



# Healthy Restart Playbook Vaccines and boosters are widely available. Now what?

There's been nothing simple about COVID-19 since the beginning, but the more we learn, the more we understand this deadly virus. This is an informational Playbook by the physicians, clinical leaders and infectious disease experts of University Hospitals on the science of COVID-19, COVID-19 variants, and the vaccines currently available to stop its spread.



### **HEALTHY RESTART PLAYBOOK**

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# What are my chances of getting COVID-19?

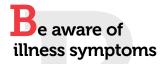
**There is no easy answer.** As an airborne virus, COVID-19 spreads when people talk, laugh, sing, sigh or breathe; in other words, whenever people get together. Community spread may surge again, as new variants or mutations of the coronavirus circulate more widely and as communities reopen.

The more people who are vaccinated, the less likely they are to get seriously ill from COVID-19.

If you are not vaccinated, you must follow these important steps to reduce the risk of getting or spreading COVID-19—easy as A-B-C-D-E:













Distance physically, but not socially

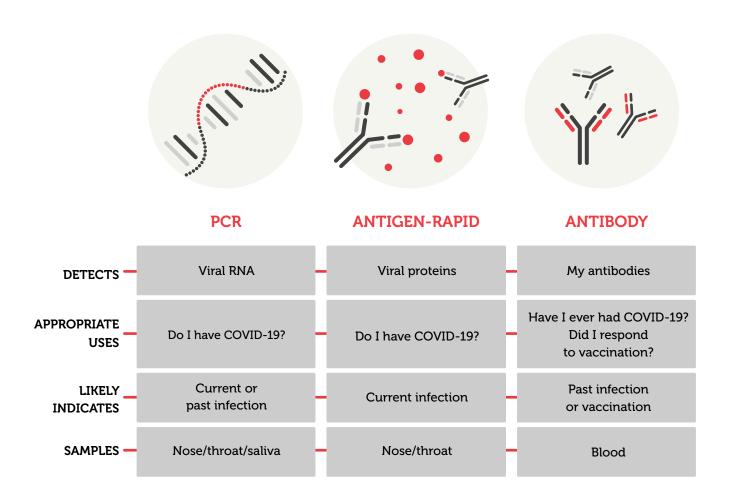


Everyone who can get vaccinated, should





## What are the different kinds of tests for COVID-19?



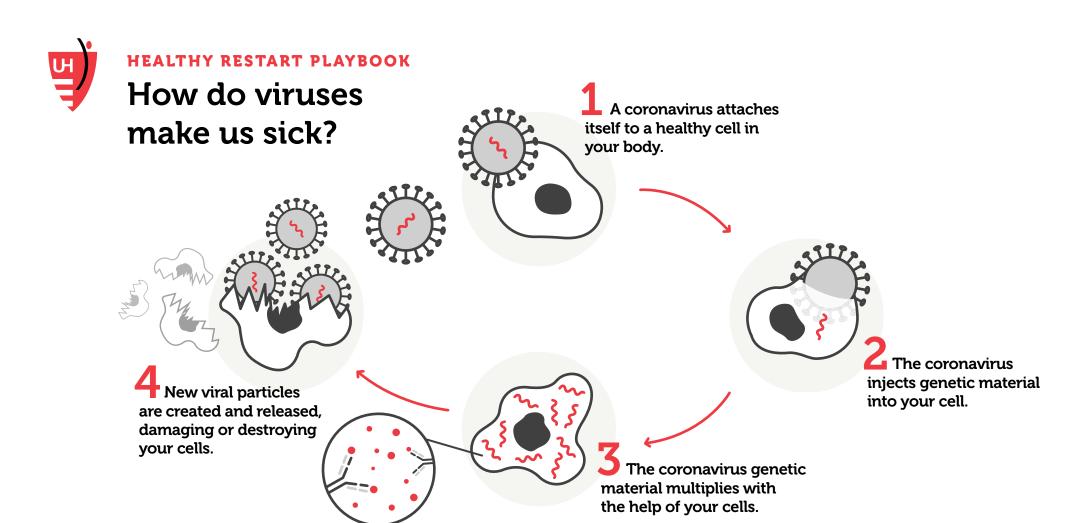
The three most common kinds of COVID-19 tests are each designed to detect the virus differently. No test is 100% right, and none of them is 100% right 100% of the time.

