COLORADO
Department of Public Health & Environment

COVID-19
Vaccine FAQ

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Getting a COVID-19 vaccine

Who is going to get the first round of vaccines?

- The first delivery of the Pfizer vaccine will provide 46,800 vaccine doses. These vaccines will go to health care workers who are treating COVID-19 patients. These workers have been on the front lines since the beginning of the pandemic and are directly exposed to COVID-19 as part of their job. Protecting the people who care for COVID-19 patients will help us save lives until the vaccine becomes widely available.

How were the first locations to receive the first round of vaccines decided?

- The Colorado Department of Public Health and Environment (CDPHE), in close collaboration with local public health agencies across the state, has identified 24 locations with ultra low temperature freezers to receive the first shipment of an ultra cold vaccine. CDPHE has purchased and distributed an additional 10 ultra low temperature freezers.
- The identified locations across the state were chosen for their unique abilities to store, monitor, and handle vaccines in ultra-cold temperatures (-60°C to -80°C) as well as their willingness to redistribute COVID-19 vaccine(s) to other Phase 1 providers in their regions. The state also considered equitable geographic distribution as well as transportation logistics given expected winter conditions in the coming months.

Where do I get the vaccine?

- The majority of early phase 1 recipients will receive the vaccine through their employer, local public health agency or through the federal government's Pharmacy Partnership for Long-term Care (LTC) Program.
- More information about provider settings and options for phase 2 and phase 3 recipients will be coming soon.
- If you are among the people in phase 1A and are not receiving the vaccine through your employer, contact the vaccine distribution location nearest you for more information.
- For additional questions about where you can receive vaccine or who to contact in your community call COHELP (1-877-462-2911).

What types of COVID-19 vaccine(s) are available? Will I get to choose?

- There are multiple COVID-19 vaccine candidates. The U.S. Food and Drug Administration (FDA) must authorize any vaccine before it will be available to Coloradans. The pharmaceutical companies Pfizer and Moderna applied for authorization through an Emergency Use Authorization. The FDA authorized the Pfizer vaccine on December 11 and is expected to authorize the Moderna vaccine soon. which will likely be granted by the FDA. The Pfizer and Moderna vaccines will be the first to be distributed in the state. Other companies are still going through the clinical research process. Pfizer and Moderna report that both vaccines are around 95% effective.
- CDC provides detailed profiles for each available vaccine on their Different COVID-19 Vaccines page.

How many doses or shots is the COVID-19 vaccine?

- Both the Pfizer and Moderna COVID-19 vaccines require two doses. The Pfizer vaccine will require two doses 21 days apart; the Moderna vaccine will require two doses 28 days apart. COVID-19 vaccines are not interchangeable. The second dose of any COVID-19 vaccine must be completed with the same vaccine product as the first dose.

Do I have to get the second dose of the vaccine at the same location where I got my first dose?

- We strongly recommend that you get both doses from the same vaccine provider. Because of limited vaccine supply, your vaccine provider will need to place the order for your second dose after administering your first dose. This process ensures that the state's weekly allocation from the federal government will have enough second doses of the same vaccine product at the right time.
- Note that the second dose of any COVID-19 vaccine must be the same vaccine product as the first dose.

When can my family and I get the vaccine?

- After the FDA authorizes a vaccine and the Advisory Committee on Immunization Practices (ACIP) makes recommendations for its use, we expect it will take several months before everyone who wants one can get one because of limited availability. Prioritizing health care workers who have been on the front lines of the pandemic and are directly exposed to COVID-19 as part of their jobs will help us save lives in the next few months.
- Until the vaccine is widely available and used, it is important to continue taking precautions to slow the spread of the virus, like wearing masks and practicing physical distancing.
- At least initially, we expect that the COVID-19 vaccines will only be authorized for use in adults. Safety and effectiveness data from clinical trials is still needed before the vaccine is available for children or pregnant adults.
- Stay up to date about vaccine distribution in Colorado at covid19.colorado.gov/vaccine.

Where can we get the vaccine?

- Visit the When can I expect to get a vaccine page for more information about who is eligible in phase 1A.

How much will the COVID-19 vaccine cost?

