West Virginia COVID-19 Vaccine Communication Toolkit Version 1 12/4/2020

Clear and consistent messaging about the COVID-19 Vaccine will be imperative to ensure vaccine confidence among key target groups and the general population. To assist with this, the West Virginia Joint Information Center for COVID-19 Vaccine has developed this communication toolkit to help partner agencies respond to questions about the COVID-19 vaccine(s). The items include frequently asked questions, talking points for general information, and sample drop-in social media posts. This information is based on currently available evidence, resources, information, emergency use authorization and expert opinion and is subject to change. As evidence regarding the use of COVID-19 vaccine for individuals emerges, it will be necessary to modify this document. Each page is dated for reference.

COVID-19 Vaccine Frequently Asked Questions

Recommended use: This document addresses commonly asked questions surrounding the COVID-19 vaccine(s). It is recommended you copy these FAQ into a solo document.

Why are COVID vaccines an important strategy against eradicating COVID-19?

Immunizations are important to prevent and reduce severity of disease. The benefits of vaccine acquired immunity outweigh the serious risk of natural infection. If a large portion of our community becomes immune to COVID via vaccination, it can reduce the spread of the disease to others.

Developer	Technology	Phase 3 Trial	Doses	Status as of
		Participants		12/3/2020
Pfizer	mRNA	44,000	2 doses 21 days apart	Requested EUA
Moderna	mRNA	30,000	2 doses 28 days apart	Requested EUA
Johnson & Johnson	Viral Vector	60,000	1 dose	Currently in phase
				3 clinical trial
Oxford/AstraZeneca	Viral Vector	30,000	2 doses 28 days apart	Currently in phase
				3 clinical trial

Which COVID-19 vaccines are expected to be available first?

What is an Emergency Use Authorization (EUA)?

Emergency Use Authorization occurs when the FDA allows a drug or vaccine to be used during a public health emergency. The FDA may choose to grant EUA once studies have demonstrated the safety and effectiveness of a vaccine but before the manufacturer has submitted, or the FDA has completed its formal review of the license application. EUAs provide timely access to critical medical products during a medical emergency when there are no sufficient treatments or vaccines available.

Which pharmaceutical company will provide the vaccine?

Pfizer was the first manufacturer to request emergency use authorization. Moderna has also requested emergency use authorization.

Will the COVID-19 vaccines be safe?

To date, no serious safety concerns have been reported by an independent Data and Safety monitoring Board overseeing Phase 3 trials of the Pfizer and Moderna mRNA COVID-19 vaccines. Both vaccines met the safety requirements outlined by the FDA to seek EUA. In the safety analysis, patients were followed for 2 months after they received their second dose of the vaccine.

Vaccine Pfizer Moderna Side effect Side effect Percent reported Percent reported 3.8% 9.7% Fatigue Fatigue Headache 2% 8.9% Muscle pain 5.2% Joint pain Headache 4.5% Pain 4.1%

What side effects will the vaccine have? Are there going to be long term side effects?

In Phase 3 clinical trials, the most common side effects reported were as follows:

Side effects have been reported to be short lived and happen within the first few days of receiving the vaccine. Side effect occurrence is typically higher after the second dose of vaccine. Historically, long term side effects from vaccines has been rare.

If you develop COVID-19 symptoms after getting the vaccine should you quarantine?

Yes, it typically takes a few weeks for the body to build immunity after vaccination. That means it is possible a person could be infected with the virus that causes COVID-19 just before or just after vaccination and get sick. This is because the vaccine has not had enough time to provide protection. If you have COVID-19 virus symptoms after getting the vaccine or at any time, you should contact your health care provider and consider getting tested for COVID-19.

What about an exposure between doses, do you need to quarantine?

Yes. Standard quarantine protocols should be followed as advised by state and local health officials.

How will side effects from the vaccines be treated?

Side effects from vaccines are typically short lived. If you are concerned about your health after getting vaccinated, talk with your health care provider. They will determine the appropriate treatment. You or your doctor can choose to report the side effect to the Vaccine Adverse Event Reporting System (VAERS).

Should premedication be given prior to vaccination?

Currently, there are no recommendations to take medication prior to receiving a vaccine.

How do the Pfizer and Moderna mRNA vaccines work?

The vaccines contain synthetic mRNA, which is genetic information used to make the SARS-CoV-2 spike protein. The spike protein is the part of the virus that attaches to human cells. The spike protein alone cannot cause COVID-19. Once the spike protein is created it causes the immune system to make antibodies against the virus. These antibodies can the provide protection if a person comes into contact with the virus. The mRNA vaccines are non-infectious and do not enter the human cell nucleus so it cannot be inserted into human DNA. Additionally, mRNA is

rapidly broken down, and this theoretically reduces chances for long term side effects. The mRNA vaccines do not have the ability to cause cancer.