**PCR** stands for polymerase chain reaction. It detects genetic material from the coronavirus.

An **antigen-rapid** test is just that—rapid. It can detect the presence or absence of antigen and provides results within minutes.

If you test positive by PCR or antigen-rapid, follow the Centers for Disease Control and Prevention (CDC) recommendations for isolating at home to avoid infecting others. **Contact tracing** can identify and warn everyone who was exposed.

An antibody test is a blood test that screens for the antibodies your body makes to fight an infection in your blood. You may temporarily have some immunity if you have a positive antibody test, but a vaccine will provide more complete protection.



A **virus** is a submicroscopic infectious molecule in a protein coat that **multiplies itself** in your living cells.

### 1. A coronavirus attaches itself to a healthy cell.

Viruses enter the body through the mouth, nose or eyes. This can happen when we touch those areas with droplets on our hands or breathe in droplets or aerosols in the air that contain the virus.

### 2. The coronavirus injects genetic material into the cell.

A coronavirus infects you when it attaches to a healthy cell inside your body and then enters that cell.

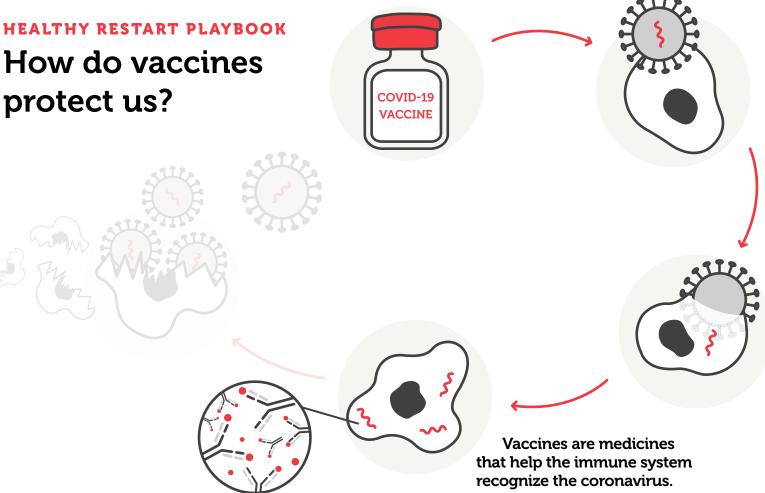
### 3. The viral genetic material multiplies with the help of your cells.

Once inside your cell, the virus directs your body's cells to make copies of itself. Many, many copies. These new copies attach to and enter other cells.

### 4. New viral particles are created and released, damaging or destroying your cells.

Coronavirus symptoms are caused by the damage to and destruction of your cells.





Vaccines don't make us well. They help our bodies make us well. Your immune system does the work.

It takes time for your immune system to recognize a new virus as something harmful and start to kill it. Over time, the immune system can get better at recognizing a virus as harmful. This memory response can be lifesaving, as your body fights the infection on its own.

Vaccines are medicines that help the immune system recognize the coronavirus and identify it as harmful, without having to get the actual virus. Vaccines help your body work quickly and precisely if it is ever exposed to the virus. This training of the immune system by a vaccine gives your immune system a head start. It helps your body recognize and fight a virus before it enters and damages too many cells—before it makes you sick.

It's important to keep yourself healthy, but that is not enough to protect you from the COVID-19 virus. Vaccines help protect your body by getting it ready with the antibodies it needs.

### HEALTHY RESTART PLAYBOOK

# What are the different kinds of vaccines?

Because of the global urgency to create a vaccine to fight COVID-19, different vaccines have been developed by different companies and countries at the same time. Although they are all designed to create **memory** in your immune system, so that it remembers how to fight the disease, they work differently to get your body in shape to fight back on its own. The three vaccines authorized so far are made by **Pfizer-BioNTech, Moderna** and **Johnson & Johnson**.