- Cost will not be an obstacle to getting the vaccine for Coloradans. Medicare, Medicaid, CHP+ and private insurance are required to cover the cost of the COVID-19 vaccines. In addition, uninsured Coloradans will have access to free vaccines.

What should I do if I'm asked to pay for the vaccine?

- Providers will not be allowed to turn away an individual because of their inability to pay or current medical coverage status. Medicare, Medicaid, and private insurance are required to cover the cost of the COVID-19 vaccines. If you do not have health insurance, providers may seek reimbursement through the Provider Relief Fund administered by the Health Resources and Services Administration (HRSA).

Can I get COVID-19 from a vaccine?

- A COVID-19 vaccine will give you protection against the disease without having to get sick with the actual virus. It is not possible to get COVID-19 from a vaccine, but it is possible to get symptoms that are consistent with COVID-19. The vaccine candidates use inactivated virus, parts of the virus (e.g., the spike protein), or a gene from the virus. None of these can cause COVID-19. The goal of the vaccine is to provide your body with the tools it needs to fight the COVID-19 virus if you were to get infected.

Will I be protected from COVID-19 if I only receive the first dose?

- It is very important to get both doses of the vaccine so that your body develops enough antibodies to fight the COVID-19 virus if you get infected at a later time.
- Getting more than one dose for a vaccine is not unusual. In fact, it's the norm. Many routine vaccines require more than one dose for maximum protection.

Will the vaccine still be effective if I wait more than a few weeks between my first and second doses?

- It is very important that you receive the second dose of your COVID-19 vaccine on time.
- The time frame between the vaccine's first and second dose is determined by the companies producing the vaccine to maximize your body's ability to create antibodies against the virus. Plan accordingly so that you are able to get the second dose of your vaccine at the right time.

Is there a non-injectable version of the vaccine?

- While the first vaccines that will be available in the U.S. will be injectable vaccines, there are other COVID-19 vaccines in research and development that will use non-injectable delivery methods. The timing and effectiveness of these potential vaccines is not yet known.

Does the vaccine protect against all strains of COVID-19?

- While there are several known variants of COVID-19, current evidence suggests the vaccine will protect against all of them.

What are the side effects of the vaccine?

- The most commonly reported side effects for the Pfizer COVID-19 vaccine are pain and redness at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever for 1-2 days after receiving the vaccine. Side effects may differ among other COVID-19 vaccines.
- The process of building immunity can cause symptoms. These symptoms are normal and show that your body's immune system is responding to a vaccine. Other routine vaccines, like the flu vaccine, have similar side effects.
- Clinical trial participants for COVID-19 vaccine reported that the discomfort from side effects went away after a day, sometimes sooner. The discomfort can be more pronounced after the second dose of the vaccine.
- If you experience discomfort after the first dose of the vaccine, it is very important that you still receive the second dose a few weeks later for full protection.
- For in-depth information about the side effects of the Pfizer vaccines, see the FDA's briefing materials on the vaccine's clinical trials.

Are there any serious side effects of receiving the COVID-19 vaccine?

- Decades of vaccine research demonstrates that most serious side effects generally occur within six weeks of administering a vaccine. For the COVID-19 vaccines, the FDA has required clinical trials to provide data from eight weeks of safety monitoring following the second dose before considering the authorization of a vaccine for public use.
- Because this is a new vaccine, researchers will be learning more about rare side effects, if any, over the next year. To identify side effects that happen only very rarely (e.g., once in 50,000 doses), hundreds of thousands of people need to be vaccinated and followed over time.
- The FDA and CDC will continue to closely monitor vaccine safety as the public begins using a new vaccine. Both agencies have both longstanding and new safety systems in place for heightened monitoring of all COVID-19 vaccines. Learn more about the vaccine safety monitoring systems.

Will the vaccine have any effect on fertility?

- Because this is a new vaccine, researchers will be learning more about rare side effects, if any, over the next year. To identify side effects that happen only very rarely (e.g., once in 50,000 doses), hundreds of thousands of people need to be vaccinated and followed over time.

What would happen if a vaccine turned out to have serious side effects?