Can I get COVID-19 from a vaccine?

No. The vaccines do not contain the full live SARS-CoV-2 virus and therefore cannot cause COVID-19. The first vaccines that will be available will either contain mRNA (non-infectious genetic material), viral vectors, (modified versions of live viruses), or protein subunits (parts of viral proteins) which cannot cause infection.

How effective will the vaccines be?

In Phase 3 trials, the Pfizer vaccine showed a 95% efficacy rate 7 days after the second dose. The vaccine was 94% effective in adults >65 years old. The Moderna vaccine showed a 94% efficacy rate 14 days after the second dose. These results were consistent across gender, age, race and ethnicity.

How long will immunity last after I get vaccinated? Will I need to be vaccinated every year?

The length of immunity following vaccination is not yet known for COVID-19. Given the novel nature of this virus and vaccine development, long term data is not yet available to guide future vaccine protocols.

Can I take the vaccine if I have already had COVID and recovered? How long after can I take it?

It is currently unknown how long natural immunity lasts after recovering from COVID-19. Early studies show that it is not long lasting, and cases of reinfection have been reported. The Pfizer trial did include individuals who previously had COVID and recovered but data from that group is still pending. The Advisory Committee on Immunization Practices (ACIP) will be making recommendations on which individuals should be vaccinated.

Can I take the vaccine if I have had convalescent plasma or monoclonal antibody?

The degree of immunity attained from receiving convalescent plasma or monoclonal antibodies is currently unknown. More studies are needed to understand this. The Advisory Committee on Immunization Practices (ACIP) will be making recommendations on which individuals should be vaccinated.

How is the COVID-19 vaccine administered?

The COVID-19 vaccines are IM or intramuscular injections.

Do I still need to wear a mask after I take the vaccine?

Yes. Wearing a mask and practicing social distancing is still important after receiving the vaccine. There will be limited doses available initially, and because people will be vaccinated in waves, it will take time to vaccinate enough of the population to stop the spread of COVID-19. Additionally, we don't know how long immunity will last. Furthermore, infection after a receiving a vaccine may still be possible, although it is likely that it would be less severe, such as

a mild or asymptomatic infection. Others can still be infected in this scenario, necessitating the continued use of masks.

If I take the vaccine will I expose my family to COVID-19?

Information currently available about the Pfizer and Moderna vaccines that have requested FDA authorization would not affect a person that is a close contact of a person taking the vaccine. It typically takes a few weeks for the body to build immunity after vaccination. That means it is possible a person could be infected with the virus that causes COVID-19 just before or just after vaccination and get sick. This is because the vaccine has not had enough time to provide protection. If you have COVID-19 symptoms after getting the vaccine or at any time, you should contact your health care provider and consider getting tested for COVID-19.

If you have had the virus do you still need the vaccine?

Due to the severe health risks associated with COVID-19 and the fact that re-infection is possible, people may be advised to get a vaccine even if they have been sick with COVID-19 before.

How many people need to get the vaccine for "herd immunity"?

The number or percentage of population that need to be vaccinated in order to reach "herd immunity" is not yet known. This number is impacted by the pathogen itself (in this case a novel virus with still unknown aspects), how efficacious these new vaccines will be (preliminary data shows both Moderna and Pfizer to be >90%), and how long immunity would last with these vaccines. This is an unknown at the moment as we do not know how long immunity lasts either from vaccination or from natural infection.

When will I get the vaccine?

The Pfizer and Moderna vaccines are under review by the FDA for Emergency Use Authorization (EUA). It is anticipated that emergency use authorization to occur by mid-December 2020 with the first shipments of vaccine to states at that point. However, supply will be limited at first and will likely be given to high risk exposure groups initially. Your timeline for vaccination depends on recommendations that will be provided by the state and the ACIP as well as how much supply of vaccine is available.

Are there any contraindications (conditions or factors that would be a reason to withhold vaccination due to harm) to receiving the vaccine?

Currently there is no information on contraindications to receiving the vaccine. The Advisory Committee on Immunization Practices (ACIP) will be making recommendations on who should or should not receive the vaccines.

How long after the flu shot do I have to wait to take the COVID-19 vaccine?

Exact recommendations are unknown at this time. The Advisory Committee on Immunization Practices (ACIP) will be making recommendations on how long after the flu shot one should wait before they receive the COVID-19 vaccine.

Why is vaccine development happening so fast?