### None of these vaccines changes your DNA.

The **Pfizer-BioNTech** and **Moderna** vaccines deliver a string of molecules called mRNA to some of your cells so that those cells will produce spike proteins. mRNA already exists naturally in both your body and in the virus, but when your cells make more of it, the vaccines teach your immune system to recognize and remember the spike protein and the coronavirus as harmful.

Johnson & Johnson teaches your immune system differently. It delivers a small piece of DNA, a string of proteins. The DNA then directs your body to make mRNA so that those cells will produce spike proteins. The harmless spike proteins, but not the whole harmful coronavirus, are made by your cells, so like the mRNA vaccines, this trains your immune system to recognize, remember and fight those spike proteins and also the real coronavirus as it tries to enter your cells.

### Johnson & Johnson

### **DELIVERS**

DNA to teach your cells about the virus

### **CAUSES CELLS**

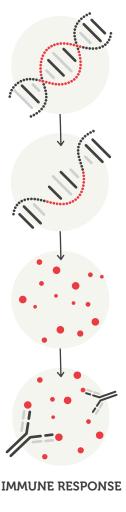
to make mRNA, which makes spike proteins

### **STORAGE**

Normal refrigeration

### DOSES NEEDED

1



### Moderna, Pfizer-BioNTech

### **DELIVERS**

mRNA to teach your cells about the virus

### **CAUSES CELLS**

to make spike proteins

### **STORAGE**

Freezer and refrigeration

### **DOSES NEEDED**

2



### Do kids get COVID-19?

Kids get COVID-19. That we know for a fact. Even if they show no symptoms, they can transmit the virus to others, and they can also get sick with COVID-19. When compared with other common childhood illnesses, COVID-19 is one of the most worrisome, and numbers have been rising.

One of the most worrisome developments with COVID-19 in kids is called multisystem inflammatory disease (MIS-C), which can lead to inflammation of many organs in the body, including the heart, lungs, kidneys, brain, skin, eyes or gastrointestinal organs. It has been reported in kids who have been diagnosed with COVID-19 or exposed to others who had COVID-19.

The same public health measures recommended for adults help us prevent COVID-19 in kids. Masking children over two years old, getting vaccinated and keeping up-to-date with vaccines, practicing physical distancing, lowering the density of people in enclosed areas and keeping sick children at home will all help slow the spread of COVID-19.

### What about kids and vaccines?

Children ages 6 months and older are eligible for a COVID-19 vaccination, and children ages 5 years and older are eligible for booster shots. Before recommending COVID-19 vaccination for children, scientists conducted clinical trials with thousands of children to establish the safety and effectiveness of the vaccines.

Millions of children and teens ages 6 months through 17 years have received the COVID-19 vaccine. Ongoing safety monitoring shows that the known risks and possible severe complications of COVID-19 outweigh the potential risks of having a rare, adverse reaction to vaccination.

Side effects from the vaccine in kids were similar to those experienced for routine vaccinations, including: pain at the shot site, fatigue, headache, muscle pain, chills and fever. There have been reports of myocarditis and pericarditis in adolescents and young adults after receiving the Pfizer and Moderna COVID-19 vaccines. The CDC states that this risk is rare and the benefits of the vaccine outweigh this potential risk, particularly because COVID-19 infection is known to cause these conditions. Review the materials provided with the vaccine carefully and discuss any concerns with your child's healthcare provider.

Except for the method of delivering information to your cells, the Pfizer-BioNTech and Moderna vaccines are very similar to other vaccines commonly given to kids. As explained on page 7, the vaccine delivers a string of molecules called mRNA to some of your cells, so that those cells will produce spike proteins. mRNA already exists naturally in both your body and in the virus, but when your cells make more of it, the vaccines teach your immune system to recognize and remember the spike proteins and the coronavirus as harmful. The mRNA does not change your DNA.



