Vaccine Research & Development

What types of COVID-19 vaccines are being tested?

There are many different kinds of vaccines being explored to combat COVID-19.

The first two vaccines that have applied for approval, use a technology called messenger RNA (mRNA) to protect against infectious diseases. To trigger an immune response, many vaccines put a weakened or inactivated germ into our bodies, but not mRNA vaccines. Instead, they teach our cells how to make a protein—or even just a piece of a protein—that triggers an immune response inside our bodies. That immune response, which produces antibodies, is what protects us from getting infected or seriously ill if the real virus enters our bodies.

COVID-19 mRNA vaccines give instructions to our cells to make a harmless piece of what is called the "spike protein." The spike protein is found on the surface of the virus that causes COVID-19 disease.

COVID-19 mRNA vaccines are given in the upper arm muscle. The cells use these instructions to make the protein piece. After the protein piece is made, the cell breaks down the instructions and gets rid of them.

Next, the cell displays the protein piece on its surface, similar to how the COVID-19 virus would. Our immune systems recognize that the protein doesn't belong there and begins building an immune response and making antibodies, like what happens in natural infection with COVID-19.

At the end of the process, our bodies have learned how to protect against future infection. The benefit of mRNA vaccines, like all vaccines, is those vaccinated gain this protection without ever having to risk the serious consequences of getting sick with COVID-19.

Sources:

- University of Michigan: The Top 5 COVID-19 Vaccine Candidates Explained
- CDC: Understanding mRNA COVID-19 Vaccines
- Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines
- CDC: Different COVID-19 Vaccines

How do mRNA vaccines work?

This first COVID-19 vaccine in the U.S. is a messenger RNA vaccine—also called mRNA vaccine. COVID-19 mRNA vaccines give instructions to our cells to make a harmless piece of a spike protein that is unique to the COVID-19 virus. When the COVID-19 mRNA vaccine is given in the upper arm muscle, the vaccine instructions are delivered to the muscle cells. The muscle cells

then use these instructions to make the protein. After the protein is made, the cell breaks down the instructions and gets rid of them.

With the cell now having made the protein, our immune system recognizes that the protein does not belong there and begins building an immune response and making antibodies. Through this process, our bodies learn how to recognize, protect against, and fight future COVID-19 infection.

There are currently no licensed mRNA vaccines in the United States. However, researchers have been studying and working with them for decades. Beyond vaccines, cancer research has used mRNA to trigger the immune system to target specific cancer cells. mRNA technology has been used successfully for cancer immunotherapy by harnessing the body's immune system to identify and kill cancer cells in the same way the immune system identifies and targets infection from viruses or diseases.

Interest has grown in these vaccines because they can be developed in a laboratory using readily available materials. This means the process can be standardized and scaled up, making vaccine development faster than traditional methods of making vaccines. For example, it can take at least six months to produce large quantities of the flu vaccine.

mRNA vaccines have been studied before for flu, Zika, rabies, and cytomegalovirus (CMV). As soon as the necessary information about the virus that causes COVID-19 was available, scientists began designing the mRNA instructions for cells to build the unique spike protein into an mRNA vaccine.

Sources:

- CDC: Understanding mRNA COVID-19 Vaccines
- CDC: Understanding how COVID-19 Vaccines Work
- CDC: Selecting Viruses for the Seasonal Influenza Vaccine

What are the different phases of clinical trials for vaccines?

The goal of the vaccine-approval process is to end up with a vaccine that is effective (the vaccine works in preventing the illness) and safe (there are no serious side effects or other problems). In the United States, this process has produced safe and effective vaccines for the flu, polio, measles, mumps, pertussis, and more. The process has saved millions of people from getting sick and dying.

The stages of development generally follow this timeline:

- **Exploratory stage**: This is the start of lab research to find something that can treat or prevent a disease. Vaccine development typically begins not at a pharmaceutical company, but in a research laboratory in a university, medical center, or small biotech

company. Scientists in these laboratories are most often funded by grants from the government or private foundations.