The vaccine process is happening faster because vaccine research and development, clinical trials, manufacturing, and plans for distribution are occurring at the same time. This method removes delays that occur when these processes are carried out one after the other. Steps to ensure safety are not being eliminated.

For 2 dose vaccines, what happens if I only receive one dose of the vaccine and not both?

It is recommended to receive both doses of the vaccine. If only one vaccine is received, immunity cannot be guaranteed.

How will the second dose of the vaccine be ensured if I do get the first dose?

The CDC, federal agencies and state public health departments are using a tool called the Vaccine Administration Management System (VAMS). This is an online tool that will allow clinicians to set up customized vaccine schedules, and allow recipients to make vaccination appointment, in addition to get a reminder about returning for a second dose if required.

Is taking the COVID-19 vaccine mandatory?

The vaccine is not mandatory, however, we do recommend that citizens take the vaccine in order to help prevent disease and reduce disease severity. Getting vaccinated will improve the health and wellbeing of our communities and get the economy moving again.

References

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html

COVID-19 Update: First two vaccines nearing approval demonstrate 95% efficacy. IPD Analytics. Nov 2020.

Food and Drug Administration. Emergency Use Authorization. Available from https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Mehta M, Reece R. WVU Medicine COVID-19 Vaccine Frequently Asked Questions. Updated 12/1/2020.

Pfizer. Pfizer and BioNTech conclude phase 3 study of COVID-19 vaccine candidate meeting all primary efficacy endpoints. Available from https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine Vaccine side effects. US Department of Health and Human Services. Available from https://www.vaccines.gov/basics/safety/side_effects Vaccine Management System. Deloitte. Available from https://www2.deloitte.com/us/en/pages/public-sector/solutions/vaccine-management-system.html

Zhang et al. Advances in mRNA vaccine for infectious diseases. Front. Immunol. March 2019; 10:594

Centers for Disease Control and Prevention. Frequently asked questions about vaccination. Available from

Centers for Disease Control and Prevention. Ensuring the safety of COVID-19 vaccines in the United States. Available from

COVID-19 Vaccine Talking Points

Recommended Use: These talking points are meant for internal use by staff or providers to use as talking points and is not intended to be used in social media platforms, please see the social media posts later in this toolkit for social media messaging.

GENERAL MESSAGES:

- \circ COVID-19 vaccination will help to protect us from the virus and save lives.
- Based on months of clinical trials, COVID-19 vaccines that receive FDA Emergency Use Authorization have met rigorous and scientific standards of safety, quality, and effectiveness.
- Clinical trials with tens of thousands of people have demonstrated that vaccination is highly effective in preventing COVID-19 and caused no serious safety concerns. (The only adverse reactions documented after being vaccinated included mild fatigue and a headache, which only occurred shortly after being vaccinated and then went away.)
- COVID-19 vaccines will not give you COVID-19. (None of the COVID-19 vaccines currently in development in the U.S. use the live virus that causes COVID-19. COVID-19 vaccines cause an immune response in your body, but do not give you the virus.)
- Getting vaccinated will help to protect the health and wellbeing of our communities and get the economy moving again.
- COVID-19 vaccination will offer a path forward to ensure our state's essential workers can safely do their jobs and provide for their families.
- Getting vaccinated not only protects you, but the people around you particularly those at risk of severe COVID-19 illness.
- When communities are vaccinated, fewer people are likely to get sick, saving taxpayers dollars and assuring the healthcare system can continue to meet the needs of those it is intended to serve.
- It is vital that each of us continues to do their part to prevent the spread of the virus.
- Stopping a pandemic requires using all the tools we have available, and vaccination is just one of those tools.
- Continue to wear a mask, stay physically distanced, wash your hands frequently, and avoid the three Cs — crowds, closed indoor spaces, and close contacts.

SUPPLY:

- There will likely be limited supply of COVID-19 vaccine when it first becomes available, so the vaccine will be distributed in phases, based on risk for COVID-19. There may be a limited supply of COVID-19 vaccines when the vaccine first becomes available, but supply will continually increase in the weeks and months that follow.
- The goal is for West Virginians to be able to easily get a COVID-19 vaccine as soon as large quantities are available.
- When the vaccine is available in larger supply, for distribution in **Phase 2**, it will become available to the general population.

