COVID-19 Vaccines

11/5/2021

© 2019 Mid-Atlantic Permanente Medical Group

Agenda

Basics of COVID-19
Overview of COVID-19 Vaccines
Myths and Facts
COVID-19 Health Disparities
Basic Facts About COVID-19

Infection with SARS-CoV-2, the virus that causes COVID-19, can result in a range of illness, from mild symptoms to severe illness and death.

We don’t know how SARS-CoV-2 will affect each person.

Anyone can get COVID-19.

Some people, such as adults 65 and older or people with certain medical conditions, are more likely than others to become severely ill.

Treatment for COVID is evolving but hospital-based therapeutic interventions have improved and saved lives.

COVID-19 Variants

Variants are expected: Viruses constantly change through mutation, and new variants of a virus are expected to occur. Sometimes new variants emerge and disappear. Other times, new variants persist. All variants of the virus that causes COVID-19 are being tracked in the United States and globally during this pandemic.

The best way to slow the emergence of new variants is to reduce the spread of infection by taking measures to protect yourself, including getting a COVID-19 vaccine when available.
COVID-19 vaccination is a safer way to build protection

Getting the virus that causes COVID-19 may offer some natural protection known as immunity. But experts don’t know how long this protection lasts.

The risk of severe illness and death from COVID-19 far outweighs any benefits of natural immunity.

COVID-19 vaccination will help protect you by building immunity without the risk of severe illness.

COVID-19 vaccines help our bodies develop immunity to the virus that causes COVID-19 without us having to get the illness.

There are three types:

1. **mRNA vaccines:** Pfizer/BioNTech & Moderna
2. **Viral vector vaccines:** Janssen
3. **Protein subunit vaccines:** none are currently approved
How mRNA COVID-19 Vaccines Work

Moderna and Pfizer/BioNTech

Understanding the virus that causes COVID-19.
Coronaviruses, like the one that causes COVID-19, are named for the crown-like spikes on their surface, called spike proteins. These spike proteins are ideal targets for vaccines.

What is mRNA?
Messenger RNA, or mRNA, is genetic material that tells your body how to make proteins.

What is in the vaccine?
The vaccine is made of mRNA wrapped in a coating that makes delivery easy and keeps the body from damaging it.

How does the vaccine work?
The mRNA in the vaccine teaches your cells how to make copies of the spike protein. If you are exposed to the real virus later, your body will recognize it and know how to fight it off.

Myocarditis after mRNA vaccines

U.S. Food and Drug Administration added a warning about rare cases of heart inflammation in adolescents and young adults to fact sheets for the Pfizer/BioNTech (PFE.N), and Moderna (MRNA.O) COVID-19 vaccines.

What You Need to Know

- Cases of myocarditis have occurred:
  - After mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna), especially in male adolescents and young adults,
  - More often after the second dose
  - Usually within several days after vaccination
- Most patients with myocarditis or pericarditis who received care responded well to medicine and rest and felt better quickly.
- Patients can usually return to their normal daily activities after their symptoms improve. Those who have been diagnosed with myocarditis should consult with their cardiologist (heart doctor) about return to exercise or sports. More information will be shared as it becomes available.

CDC/ACIP recommendations are:

- Benefits greatly outweigh risks
- Take complaints of chest pain seriously post-vaccination and rule out serious conditions


How the viral vector COVID-19 Vaccines Work

Janssen/J&J

Thrombosis with Thrombocytopenia Syndrome (TTS) after Vaccination with J&J/Janssen COVID-19 Vaccination

After receiving the J&J/Janssen COVID-19 Vaccine, there is risk for a rare but serious adverse event—blood clots with low platelets (thrombosis with thrombocytopenia syndrome, or TTS).

Women younger than 50 years old should especially be aware of their increased risk for this rare adverse event. There are other COVID-19 vaccines available for which this risk has not been seen.

This adverse event is rare, occurring at a rate of about 7 per 1 million vaccinated women between 18 and 49 years old.