- Science shows that generally the most serious side effects occur within six weeks of vaccine administration. The current available COVID-19 vaccines have been studied for longer than six weeks, and the companies have not identified or reported serious safety concerns. To date, the independent safety monitoring board overseeing Phase 3 trials of the Pfizer and Moderna vaccines has not found any serious safety concerns. The FDA reviews all research before authorizing any vaccine for use.
- The FDA and CDC will continue to closely monitor vaccine safety as the public begins using a new vaccine. If safety monitoring reveals new information about vaccine risks, such as new serious side effects, a vaccine may be removed from the market. Learn more about the vaccine safety monitoring systems.

How much of my personal information will I need to share to get the vaccine?

- Your privacy is a top priority, and your information won't be used for anything other than vaccine distribution and follow-up information about the vaccine. Like other routine vaccinations, you will need to share some personal information with your vaccine provider when you get a COVID-19 vaccine. This may include your name, date of birth, and contact information.
- Sharing your identity and some of your medical history ensures that the vaccine is administered safely, effectively, and responsibly. Your immunization records are

confidential, personal medical information, and public health will never share them publicly.

- The state health department maintains the Colorado Immunization Information System (CIIS), a confidential, population-based, secure computerized system that collects and consolidates individual-level vaccine and exemption data for Coloradans of all ages from a variety of sources. Health care providers have limited access to CIIS based on their need to input and access data for their patients.
- Under Colorado law, you can choose to remove your immunization information from CIIS at any time. This is called an opt-out.
- The state health department will submit daily, anonymous COVID-19 vaccine administration data to the CDC as required. No personally identifiable information will be shared with CDC like your name or full address.

Do I need to be a U.S. citizen to get a vaccine?

- You do not need to be a U.S. citizen, and you will not need to prove lawful presence to get a COVID-19 vaccine in Colorado. Further, public health will never share your information with any immigration or law enforcement agency.

Do I still need to wear a mask and physical distance after receiving the vaccine?

- It will take time after the vaccination for your body to respond and make enough antibodies to protect you. This could take up to one to two weeks after your last dose.
- Current info suggests that it is possible that someone who has been vaccinated against COVID-19 may still have a mild or asymptomatic infection or spread the virus to others. So it is important to continue taking precautions. Continue wearing masks and practicing physical distancing until it is clear that it is safe to stop.

Do I need to quarantine from possible exposure if I have received two doses of the vaccine?

- It could take up to one to two weeks after your last dose of the vaccine to have protection. After that time, because the vaccine has shown high effectiveness, we are hopeful that most people who have received two doses of the vaccine will not be required to quarantine, but we await further guidance from the Advisory Committee on Immunization Practices (ACIP).

Do I need to quarantine from possible exposure between doses?

- Yes, you should follow standard quarantine as advised by state and local public health officials if you are possibly exposed between doses of COVID-19 vaccine. It could take up to one to two weeks after your last dose of the vaccine to have protection.

Do I need to isolate if I develop COVID-19-like symptoms more than one to two weeks after getting the second dose of the vaccine?

- Yes. If you develop COVID-19 symptoms more than one to two weeks after being fully vaccinated, you should isolate and contact your health care provider for instructions on whether to be tested for COVID-19 or other infections.

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

- It is currently unknown how long natural immunity lasts after recovering from COVID-19.
- Early evidence suggests natural immunity from COVID-19 may not last very long, and cases of reinfection have been reported.
- Limited data suggest that previously infected individuals can be at risk of reinfection. In the Emergency Use Authorization review memo, the FDA noted that very few participants in the Pfizer clinical trials previously had COVID-19 before getting the vaccine. More research is needed to determine whether people who have already had COVID-19 would benefit from getting vaccinated.
- The Advisory Committee on Immunization Practices (ACIP) makes recommendations on how to best use COVID-19 vaccines, and the FDA authorizes use. We will allow for all permissible uses once they are authorized.

If I get vaccinated, is it possible for me to still get a milder form of COVID-19 than if I hadn't been vaccinated?

- The COVID-19 vaccines have gone through large clinical trials and have shown to be very effective in preventing symptoms of the disease. However, current information suggests it is possible that someone who has been vaccinated against COVID-19 may still have a mild or asymptomatic infection or spread the virus to others. Until we know more, it is important to continue taking precautions, like wearing masks and practicing physical distancing, even after you have been vaccinated.

