



County of Bucks

POLICE TRAINING CENTER

1760 S. EASTON ROAD, DOYLESTOWN, PA 18901
PHONE 215-340-8410 -- FAX 215-343-6794



County Commissioners

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ROBERT J. HARVIE, JR., Vice Chair

GENE DIGIROLAMO

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Director

In late 2019, a new coronavirus, SARS-CoV-2, was identified in China. The new virus had two important features. First, it could infect people. Second, infected people could easily spread the virus to others. These characteristics set the stage for a COVID-19 pandemic, or worldwide epidemic, which was declared by March 2020. Knowing the important role that vaccines would play, scientists, pharmaceutical companies and governments immediately started working to develop COVID-19 vaccines. With unprecedented speed, and fortuity, the first vaccines were ready by December 2020. Because vaccines typically take years — if not decades — to create, some wondered whether this shortened timeline affected COVID-19 vaccine safety.

Q. Are mRNA vaccines effective?

A. Two companies, Pfizer and Moderna, have made mRNA vaccines. Both vaccines were found to be about 95% effective at preventing COVID-19. This high level of protection extended to people over 65, people with a variety of medical conditions that put them at risk of severe disease, and people with different racial and ethnic backgrounds. Both vaccines were released to the public in December 2020. During 2021 and 2022, studies will determine whether this high level of protection lasts.

Q. Can mRNA vaccines change a person's DNA?

A. No. In order for mRNA to alter someone's DNA, several events would need to occur. First, mRNA would need to enter the cell nucleus, where DNA resides. However, mRNA does not have the nuclear access signals that would allow it to enter. Put quite simply, mRNA vaccines can't get into the nucleus. Second, even if mRNA did enter the nucleus, it would have to be converted to DNA. This would require an enzyme called reverse transcriptase, which the mRNA vaccines don't contain. Third, the mRNA vaccines don't contain an enzyme called integrase, which would also be needed for mRNA to insert itself into the DNA. In short, the mRNA vaccines lack all

of the basic requirements necessary to alter DNA. They remain in the cell cytoplasm for just a few days before they are destroyed. One other thing to remember is that there are more than 200,000 cellular mRNAs making a host of proteins and enzymes. The mRNA vaccines introduce only a few copies of mRNA into cells

Q. What is mRNA?

A. mRNA stands for messenger RNA, which is the blueprint for making proteins. DNA, which lives in the nucleus of cells, makes mRNA and ships it

outside the nucleus to the surrounding cell cytoplasm. Once in the cytoplasm, mRNA is translated into a host of cell proteins and enzymes. Because our cells make proteins all the time, they also make mRNA all the time. Soon after making proteins, mRNA breaks down.

Q. How do mRNA vaccines work?

A. COVID-19 mRNA vaccines take advantage of the cellular process of making proteins by introducing mRNA that contains the blueprint for one of the coronavirus proteins, specifically the spike protein. This is the protein that attaches coronavirus to our cells. If we can prevent virus-cell

attachment by making antibodies against the spike protein, then we can prevent coronavirus from infecting cells. The mRNA that codes for the SARS-CoV-2 spike protein is taken up by specialized cells of the immune system, called dendritic cells, which put small pieces of the spike protein on their surface, travel to a nearby lymph node, and stimulate other cells of the immune system (B cells) to make antibodies. This is why some people who get the mRNA vaccine have swelling in the lymph nodes under the arm that was inoculated. The antibodies made during this process prevent virus-cell attachment in the future.

Q. Who should get the COVID-19 mRNA vaccine?

A. Because SARS-CoV-2 virus can affect all people in all age groups, most people should get the COVID-19 vaccine, once supplies allow for their priority group to be vaccinated.

Q. Who should NOT get the COVID-19 mRNA vaccine?

A. A few groups should not get the vaccine, and some others should consult with their doctor or follow special procedures.

