Addressing concerns about COVID-19 vaccine side effects

The Issue

Concerns about possible 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 side effects, and rumored side effects with no basis in fact.

Sound Bites

- Some people who receive COVID-19 vaccines may experience discomfort and predictable mild side effects. This is normal and means the vaccines are working to create an immune response.
- 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.
- Many people have *no* side effects from COVID-19 vaccines.
- 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, side effects may be more intense after the second shot than the first shot.
- Serious side effects that could cause a long-term health problem are extremely unlikely following any vaccination, including COVID-19 vaccination.
- 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 CDC if you have any side effects after getting a COVID-19 vaccine.

Questions for Exploring Patient Concerns

- What have you heard about possible side effects of COVID-19 vaccines?
- What is your understanding of [possible side effect]?
- What is your biggest concern about [possible side effect]?
- What would make you less concerned about [possible side effect]?
- 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 that this effect has not been seen with the Pfizer-BioNTech or Moderna vaccines.)*

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What We Know

Expected Short-Term Side Effects. A number of side effects or reactions associated with the COVID-19 vaccines represent predictable vaccine reactogenicity. These include local 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).

There is some evidence that COVID-19 vaccines may be more reactogenic than other vaccines that people may be more familiar with receiving. For vaccines that require two doses (Pfizer-BioNTech and Moderna), side effects after the second dose may be more intense than those experienced after the first shot.1 Importantly, some people have no side effects at all; 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 a local reaction.[1,2] Women tend to report side effects more frequently than men do.[3]

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 resolve in a few days.

Serious Adverse Events. Serious adverse events after COVID-19 vaccination may occur, but they are rare. The Centers for Disease Control and Prevention (CDC) is providing timely updates on the following serious adverse events of interest:[4]

- Anaphylaxis.
- Thrombosis with thrombocytopenia syndrome (TTS).
- Myocarditis and pericarditis.
- Guillain-Barré syndrome.

Anaphylaxis. Severe allergic reactions, including anaphylaxis, can occur after any vaccination. Anaphylaxis after COVID-19 vaccination has occurred in approximately 2 to 5 people per million vaccinated in the United States. If anaphylaxis occurs, vaccination providers can effectively and immediately treat the reaction.

TTS. TTS is characterized by blood clots with low platelets. Of the more than 13 million doses of the Johnson & Johnson/Janssen vaccine that had been administered in the United States through July 19, 2021, the CDC and the U.S. Food and Drug Administration (FDA) had identified only 39 confirmed reports of TTS; nearly all occurred in adult women younger than 50 years of age. A review of all available data show that the known and potential benefits of the Johnson & Johnson/Janssen vaccine outweigh the known and potential risks.[5] Women younger than 50 years old especially should be aware of the rare but increased risk of this adverse event and that there are other COVID-19 vaccine options available for which this risk has not been seen.

As of July 21, 2021, there had been two confirmed cases of TTS following vaccination with the Moderna mRNA vaccine, after more than 324 million doses of mRNA vaccines administered in the United States. Based on available data, there is not an increased risk for TTS after mRNA COVID-19 vaccination.

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Myocarditis and pericarditis. As of July 19, 2021, the Vaccine Adverse Event Reporting System (VAERS) had received 1,148 reports of myocarditis or pericarditis—inflammation of the heart—among people 30 years of age or younger who received a COVID-19 vaccine.[6] These reports are rare, given the hundreds of millions of vaccine doses administered. Most cases have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna).

Through follow-up, including medical record reviews, the CDC and FDA have confirmed 674 reports of myocarditis or pericarditis. Confirmed cases have occurred:

- Mostly in male adolescents and young adults 16 years of age or older.
- More often after getting the second dose than after the first dose of an mRNA vaccine.
- Typically, within several days after COVID-19 vaccination.

Most patients who received care responded well to treatment and rest, and they quickly felt better. The CDC and its partners are investigating these reports to assess whether there is a relationship to COVID-19 vaccination.

Guillain-Barré syndrome. The CDC and FDA are monitoring reports of Guillain-Barré syndrome in people who have received the Johnson & Johnson/Janssen vaccine. 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.

Approximately 100 preliminary reports of Guillain-Barré syndrome had been identified in VAERS as of July 12, 2021. Most cases were reported about 2 weeks after vaccination and occurred mostly in men, many 50 years of age or older.

Long-Term Side Effects. Serious side 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 side effects generally occur within 6 weeks of receiving a vaccine dose. The FDA required each of the authorized COVID-19 vaccines to be studied for at least 2 months (8 weeks) after the final dose.

Millions of people have received COVID-19 vaccines, and no long-term side effects have been detected.[7]

Rumored Side Effects. People may be concerned about any number of rumored side 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 currently authorized 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 material never enters the cell nucleus, so it cannot affect or interact with a person's DNA.

Other rumored side effects of COVID-19 vaccines include cancer, birth defects, and infertility. There is no reason to believe, nor is there any evidence to suggest, that any of these effects are possible.

References

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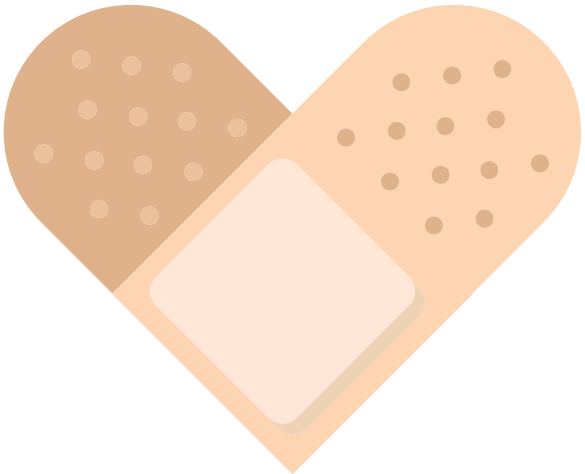

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