# How effective are the vaccines?

Clinical trials have shown all authorized and approved vaccines to be highly effective in preventing severe illness, hospitalization and death. COVID-19 vaccine efficacy was measured at different times, and the studies had different exact definitions of COVID-19 disease. This makes it difficult to make a direct comparison of the three.

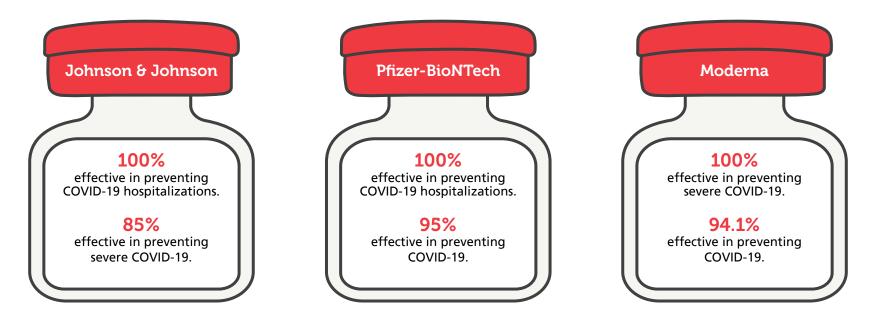
At the time of the **Johnson & Johnson vaccine** clinical trials, new faster-spreading and more severe variants were arising. The Pfizer-BioNTech and Moderna trials were concluded before these variants were being tracked. Recent studies reported by the CDC suggest that the **Moderna and Pfizer-BioNTech vaccines** are highly effective against the current variants, but the vaccines continue to be studied.

The studies measured levels of protection:

- if the vaccine stops you from getting sick with COVID-19
- if it stops you from getting very sick or severely ill
- if it stops hospitalizations from severe COVID-19
- if it stops you from dying from COVID-19

The CDC, the FDA and each of the vaccine manufacturers continue to collect information, study and report on the efficacy of the vaccines and recommended boosters where needed.

This is what each manufacturer reported about their clinical trials when they applied to the FDA for Emergency Use Authorization:



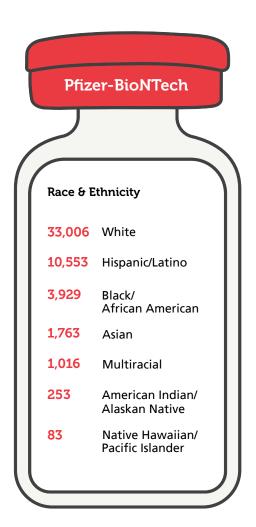


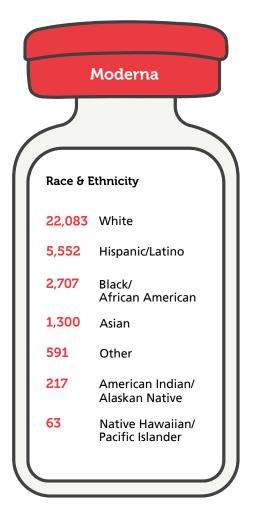
# How do I know these vaccines are right for me?

The initial clinical trials for Johnson & Johnson, Pfizer\_BioNTech, and Moderna included people who identified themselves as members of racial or ethnic groups at greater risk for COVID-19.

Below is what each company reported about their internal studies when they applied to the FDA for Emergency Use Authorization.

### Johnson & Johnson Race & Ethnicity **24,416** White 17,729 Hispanic/Latino 6.764 Black/ African American 3,271 American Indian/ Alaskan Native 2.123 Multiracial 1,383 Asian Native Hawaiian/ Pacific Islander





# **H**

### **HEALTHY RESTART PLAYBOOK**

# How were these vaccines developed so fast?

### These vaccines were developed at the speed of science.

Physician scientists here at UH and around the world worked with an unwavering intensity and dedication to discover, develop and manufacture these vaccines in record time, but **no steps were skipped**. The timelines were just overlapped. The mRNA technology used in the COVID-19 vaccines has been in development for the past 10 years.