- **Pre-clinical stage**: Scientists use lab tests and testing in animals, such as mice or monkeys, to learn whether a vaccine might work. Many potential vaccines don't make it past this point. But if the tests are successful and the U.S. Food and Drug Administration (FDA) signs off, it's on to clinical testing.
- **Clinical development:** This is a three-phase process of testing in humans.
    - **Phase I** usually involves fewer than 100 people and seeks to answer two main questions: does the vaccine generate the expected immune response (does it work in creating antibodies to protect someone from the disease) and is the vaccine safe (does the vaccine show any serious side effects)?
    - **Phase II** involves several hundred people, comparing those who did and did not receive vaccine. During this phase, scientists try to determine the proper dose of vaccine to be given, and they continue to study the vaccine's safety. They also determine how to manufacture the vaccine — making sure the process and packaging creates a consistent vaccine, so that each batch produces similar results.
    - **Phase III** involves thousands of study participants who are similar to the population that will receive the vaccine, again comparing those who did and did not receive vaccine. During these studies, as with the previous phases, no one working with the patients, testing the samples collected from patients, or calculating the results, knows which participants received the vaccine and which did not (this is called a "double-blind" study). Researchers are also studying how long the vaccine can be used before it expires, taking into consideration how it will be transported and stored.
- **Regulatory review and approval:** Scientists with the FDA and U.S. Centers for Disease Control and Prevention closely review the data from the clinical trials before a vaccine can be licensed and approved.
    - Additionally, the Advisory Committee on Immunization Practices (ACIP) – a group of independent medical and public health experts who review data on new and existing vaccines and diseases – will make recommendations for approval and use within specific age groups.
- **Manufacturing:** The vaccine goes into production. The FDA inspects the factory and approves drug labels.
- **Quality control:** Scientists and government agencies use databases such as the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink Project to monitor vaccine safety.
    - VAERS collects and analyzes reports of adverse events that happen after vaccination. Anyone can submit a report, including parents, patients, and health care professionals. That report is then evaluated by medical experts and examined for trends to identify any vaccine safety issues.
    - The Vaccine Safety Datalink Project, a network of health care organizations across the U.S., analyzes health care information from over 24 million people, which scientists use to actively monitor safety.

    - Vaccine recommendations may change if safety monitoring reveals new information on vaccine risks (like if scientists detect a new serious side effect).
    - The approved COVID-19 vaccines will be utilizing these standard safety programs, which are already in place, and will also be utilizing the new quality control program known as V-Safe. This new program is a vaccination health checker which uses smartphone technology to monitor and receive reports about adverse side effects.

Sources:

- CDC: Ensuring the Safety of COVID-19 Vaccines in the United States
- CDC: Ensuring COVID-19 Vaccines Work
- Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines

How were they able to develop the COVID-19 vaccine so much faster than other vaccines from the past?

The first two COVID-19 vaccines that have applied for approval were built using a technology called mRNA, rather than using a weakened or dead virus as traditional vaccines do. mRNA technology has been used successfully for cancer immunotherapy by harnessing the body's immune system to identify and kill cancer cells in the same way the immune system identifies and targets infection from viruses or diseases.

mRNA vaccines teach our cells how to make a protein, or even just a piece of a protein, that triggers an immune response inside our bodies. That immune response, which produces antibodies, is what protects us from getting infected if the real virus enters our bodies. mRNA vaccines are being held to the same rigorous safety and effectiveness standards as all other types of vaccines in the United States.

While COVID-19 vaccines have been developed more quickly than has been done in the past, speed did not decrease safety. The timeline was shortened without sacrificing quality by:

- Overlapping phase I and phase II clinical trials. Phase I studies include a small number of people and evaluate whether the vaccine causes an immune response and is safe. Scientists could look at data from a group of people as phase II was progressing to make these evaluations.
- While completing large phase III trials, manufacturers began producing the vaccine, so that if it were shown to be safe and effective, they would have large numbers of doses ready. This is not normally done because if the vaccine does not work, the manufacturer will have spent a significant amount of money to produce something that needs to be thrown away.
- Traditional vaccine production involves growing viruses in living cells and purifying the virus. There are challenges associated with this process that takes time. The mRNA vaccine has an advantage in that large amounts of the mRNA can be synthesized very rapidly.