For women 50 years and older and men of all ages, this adverse event is even more rare.
Overview of COVID-19 Vaccines

<table>
<thead>
<tr>
<th></th>
<th>Pfizer-BioNTech</th>
<th>Moderna</th>
<th>Johnson &amp; Johnson's Janssen</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Who Can Get this Vaccine</strong></td>
<td>People 5 years and older</td>
<td>People 18 years and older</td>
<td>People 18 years and older</td>
</tr>
<tr>
<td><strong>Number of Shots</strong></td>
<td>2 shots, Given 3 weeks (21 days) apart</td>
<td>2 shots, Given 4 weeks (28 days) apart</td>
<td>1 shot</td>
</tr>
<tr>
<td><strong>When Fully Vaccinated</strong></td>
<td>2 weeks after your second shot</td>
<td>2 weeks after your second shot</td>
<td>2 weeks after your second shot</td>
</tr>
<tr>
<td><strong>Additional Dose</strong></td>
<td>Recommended for <strong>moderately to severely immunocompromised people</strong>, Given 4 weeks after second shot</td>
<td>Recommended for <strong>moderately to severely immunocompromised people</strong>, Given 4 weeks after second shot</td>
<td>Not recommended at this time</td>
</tr>
<tr>
<td><strong>Booster Dose</strong></td>
<td>Recommended for some people who are at higher risk for COVID-19 exposure or severe illness, Given 6 or more months after second shot</td>
<td>Not recommended at this time</td>
<td>Not recommended at this time</td>
</tr>
</tbody>
</table>

Why Are Additional Doses and Booster Shots Needed?

COVID-19 Vaccines are safe and effective. They are working well to prevent severe illness, hospitalization, and death, even against the widely circulating Delta variant.

Additional Dose (sometimes called a Third Dose)
- An additional dose refers to people with compromised immune systems who may not have gotten the level of protection they need from the first two doses.
- The additional dose provides a stronger level of immunity.

Booster Shot
- A booster shot is recommended due to concern that the effectiveness of the vaccine decreases over time and may not protect against a new strain, such as delta.

Who’s Eligible for Booster Shots?

IF YOU RECEIVED Pfizer-BionTech or Moderna

You are eligible for a booster if you are:
- 65 years or older
- Age 18+ who live in long-term care settings
- Age 18+ who have underlying medical conditions
- Age 18+ who work or live in high-risk settings

When to get a booster:
At least 6 months after your second shot

Which booster should you get?
Any of the COVID-19 vaccines authorized in the United States

IF YOU RECEIVED Johnson & Johnson’s Janssen

You are eligible for a booster if you are:
- 18 years or older

When to get a booster:
At least 2 months after your shot

Which booster should you get?
Any of the COVID-19 vaccines authorized in the United States
How do the three vaccines compare?

The only way to accurately compare the effectiveness is by direct head-to-head clinical trials, which have not been done for these vaccines.

The clinical trials for these vaccines were conducted in different geographic regions and at different points during the pandemic with varying COVID-19 infection rates.

The Centers for Disease Control and Prevention (CDC), vaccine experts, and Kaiser Permanente do not advocate any one COVID-19 vaccine over another.

All 3 vaccines are highly effective (greater than 90%) at preventing severe disease and hospitalization from COVID.

All 3 vaccines were effective across gender, age, race and ethnicities in clinical trials.

It is important to understand the full immune protection is expected two weeks after completing vaccination.
Vaccine Effectiveness

Vaccine effectiveness studies provide a growing body of evidence that mRNA COVID-19 vaccines offer similar protection in real-world conditions as they have in clinical trial settings. Reducing the risk of COVID-19, including severe illness, among people who are fully vaccinated by 90 percent or more.

CDC and other experts continue to study the effectiveness of both mRNA vaccines and the Johnson & Johnson’s Janssen (J&J/Janssen) COVID-19 vaccine in real-world conditions.

Possibility of COVID-19 Illness after Vaccination

Slowing the Spread of COVID-19

- COVID-19 vaccines protect people from getting infected and severely ill, and significantly reduce the likelihood of hospitalization and death.
- Getting vaccinated is the best way to slow the spread of COVID-19 and to prevent infection by Delta or other variants.

Vaccine Breakthroughs

- A vaccine breakthrough infection happens when a fully vaccinated person gets infected with COVID-19. People with vaccine breakthrough infections can be contagious.
- Fully vaccinated people with a vaccine breakthrough infection are less likely to develop serious illness than those who are unvaccinated and get COVID-19.

Vaccine Breakthroughs & Variants

- Research shows that the FDA-authorized vaccines offer protection against severe disease, hospitalization, and death against currently circulating variants.
- The risk of complications from COVID-19 variants is much greater in unvaccinated compared to vaccinated people.

How CDC Monitors Breakthrough Infections

- CDC collects data on vaccine breakthrough infections through outbreak investigations.
- CDC also conducts ongoing research studies to monitor the performance of vaccines in preventing infection, disease, hospitalization, and death.
Studies so far show that vaccinated people are 8 times less likely to be infected and 25 times less likely to experience hospitalization or death.

Among fully vaccinated people, those aged 80 or older had a almost 13 times greater risk of dying from COVID than people of all ages.


