

West Virginia COVID-19 Vaccines Communication Toolkit

Version 6 3/12/2021

West Virginians want information about COVID-19 vaccines. Clear, consistent, and scientifically sound messaging about COVID-19 vaccines is imperative to ensure everybody has the knowledge and confidence that they need to make a decision about getting vaccinated. The West Virginia Joint Information Center (WV JIC) for COVID-19 Vaccines recognizes the essential roles that partner agencies hold as trusted information sources and tireless advocates for communities in our Mountain State.

Thus, the WV JIC for COVID-19 Vaccines developed the following communication toolkit to help our valued partner agencies respond to questions about COVID-19 vaccines. This is intended as a reference guide for healthcare and public health and community outreach agencies to use in communication with their audiences.

For more information, we encourage individuals to speak with a healthcare provider and/or contact the COVID-19 Vaccine Info Line. For questions, please call 1-833-734-0965, Monday through Friday between 8 a.m. – 6 p.m., and on Saturdays from 9 a.m. – 5 p.m. (closed Sundays). You can also access <u>vaccinate.wv.gov</u> at any time. The site is updated regularly and includes an abbreviated version of the FAQs contained in this document. West Virginians can also pre-register at that site for vaccination.

The WV COVID-19 Hotline also remains available toll-free at 1-800-887-4304. The hotline is being provided through a longstanding emergency preparedness partnership between DHHR's Bureau for Public Health and the West Virginia Poison Center, and operators are available 24/7 to provide accurate information about COVID-19, the risk to the public, and the state's response.

For information in Spanish, Chinese, Vietnamese, and Korean, please visit CDC resources <u>here</u> and click on the "Languages" drop-down option near the top of the page.

The items in this document include frequently asked questions, key messages for general information, a link to the <u>social</u> <u>press kit</u> that includes sample social media posts and printable resources that are shareable from within the site, a resources page, and appendix containing a "how-to" for using the new West Virginia COVID-19 Vaccine Registration System. Content is based on available evidence, resources, information, emergency use authorization and expert guidance and is subject to change. As information regarding the use of COVID-19 vaccine for individuals emerges, it will be necessary to modify this document. Each page is dated for reference.

Thank you for your partnership in protecting health and livelihoods in our communities—particularly now in helping to give West Virginians unified, accurate, scientifically sound information about COVID-19 vaccines.

For more information, please call the COVID-19 Vaccine Info Line 1-833-734-0965 M-F 8am - 6pm, Sat 9am - 5pm, closed Sunday or visit vaccinate.wv.gov



Overview of Main Updates since Version 5

The updates below reflect new questions added or substantive edits to existing questions.

In Version 6, we:

Added the following questions (and answers):

- How do COVID-19 viral vector vaccines (Johnson & Johnson's Janssen vaccines) work?
- What are "variants" and what do they mean for individuals considering vaccination?
- Could getting a COVID-19 vacine affect the results of a mammogram?
- Which COVID-19 vaccine should I receive?
- If I had one type of COVID-19 vaccine (e.g., mRNA) could/should I get another type (e.g., viral vector) too?

Updated answers to the following questions from previous versions:

- How effective will the vaccines be for disease prevention?
- Which COVID-19 vaccines have been authorized for use by the FDA?
- Should I take COVID-19 vaccines if I have a significant history of allergic reactions?
- Should I take the vaccine if I've had Guillain-Barré syndrome?
- When will I get the vaccine?
- Can I get one dose of one mRNA vaccine (e.g., Pfizer) and the second dose of another mRNA vaccine (e.g., Moderna)?
- What are common side effects or immune responses after receiving mRNA COVID-19 vaccines?
- Do I still need to wear a mask and take other COVID-19 precautions after getting the vaccine?

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COVID-19 Vaccination Basics

What role do COVID-19 vaccinations play in helping to curb the pandemic?

COVID-19 vaccination will help protect ourselves, our families, and our communities from the disease and save lives. Vaccines can both prevent and reduce the severity of disease. Vaccines provide immunity without the serious risks associated with getting infected naturally. Wearing masks and physical distancing help reduce the chance of being exposed to the virus or spreading it to others, but these measures are not enough.

The COVID-19 vaccines are designed to work with our immune systems so the body is ready to fight the virus if we are exposed to it. When enough people in a community get vaccinated against COVID-19, immunity rates in our communities substantially increase, which reduces the spread of the virus.

Are the COVID-19 vaccines safe?

Yes. COVID-19 vaccines have been evaluated in tens of thousands of individuals who volunteered to participate in clinical trials. These clinical trials met the same rigorous standards set for all vaccines by the Food and Drug Administration (FDA).