- While waiting for a vaccine to be ready, many other aspects of vaccine delivery were prepared (e.g., developing plans for how to distribute the first, limited quantities available, ensuring adequate supplies for distributing and administering vaccine.)

Past research on vaccines has identified potential successful approaches which has reduced the development time for a COVID-19 vaccine. These mRNA vaccines are a product of decades of study on RNA therapies and treatment by medical scientists. Beyond vaccines, cancer research has used mRNA to trigger the immune system to target specific cancer cells. mRNA technology has been used successfully for cancer immunotherapy by harnessing the body's immune system to identify and kill cancer cells in the same way the immune system identifies and targets infection from viruses or diseases.

Sources:

- CDC: Understanding mRNA COVID-19 Vaccines
- Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines

Planning for a Vaccine

What is Operation Warp Speed's role with COVID-19 vaccines?

The significant impact of COVID-19 has led to unprecedented, worldwide collaboration amongst scientists, health and government officials, and manufacturers.

A national program was announced earlier this year to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, treatments and medical countermeasures, called Operation Warp Speed. Operation Warp Speed is a partnership among components of the Department of Health and Human Services (HHS) and the Department of Defense to help develop, make, and distribute millions of vaccine doses for COVID-19 as quickly as possible while ensuring that the vaccines are safe and that they work.

Source:

- HHS: Explaining Operation Warp Speed

When will a COVID-19 vaccine be available in Michigan and the United States?

As of December 2, 2020, two vaccine manufacturers have submitted applications to the U.S. Food and Drug Administration (FDA) for approval to distribute safe and effective COVID-19 vaccines before the end of the year. These applications are pending scientific and medical expert review and approval.

Source:

- CDC: Frequently Asked Questions about COVID-19 Vaccination

When does Michigan anticipate a COVID-19 vaccine will be available?

In December 2020, two COVID-19 vaccines will be reviewed by the U.S. Food and Drug Administration and medical and scientific experts. If a vaccine is approved, Michigan will receive a limited supply for distribution to health care personnel and long-term care facilities.

While there may be a limited supply of COVID-19 vaccines before the end of 2020, supply will continually increase in the weeks and months that follow. If a vaccine is approved before the end of 2020, Michigan anticipates being able to begin vaccinating the broader public sometime in the spring or summer of 2021.

Learn more about Michigan's COVID-19 vaccine plan here.

Source:

- Michigan COVID-19 Vaccination Plan

How many doses will be needed to vaccinate everyone in Michigan? Will there be enough vaccine for everyone?

There may be a limited supply of COVID-19 vaccines before the end of 2020, but supply will continually increase in the weeks and months that follow. While there is limited supply, some groups may be recommended to get a COVID-19 vaccine first.

Experts are working on how to distribute these limited vaccines in a fair, ethical, and transparent way. The Advisory Committee on Immunization Practices (ACIP) – a group of medical and public health experts who review data on new and existing vaccines and diseases – will make recommendations once a vaccine(s) is authorized or approved for use. It is understandable to be concerned about when individuals will be able to receive the vaccine, especially for those who are at an increased risk for serious illness from this virus and for their loved ones.

At first, COVID-19 vaccines may not be recommended for children. In early clinical trials for COVID-19 vaccines, only non-pregnant adults participated. However, clinical trials continue to expand who they are recruiting to participate. Those persons recommended to receive the vaccine could change in the future. That is why, early in the response, the federal government began investing in select vaccine manufacturers to help them increase their ability to quickly make and distribute a large amount of COVID-19 vaccine. This will allow the United States to start with as much vaccine as possible and continually increase the supply in the weeks and months to follow. The goal is for everyone to be able to easily get a COVID-19 vaccine as soon as large quantities are available. As more vaccine arrives, our list of places to receive vaccine will expand to eventually having several thousand vaccination providers available, including doctors' offices, retail pharmacies, hospitals, and federally qualified health centers.

Source:

- CDC: Frequently Asked Questions about COVID-19 Vaccination

Who will be approved to administer the vaccine? Is there any special training for handling the vaccine or the administration itself?