COVID-19 Vaccine Safety
Safety of COVID-19 Vaccines: What You Need To Know

COVID-19 vaccines are **safe and effective**:

- Vaccines went through rigorous clinical trials
- Millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring in U.S. history.
- Results from vaccine safety monitoring efforts are reassuring
- Serious safety problems are rare:
  - Anaphylaxis
  - Thrombosis with Thrombocytopenia Syndrome (TTS) after vaccination with Janssen/J&J COVID-19 Vaccination
- Long-term side effects are unlikely

Clinical Trials

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Phase 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-100 Healthy Volunteers</td>
<td>Several Hundred Volunteers</td>
<td>1000+ Volunteers</td>
<td>Vaccine is Approved</td>
</tr>
</tbody>
</table>

Researchers try to answer these questions:

- Is this vaccine safe?
- Are there any serious side effects?
- How does the vaccine dose relate to any side effects?
- Is the vaccine causing an immune response?

Researchers try to answer these questions:

- What are the most common short-term side effects?
- What's the body's immune response?
- Are there signs that the vaccine is protective?

Researchers try to answer these questions:

- How do disease rates compare between people who get the vaccine and those who do not?
- How well can the vaccine protect people from disease?

Researchers try to answer these questions:

- FDA approves a vaccine only if it's safe, effective, and benefits outweigh the risks.
- Researchers continue to collect data on the vaccine's long-term benefits and side effects.
Fast-tracking COVID-19 vaccines while ensuring safety

The science behind the breakthrough had a head start. Researchers used existing vaccine clinical trial networks to conduct the COVID-19 vaccine trials. Manufacturing began while clinical trials were still underway. Normally, manufacturing doesn’t begin until after completion of the trials.

mRNA vaccines are faster to produce in large amounts than traditional vaccines. FDA and CDC are prioritizing review and authorization of COVID-19 vaccines. The rapid spread of COVID-19 made developed these vaccines an international priority, unlocking billions of dollars in funding to ensure safety while moving with urgency to save lives.

*For more information, visit the COVID-19 Prevention Network: [www.coronaviruspreventionnetwork.org/about-covpn](http://www.coronaviruspreventionnetwork.org/about-covpn)

**For more information, visit FDA’s Emergency Use Authorization for Vaccines Explained: [https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained](https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained)

Safety of COVID-19 vaccines is a top priority

COVID-19 vaccines are being held to the same safety standards as all vaccines. No significant safety concerns were identified in the clinical trials.

### Before Authorization

- FDA carefully reviews all safety data from clinical trials.
- ACIP reviews all safety data before recommending use.

### After Authorization

- FDA and CDC closely monitor vaccine safety and side effects. There are systems in place that allow CDC and FDA to watch for safety issues.
- This is how vaccine safety concerns continue to be identified.

Robust vaccine safety monitoring systems exist

Existing systems and data sources are used to monitor safety of vaccines post-authorization and post-licensure, such as:

- Vaccine Adverse Event Reporting System (VAERS)
- Vaccine Safety Datalink (VSD)
- Clinical Immunization Safety Assessment (CISA)
- Biologics Effectiveness and Safety System (BEST)

New systems have been developed to monitor COVID-19 vaccine safety, such as v-safe:

- Active surveillance that uses text messaging to initiate web-based survey monitoring.
- Will provide telephone follow up to anyone who reports medically significant adverse events.

Side Effects

After getting vaccinated, you may have some side effects, most are normal signs that your body is building protection. These side effects may affect your ability to do daily activities, but they should go away in a few days. For the 2 dose vaccines, these are expected to be worst after the second dose.

On the arm where you got the shot:
- Pain
- Redness
- Swelling

Throughout the rest of your body:
- Tiredness
- Headache
- Muscle pain
- Chills
- Fever
- Nausea
COVID Vaccine and Pregnancy

Pregnant and recently pregnant people are more likely to get severely ill with COVID-19 compared with non-pregnant people.

Evidence about the safety and effectiveness of COVID-19 vaccination during pregnancy has been growing.

COVID-19 vaccination is recommended for all people 5 years and older, including people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future.

There is currently no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems in women or men.

Source: NIH Director’s Blog
Studies Confirm COVID-19 mRNA Vaccines Safe, Effective for Pregnant Women
COVID Vaccine in Children 5-11 Years Old

FDA and CDC approved the Pfizer-BioNTech COVID-19 vaccine for all children 5 through 11 years of age.