### TYPICAL VACCINE DEVELOPMENT TIMELINE Research & **Development** Licensing Distribution Phase I Phase II Phase III **Preclinical** Manufacturing **Clinical Trials Trials COVID-19 VACCINE DEVELOPMENT TIMELINE** mRNA Research & Phase III Research **Development** Licensing Distribution Phase II Phase I **Preclinical Trials Clinical Trials** Manufacturing

# **H**

### **HEALTHY RESTART PLAYBOOK**

# How do I know these vaccines are safe?

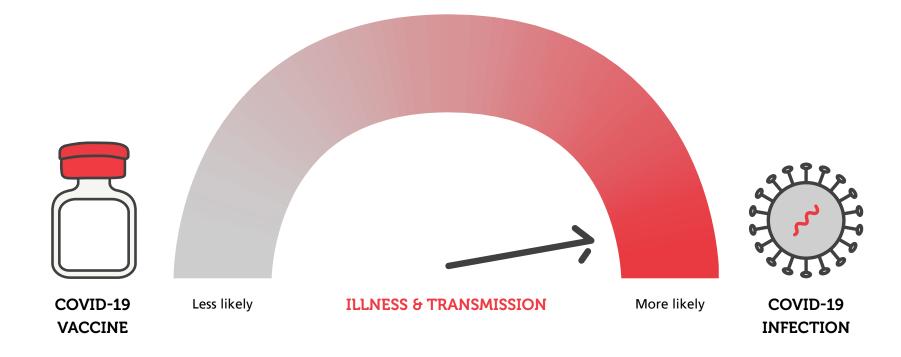
Health experts and public health officials believe the benefits of vaccination far outweigh the risks associated with it for most people, especially when compared to the potential for serious illness and death from COVID-19. Before being made available for public use, each of the three vaccines was carefully studied for safety, efficacy and any undesirable side effects. Each passed those initial inspections and was granted an Emergency Use Authorization by the FDA. Even as the FDA and the CDC continue to study long-term effects, the protocols and results of those initial studies are available to clinicians and the public.

After rigorous review of data and inspections of factories where the vaccines are made, Pfizer BioNTech received full approval from the FDA for its COVID-19 vaccine for recipients age 16 and up and Moderna received full approval for recipients age 18 and up.

Review the Vaccine Information or EUA Fact Sheet for each vaccine carefully. Discuss any specific health concerns with your healthcare provider.

The CDC and the FDA recommended resuming use of the Johnson & Johnson vaccine after a temporary pause to review reports of rare but serious adverse events. As per the CDC, nearly all reports of this serious condition, involving blood clots with low platelets, have been in adult women younger than 50 years old. After a review of all available data, the CDC and the FDA determined that the vaccine's known and potential benefits may outweigh its known and potential risks, and it may be considered in some limited situations. Please consult your medical provider to learn more or if you are considering Johnson & Johnson and are a woman under 50.

The CDC and FDA have also considered reports of myocarditis and pericarditis in adolescents and young adults after receiving the Pfizer and Moderna COVID-19 vaccines. The CDC states that this risk is rare and the benefits of the vaccine outweigh this potential risk, particularly because COVID-19 infection is known to cause these conditions.

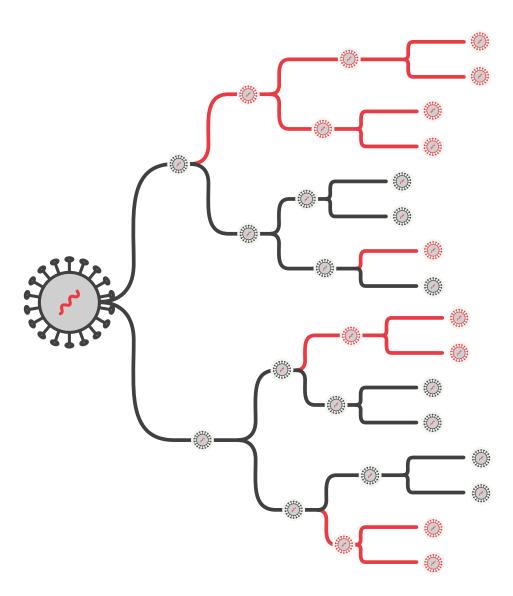


# What about the virus variants?

The faster people get vaccinated, and the more people who get vaccinated, the better chance we have of preventing more variants.