Only providers enrolled in the COVID-19 vaccination program in Michigan can receive and administer vaccines. COVID-19 vaccination providers must have a valid license in order to receive vaccine. License verification is needed for those with prescribing authority who will oversee COVID-19 vaccine administration. Appointed staff of the COVID-19 provider, EMS, and other trained health care personnel can administer COVID-19 vaccine in Michigan working under the direction of a physician.

For further information review the public health code and the Michigan State Medical Society document on scope of practice:

- Michigan's public health code identifies that vaccines must be administered under the direction of a physician.
- The Scope of Practice of Health Professionals in the State of Michigan discusses that the "State of Michigan law holds physicians liable if the health professionals to whom they assign tasks cause patient harm in the course of completing the tasks."

Proper vaccine administration is critical to ensure that vaccination is safe and effective. The U.S. Centers for Disease Control and Prevention (CDC) recommends that all health care personnel who administer vaccines receive comprehensive, competency-based training on vaccine administration policies and procedures BEFORE administering vaccines. CDC has some great materials on training for vaccine administration. Visit the COVID-19 Vaccination webpage for training and educational materials for providers along with information on program implementation, talking to patients, making a strong recommendation, frequently asked questions link, and so much more. The Michigan Department of Health and Human Services (MDHHS) strongly recommends that providers review this webpage and complete the COVID-19 Vaccine Training Module.

CDC also has a resource document that contains a wealth of information about vaccination: COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals. Here are some of the topics that this CDC resource document will link to:

- You Call the Shots: Vaccine Storage and Handling An interactive, web-based immunization training course on storage and handling best practices and principles.
- "Keys to Storing and Handling Your Vaccine Supply" video This video is designed to decrease vaccine storage and handling errors by demonstrating recommended best practices and addressing frequently asked questions.
- Vaccine Storage and Handling Toolkit Comprehensive guide that reflects best practices for vaccine storage and handling from Advisory Committee on Immunization Practices (ACIP) recommendations, product information from vaccine manufacturers, and scientific studies.
- Vaccine Storage and Handling Toolkit, COVID-19 Vaccine Addendum The Vaccine Storage and Handling Toolkit, COVID-19 Vaccine Addendum, provides information, recommendations, and resources on storage and handling best practices to help safeguard the COVID-19 vaccine supply and ensure patients receive safe and effective vaccines.
- Epidemiology and Prevention of Vaccine-Preventable Diseases Comprehensive information on routinely used vaccines and the diseases they prevent. Chapter 5

MDHHS also has a great deal of information that is continually being updated as new information arises. You may find MDHHS's material at our Covid-19 Vaccine Provider Guidance and Educational Resources webpage. At this webpage you will also find our detailed guidance for providers (MDHHS COVID-19 Vaccination Information for Providers), this guidance reviews COVID-19 vaccine storage and handling, along with other Michigan specific information.

Who will be the first to get the vaccine, and who will be eligible after that?

Experts are working on how to distribute these limited vaccines in a fair, ethical, and transparent way, and by evaluating the data on the vaccines and risk levels of various populations.

The initial COVID-19 vaccine(s) will be prioritized for health care personnel and long-term care residents. This will include hospitals, long-term care facilities, outpatient clinics, home health care, pharmacies, emergency medical service providers, public health, skilled nursing facilities, assisted living, and other residential care.

Health care workers will be among the first people in Michigan to get the vaccine. Who in the hospital will get it?

The Advisory Committee on Immunization Practices (ACIP) – a group of medical and public health experts who review data on new and existing vaccines and diseases – have made recommendations about who can receive the vaccine once a vaccine(s) is authorized or approved for use. The State of Michigan is using those recommendations to finalize state-level priority groups. Hospitals and long-term care facilities will work to prioritize and vaccinate those workers who are in higher risk, direct patient care roles in accordance with the ACIP recommendations. Higher priority groups may also include older employees or those with pre-existing conditions that place them at higher risk of severe illness.

Where will people go to get the vaccine?

In the beginning stages of vaccine distribution, the vaccine will be limited to those in phase one. As we receive additional vaccine in the State of Michigan, vaccination providers and services will eventually be expanded to several thousand providers, including doctor offices, retail pharmacies, hospitals, and federally qualified health centers. Michigan is working with the federal government, and local health care providers to prepare sites to receive vaccine as soon as one is approved.