People who should NOT get the COVID-19 vaccine

- Anyone with a severe allergy to an mRNA vaccine component (i.e., one that causes anaphylaxis or requires medical intervention).
- Those younger than 16 years of age.
- People currently isolating or experiencing symptoms of COVID-19. These people can get vaccinated once they have finished isolation and their primary symptoms have resolved.

People who may get the vaccine after considering risks, benefits, and consulting with their healthcare provider

- Individuals with a history of severe allergy to any vaccine or injectable medication
- Pregnant women
- People with certain immune-compromising or autoimmune conditions
- Breastfeeding women
- People on anticoagulants

People who should follow special procedures

- Someone with a history of severe allergy (requiring medical intervention) to anything other than a vaccine or injectable medication can get the vaccine, but they should remain at the vaccination location for medical observation for 30 minutes after receipt of the vaccine.
- Pregnant women who develop a fever after vaccination should take acetaminophen.
- People who recently had COVID-19 and were treated with antibody-based therapies (e.g., monoclonal antibodies or convalescent plasma) should wait until 90 days after treatment to be vaccinated.
- People with a known COVID-19 exposure should wait until their quarantine is over before getting vaccinated (unless they live in a group setting, such as a nursing home, correctional facility, or homeless shelter, in which case they can be vaccinated during the quarantine period).
- People who got another vaccine (non-COVID-19 vaccine) should wait at least 14 days before getting COVID-19 vaccine. Likewise, if a person got the COVID-19 vaccine, they should wait at least 14 days before getting any other vaccines (non-COVID-19 vaccines).

Q. How many doses of a COVID-19 mRNA vaccine are needed?

A. The mRNA vaccines require two doses. For the Pfizer vaccine, doses should be separated by 21 days. For Moderna's vaccine, doses should be separated by 28 days. The two mRNA vaccines are NOT interchangeable. A person should be sure they know which one they got as the first dose and be clear about when they should return for the second dose, particularly because both doses of the vaccine are required to have the best protection. However, even if more than the recommended time interval has elapsed between the first and second dose, the series doesn't need to be restarted. It can just pick up where it was left off.

Q. Can pregnant women get the COVID-19 mRNA vaccine?

A. Pregnant women were not included in the early COVID-19 vaccine studies, but some participants were either pregnant and did not know it or became pregnant during the course of the study. About two dozen women found out they were pregnant during the Pfizer vaccine trial and one dozen during the Moderna vaccine trial. As a result, we only have a small amount of data regarding the safety of these vaccines in pregnant women. The good news is that in this small group of women, no concerns were found and the vaccine worked, but it will be important to get data on larger numbers of women moving forward. Despite the limited amount of data, both the Centers for Disease Control and Prevention (CDC) and the American College of Obstetricians and Gynecologists (ACOG) have recommended that pregnant women who are part of a group recommended to get the COVID-19 vaccine may be vaccinated if they choose to do so. These women should be supported in their decision-making efforts by their doctors and be provided with information related to the potential risks and benefits, but they do not have to wait to have a

consultation with their healthcare provider before being vaccinated if they are comfortable doing so. Two factors, in addition to the limited vaccine data, were important for informing these recommendations. First, some pregnant women will be at high risk for COVID-19, such as healthcare workers or those with certain health conditions. Second, pregnant women are at increased risk of developing complications, compared with their nonpregnant peers, when infected with COVID-19.

All pregnant women should know these two things:

1. Pregnant women who decide to get the COVID-19 vaccine should take acetaminophen if they develop a fever after vaccination, as fever during pregnancy can negatively affect a developing baby. Taking acetaminophen during pregnancy has been found to be safe.
2. Likewise, regardless of whether a pregnant woman decides to be vaccinated, she should practice recommended public health measures, particularly because of the increased risk to pregnant women infected with COVID-19.

Q. Can I get the COVID-19 mRNA vaccine if I am trying to get pregnant?

A. Yes. Women who are trying to get pregnant can get the vaccine. Likewise, if a woman gets the first dose and then finds out she is pregnant, she can still get the second dose on time.