When the human body is multiplying the virus, sometimes the mRNA does not replicate exactly. Any change or mutation in the virus mRNA may make a new type of virus, one that has what scientists call a selective advantage. For example, it may spread more easily from person to person or cause more severe infections. These are called COVID-19 variants.

Viruses and variants can happen anywhere. Doctors and researchers are still learning about variants, but historically, even if you've already had the original virus, you can be reinfected by a variant and possibly suffer a more severe illness.



# What can I expect from my medical provider?

How they will help you get

R.E.A.D.Y.

for COVID-19 vaccines.

Raise the question. Your doctor should discuss the COVID-19 vaccines and ask you if you have questions or concerns.

Encourage open dialogue and questions. Your doctor should welcome your questions.

Acknowledge and respect your concerns. Make sure your questions about COVID-19 and the vaccines are answered by your doctor.

Disclose medical information in a way that allows you to better understand your personal risks and benefits when considering the COVID-19 vaccines.

You are important to us. Your provider is there to care for you whatever your decision about the vaccines.

### HEALTHY RESTART PLAYBOOK

# Questions your doctor can help answer

Print this page and bring it with you when you talk with your doctor, so you can share what you already know and learn more.

### Should I get the vaccine if I've already had COVID-19?

Yes. Because it is not known how long the antibodies created by your body in response to your COVID-19 infection last and because there are cases of reinfection, it is advised that you still get the COVID-19 vaccine. It will definitely provide you with greater protection against being reinfected.

If you have recently tested positive for COVID-19, you may need to wait before getting the vaccine to ensure it is as effective as possible. Please talk with your provider.

### What if I have allergies?

None of the authorized vaccines is recommended for people who are severely allergic to their ingredients, especially polyethylene glycol (PEG). The CDC notes that patients with a PEG allergy may be able to get the Johnson & Johnson or Novavax vaccine. Those with a polysorbate allergy may be able to get the Pfizer BioNTech or Moderna vaccine.

Serious allergic reactions that prevent getting a COVID-19 vaccine are very rare. A board-certified allergist will be able to help you determine if you have a severe allergy that prevents you taking one of the available vaccines.

All three vaccines are egg-free and preservative-free. As an extra safety precaution, there is no natural rubber latex in any of the vial stoppers. You should tell your vaccinator about any allergies you may have, and they may have you stay for an extended observation time to monitor you for an allergic reaction.

### I'm immunocompromised. Can I still get a COVID-19 vaccine?

People who are immunocompromised can get any of the vaccines. Please discuss with your treating provider, who will have the most up-to-date information regarding the timing of vaccines and infusions or other treatments, if you are receiving them.

The authorizations for Moderna and Pfizer-BioNTech have been amended by the FDA to allow for a third dose to be administered at least 28 days following the two-dose regimen of the same vaccine and a fourth dose at least 4 months after receipt of a first booster dose to individuals 18 years of age or older (ages 12 or older for Pfizer-BioNTech) who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. Many people who are immunocompromised are recommended to get a booster dose as well.

### What side effects can I expect?

If you have a severe allergic reaction—difficulty breathing, swelling of the face and throat, fast heartbeat, a bad rash all over your body or dizziness and weakness—call 911 or seek immediate medical attention.

Check the Vaccine Information Sheet or the EUA Fact Sheet for the vaccine you receive. You may experience the following normal reactions, which occur more often among people who had COVID-19 and after the second dose:

- tiredness
- nausea and vomiting
- headache
- fever
- pain at the shot site
- swelling/redness at the shot site

- chills
- muscle pain
- joint pain
- swelling/tenderness in your armpit area

# Questions your doctor can help answer

Print this page and bring it with you when you talk with your doctor, so you can share what you already know and learn more.

