

Association of Immunization Managers

What you need to know about mRNA COVID-19 vaccines

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The first 2 COVID-19 vaccines distributed in the United States are messenger ribonucleic acid, or mRNA, vaccines. **Use the talking points in this document to talk with health care providers, the media, and other stakeholders about these new COVID-19 vaccines.**

If you have any more questions about mRNA vaccines after reading this document, please contact Jasmine Berry (jberry@immunizationmanagers.org). You can also direct media requests to the Association of Immunization Managers (AIM).

For talking points that providers can use to answer patients' questions about the new mRNA COVID-19 vaccines, see page 9 of this document.

What are mRNA vaccines?

Key message: mRNA vaccines are a new type of vaccine. Instead of using a weakened or dead version of the COVID-19 virus, they use a small strip of genetic code — the mRNA. This code teaches the body to make the spike protein that's found on the COVID-19 virus.

Once the immune system recognizes the spike protein, it creates antibodies — which are proteins that fight infections. These antibodies will stay in your body, and if the COVID-19 virus enters your body, the antibodies will fight it.

Additional talking points

- You can't get COVID-19 from an mRNA vaccine. There's no COVID-19 virus in the vaccines, and the spike protein can't make you sick either.
- The genetic code in mRNA vaccines is inside an oily bubble that's made of lipids. The lipid bubble protects the mRNA from enzymes in the body and helps the mRNA enter cells.
- The mRNA gives cells instructions to make copies of the COVID-19 spike protein. After a cell is finished making the protein, it destroys the mRNA. This happens within a few hours after you get the vaccine.
- The mRNA never enters the cell's nucleus, which is where cells store DNA. This means mRNA vaccines don't change your DNA or your genes in any way.
- Scientists have been studying mRNA and how it works in the body for many years. These are the first mRNA vaccines, but there will probably be many more mRNA vaccines in the future.

More information

- mRNA vaccines are new, but researchers have been studying them for many years — including in early-stage clinical trials on mRNA vaccines for diseases like cancer, rabies, influenza, cytomegalovirus (CMV), and Zika.
- Past research on other coronaviruses, like severe acute respiratory syndrome coronavirus (SARS) and Middle East respiratory syndrome coronavirus (MERS), also taught researchers important lessons that they've used to develop COVID-19 vaccines.¹
- mRNA vaccines are easier and quicker to develop and produce than conventional vaccines. That's because for mRNA vaccines, there's no need to grow viruses in eggs or cells — a process that's expensive and takes a long time.

What mRNA vaccines are available?

Key message: There are 2 mRNA vaccines — 1 developed by Pfizer and 1 developed by Moderna. People have started getting both vaccines.

Additional talking points

- The Pfizer and Moderna vaccines are the first COVID-19 vaccines in the United States to get an Emergency Use Authorization (EUA).
- In clinical trials, both the Pfizer vaccine and the Moderna vaccine were effective at preventing COVID-19 in over 9 out of 10 people.
- The federal government already sent the first shipments of the Pfizer and Moderna vaccines to states, and states are working to get health care providers and other priority groups vaccinated.
- mRNA vaccines must be stored at very cold temperatures. This is because mRNA breaks down very easily when it interacts with other molecules in the environment. Very cold temperatures slow down the chemical reactions that cause mRNA to break down.

More information

For more details about the Pfizer and Moderna vaccines, check out the table on the next page.

¹ <https://jamanetwork.com/journals/jama/fullarticle/2770485>

	Pfizer²	Moderna³
Status	FDA issued an EUA on December 11, 2020	FDA issued an EUA on December 18, 2020
ACIP recommendation	Recommended for people age 16 and older	Recommended for people age 18 and older
Efficacy	95%	94.1%
Dosing schedule	2 doses, 3 weeks apart	2 doses, 4 weeks apart
Common reactions and side effects	<ul style="list-style-type: none"> • Pain at injection site (84.1%) • Fatigue (62.9%) • Headache (55.1%) • Muscle pain (38.3%) • Chills (31.9%) • Joint pain (23.6%) • Fever (14.2%) • Injection site swelling (10.5%) <p>Less common reactions and side effects include injection site redness, nausea, malaise, and swollen lymph nodes.</p>	<ul style="list-style-type: none"> • Pain at injection site (91.6%) • Fatigue (68.5%) • Headache (63.0%) • Muscle pain (59.6%) • Joint pain (44.8%) • Chills (43.4%) • Fever (14.8%) <p>Less common reactions and side effects include injection site swelling or redness, nausea or vomiting, and swollen lymph nodes.</p>
Storage and handling*	<p>Freezer: Must be stored between -80 and -60 degrees Celsius (-112 to -76 degrees Fahrenheit)</p> <p>Refrigerator: Before mixing, can be stored between 2 and 8 degrees Celsius (36 to 46 degrees Fahrenheit) for up to 5 days</p>	<p>Freezer: Must be stored between -25 and -15 degrees Celsius (-13 to -5 degrees Fahrenheit)</p> <p>Refrigerator: After vials are punctured, can be stored between 2 and 8 degrees Celsius (36 to 46 degrees Fahrenheit) for up to 30 days</p>