Q. Are mRNA vaccines safe?

A. Yes. But, both mRNA vaccines do cause side effects as a consequence of the immune response to the SARSCoV-2 spike protein produced by the mRNA. Side effects occur more often after the second dose and are more common in people younger than 55 years of age. In some ways, the more

vigorous the immune response, the more common the side effects.

The most common side effects from the mRNA vaccines are:

- Fatigue
- Headache
- Muscle aches
- Low-grade fever
- Chills
- Joint pain

Typically, these side effects last for only one or two days. Although most people will not have significant side effects, some people may wish to schedule their vaccination, so that they will not need to call out of work the next day if they don't feel well.

Q. What are the expected long-term side effects of the vaccination for COVID-19?

A. The vaccine is not expected to have long-term negative effects for a few reasons:

- First, most negative effects occur within 6 weeks of receiving a vaccine, which is why the FDA asked the companies to provide 8 weeks of safety data after the last dose.
- Second, the mRNA in the vaccine breaks down pretty quickly because our cells need a way to stop mRNA from making too many proteins or too much protein.
- But, even if for some reason our cells did not breakdown the vaccine mRNA, the mRNA stops making the protein within about a week, regardless of the body's immune response to the protein.

Q. What ingredients are in the mRNA vaccines?

A. The mRNA vaccines contain: mRNA – The mRNA is for the spike protein of SARSCoV-2, the virus that causes COVID-19.

Lipids – These are molecules that are not able to dissolve in water. They protect the mRNA so that it does not break down before it gets into our cells. These lipid particles can be thought of as little “bubbles of fat” that surround the mRNA like a protective wall and make it easier for the mRNA to enter cells.

Salts – Salts, similar to table salt, are used to keep the pH of the vaccine close to that found in the body, so the vaccine does not damage cells when it is administered.

Sugar – This ingredient is the same as the sugar you put in your coffee or on your cereal. In the vaccine, it helps keep the “bubbles of fat” from sticking to each other or to the sides of the vaccine vial.

mRNA vaccines do NOT contain:

- Blood products
- Antibiotics
- DNA
- Fetal cells
- Pork products
- Egg proteins
- Preservatives (e.g., thimerosal)

Q. If I had COVID-19, do I need the vaccine?

A. Yes. People who had COVID-19 are recommended to get the vaccine after they have recovered. The Pfizer vaccine trial included people who were previously infected with SARS-CoV-2, and the vaccine was found to be safe and highly effective. Because we do not know how long antibodies last after infection and a small number of people have had more severe second bouts of infection, the vaccine can be beneficial in boosting a person's existing immunity from infection.

Q. Can a person spread the virus after they are vaccinated against COVID-19?

A. mRNA vaccines against COVID-19 have been shown to be highly effective at preventing disease, but they might not prevent infection without symptoms. What this means is that if a vaccinated person can

still be infected, even without symptoms, they could spread the virus. Studies will soon be completed to determine whether this is possible. However, given this uncertainty, vaccinated people should still use masks

Q. Does a vaccinated person present a risk to unvaccinated family members in the same house?

A. The mRNA vaccines are not composed of live viruses, so there is no infectious virus to spread from a vaccinated person to someone else. But, we do not yet know if a vaccinated person who encounters the virus can still experience what is referred to as “asymptomatic infection.” An asymptomatic infection occurs when a person is exposed to the virus in the community and the virus can still replicate in their body, but they don’t have symptoms because their immune system stifles the infection as a result of vaccination. In this scenario, the person could potentially spread the virus without even knowing they are infected.

Given that families may not all get vaccinated at the same time, those who have been vaccinated should continue to practice public health measures when they are out in the community to decrease the chance of introducing the virus in the home through asymptomatic infection. Likewise, even when a whole family is vaccinated, continuing to practice these measures will be important for two reasons:

1. The vaccine will not work for everyone, so someone in the home who has been vaccinated may still be susceptible.
2. People outside of the family’s “bubble,” like co-workers, extended family members, neighbors, and others they come into contact with, may not have been vaccinated (or may be in the group for whom the vaccine does not work).