How can I start to make a vaccine plan for myself and my family?

- Being informed is the first part of making a plan. Get your information from reliable public health sources such as the Center for Disease Control and Prevention (CDC), Colorado Department of Public Health and Environment, and your local public health agency.
- When it's your turn to get the vaccine, ask your primary care provider whether they plan to give the vaccine in their office or what they recommend for you based on your personal medical history.
- You can learn more about COVID-19 at covid19.colorado.gov.

What if I am injured by the vaccine? Will I have to pay my own medical bills?

- In very rare cases, a vaccine can cause a serious problem, such as a severe allergic reaction. COVID-19 vaccines are covered under the Countermeasure Injury Compensation Program (CICP), not the National Vaccine Injury Compensation Program (VICP). The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the CICP to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration of COVID-19 vaccines.

Planning and implementation

Why do we need a phased approach to distribute the vaccine?

- We expect that the initial supply of COVID-19 vaccine(s) will be very limited for several months. This means that a vaccine will not be immediately available to everyone who wants one.
- To be as fair and efficient with distribution as possible, the state has developed a phased approach to vaccine distribution to save lives and end the crisis that has been brought on by the pandemic as quickly as possible. The phased allocation plan will prioritize people at high risk of getting exposed to COVID-19, people who work in essential or critical jobs, and people who are at high risk for getting very sick or dying of COVID-19.
- Prioritization is subject to change based on data, science, and availability.
- The Colorado Department of Public Health and Environment recognizes the Tribal sovereignty of the Ute Mountain Ute and Southern Ute Indian Tribes, and that the Tribes have the authority to determine how vaccine supply will be prioritized for their populations, even if their prioritization scheme is different than what the department recommends.

What are the phases?

- The vaccine prioritization plan has three phases:
    - 1A: Highest-risk health care workers and individuals. These are the people who must have direct contact with COVID-19 patients for longer periods of time (defined as 15 minutes or more over a period of 24 hours) as part of their jobs. This phase also includes long-term care facility staff and residents.
    - 1B: Moderate-risk health care workers and responders. Health care workers who do not have prolonged direct contact with COVID-19 patients, but still work in direct patient care or as direct patient care support staff. This phase also includes EMS, firefighters, police, correctional workers, dispatchers, funeral services, other first responders, and COVID-19 response personnel.

    - 2: Higher-risk individuals and essential workers. People who are at an elevated risk of getting very sick or dying of COVID-19, including any adult age 65 and older, as well as adults of any age with obesity, diabetes, chronic lung disease, significant heart disease, chronic kidney disease, cancer, or who are immunocompromised.
    - This phase also includes people who have direct interactions with the public as part of their jobs, such as grocery store workers and school and child care staff, as well as people who work in high density settings like farms and meat-packing plants. Also included are workers who serve people that live in high-density settings (e.g. homeless shelter or group home workers), other health care workers not included in Phase 1, and adults who received a placebo during a COVID-19 vaccine clinical trial.
    - 3: The general public. Any individuals age 18-64 without high-risk conditions.
- Prioritization is subject to change based on data, science, and availability.

What determines when Colorado moves from one phase to the next?

- In the early stages of vaccine distribution, health care providers will provide information to the Colorado Department of Public Health and Environment on how much vaccine they need and how many people are getting vaccinated. Once we believe we have distributed enough vaccine to those who want a vaccine in the first phase, we will move to the next phase. The speed at which we are able to move through the phases will largely depend on the supply of vaccine.

How does Colorado's rollout compare with neighboring states?

- Like Colorado, other states have made plans to receive and distribute available vaccines. The CDC required every state to submit a draft vaccination plan to them in October 2020.

Vaccine Safety and Development

For additional information, visit CDC:
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

Who approves the use of vaccines in the United States?

- The Food and Drug Administration (FDA) licenses and approves the use of vaccines. Before the FDA approves a vaccine, the manufacturer must do rigorous research and testing to ensure the vaccine's safety and effectiveness. The FDA independently reviews and verifies the information from these tests. It then decides whether the vaccine can be licensed and given to the public.

- In certain emergency situations, the FDA may issue an Emergency Use Authorization (EUA) to provide more timely access to critical medical products when there are no other options available.