The information from these clinical trials allowed the FDA to determine that the newly authorized COVID-19 vaccines meet its safety and effectiveness standards. Based on these findings, the FDA has made the vaccines available for use in the United States under what is known as an Emergency Use Authorization (EUA).

The Centers for Disease Control and Prevention (CDC) and the FDA is continuing to monitor the safety of the vaccines now that they are in use.

How effective will the vaccines be for disease prevention?

The COVID-19 vaccines currently authorized for use were found to be highly effective in preventing COVID-19 in clinical trials.

All authorized COVID-19 vaccines have high efficacy in protecting against severe COVID-19 disease as well as COVID-19 related hospitalizations and death. They all have been reviewed rigorously by the scientific experts and have met the FDA efficacy standards for emergency use authorization.

How do COVID-19 mRNA vaccines (Pfizer and Moderna) 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. <u>The spike protein alone cannot cause COVID-19</u>.

Once the spike protein is created, it causes the immune system to make antibodies against the virus. These antibodies can then provide protection if a person comes into contact with the virus.

Since the vaccine does not contain any virus, it is not possible to spread COVID-19 from receiving the vaccine. The mRNA does not enter the center of the human cell where DNA is made (the nucleus); so, it cannot alter the genetic material of the cell (DNA). The mRNA is rapidly broken down, making the chance for long-term side effects less likely. The mRNA vaccines do not have the ability to cause cancer.

Learn more here: <u>https://www.cdc.gov/vaccines/covid-19/downloads/healthcare-professionals-mRNA.pdf</u>

How do COVID-19 viral vector vaccines (Johnson & Johnson's Janssen vaccine) work?

The J&J/Janssen COVID-19 vaccine contains an inactivated "common cold" virus called an adenovirus. This virus cannot replicate in the human body, will not cause an infection, and does not enter DNA. The adenovirus carries a gene for the coronavirus spike protein that allows it to be created and recognized by the immune system. The spike protein is the part of the coronavirus 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 coronavirus.

Can I get COVID-19 from a vaccine?

No. None of the COVID-19 vaccines currently authorized for use or in development in the United States use the live virus that causes COVID-19.

What many people experience as a result of receiving the vaccine are the body's immune system responding to the COVID-19 vaccine. All of the COVID-19 vaccines work with your immune system so it will be ready to fight the virus if you are exposed. Common immune responses are pain, redness, and swelling in the arm of the injection, along with possible tiredness, headache, muscle pain, chills, fever, and nausea.

It usually takes a few weeks for the body to build immunity after being fully vaccinated (that is, two doses for Pfizer and Moderna or one dose for J&J/Janssen). That means it is possible for an individual to be infected with the virus that causes COVID-19 if exposed just before or just after vaccination. The vaccine itself does **not** cause infection. Similarly, the vaccine **cannot** cause you to have a positive COVID-19 test.

What are "variants" and what do they mean for individuals considering vaccination?

Viruses constantly change through mutation, and new variants of a virus are expected to occur over time. Sometimes new variants emerge and disappear. Other times, new variants emerge and stay. Multiple variants of the virus that causes COVID-19 have been documented in the United States and globally during this pandemic. Scientists are studying these variants to understand whether they:

- Spread more easily from person to person
- Cause milder or more severe disease in people
- Detected by available diagnostic tests
- Respond to therapies to treat COVID-19
- Change effectiveness of COVID-19 vaccines

Preliminary data concerning vaccine effectiveness and variants indicates the B.1.1.7 (first detected in the United Kingdom) has had minimal impact on vaccine effectiveness. The B.1.351 (first detected in South Africa) has shown to have moderate impact on vaccine effectiveness, and the P.1 (first detected in Brazil/Japan) is still be studied to evaluate the potential impact on vaccine effectiveness. Current public health actions such as wearing a mask, staying at least 6 feet apart, avoiding crowds, and getting vaccinated when it is available combined are the best protection against variants of the virus that causes COVID-19.

For more information on variants of concern please visit: <u>https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html</u>.

What is an Emergency Use Authorization (EUA)?

During a public health emergency, the FDA can use a process called "Emergency Use Authorization" (EUA). This process allows 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.

Several additional COVID-19 vaccines are currently being developed and tested for their safety and effectiveness in clinical trials (efficacy). Once vaccine manufacturers submit for authorization, the FDA evaluates the EUA request and determines whether they are safe and effective, taking scientific evidence into account. For a vaccine to receive an EUA, the FDA must determine if the vaccine's benefits outweigh its risks based on data from rigorous clinical trial(s).