Early in the COVID-19 response, the federal government began investing in select vaccine manufacturers to help them increase their ability to quickly make and distribute a large amount of COVID-19 vaccine. This will allow the United States to start with as much vaccine as possible once a vaccine is approved, and continually increase the supply in the weeks and months to follow. The goal is for everyone to be able to easily get a COVID-19 vaccine as soon as large quantities are available.

Source:

- CDC: Frequently Asked Questions about COVID-19 Vaccination

What is the state doing to help residents understand that the vaccine is safe and effective?

The State of Michigan is partnering with public health, education, business, and industry leaders to communicate about the vaccine.

A COVID-19 vaccine, once available, will be a vital part of Michigan's reopening. Until a significant portion of our population is vaccinated, we will all need to continue some preventative measures such as wearing masks, social distancing, and handwashing to reduce the spread of COVID in our communities. Our best protection from COVID-19 will be to complete the vaccine series, once it is available.

What is the approval process for COVID-19 vaccines?

COVID-19 vaccine approval will be made by medical and scientific experts based entirely on safety and effectiveness data, with any and all political pressure rejected.

The first COVID-19 vaccine(s) might be used under an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA). The EUA authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear threats by facilitating the availability and use of medical countermeasures needed during public health emergencies.

The FDA will review the scientific data and approve the vaccine(s). The Advisory Committee on Immunization Practices (ACIP) – a group of medical and public health experts who review data on new and existing vaccines and diseases – will make recommendations about who can receive the vaccine once a vaccine(s) is authorized or approved for use.

Like with other vaccines, providers will give a fact sheet to all recipients of COVID-19 vaccine so that they receive information on the product, including its safety and side effects.

Source:

- FDA: Emergency Use Authorization for Vaccines Explained

What is the distribution plan for COVID-19 vaccines?

Once a vaccine is approved for use, an initial limited vaccine allocation will be distributed to states for specific priority populations. In the weeks that follow, as vaccine manufacturing increases, more shipments will come in and be distributed to priority populations based on Michigan's allocation plan.

Sources:

- Michigan COVID-19 Vaccination Plan
- Operation Warp Speed Vaccine Distribution Process

How much will people have to pay to get the vaccine?

No fees will be charged to get vaccinated. There will be no cost sharing from insurance plans. Vaccine doses purchased with U.S. taxpayer dollars will be given to the American people at no cost. COVID-19 providers agree to administer vaccine regardless of an individual's ability to pay and regardless of their coverage status, and may not seek any reimbursement, including through balance billing, from a vaccine recipient. However, vaccine providers will be able to charge administration fees for giving or administering the shot to someone. Vaccine providers can get this fee reimbursed by the patient's public or private insurance company or, for uninsured patients, by the Health Resources and Services Administration's Provider Relief Fund.

Source:

- MDHHS COVID-19 Vaccine Information for Providers

What are the transportation and storage considerations for COVID-19 vaccines in Michigan?

The current vaccines pending approval have very cold storage requirements. To address this, the vaccine will be shipped in special storage containers, including dry ice, that should keep the vaccine at the appropriate ultracold temperature. To learn more about storage and handling of the first two COVID-19 vaccines submitted for approval, review the MDHHS COVID-19 Vaccine Information for Providers.

Will there be a statewide COVID-19 vaccine mandate?

No, there is no plan for the state to mandate that health care workers or the public get the COVID-19 vaccine.

We don't talk about "herd immunity" for protection against influenza or other common viral infections, so why is it discussed so much with COVID?

Herd immunity is a concept used in public health to describe a situation in which the more people in a community that are immune to a particular virus, the fewer people are available for that virus to infect. As the infectious agent spreads through a community, it has more trouble finding susceptible people if most of those around them are immune. We rely on herd immunity for viruses such as measles, rubella, polio, and chickenpox, among others, even if we are not having conversations about it. Influenza is more difficult because the virus changes so much from one year to the next, so new vaccines are developed each year to try to address the strains that might be the most common.