How are vaccines tested for safety and effectiveness?

- Vaccines must go through a detailed scientific evaluation before they can be submitted to the FDA for approval. Each phase of the evaluation includes three different clinical research studies. In the clinical research study or trial, people volunteer to be part of the study. Each clinical trial emphasizes safety of the vaccine on people. As the research moves through to the next phase, the group of volunteers becomes bigger to include more diversity in people and circumstances.
    - Phase 1 involves 20 to 100 healthy volunteers to evaluate safety and common side effects of the vaccine.
    - Phase 2 involves several hundred volunteers to gather information on safety, vaccine dosing, and ability to stimulate an immune response.
    - Phase 3 involves several thousand volunteers and a longer time frame than the earlier studies. Along with safety and side effects, most Phase 3 studies focus on efficacy -- how well the vaccine works in clinical trials -- and compare people who have received the vaccine to those who receive a placebo (a shot without the real vaccine). During these studies, neither the participants nor the study managers know who received the vaccine and who received the placebo until the end of the study. This phase provides the most firm scientific evidence possible showing the difference between people who have been vaccinated and people who have not been vaccinated for both safety and effectiveness.

Who are the volunteers in vaccine clinical trials?

- People volunteer to take part in clinical research studies. All study volunteers must go through a process called informed consent that ensures they understand all of the risks and benefits of being in a study, and those volunteers are reminded that they may leave a study at any time without losing any of their rights or benefits.
- Each clinical trial emphasizes the safety of the vaccine on people. As the research moves through to the next phase, the group of volunteers becomes bigger to include more diversity in people and circumstances.
- A diverse group of people volunteered to participate in every phase of the clinical trials, including populations disproportionately impacted by COVID-19 due to generations of systemic inequities. For example, in Pfizer's clinical trials, about 42% of volunteers identified as Asian, Black/African American, Hispanic/Latino/a, or Native American. About 37% of volunteers for Moderna's trials identified as Asian, Black/African American, Hispanic/Latino/a, or other.

What happens after clinical trials are finished?

- Once the clinical trials can demonstrate vaccine safety and effectiveness at an appropriate dose, the manufacturer applies to the FDA to license the vaccine so that it can be used in the general population.
- The FDA reviews all of the data from the phased clinical studies using rigorous protocols and procedures. The vaccine is not licensed or approved until the FDA can ensure the vaccine is safe and effective.
- In emergencies, such as the current COVID-19 pandemic, vaccines can also be authorized through an Emergency Use Authorization (EUA). The FDA usually authorizes an EUA for a specific population. After receiving an EUA, the manufacturer continues monitoring clinical trials as well as gathering and analyzing data. With more data, the manufacturer can then submit to the FDA for a Biologic License Application (BLA) so that the vaccine is able to be used more widely than originally covered in the EUA.

Who else reviews the safety and effectiveness data from the clinical trials?

- For each vaccine authorized by the FDA, the Advisory Committee on Immunization Practices (ACIP) carefully reviews all available data about the vaccine from clinical trials and other studies, and makes recommendations for vaccine use in the general public. Recommendations include groups that should and should not receive the vaccine, as well as the timing, volume, number, and spacing of doses in a vaccine series.
- The ACIP is an independent advisory committee that provides guidance on the best use of vaccines to the Centers for Disease Control and Prevention (CDC) and U.S. Department of Health and Human Services (HHS).
- Once ACIP recommendations have been reviewed and approved by the CDC and HHS, they are published in CDC's Morbidity and Mortality Weekly Report (MMWR). The MMWR publication represents the final and official CDC recommendations for immunization of the U.S. population.

How is vaccine safety monitored after it's been approved or authorized?

- The FDA and CDC continue to closely monitor vaccine safety after the public begins using the vaccine. Both agencies have both longstanding and new safety systems in place for heightened monitoring of all COVID-19 vaccines. Learn more about the vaccine safety monitoring systems:
    - CDC's V-SAFE is a new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines. Vaccine recipients can opt-in to receive text messages and web surveys from CDC on how to report health problems following COVID-19 vaccination. The system will also provide telephone follow-up to anyone who reports medically significant adverse events. The report will be submitted to the Vaccine Adverse Event Reporting System (VAERS) while keeping patient identity confidential.