Additional information on EUAs: <u>https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained</u>

How does the FDA Assess Safety and Effectiveness of a COVID-19 Vaccine Submitted for Emergency Use Authorization (EUA)?

COVID-19 vaccines are undergoing a rigorous development process that includes tens of thousands of study participants to gather required safety and efficacy data, in the same way as many other currently approved vaccines. The FDA evaluates the information submitted by a vaccine manufacturer and uses all available tools and information, including records reviews, site visits, and previous manufacturing compliance history.

For an EUA to be issued, the FDA must determine that the known and potential benefits outweigh the known and potential risks of the vaccine.

Link: <u>https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained</u>

Which COVID-19 vaccines have been authorized for use by the FDA?

At this time, there are three COVID-19 vaccines authorized for use by the FDA. The **Pfizer-BioNTech mRNA COVID-19 vaccine** received FDA authorization December 11, 2020 for individuals **ages 16 and older**. It is a 2-dose vaccination series, given intramuscularly, recommended **at least 3 weeks apart**. For the full FDA statement on the authorization of this vaccine: <u>https://www.fda.gov/news-events/press-</u> <u>announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-</u> <u>first-covid-19</u> The Moderna mRNA COVID-19 vaccine received FDA authorization December 18, 2020 for individuals 18 and older. It is a 2-dose vaccination series, given intramuscularly, recommended at least 1 month apart. For the full FDA statement on the authorization of this vaccine: <u>https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid</u>

Johnson & Johnson's Janssen vaccine received FDA authorization February 27, 2021 for individuals ages **18 and older**. It is a 1-dose vaccination, injected into the muscle, typically of the upper arm. For the full FDA statement on the authorization of this vaccine: <u>https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine</u>

Why have vaccines been developed so quickly?

The vaccine process has happened faster because vaccine research and development, clinical trials, manufacturing, and plans for distribution have occurred at the same time. This method removed delays that occur when these processes are carried out one after the other. Steps to ensure safety were **NOT** eliminated.

What can individuals do to protect themselves and others until COVID-19 vaccines are more widely available?

It is vital that each person uses all tools available to stop the pandemic. Tools include:

- wearing masks/face coverings properly,
- washing hands with warm water and soap for at least 20 seconds (or rubbing hands with at least 60% alcohol-based hand sanitizer when soap/water is not available),
- staying at least 6 feet away from others,
- avoiding indoor gatherings as possible, and
- getting vaccinated against COVID-19 with any authorized vaccine as soon as it is offered.

Why do we need a vaccine if we can take other COVID-19 precautions, like masking and physical distancing, to slow or prevent the spread?

It is vital that each person uses all tools available to stop the pandemic. Vaccines work with the immune system and allow a strengthened response to the virus if exposed.

Other steps, like covering the mouth and nose with masks/face coverings worn properly, washing hands, and staying at least 6 feet away from others, help reduce chances of exposure to the virus or spreading it to others.

Together, COVID-19 vaccination and following recommendations <u>for self-protection and to protect</u> <u>others</u> will offer the best prevention for further spread of COVID-19. For more information: <u>https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html</u>

Before Getting Vaccinated

How do West Virginians sign up to get registered?

COVID-19 vaccine appointments are coordinated through a centralized statewide system. All West Virginians 16 years of age and older are encouraged to pre-register for COVID-19 vaccination by

creating a WV COVID-19 Vaccine Registration System account at vaccinate.wv.gov or by calling the WV COVID-19 Vaccine Info Line at 1-833-734-0965.

Pre-registering allows West Virginians to receive updates on COVID-19 vaccine availability and to get contacted with a vaccination appointment when available to them as limited supplies allow. More information is available at vaccinate.wv.gov.

Should I take COVID-19 vaccines if I have a significant history of allergic reactions?

This section addresses contraindications and precautions to COVID-19 vaccines.

Individuals with allergy questions or concerns should consult a health care provider. Disclose any allergies to medical staff prior to vaccination.

While rare, anaphylactic reactions have been reported following vaccination with COVID-19 vaccines. Although investigations are ongoing, persons with a history of an immediate allergic reaction (of any severity) to an mRNA COVID-19 vaccine or any of its components might be at greater risk for severe reaction upon taking additional doses. For the purposes of this guidance, **an immediate allergic reaction** to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms such as hives (urticaria); swelling around the face, lips, and tongue (angioedema); wheezing or other respiratory distress; or anaphylaxis that occur within four hours following getting the vaccine.

Recommendations for contraindications and precautions are described below and summarized in the figure from CDC at the end of this question section. The following recommendations may change as further information becomes available.