*For more information about storage and handling, see:

- Pfizer: <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html>
- Moderna: <https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html>

² <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html>

³ <https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html>

How were these vaccines tested?

Key message: Just like all new vaccines, the mRNA COVID-19 vaccines have been tested for safety and effectiveness. Researchers are continuing to study the vaccines in large clinical trials with people of different ages, races, and ethnicities, and people who have different health conditions.

Additional talking points

- Normally it takes years to test a new vaccine. Because of the urgent need to find a vaccine to end the COVID-19 pandemic, researchers sped up the process. For example, they combined phases of clinical trials and got more resources from the federal government. But they didn't skip any key safety steps.
- Vaccines usually have to go through a long FDA approval process before people can get them. But during a public health emergency like the COVID-19 pandemic, the FDA can issue an Emergency Use Authorization (EUA) to get the vaccine to people faster. EUA is different from FDA approval.
- After the FDA gives a vaccine an EUA or approves it, the Advisory Committee on Immunization Practices (ACIP) makes recommendations about who should get the vaccine. ACIP, a group of medical and public health experts, recommends the Pfizer vaccine for people age 16 and older, and it recommends the Moderna vaccine for people age 18 and older.

More information

- In clinical trials, new vaccines go through different study phases to make sure they're safe and effective. This starts with a Phase 1 study where researchers give the vaccine to a small number of people — usually 20 to 100 — to see if it's **safe**. During Phase 2, researchers give the vaccine to hundreds of people to see if it **works**, and in Phase 3 they test it in thousands of people to learn more about **safety and effectiveness**.
- Researchers are continuing to study the Pfizer and Moderna vaccines in Phase 3 trials. If the FDA approves the vaccines after the Phase 3 trials are finished, researchers will study them in Phase 4 trials. This is when researchers will gather longer-term data to make sure the vaccines continue to work well and learn more about any long-term side effects.
- In October 2020, the FDA announced the criteria for issuing an EUA for COVID-19 vaccines. Vaccines must have efficacy of at least 50 percent and safety data for at least 2 months after people complete the vaccine series.⁴ The Pfizer and Moderna vaccines met these criteria (see table on page 3).

⁴ <https://www.fda.gov/media/142749/download>

Are these vaccines safe?

Key message: Scientists have tested these vaccines in thousands of volunteers to make sure they're safe. Based on the results so far, the vaccines are safe for the general public.

Additional talking points

- The FDA carefully reviews all the safety data from clinical trials. The FDA only authorizes a vaccine for emergency use when it believes the benefits outweigh the risks.
- The Advisory Committee on Immunization Practices (ACIP), a group of medical and public health experts, then reviews all the safety data before making recommendations about how to use these vaccines.
- Most people don't have serious side effects after they get an mRNA COVID-19 vaccine. Like with many other vaccines, people may notice that their arm is red, sore, or warm to the touch. Many people also get headaches, have a fever, or feel tired or achy for a day or 2 after getting an mRNA COVID-19 vaccine. These are all signs that your body is building up protection — which means the vaccine is working.
- Experts are still studying the long-term effects of getting COVID-19 vaccines — but most vaccines don't have side effects that last more than 2 weeks.
- A few people have had severe (anaphylactic) reactions after getting an mRNA COVID-19 vaccine. Scientists are working to figure out whether these reactions were caused by the vaccine. To be safe, the Centers for Disease Control and Prevention (CDC) recommends that providers observe patients with a history of anaphylaxis for 30 minutes after they get the vaccine. The CDC recommends observing all other patients for 15 minutes after they get the vaccine.⁵
- According to the CDC, people need to wait at least 2 weeks after getting an mRNA COVID-19 vaccine before getting another vaccine — like the flu vaccine. Similarly, people who first get a flu shot or other vaccine need to wait at least 2 weeks before getting an mRNA COVID-19 vaccine.⁶

More information

- The safety data from clinical trials for the Pfizer and Moderna vaccines are available for anyone to review:
 - Pfizer: <https://www.fda.gov/media/144246/download>
 - Moderna: <https://www.fda.gov/media/144434/download>
- The CDC recommends that people sign up for the v-safe smartphone app after they get the vaccine. They can report side effects through the app, which helps the CDC track the vaccine's effects over time. Learn more about v-safe at: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>

⁵ <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

⁶ <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

Who needs to get the vaccine?