VACCINE DEVELOPMENT:

- COVID-19 vaccines are being carefully evaluated in clinical trials and will be authorized or approved only if they make it substantially less likely you'll get COVID-19. The clinical trials must first show that the COVID-19 vaccines are safe and effective before any vaccine can be authorized or approved for use.ⁱ
- These clinical trials are being conducted according to the **standards set by the FDA**. If the FDA determines that a vaccine meets its safety and effectiveness standards, it can approve or authorize the vaccines for use in the United States.ⁱⁱ

VACCINE SAFETY:

- Ensuring the safety of vaccines, including the COVID-19 vaccines, is a top priority. The **U.S. vaccine safety system** is designed to ensure that all vaccines are as safe as possible. Specific information about the steps that are being taken to ensure the safety of COVID-19 vaccines is available at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html.
- To date, no serious safety concerns have been reported by an independent Data and Safety monitoring Board overseeing Phase 3 trials of the Pfizer and Moderna mRNA COVID-19 vaccines. Both vaccines met the safety requirements outlined by the FDA to seek EUA. In the safety analysis, patients were followed for 2 months after they received their second dose of the vaccine.
- After a vaccine is approved or authorized for use, COVID-19 vaccine safety monitoring will be conducted by multiple federal agencies to watch for adverse events (possible side effects) that may not have been seen in clinical trials. They will use established systems to monitor COVID-19 vaccine safety and develop new platforms, such as V-SAFE to compliment those systems.^{vi}

EMERGENCY USE AUTHORIZATION PROCESS:

- At least at first, COVID-19 vaccines might be used under an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA). During a public health emergency, the FDA can use an EUA to allow the use of medical products that are not yet approved to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives.ⁱⁱⁱ
- For a vaccine to receive an EUA, the FDA must determine if the vaccine's benefits outweigh its risks based on data from **Phase 3 clinical trial**(s), which demonstrates the vaccine's safety and efficacy.^{iv}
- Emergency use authorizations (EUAs) can be used by the FDA to help make medical products available quickly during a public health emergency.

INFORMATION REGARDING CERTAIN POPULATIONS:

- At first, COVID-19 vaccines may not be recommended for children. In early clinical trials for various COVID-19 vaccines, only adults, who are not pregnant, participated. Older children (12 and up) were added in later trials. However, clinical trials continue to expand and include other groups. It is anticipated that when the COVID-19 vaccine(s) first becomes available, that it will not be available for children at first. However, the groups recommended to receive the vaccines could change in the future.ⁱⁱ We will need to wait to see what the Advisory Committee on Immunization Practices (ACIP) recommends based upon any studies in immunocompromised patients.
- Currently there is no information on contraindications to receiving the vaccine. The Advisory Committee on Immunization Practices (ACIP) will be making recommendations on who should or should not receive the vaccines.

COST:

 The federal government has committed to providing free or low-cost COVID-19 vaccines. However, vaccine providers may charge administration fees for giving or administering the vaccine to someone. Most public and private insurance companies will cover that fee so there is no cost for the person getting vaccinated. In addition, people without health insurance will also be able to get COVID-19 vaccines at no cost.ⁱⁱ

IMMUNITY FROM VACCINE:

• There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again; this is called natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this.

- The length of immunity following vaccination is not yet known for COVID-19. Given the novel nature of this virus and vaccine development, long term data is not yet available to guide future vaccine protocols.
- The vaccines contain synthetic mRNA, which is genetic information used to make the SARS-CoV-2 spike protein. The spike protein is the part of the virus that attaches to human cells. The spike protein alone cannot cause COVID-19. Once the spike protein is created it causes the immune system to make antibodies against the virus. These antibodies can the provide protection if a person comes into contact with the virus. The mRNA vaccines are non-infectious and do not enter the human cell nucleus so it cannot be inserted into human DNA. Additionally, mRNA is rapidly broken down, and this theoretically reduces chances for long term side effects. The mRNA vaccines do not have the ability to cause cancer.
- While experts learn more about the protection that COVID-19 vaccines provide under reallife 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.
- Information about COVID-19 vaccines will evolve as new vaccines become available, vaccine supply increases, and the state proceeds through the phases of vaccine distribution. Ensuring all partners and stakeholders are providing timely, accurate, and understandable information across their networks will be critical to the success of the program.

Draft Social Media Posts about #COVID19Vaccine

Recommended Use: Adapt these social media posts to use on social media platforms.

