRNA vaccines), side effects after the second dose may be more intense than those experienced after the first shot.[2]

Importantly, some people have no side effects at all after COVID-19 vaccination. In one study conducted in the United Kingdom, only 25% of people who received an mRNA vaccine reported experiencing a systemic side effect, and 66% had an injection-site reaction.[3] Women tend to report side effects more frequently than men do.[4]

Setting appropriate expectations is important. People contemplating vaccination should know which side effects to anticipate and understand why they occur (i.e., these side effects are normal signs that the body is building protection). People also should know that side effects may affect their ability to engage in usual daily activities, but the side effects should go away in a few days.

Serious Adverse Events. Serious adverse events after COVID-19 vaccination may occur, but they are rare. The CDC provides updates on the following serious adverse events of interest[5]:

- Anaphylaxis.
- Thrombosis with thrombocytopenia syndrome (associated primarily with the Johnson & Johnson/Janssen vaccine).
- Guillain-Barré syndrome (associated primarily with the Johnson & Johnson/Janssen vaccine).
- Myocarditis and pericarditis (associated primarily with mRNA vaccines).

Anaphylaxis. Severe allergic reactions, including anaphylaxis, can occur after any vaccination. Anaphylaxis after COVID-19 vaccination is rare and has occurred in approximately 5 people per 1 million people vaccinated in the United States. If anaphylaxis occurs, vaccination providers can effectively and immediately treat the reaction.

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Thrombosis with Thrombocytopenia Syndrome (TTS). TTS is characterized by blood clots in large vessels with accompanying low platelet levels. Of the more than 18.5 million doses of the Johnson & Johnson/Janssen vaccine that had been administered in the United States through March 2022, the CDC and the U.S. Food and Drug Administration (FDA) identified 60 confirmed reports of TTS; nearly all occurred in adult women younger than 50 years of age. The CDC also has identified 9 deaths that have been caused by or were directly attributed to TTS following Johnson &Johnson/Janssen COVID-19 vaccination. Women 30 to 49 years of age especially should be aware of the increased risk of this rare adverse event.

There have been 4 confirmed cases of TTS following vaccination with an mRNA vaccine, after more than 540 million doses administered in the United States. Based on available data, there is not an increased risk for TTS after mRNA COVID-19 vaccination.

Guillain-Barré Syndrome. Guillain-Barré syndrome is a rare disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. Most people recover fully, but some have permanent nerve damage.

There were 310 preliminary reports of Guillain-Barré syndrome among people who received the Johnson & Johnson/Janssen vaccine, at the point when more than 18.5 million doses had been administered. Most cases were reported about 2 weeks after vaccination and occurred mostly in men, especially men 50 years of age and older.

There is no evidence of an increased risk of Guillain-Barré syndrome following vaccination with an mRNA vaccine.

Myocarditis and Pericarditis. As of March 2022, the Vaccine Adverse Event Reporting System (VAERS) had received 2,323 preliminary reports of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the outer lining of the heart) among people 30 years of age or younger who received COVID-19 vaccines.2,6 Most cases have been reported after receiving mRNA vaccines (Pfizer-BioNTech or Moderna), especially in male adolescents and young adults. Cases occurred more often after the second dose of mRNA vaccine, usually within 1 week of vaccination.[6]

Through follow-up, including medical record reviews, the CDC and FDA have verified 1,396 reports of myocarditis or pericarditis.2 Most patients who received care responded well to treatment and rest, and they felt better quickly.

Cases of myocarditis and pericarditis have also been reported in people who received Novavax COVID-19 vaccine.[7]

Long-Term Adverse Effects. Adverse effects that could cause a long-term health problem are extremely unlikely following any vaccination, including COVID-19 vaccination. According to the CDC, vaccine monitoring has historically shown that adverse effects generally occur within 6 weeks of receiving a vaccine dose.2 The FDA required each of the available COVID-19 vaccines to be studied for at least 2 months (8 weeks) after the final dose.

Rumored Effects. People may be concerned about any number of rumored side effects or adverse effects of COVID-19 vaccines that have no basis in fact. A common fear is contracting COVID-19 illness from the vaccine. None of the available COVID-19 vaccines (or any of the vaccines in development) contain a live attenuated virus or any other infectious material. People with this fear should be reassured that they *cannot* and *will not* get COVID-19 from any of the vaccines.

Some people are concerned that COVID-19 vaccines—especially mRNA vaccines—will alter their DNA. The vaccines do not change or interact with DNA in any way. It is true that both mRNA and viral vector COVID-19 vaccines deliver genetic material to cells to produce copies of the "spike protein" found on the surface of SARS-CoV-2 (the virus that

causes COVID-19). However, the genetic material never enters the cell nucleus, so it cannot affect or interact with a person's DNA.

Other rumored adverse effects of COVID-19 vaccines include cancer, birth defects, and infertility. There is no evidence to suggest that any of these effects are possible.

References

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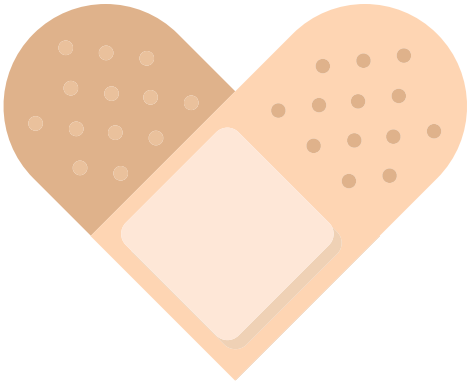

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