• **Administration:** two-dose primary series, 21 days apart,

• **Dosage:** lower dose (10 micrograms) and with smaller needles than that used for individuals 12 years of age and older (30 micrograms)

• **Effectiveness:** 90% effective in clinical trial

• **Expected side effects:** children may experience fewer side effects than adolescents or young adults. Expected side effects include:
  - Local: pain, swelling, erythema at the injection site
  - Systemic: fever, fatigue, headache, chills, myalgia, arthralgia, lymphadenopathy

• **Myocarditis:** There were no cases of myocarditis after vaccination in the clinical trial

Myths and Facts
Will a COVID-19 vaccine alter my DNA?

No. COVID-19 vaccines do not change or interact with your DNA in any way.


Do COVID-19 vaccines contain microchips?

No. COVID-19 vaccines do not contain microchips.

Vaccines are developed to fight against disease and are not administered to track your movement.

Vaccines work by stimulating your immune system to produce antibodies, exactly like it would if you were exposed to the disease.

After getting vaccinated, you develop immunity to that disease, without having to get the disease first.

Was the vaccine developed so quickly because science was skipped?

No.

The COVID-19 vaccine was created in record time because tremendous resources were dedicated to developing this vaccine due to the serious health risks from the virus.

Also, while mRNA vaccines are newly available to the public, researches have been studying and working with mRNA vaccines for decades.


If I have already had COVID-19 and recovered, do I still need to get vaccinated with a COVID-19 vaccine?

Yes.

You should be vaccinated regardless of whether you already had COVID-19.

That’s because experts do not yet know how long you are protected from getting sick again after recovering from COVID-19. Even if you have already recovered from COVID-19, it is possible—although rare—that you could be infected with the virus that causes COVID-19 again.

Is it safe for me to get a COVID-19 vaccine if I would like to have a baby one day?

Yes.

People who want to get pregnant in the future may receive the COVID-19 vaccine.

The COVID-19 vaccine, like other vaccines, works by training our bodies to develop antibodies to fight against the virus that causes COVID-19, to prevent future illness.

There is currently no evidence that antibodies formed from COVID-19 vaccination cause any problems with pregnancy, including the development of the placenta.

In addition, there is no evidence suggesting that fertility problems are a side effect of ANY vaccine.


Can being near someone who received a COVID-19 vaccine affect my menstrual cycle?

No. Your menstrual cycle cannot be affected by being near someone who received a COVID-19 vaccine.

Many things can affect menstrual cycles, including stress, changes in your schedule, problems with sleep, and changes in diet or exercise. Infections may also affect menstrual cycles.
COVID Shines a Light on Pre-existing Disparities

Age-adjusted Laboratory-Confirmed COVID-19-Associated Hospitalization Rates by Race/Ethnicity*† — COVID-NET, March 1, 2020—October 16, 2021

![Chart showing hospitalization rates by race/ethnicity.]

*Calculated using hospitalized COVID-19 cases with known race/ethnicity for the numerator and NCHS bridged race estimates for the denominators. Rates are age-adjusted to account for differences in age distributions within race/ethnicity groups in the COVID-19 study population.

†Racial and ethnic groups may not add to total due to rounding.

The COVID-NET hospitalization data are preliminary and subject to change as more data become available. In particular, case counts and rates for recent hospital admissions are subject to lag. As data are received, prior case counts and rates are updated accordingly.


COVID Shines a Light on Pre-existing Disparities

Risk for COVID-19 Infection, Hospitalization, and Death By Race/Ethnicity

Updated Sept. 8, 2021

<table>
<thead>
<tr>
<th>Rate ratios compared to White, Non-Hispanic persons</th>
<th>American Indian or Alaska Native, Non-Hispanic persons</th>
<th>Asian, Non-Hispanic persons</th>
<th>Black or African American, Non-Hispanic persons</th>
<th>Hispanic or Latino persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases</td>
<td>1.7x</td>
<td>0.7x</td>
<td>1.1x</td>
<td>1.9x</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>3.5x</td>
<td>1.0x</td>
<td>2.8x</td>
<td>2.8x</td>
</tr>
<tr>
<td>Death</td>
<td>2.4x</td>
<td>1.0x</td>
<td>2.0x</td>
<td>2.3x</td>
</tr>
</tbody>
</table>

Race and ethnicity are risk markers for other underlying conditions that affect health, including socioeconomic status, access to healthcare, and exposure to the virus related to occupation, e.g., frontline, essential, and critical infrastructure workers.

Factors that Drive Health Decision Making

Possible patient barriers

- Different:
  - Beliefs
  - Backgrounds
  - Culture
- Socio-economic concerns:
  - Taking time off work
  - Finding reliable transportation

Community Engagement: The Role of Trusted Messengers

Mid-Atlantic Permanente Medical Group
Questions?