Key message: The Pfizer vaccine is recommended for people age 16 and older, and the Moderna vaccine is recommended for people age 18 and older. But there won't be enough vaccines for everyone right away. When you can get the vaccine depends on your job, your age, and your health.

Additional talking points

- The Centers for Disease Control and Prevention (CDC) recommends vaccinating health care workers and people who live in long-term care facilities first. That's because health care workers are at high risk to get COVID-19, and people in long-term care facilities are at high risk to get very sick or die if they get COVID-19. Vaccinating health care workers helps protect patients, too.
- Experts are still studying whether these vaccines are safe for kids. Pfizer is currently testing its vaccine with kids age 12 and older, and Moderna is testing its vaccine in teens. If researchers learn that these vaccines are safe for teens, they'll test the vaccines with younger kids.
- The Advisory Committee on Immunization Practices (ACIP) at the CDC reviews safety data to make recommendations about who should get a vaccine. ACIP recommends the Pfizer vaccine for people age 16 and older,⁷ and it recommends the Moderna vaccine for people age 18 and older.⁸
- People who are pregnant or breastfeeding can choose to get an mRNA COVID-19 vaccine, but researchers haven't studied whether the vaccines are safe and effective in these groups. The CDC and the American College of Obstetricians and Gynecologists recommend that people who are pregnant or breastfeeding talk to their doctor about the vaccines.
- Experts expect that most people will be able to get vaccinated by the summer or fall of 2021.⁹
- The CDC recommends that people who already had COVID-19 and have recovered get vaccinated. Experts still don't know how long you're protected from COVID-19 after you get better.¹⁰

⁷ <https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm>

⁸ <https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm>

⁹ <https://www.chop.edu/centers-programs/vaccine-education-center/making-vaccines/prevent-covid>

¹⁰ <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

Once someone gets vaccinated, how long will they be protected?

Key message: These vaccines are new, so scientists are still studying how long they'll provide protection against COVID-19.

Additional talking points

- It's possible that you'll need to get a COVID-19 vaccine every year, like the flu vaccine — or that you'll be protected against COVID-19 for longer than a year.
- Scientists won't know for sure how long the vaccine protects people against COVID-19 until the vaccine's protection starts to wear off for people who got the vaccine during clinical trials.

How many doses are in the vaccine series?

Key message: People need 2 doses of the Pfizer vaccine or the Moderna vaccine. The first dose starts building protection against COVID-19 by helping the immune system recognize the virus. The second dose makes the immune system's response stronger.

Additional talking points

- For the Pfizer vaccine, people need to get the second dose **3 weeks** after the first dose. For the Moderna vaccine, people need to get the second dose **4 weeks** after the first one.
- If people don't get the second dose, the vaccine won't be as effective.

More information

- Health care providers can use the Vaccine Administration Management System (VAMS) to keep track of COVID-19 vaccines. This includes keeping track of patients who need to get their second dose. Learn about VAMS at <https://www.cdc.gov/vaccines/covid-19/reporting/vams/index.html>.

What's the cost for patients?

Key message: People can get the vaccine at no cost — but providers can get reimbursed for the administrative costs of providing the vaccine.

Additional talking points

- The federal government is buying COVID-19 vaccines and distributing them to providers for free.
- The government is requiring private insurance companies, Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) to cover the vaccine with no cost sharing for patients. That means providers can't charge patients for the vaccine — including any fees for the cost of administering the vaccine.

- For people who are uninsured, providers can get reimbursed for the cost of administering the vaccine through the Health Resources and Services Administration’s Provider Relief Fund. Learn more about the Provider Relief Fund at: <https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html>.

More information

- The Medicare payment rates to administer a 2-dose vaccine series are \$16.94 for the first dose and \$28.39 for the final dose. For any future single-dose vaccines, the Medicare payment rate will be \$28.39.¹¹
- The Centers for Medicare and Medicaid Services (CMS) is encouraging states and private insurance companies to use the Medicare payment rate to set payment rates for Medicaid, CHIP, and private plans.