Related to COVID-19, herd immunity has been discussed more frequently for a couple of reasons. First, because this is a completely new virus, virtually no one has existing immunity. People can become immune to SARS-Co-V2, the virus that causes COVID-19, in two ways —

through getting the disease or through vaccination. Conversations have been about both of these concepts:

- As vaccines are developed, one way to describe how well a vaccine works is to describe how many people would need to be immunized to achieve herd immunity.
- Some people have discussed a "herd immunity" strategy for addressing the pandemic, which would involve the vast majority of people in a community contracting COVID-19. Unfortunately, there are dangers involved with this because:
    - The disease is more fatal than a virus like influenza.
    - We don't know who will become severely ill if infected.
    - If too many people get sick at the same time, we will overwhelm medical resources.
    - We don't know everything we need to know about how long immunity lasts following infection; we don't understand the long-lasting effects of infection; and we have limited treatments at this stage (although we are learning more every day).

Herd immunity through vaccination is the safest and most effective way to protect our communities from disease.

Source:

- Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines

Getting Vaccinated

How will a person who has received the COVID-19 vaccine know if they are experiencing side effects or actual symptoms of the virus?

Sometimes after vaccination side effects can occur such as fever, headache, and muscle aches. These symptoms are normal and are a sign that the body is building immunity. Because these are also symptoms of COVID-19 disease, it can be difficult to distinguish an immune response due to vaccination from actual symptoms of the virus. However, a vaccine immune response generally occurs soon after vaccination, is mild, and last 2-3 days. This is a sign that the immune system is working.

If the symptoms are not mild and last more than a few days, it would be recommended to contact your health care provider. It typically takes a few weeks for the body to build an immune response. It is possible that a person could be infected with the virus that causes COVID-19 just before or just after vaccination and then get sick before the vaccine has had time to provide protection.

Will the initial vaccine that is going through the EUA process be for all adults and children? If not, why not, and when do you anticipate a vaccine for kids, pregnant women, and other populations?

There may be a limited supply of COVID-19 vaccines before the end of 2020, but supply will continually increase in the weeks and months that follow. While there is limited supply, some groups may be recommended to get a COVID-19 vaccine first.

At first, COVID-19 vaccines may not be recommended for children. In early clinical trials for COVID-19 vaccines, only non-pregnant adults participated. However, clinical trials continue to expand those recruited to participate. The groups recommended to receive the vaccines could change in the future.

As with most vaccines, studies will need to be conducted in children and in pregnant women, but these studies are often done after the vaccine has been shown to work and be safe in healthy adults. This will be particularly important since we have seen that children may not be affected in the same way by COVID-19 infections. Some studies have recently started in older children but will lag behind studies in adults and will gradually be expanded to include younger children.

Source:

- Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines

What are the most common side effects, if any, from a COVID-19 vaccine?

Most people do not have serious problems after being vaccinated. We will understand more about mild side effects of the COVID-19 vaccine before we start to use it and as the vaccine recommendations come out.

Some studies have begun to show that COVID-19 vaccines may be more reactogenic than other vaccines that people are familiar with. Some side effects that have been reported are a sore arm, redness, or warm to the touch. Also, some have reported a low-grade fever, headache, and a general feeling of "not feeling like their self". These are all signs that the immune system is doing exactly what it is supposed to, which is produce an immune response in order to develop protection against disease. This is a normal response in the process of building immunity.

Source:

- CDC COVID-19 Vaccination Answering Patients' Questions

How many doses of a COVID-19 vaccine will be needed? Will a booster dose be needed?

The COVID-19 vaccines being studied are evaluating one or two doses. Currently, the COVID-19 vaccines pending approval are two doses. When giving two doses, they are usually given one or two months apart. As each vaccine is approved for use, we will learn more about the number of doses needed for each vaccine and the intervals between doses when two doses are needed.

It is possible that over time, additional doses of vaccine may be needed to provide continued protection. It will take ongoing evaluation over several months and years to understand how our immune systems respond to this virus and how vaccines assist in that response.

Source:

- Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines

How long will vaccine immunity last?

COVID-19 is still a very new virus and has only existed for about a year. Experts are still researching COVID-19 immunity. Since we do not yet know how long immunity after infection lasts, immunity following vaccination will also have to be determined. Likewise, immunity following vaccination will depend in part on which types of vaccines are licensed, what part of the immune system responds to the vaccine, and the level of immunity that is generated by the vaccine. These factors and more will be studied in the ongoing monitoring of the phase III trials.