### What if I am pregnant or recently pregnant?

Pregnant and recently pregnant people are at increased risk for severe COVID-19 illness, especially if you have other conditions that already put you at higher risk, like certain lung problems or diabetes. In addition, pregnant people with COVID-19 are more likely to experience preterm birth.

Due to the increasing cases of COVID-19 in pregnant and recently pregnant women, the CDC strongly recommends COVID-19 vaccination either before or during pregnancy because the benefits of vaccination outweigh known or potential risks.

If you are pregnant, trying to get pregnant, recently pregnant or breastfeeding you should talk with your doctor about which COVID-19 vaccine is right for you.

### Which vaccine should women get?

Women younger than 50 years old should be aware of the rare risk of blood clots with low platelets after vaccination with the Johnson & Johnson's Janssen COVID-19 vaccine. There are other COVID-19 vaccines, including the Pfizer and Moderna COVID-19 vaccines that are available for which this risk has not been seen.

### Should I get vaccinated if I am breastfeeding?

If you are infected with COVID-19, it is possible to spread COVID-19 to your baby during the close contact of breastfeeding. COVID-19 vaccination is recommended for all people 6 months and older, including people who are breastfeeding.

Recent reports have shown that breastfeeding people who have received mRNA COVID-19 vaccines have antibodies in their breastmilk, which could help protect their babies.

If you are pregnant, trying to get pregnant, recently pregnant or breastfeeding you should talk with your doctor about which COVID-19 vaccine is right for you.

### Can the vaccine I get give my baby COVID-19 if I am breastfeeding?

Vaccines will not give you or the baby you are breastfeeding COVID-19.

### Should I take a pregnancy test before I get a COVID-19 vaccine?

The CDC does not recommend routine pregnancy testing before COVID-19 vaccination.

### What if I'm trying to get pregnant?

If you are trying to become pregnant, you do not need to avoid pregnancy after receiving a COVID-19 vaccine. The CDC strongly recommends that pregnant women get vaccinated.

### Can the vaccine cause infertility?

According to the CDC, there is currently no evidence that any presently authorized or approved COVID-19 vaccines cause fertility problems.



### I've been vaccinated. May I get back to normal?

You are considered fully vaccinated 14 days after your second dose of the Moderna or Pfizer-BioNTech two-dose vaccines and 14 days after the one-dose Johnson & Johnson vaccine. Boosters are now recommended for most people to be considered up-to-date on vaccines.

According to the CDC, once you are up to date on vaccines, you can resume many activities without wearing a mask or physically distancing, except where required by federal, state, local, tribal or territorial laws, rules and regulations, including local business and workplace guidance.

You should still watch out for symptoms of COVID-19, especially if you've been around someone who is sick. If you have symptoms of COVID-19, you should get tested and stay home and away from others. It is important to pay attention to the level of COVID-19 transmission in your area to determine whether to implement additional precautions.

If you have a condition or are taking medications that weaken the immune system, please talk to your healthcare provider to discuss your activities. You may need to keep taking all precautions to prevent COVID-19.

#### Can I travel?

With the most recent escalation is transmission from the more contagious variants, please check the CDC travel advisories, your provider, and assess the vaccination and health status of those you will be traveling with before making travel plans.

### Why should I get the vaccine?

While detailed guidance about how to do each of the activities on this page is available from the CDC, vaccinated people are now able to more safely engage with the world. If you're nervous about getting the vaccine, just keep reminding yourself why it's important to you:

- I am getting the vaccine so I can hug my grandmother again.
- I am getting the vaccine so I can go to church again.
- I am getting the vaccine so I can go to concerts again.
- I am getting the vaccine so I can have dinner with vaccinated friends.
- I am getting the vaccine so I can celebrate birthdays again.

What are you looking forward to?