- Vaccines have two benefits: 1) protecting those who are vaccinated and 2) when
 vaccination rates are high, they create herd immunity, disrupting the spread of disease and
 protecting those who cannot be vaccinated. Here's how herd immunity works in a
 community with high vaccination rates: (herd immunity GIF can be downloaded from
 https://imgur.com/gallery/8M7q8#J7LANQ4 then posted in social media platforms)
- As we await a #COVID19Vaccine, locally, <u>(Insert health department or organization name)</u> has been working with @WV_DHHR and local partners to plan for when #COVID19Vaccine is available.
- Planning for the rollout of the COVID-19 vaccines has been underway in West Virginia since August. This **Friday, December 4, 2020** @WVGovernor Justice will announce the final WV COVID-19 Vaccination Plan.
- #COVID19Vaccines are currently being developed and tested for their safety and efficacy (effectiveness in clinical trials). The Pfizer and Moderna vaccines recently completed this process and have requested an Emergency Use Authorization (EUA) from the @US_FDA so that their vaccines can soon be used in the U.S. in response to the #COVID-19 pandemic. The FDA describes what an EUA is in this short video:

https://www.youtube.com/watch?v=iGkwaESsGBQ

During a public health emergency, emergency use authorizations (EUAs) can be used by the @US_FDA to help make medical products available quickly. For a vaccine to receive an EUA, the FDA must determine if the vaccine's benefits outweigh its risks based on data from Phase 3 clinical trial(s), which demonstrates the vaccine's safety and efficacy (effectiveness in clinical trials). The @US_FDA describes what an EUA is in this short video.

The @US_FDA may grant an Emergency Use Authorization (EUA) for a vaccine that shows that its benefits outweigh its risks so that it may be used to quickly respond to the pandemic. The FDA describes what an EUA is in this short video: https://www.youtube.com/watch?v=iGkwaESsGBQ

 Once a #COVID19Vaccine is authorized for use, the Advisory Committee on Immunization Practices will make recommendations to the @CDCGOV director on how the vaccine should be used. But who is the ACIP? They are an external team of medical and infectious disease experts who are responsible for making recommendations on how to use vaccines to control diseases in the U.S. Learn more here:

https://www.CDC.gov/vaccines/acip/committee/role-vaccine-recommendations.html

#DYK? A committee of external medical and public health experts advises CDC on U.S. vaccine recommendations. If a #COVID19 vaccine is authorized or approved, this committee will vote on whether to recommend it and who should receive it. Learn more: <u>https://www.CDC.gov/vaccines/acip/committee/role-vaccine-recommendations.html</u>

- To make a #COVID19Vaccine available quickly, the federal government has been investing in vaccine manufacturers to help them start manufacturing vaccine at industrial scale before the vaccines have completed clinical trials. By getting ahead in the manufacturing process, this enables the vaccine to be developed and delivered quickly, without compromising safety and efficacy.
- Wondering how a #COVID19Vaccine has been developed so quickly? This graphic by Operation Warp Speed illustrates how the vaccine development process was accelerated in response to the pandemic but continues to meet the same safety and efficacy requirements of other vaccines: <u>https://media.defense.gov/2020/Aug/13/2002476369/-1/-1/0/200813-D-ZZ999-100.JPG</u>.

OPERATION WARP SPEED ACCELERATED VACCINE PROCESS



Source: https://media.defense.gov/2020/Aug/13/2002476369/-1/-1/0/200813-D-ZZ999-100.JPG

- Ensuring the safety of vaccines, including the #COVID19Vaccines, is a top priority. The U.S. vaccine safety system is designed to ensure that all vaccines are as safe as possible. Learn more about the steps that are being taken to ensure the safety of #COVID19Vaccines:
 www.CDC.gov/coronavirus/2019-ncov/vaccines/safety.html.
- The federal government has committed to providing free or low-cost #COVID19Vaccines. However, there may be a fee for administering the vaccine that most public and private insurance companies will cover, so there is no cost for the person getting vaccinated. In

addition, those without health insurance will be able to get the #COVID19Vaccines at no cost.

 The two leading #COVID19Vaccine candidates are mRNA vaccines. In this brief video, Dr. Paul Offit, the Director of the Vaccine Education Center at the Children's Hospital of Philadelphia explains how #COVID19Vaccines based on messenger RNA technology work: <u>https://www.youtube.com/watch?v=S8Wd-NMqvno</u>.

Or

 The two leading #COVID19Vaccine candidates are mRNA vaccines. This brief video from STAT news explains how #COVID19Vaccines based on messenger RNA technology work: <u>https://www.youtube.com/watch?v=S8Wd-NMqvno</u>.

ⁱ CDC, *Benefits of Getting a COVID-19 Vaccine*: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/about-vaccines/vaccine-benefits.html</u>

ⁱⁱ CDC, Ensuring the Safety of COVID-19 Vaccines in the United States: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html</u>

^{III} FDA, FAQs on Emergency Use Authorizations (EUAs) for Medical Devices During the COVID-19 Pandemic: <u>https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/faqs-emergency-use-authorizations-euas-medical-devices-during-covid-19-pandemic</u>

^{iv} FDA, Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry: <u>https://www.fda.gov/media/142749/download</u>