Learn more

Clinical Considerations for mRNA COVID-19 Vaccines — CDC

<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

Recommendations for Use of the Pfizer Vaccine — CDC

<https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm>

Recommendations for the Use of the Moderna Vaccine — CDC

<https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm>

Clinical Resources for COVID-19 Vaccines — CDC

<https://www.cdc.gov/vaccines/covid-19/index.html>

COVID-19 Updates — AIM

<https://www.immunizationmanagers.org/page/COVID-19updates>

Questions and Answers about COVID-19 Vaccines — Children’s Hospital of Philadelphia

<https://www.chop.edu/centers-programs/vaccine-education-center/making-vaccines/prevent-covid>

¹¹ <https://www.cms.gov/newsroom/press-releases/trump-administration-acts-ensure-coverage-life-saving-covid-19-vaccines-therapeutics>

Explaining mRNA vaccines to patients

Providers can use these talking points to answer patients' questions about the new mRNA COVID-19 vaccines.

I heard this is a new kind of vaccine. How does it work?

The first COVID-19 vaccines are a new type of vaccine, but scientists have been studying them for years. This includes research on past outbreaks of other coronaviruses, like severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS).

The new COVID-19 vaccines use a small strip of genetic code called mRNA. This code teaches your body to make the spike protein that's found on the COVID-19 virus.

Once your immune system recognizes the spike protein, it creates antibodies, which are proteins that fight infections. These antibodies will stay in your body, and if the COVID-19 virus enters your body, the antibodies will fight it.

Is it safe?

Scientists have tested these vaccines in thousands of people to make sure they're safe and that they work. Based on what scientists have learned so far, the vaccines are safe and work very well. Scientists will also keep studying the vaccines to learn more about them.

Because of the COVID-19 pandemic, scientists were able to speed up the research process and get results more quickly — for example, by combining phases of clinical trials and getting more resources from the federal government. But they didn't skip any key safety steps.

Will it change my DNA?

No. The vaccine won't change your DNA or your genes in any way. And your body destroys the mRNA from the vaccine within a few hours after you get vaccinated.

Is it approved by the FDA?

The Food and Drug Administration (FDA) hasn't approved any COVID-19 vaccines yet. But because of the COVID-19 pandemic, the FDA has given a vaccine made by Pfizer and a vaccine made by Moderna an Emergency Use Authorization. This means that based on what scientists have learned so far, the FDA thinks these vaccines have more benefits than risks.

When can I get the vaccine?

When you can get the vaccine depends on your job, your age, and your health. There won't be enough vaccines for everyone right away, so the first vaccines will go to people who need them most — like health care workers and people living in nursing homes. Experts expect that most people will be able to get vaccinated by the summer or fall of 2021. Researchers are still studying whether these vaccines are safe for kids, so we don't know yet when kids will be able to get vaccinated.

Who needs to get vaccinated?

The Pfizer vaccine is recommended for people age 16 and older, and the Moderna vaccine is recommended for people age 18 and older. If you're pregnant or breastfeeding, talk to your doctor about whether you need to get vaccinated.

If I had COVID-19, do I still need to get vaccinated?

Yes. Experts are still studying how long your immune system protects you from COVID-19 after you had it — and they recommend that people who had COVID-19 and got better get the vaccine.

How many shots do I need to get?

You'll need to get 2 shots, a few weeks apart. You need both shots to be fully protected.

Are there any side effects?

Most people don't have serious side effects after they get vaccinated. Just like with other vaccines, your arm may be red, sore, or warm to the touch.

You may also get a headache or a fever, or feel tired and achy for a day or 2. These side effects are very common in people who get mRNA COVID-19 vaccines. They're signs that your body is building up protection — and that means the vaccine is working.

Can I get COVID-19 from the vaccine?

No. These vaccines don't have the COVID-19 virus in them, so they can't make you sick. They teach your body to protect you from COVID-19 without ever giving you the disease.

Do I still need to wear a mask and socially distance after I get the vaccine?

Yes — at least at first. There won't be enough vaccines for everyone right away, so it's important to keep taking steps to protect people who haven't gotten the vaccine yet. That includes wearing a mask when you're in public and keeping a safe distance from other people.

How much will the vaccine cost?

For most people, the COVID-19 vaccine will be free. Some health care providers may charge a small fee for giving the shots, but that fee should be covered by your insurance or the government.

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