    - Vaccine Adverse Event Reporting System (VAERS) - VAERS is an early-warning system that collects and analyzes reports of any problems that happen after vaccination. Anyone can submit a report, including parents, patients, and health care professionals.
    - Vaccine Safety Datalink (VSD) - VSD is a collaboration between CDC and several health care organizations to monitor vaccine safety. The system analyzes healthcare information for over 24 million people to conduct studies about rare and serious adverse events after immunization.
    - Post-licensure Rapid Immunization Safety Monitoring (PRISM) - PRISM is the FDA's immunization safety monitoring program. PRISM actively monitors the safety of medical products using electronic health information from over 190 million people.
    - Clinical Immunization Safety Assessment Project (CISA) - CISA is a collaboration between CDC and seven medical research centers to answer complex safety questions. CISA conducts clinical research studies to further understand vaccine safety and recommend prevention strategies for adverse events following immunization.
- Vaccine recommendations may change if safety monitoring reveals new information about vaccine risks, such as a new serious side effect. The CDC, with the help of the Colorado Department of Public Health and Environment, will send safety alerts to health care providers. If necessary, a vaccine may be removed from the market.

About COVID-19 vaccine(s)

What types of COVID-19 vaccines could be authorized or approved for use in the general public?

- Many companies are working to develop a COVID-19 vaccine. For the most up-to-date information about each vaccine, visit CDC's Different COVID-19 Vaccines.
- The FDA has authorized the Pfizer vaccine for emergency use and is currently determining whether to authorize the Moderna vaccine so that it can become available to the public.
- Scientists developed both the Pfizer and Moderna vaccines using a new vaccine technology called messenger RNA (mRNA).

How do mRNA vaccines work?

- mRNA vaccines help our bodies build an immune response to the COVID-19 virus. The mRNA vaccine teaches our cells how to make a harmless protein that is unique to the virus that causes COVID-19. After our cells make copies of the protein, our immune system recognizes that the protein should not be in our body and builds antibodies to remember how to fight the virus if we are infected in the future.
- An antibody is a protein produced by your immune system that can recognize a specific type of virus in your body. When you get infected, your body's antibodies are able to

recognize proteins on the surface of the COVID-19 virus to attack and stop it from replicating in your body.

- For a visual explanation of how mRNA vaccines work, watch Stat's video "What are mRNA vaccines?"
- To learn more, visit CDC's Understanding How COVID-19 Vaccines Work.

Can mRNA vaccines change my genes?

- No, mRNA from the COVID-19 vaccine never enters the nucleus of the cell and does not affect or interact with your DNA. mRNA are naturally occurring genetic molecules that instruct our cells how to create proteins that build, maintain, and repair things in the body. Minutes after our cells make the proteins, the body destroys the mRNA using a special enzyme. mRNA in vaccines are designed to withstand the enzyme a little bit longer (a few days at most) so that our cells can create enough of a harmless protein that is unique to the virus. After our cells make copies of the virus' protein, our immune system is triggered and recognizes that the protein should not be in our body. Our body then builds antibodies so that it remembers how to fight the virus if we are infected in the future.

I heard several COVID-19 vaccines were approved for Emergency Use Authorization. What does that mean?

- In certain emergency situations, the Food and Drug Administration (FDA) may issue an Emergency Use Authorization to provide more timely access to critical medicines when there are no other options available. An Emergency Use Authorization permits the FDA to allow medical products that have met certain criteria, to treat, diagnose, or prevent serious or life-threatening diseases to be used.
- Watch this short video from the FDA about Emergency Use Authorization.

How will we know if the vaccine is safe?

- The FDA requires that vaccines undergo a rigorous scientific process, including three phases of clinical trials, before they authorize or approve the vaccine. The COVID-19 vaccines are subject to the same safety standards as other vaccine trials.
- To date, the independent Data and Safety Monitoring Board overseeing Phase 3 trials of the Pfizer and Moderna vaccines has not identified or reported any serious safety concerns. All phase 3 studies have Data Safety and Monitoring Boards. The boards are made up of independent scientists hired by the company to look at the safety data and check at regular intervals whether the company should cancel or continue with the study.
- Additionally, two independent advisory committees will review a vaccine's safety data before it is made available to the public. These committees are the Vaccines and Related Biological Products Advisory Committee (VRBPAC), which advises the FDA, and the Advisory Committee on Immunization Practices (ACIP), which advises the CDC.