Watch for the CDC's guidance on more things you'll be able to do as more people get vaccinated.

### How long will the effect of the vaccine last?

All people over the age of 5 years are recommended to get a booster shot. The CDC recommends booster shots with the new bivalent vaccine for all people ages 12 and older, at least two months after a previous COVID-19 vaccine. Children ages 5 years and older are eligible for a booster with the original vaccine five months after their second dose of the primary vaccine series. Adults who are moderately or severely immunocompromised, are eligible for a third booster with the bivalent vaccine.

If you are eligible for a booster, you may be able to choose which vaccine – Pfizer or Moderna – you receive as a booster dose. Some people may prefer the vaccine type that they originally received; others may prefer to get a different booster.

Please follow the CDC guidance for the latest on vaccine boosters. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html



One mask or two? The CDC suggests that two masks—a paper isolation mask covered by a cloth mask—are better than one against the more contagious variants of COVID-19. Wash your hands before putting a mask on, taking it off or touching it.

### How to put on an earloop mask:



Make sure the nose wire is at the top of the mask.



Put your fingers through the earloops and place the loops around your ears. The fit and filtration of your mask help protect you and others.



Open the mask from the top and bottom so it goes from the top of your nose to under your chin.



Gently press the nose wire against your nose to ensure a secure fit. Your nose should always be under your mask.

### Why masking still matters.

We have been wearing masks during this pandemic to protect ourselves and other people. Masking has been one of the public health efforts to prevent people from getting sick and also to prevent people who are infected from transmitting COVID-19 to others. With the emergence of the more contagious variants and understanding that vaccinated people may be infected and transmit the virus, masks are advisable indoors in public spaces and where distance cannot be maintained outside.

There may be federal, state, local or business guidelines that require masking. For instance, healthcare facilities still require masks.

Special consideration may be needed around people who aren't vaccinated, people who are at higher risk of infection, people who are in hospitals, and people who live in close quarters—they may need masks and they may also need people who are in contact with them to wear masks as well. Vaccines provide great protection, but they are not perfect.



## What are the best resources if I want to learn more?

The world is still learning about this disease. As studies continue, new information develops. This Playbook is not intended as a substitute for following applicable federal, state or local laws, regulations or guidelines. These recommendations are not intended to supersede or replace the recommendations of the FDA, the CDC, the Ohio Department of Health (ODH), the State Department of Health, the Occupational Health and Safety Administration, the World Health Organization or similar authorities. If you have questions, please turn to trusted resources like the CDC and the ODH.

Although the information in this Playbook is reviewed and approved by healthcare professionals, UH does not guarantee the accuracy, completeness or timeliness of this information. As understanding of COVID-19, vaccinations and applicable guidelines is changing quickly, the information in this Playbook is current as of the last update. UH is not responsible for any errors, omissions or actions taken in reliance on or from use of this information. Please contact your healthcare provider for any questions about your medical condition or any questions you have about a vaccine.

There is no guarantee that following all of these recommendations will prevent transmission of COVID-19, and adherence to any recommendations included in this Playbook will not ensure successful results in every situation. Furthermore, the recommendations contained in this Playbook should not be interpreted as setting a standard of care, or be deemed inclusive of all proper methods of operations.

### Here are a few quick links:

UH: Vaccine Scheduling, or Call (216) 983-0012

**Ohio Vaccine Locator** 

**CDC: Vaccine Finder** 

**HHS: Vaccine Finder** 

FDA EUAs and Other Information

**ODH: COVID-19 Frequently Asked Questions** 

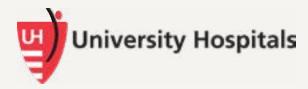
ODH: Myths vs. Facts About COVID-19 Vaccines

**CDC: COVID-19 Vaccine Information** 

CDC: Recommendations on Allocating Initial Supplies of COVID-19 Vaccine

CDC: Vaccine Safety: No Connection Between Autism and Vaccines

<u>Health and Human Services Fact Sheet: Explaining Operation</u>
<u>Warp Speed</u>



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