Source:

- Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines

If I've had COVID-19 and recovered, will I still be able or need to get the vaccine?

Right now, we do not know how long antibodies last after infection. There is not enough information currently available to say if or for how long after infection someone is protected from COVID-19, which is also known as natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this. However, we will not know if it will be recommended for those who have had and recovered from COVID-19 until we receive the official recommendations.

To learn more, the vaccine trials have included immunizing people who have never been infected with SARS-CoV-2 as well as those who were previously infected. We will soon know whether vaccination of those who were previously infected affords more complete or longer lasting protection than those who were previously infected but haven't been vaccinated.

Sources:

- CDC: Frequently Asked Questions about COVID-19 Vaccination
- Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines

Can we give COVID-19 vaccine to a person sick with COVID-19?

Currently, there is not a COVID-19 vaccine available, so we do not have information about when the vaccine will be recommended to be given and to whom. However, we anticipate that the guidance will depend on the degree of illness. Typically, the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) will make this clear in its "precautions and contraindications" advice regarding each of these vaccines.

Source:

- Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines

If a person is vaccinated against COVID-19, will they still be able to spread the virus to susceptible people?

If an individual is vaccinated and they are protected from all forms of infection (asymptomatic to severe), they will not transmit the virus to someone else. However, it is expected that COVID-19 vaccines may protect against severe infection, but not necessarily prevent mild or asymptomatic infection. If this is the case, a vaccinated person could still spread the virus if they are infected. This is why it is expected that even after a vaccine becomes available, people will need to use masks and practice social distancing measures for some time.

Source:

- Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines

If more than one vaccine becomes available, could taking two different vaccines boost the effectiveness?

At least at first, COVID-19 vaccines will not be interchangeable. Three scenarios can occur if a person is vaccinated with two versions of vaccines against the same disease particularly close in time:

- They get a stronger immune response. An example of this was when children got inactivated polio vaccine and later got oral polio vaccine.
- The second vaccine causes immunity that would be similar to receiving a second dose of the original vaccine. Using a different brand of hepatitis B vaccine for one or more doses would be an example of this.
- The immune response generated by the first vaccine interferes with components of the response to the second vaccine, in some cases causing lower immunity.

For these reasons, studies will need to be done to determine the effects of getting a second type of COVID-19 vaccine shortly after receiving a different one. If, however, we find that COVID-19 vaccines are like influenza vaccines and we need to get vaccinated annually, concerns about switching types from one year to the next are less likely to be an issue.

Source:

- Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines

Will a coronavirus vaccine need to be given annually?

When a vaccine is licensed, we will only have information about length of immunity for as long as we are from the trials. For example, if the first people in the study were vaccinated in July 2020 and the vaccine is licensed in December 2020, we will only have information about the immune response up to 5 months after vaccination. The vaccine manufacturer will continue to monitor vaccine recipients for several months or more, so that over time, we will continue to get a better picture of the duration of immunity. With this information, we will be better able to understand whether vaccines against COVID-19 will require an annual vaccine.

Source:

- Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines

How long before a coronavirus vaccine takes effect?

Generally speaking, it takes approximately two weeks for immunity to develop following vaccination, but the specific timeline for any coronavirus vaccine will depend to some extent on which type of vaccine is licensed. For example, a live, weakened vaccine requires time to reproduce in the body, whereas an inactivated vaccine is given at a dose that will generate

immunity. On the other hand, because the live, weakened vaccine reproduces to generate immunity, it might provide a more robust immune response than an inactivated vaccine.

Source:

- Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines

When can I stop wearing a mask and avoiding close contact with others after I have been vaccinated?

There is not enough information currently available to say if or when U.S. Centers for Disease Control and Prevention (CDC) will stop recommending that people wear masks and avoid close contact with others to help prevent the spread of the virus that causes COVID-19. Experts need to understand more about the protection that COVID-19 vaccines provide before making that decision. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will also affect this decision.