- Learn more about the Vaccine safety and development process.

Do any of the vaccines contain harmful ingredients?

- Today's vaccines use only the ingredients they need to be as safe and effective as possible. Each ingredient in a vaccine serves a specific purpose: provide immunity (protection), keep the vaccine safe and long-lasting, and for the production of the vaccine.
- All vaccines contain antigens or elements that trigger the production of antigens. Antigens make vaccines work. They prompt the body to create the immune response needed to protect against infection. Antigens come in several forms. The form used in a vaccine is chosen because studies show it is the best way to protect against a particular infection.
- Other ingredients in vaccines may include preservatives, to keep germs out; adjuvants, to help boost the immune response to the vaccine; and additives, which help the vaccine stay effective while being stored. Each ingredient has a specific function and has been rigorously studied. These ingredients are safe for humans in the amounts used in vaccines.

COVID-19 immunity

Isn't natural immunity from having COVID-19 better than getting a vaccine?

- The protection someone gains from having an infection (called natural immunity) varies depending on the disease, and it varies from person to person. Because this virus is new, we don't know how long natural immunity might last. Some early evidence—based on a small sample size of people—seems to suggest that natural immunity may not last very long.
- Regarding vaccination, we won't know how long immunity lasts until we have more data on how well it works over time.
- Experts are trying to learn more about both natural immunity and vaccine-induced immunity of COVID-19.

When will we be protected after we get the vaccine?

- You will not be immediately protected from COVID-19 after receiving the vaccine. Studies show that it takes about one to two weeks after your last dose for your body to be able to protect itself against illness.
- Current information suggests it is possible that someone who has been vaccinated against COVID-19 may still have a mild or asymptomatic infection or spread the virus to others. So it is important to continue taking precautions. Continue wearing masks and practicing physical distancing until it is clear that it is safe to stop.
- While no vaccine is 100% effective, Pfizer and Moderna have reported that their vaccines are about 95% effective.

Why would a vaccine be needed if we can do other things, like physical distancing and wearing masks, to prevent COVID-19 from spreading?

- Stopping a pandemic requires using all the tools available to us. Vaccines are the first step in returning to a more normal life. Still, we need Coloradans to continue to use basic public health guidance, like physical distancing and mask wearing, until a vaccine is widely available and used by Coloradans.

If some members of my household get the vaccine and others don't, is it safe to return to our normal life?

- It is still possible that members of your household could get COVID-19 because they have not been vaccinated. Until the vaccine is widely available and all household members are fully immunized (and have waited the appropriate time after the second dose), you will need to continue to follow critical public health guidance, including: wearing a mask in public, maintaining at least 6 feet physical distance from others not in your household, avoiding large crowds, washing your hands often and staying home when you are sick. Distributing a COVID-19 vaccine to the entire state of Colorado will take time. Stay the course until it is your turn for a vaccine.

Can I visit older, at-risk family members once they've been vaccinated but before I have gotten a vaccine?

- To be as safe as possible, until the vaccine is widely available and both parties are fully immunized, we all need to continue to follow critical public health guidance. Prevention methods still include: wearing a mask in public, maintaining at least 6 feet physical distance from others not in our household, avoiding large crowds, washing our hands often, and staying home when we are sick.

Can family members of high-risk individuals get vaccinated early, too?

- Once a vaccine is available, we expect it will take several months until everyone can access it because of limited availability. To save lives, we need to first prioritize health care providers and Coloradans who are most at risk for getting severely sick or even dying.

What is community immunity or herd immunity? How many people need to get vaccinated to develop community immunity from COVID-19?

- Community immunity means that enough people have developed immunity to a disease (either naturally or through vaccination) that there is no longer a risk of community transmission or outbreaks.
- Until we better understand COVID-19 immunity, we won't know the percent of people needed for community immunity (sometimes called herd immunity).

Will we see a dramatic reduction in the number of cases in Colorado soon after a vaccine becomes available?