This approach will be important until we can get control over the spread of virus. Once enough people have been vaccinated to slow the spread of the virus, we will all be able to move away from these public health measures. But, for now, we need to continue working together to decrease spread of the virus by masking, physical distancing, handwashing, and getting vaccinated.

Q. Is it safe to get the COVID-19 vaccine if I have COVID-19 and don’t know it?

A. The CDC does not recommend testing prior to vaccination because it would be very difficult to coordinate and there is no reason to suspect that there would be an issue. For example, we give vaccines for measles, chickenpox, and rabies after a person has been exposed (meaning when they are already infected), and there are not issues. Likewise, the Pfizer clinical trials included people who did or did not have COVID-19 previously and some people got the virus during the study. These situations did not present any issues of concern either.

Q. Can I drink alcohol after getting the COVID-19 vaccine?

A. Alcohol suppresses the immune system, so it would be advisable not to drink alcoholic beverages for about 2 weeks after getting vaccinated.

Q. How long will vaccine immunity last?

A. We do not yet know how long immunity lasts after infection or vaccination:

- Infection - Scientists are working to learn more about immunity following infection. While some people have been re-infected after recovering from COVID-19, the number of people who have experienced this is small compared with the total number of people who have been infected. Likewise, although the virus has been changing since it was first recognized, antibodies from people who were

sick early during the pandemic are still effective against the slightly modified version. For these reasons, scientists are hopeful that people will be protected for one or more years.

- Vaccination - Clinical trial participants will be monitored to understand how long immunity lasts after vaccination.

Q. Will booster doses or annual vaccines be needed?

A. Since the first people in the trials were vaccinated at the end of July 2020 and the first vaccines were approved in December 2020, we only have information about protection against disease for a few months after vaccination. The degree to which these vaccines protect against COVID-19 one or two years after vaccination will be determined later. Trial participants will continue to be monitored, so we will learn more, but we do not yet know whether booster doses will be needed.

Q. Does the mutation of coronavirus affect the capacity of vaccines to prevent disease?

A. Viral mutations can cause vaccines to be less effective, such as we see with the influenza virus, so it is reasonable to wonder whether changes to SARS-CoV-2 will affect COVID-19 vaccines. Although SARS-CoV-2 is constantly mutating, the critical question is does the virus's mutation change function, making the virus more or less virulent or more or less contagious. So far, the virus that causes COVID-19 does not appear to have functionally changed in an important way. But, it does happen and at some point a change could affect how well a vaccine works. Right now, that does not appear to be happening. For example, recent changes enabled the virus to spread more easily, but those changes do not appear to make people sicker and the vaccine appears to protect against the newer version. Likewise, antibodies from people who had an earlier

version of the virus are still able to protect against the newer version. In other words, at least to date, the virus hasn't mutated away from the approach taken to combat COVID-19 with vaccines.

Q. Does the mRNA vaccine cause fertility issues?

A. Infertility has not been found to be an issue in women infected with COVID-19, so it would not be expected to be a concern for the vaccine.

Concerns about antibodies generated by the COVID-19 vaccine attacking syncytin-1, a protein associated with the placenta during pregnancy, are unfounded. The claims, which circulated online, were based on a small number of similar amino acids in the two proteins, but the overlap is not sufficient to cause such a reaction.

Q. Will the COVID-19 vaccine interact with other medications?

A. Generally speaking, with an approved vaccine it should not have interactions with other medications. It is recommended that patients discuss the vaccine with their physician before receiving it.

References

Children's Hospital of Philadelphia Vaccine Education Center. (2021, January 12). Retrieved from Children's Hospital of Philadelphia : <https://media.chop.edu/data/files/pdfs/vaccine-education-center-covid-qa.pdf>