While experts learn more about the protection that COVID-19 vaccines provide under real-life conditions, it will be important for everyone to continue using **all the tools** available to us to help stop this pandemic, like covering your mouth and nose with a mask, washing hands often, and staying at least 6 feet away from others. Together, COVID-19 vaccination and following CDC's recommendations for how to protect yourself and others will offer the best protection from getting and spreading COVID-19.

Source:

- CDC: Frequently Asked Questions about COVID-19 Vaccination

Safety Monitoring & Tracking

How is Michigan and the federal government tracking who has received a vaccine and any side effects people experience?

COVID-19 vaccine providers in Michigan are required to enter vaccine administration information into the patient medical record and to the Michigan Care Improvement Registry (MCIR) within 24 hours. MCIR is an immunization database that tracks the immunizations given to Michiganders throughout life.

Vaccine safety has been and will continue to be one of Michigan's and U.S. Centers for Disease Control and Prevention's (CDC) top priorities. Once COVID-19 vaccines are made available in the United States, we will rely on existing and new systems:

- Vaccine Adverse Event Reporting System (VAERS)—A national reporting system to detect possible safety problems with vaccines. VAERS is not designed to detect whether a vaccine caused an adverse event (AE), but it can identify "signals" that might indicate possible safety problems requiring additional investigation. COVID-19 vaccination providers are required to report to VAERS any adverse event.
- New system, called V-safe—A smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after someone receives a COVID-19 vaccination. Through V-safe, vaccine recipients can quickly tell CDC if they have any side effects after getting the COVID-19 vaccine. Depending on their responses, CDC may follow up with them by phone to get more information. V-safe will also remind them to get their second COVID-19 vaccine dose, if needed.

After a vaccine is authorized or approved for use, many vaccine safety monitoring systems watch for adverse events (possible side effects). This continued monitoring can pick up on adverse events that may not have been seen in clinical trials. If an unexpected adverse event is seen, experts quickly study it further to assess whether it is a true safety concern. Experts then decide whether changes are needed in U.S. vaccine recommendations. This monitoring is critical to help ensure that the benefits continue to outweigh the risks for people who receive vaccines.

Learn more about these safety monitoring systems here.

Source:

- CDC: Ensuring the Safety of COVID-19 Vaccines in the United States

How will we know if a COVID-19 vaccine is safe?

Given that COVID-19 vaccines were made quicker than other vaccines, it is understandable to be concerned about their safety. COVID-19 vaccine approval will be a medical and scientific

approval based entirely on safety and effectiveness data, with any and all political pressure rejected. A vaccine will not be approved unless it has been proven to be both safe and effective.

While mild side effects have been reported, there is no evidence to suggest that the vaccines that have submitted applications for approval are not safe. Sometimes after vaccination mild side effects can occur such as fever, headache, and muscle aches. These symptoms are normal and are a sign that the body is building immunity and the vaccine is working.

What are the long-term effects of an mRNA vaccine?

Long term side effects of mRNA vaccines remain theoretical and there is no evidence to support them at this time. While the early vaccines use a technology that is new to vaccination, the mRNA technology is asking our cells to do something they do every day: create proteins to do different work in our bodies.

There are currently no licensed mRNA vaccines in the United States. However, researchers have been studying and working with them for decades. Beyond vaccines, cancer research has used mRNA to trigger the immune system to target specific cancer cells. mRNA technology has been used successfully for cancer immunotherapy by harnessing the body's immune system to identify and kill cancer cells in the same way the immune system identifies and targets infection from viruses or diseases.

Sources:

- CDC: Understanding mRNA COVID-19 Vaccines

What ingredients will be in a COVID-19 vaccine?

The ingredients that will be used in a COVID-19 vaccine will depend on the type of vaccine. As vaccines are approved, better answers will become available because that is part of the information that companies submit during the approval process.

Source:

- Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines

Can mRNA vaccines change the DNA of a person?

mRNA vaccines do not affect or interact with our DNA in any way. mRNA never enters the nucleus of the cell, where our DNA (genetic material) is kept. Our bodies naturally break down and get rid of mRNA after it has been used to develop a piece of protein to build immunity.

Source:

- CDC: Understanding mRNA COVID-19 Vaccines