- We will be closely monitoring the vaccine's effect on the number of new COVID-19 cases in Colorado.
- Because the initial supply of vaccine is expected to be limited, we still need all Coloradans to do their part to prevent the spread of the virus. Wear a mask, keep 6 feet of distance from others who don't live with you, avoid gatherings, wash your hands often, and stay home when you are sick.

Vaccine policy and regulation

Will I be turned away if I try to get a vaccine before it becomes available to the general public?

- The initial supply of COVID-19 vaccine(s) is expected to be very limited for several months. This means that a vaccine will not be immediately available to everyone who wants one. Colorado's phased implementation plan is designed to save the lives of health care workers who are directly exposed to COVID-19 as part of their jobs. Individual vaccine providers, in consultation with their local public health agencies, will need to use their best judgement about which patients may be eligible for vaccination during each of the phases.

Will I be required to get a COVID-19 vaccine?

- The state is not considering a COVID-19 vaccine mandate at this time.

Will businesses be allowed to require patrons to prove they have been vaccinated before entering the premises?

- No, business owners will not be able to access a customer's protected health information, such as their COVID-19 immunization status, as a requirement for entry.

How will I know if others are vaccinated without compromising their personal health information?

- Every Coloradan's immunization records are confidential, personal medical information that will never be shared publicly. The state will report information on

the total number of residents who have been vaccinated in Colorado, but this data will not be attached to any individual's personally identifying information.
- The state health department maintains the Colorado Immunization Information System (CIIS), a confidential, population-based, secure computerized system that collects and consolidates individual-level vaccine and exemption data for Coloradans of all ages from a variety of sources.
- Under Colorado law, you can choose to remove your immunization information from CIIS at any time. This is called an opt-out.

Can public and private sector employers mandate employees obtain a COVID-19 vaccine authorized by the FDA via an EUA?

- Employers may be able to require COVID-19 vaccination for in-person work for their employees, but an employee may be entitled to an exemption through the ADA and Civil Rights Act of 1964. The state of Colorado is not currently pursuing any mandates. The U.S. Equal Opportunity Commission has more information on this on their website: https://www.eeoc.gov/laws/guidance/pandemic-preparedness-workplace-and-americans-disabilities-act

Emergency Use Authorization

What is an Emergency Use Authorization (EUA)?

- In certain emergency situations, the Food and Drug Administration (FDA) may issue an Emergency Use Authorization to provide more timely access to critical medical products when there are no other options available. An EUA permits the FDA to release unapproved medical products or allow for unapproved uses of medical products that have met certain criteria, to treat, diagnose, or prevent serious or life-threatening diseases.

Why do EUAs exist?

- EUAs were initially introduced in 2004 to prepare for bioterrorism attacks. Under an EUA, the government is able to authorize medical treatments and products in the event of a Chemical, Biological, Radiological, and Nuclear (CBRN) attack.

What is the criteria for an EUA?

- The FDA may issue an EUA for a medical product if it meets the following criteria:
    a. The disease or CBRN agent in question can cause a serious or life-threatening illness or condition.
    b. There is reasonable belief, after looking at all the scientific evidence, that the product may be effective for its intended use. The phrase "may be effective"

lowers the standards for scientific evidence typically required for FDA approvals.

c. The known and potential benefits outweigh the known and potential risks. The FDA will look at all available scientific evidence to determine the risk and benefits of a product.
d. There is no adequate, approved, and available alternative to the product.

Is it common for vaccines to be authorized under an EUA?

- The only vaccine that has been authorized under an EUA so far was an anthrax vaccine in 2005. This vaccine was given to certain military personnel who were at heightened risk of exposure to anthrax.

When have EUAs been issued in the past?

- Although not common, EUAs have been issued multiple times in the past for tests, treatments, and medical equipment.
    - In 2009, EUAs were issued for diagnostic tests, personal protection equipment, and certain antiviral drugs during the H1N1 Swine Influenza pandemic.
    - In 2013, EUAs were issued for diagnostic tests related to H7N9 influenza and Middle East Respiratory Syndrome (MERS).
    - Several EUAs have already been issued for some COVID-19 tests and treatments, for example the antiviral medication remdesivir (recently approved), convalescent plasma, and multiple COVID-19 tests.