Contraindication to vaccination:

Contraindications are conditions or factors that would be a reason to not get vaccination due to harm. (Individuals with a contraindication should **not** get the COVID-19 vaccine.)

<u>CDC considers a history of the following to be a contraindication to vaccination with COVID-19</u> vaccines:

- <u>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19</u> vaccine.
- <u>Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a</u> <u>component of the vaccine (see list of ingredients below).</u>

Providers should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as passing out (a vasovagal reaction) or post-vaccination side effects— which are not contraindications to receiving the second vaccine dose (see the figure at the bottom of this question section).

The safety and efficacy of the J&J/Janssen COVID-19 vaccine administered after an mRNA COVID-19 vaccine has not been established. However, in limited, exceptional situations where a patient received

the first dose of an mRNA COVID-19 vaccine but is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to contraindication), a single dose of Janssen COVID-19 vaccine may be considered at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose. Patients who receive Janssen COVID-19 vaccine after a dose of an mRNA COVID-19 vaccine should be considered to have received a valid, single-dose Janssen vaccination—not a mixed vaccination series.

The following fact sheets contain additional information about who should not receive the vaccine.

Pfizer-BioNTech Fact Sheet for Vaccine Recipients and Caregivers: <u>https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine</u>

Moderna Fact Sheet for Vaccine Recipients and Caregivers: <u>https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine</u>

Johnson & Johnson's Janssen Vaccine Fact Sheet for Vaccine Recipients and Caregivers: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssencovid-19-vaccine

For more information about contraindications and precautions on use of the J&J/Janssen COVID-19 vaccine and additional precautions in people with a contraindication to mRNA COVID-19 vaccines: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-C

The following vaccines ingredients list (next page) is available from: <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-C</u>

Figure: Ingredients included in COVID-19 vaccines

The following is a list of ingredients for the Pfizer-BioNTech 🖸 , Moderna 🖸 , and Janssen 🖸 COVID-19 vaccines reported in the prescribing information for each vaccine.

Description	Pfizer-BioNTech (mRNA)	Moderna (mRNA)	Janssen (viral vector)
Active ingredient	Nucleoside-modified mRNA encoding the viral spike (5) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication- incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV- 2 Spike (S) protein
Inactive ingredients	2[(polyethylene glycol (PEG))-2000]- N,N-ditetradecylacetamide	PEG2000-DMG: 1,2- dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3- phosphocholine	1,2-distearoyl-sn-glycero-3- phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol	Cholesterol	Citric acid monohydrate
	(4- hydroxybutyl)azanediyl)bis(hexane- 6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8- ((2-hydroxyethyl) (6-oxo-6- (undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Sodium chloride	Tromethamine	Sodium chloride
	Monobasic potassium phosphate	Tromethamine hydrochloride	Sodium hydroxide
	Potassium chloride	Acetic acid	Hydrochloric acid
	Dibasic sodium phosphate dihydrate	Sodium acetate	Ethanol
	Sucrose	Sucrose	Water for injection

* None of the vaccines contain eggs, gelatin, latex, or preservatives.

Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called "pegylation" to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur. Information on active or inactive ingredients for vaccines and medications can be found in the package insert. <u>CDC's vaccine excipient summary</u> and the National Institutes of Health <u>DallyMed database</u> [] can also be used as a resource.

Precaution to vaccination:

Precautions are conditions or factors that would be a reason to consult with a health care provider before proceeding with vaccination. Vaccine providers should observe these patients for 30 minutes after vaccination to monitor for the development of immediate adverse reactions.

The CDC considers a history of immediate allergic reaction to *any other* vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) as a **precaution** but not a contraindication to vaccination. These persons may still receive vaccination but should be counseled about unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. All vaccination sites will have the medication they need, and the trained medical professionals, to respond to an allergic reaction if one occurs. The CDC advises that individuals who are concerned about their history of allergies may prefer to be vaccinated in a setting where more comprehensive medical care is immediately available for anaphylaxis.

People with a contraindication to one type of the currently authorized COVID-19 vaccines (e.g., mRNA) have a *precaution* to the other (e.g., J&J/Janssen viral vector). For individuals who have a contraindication for one type of COVID-19 vaccine may consider consulting with an allergist-immunologist to help determine whether the patient can safely receive vaccination.

3/12/2021

Information by vaccine type

m	RNA COVID-19 vaccines	Jans	ssen COVID-19 vaccine
•	Persons with contraindication to one mRNA vaccine should not receive doses of either vaccine (Pfizer- BioNTech or Moderna)	 Pe va po va 	rsons with a contraindication to Janssen COVID-19 ccine (including due to a known allergy to olysorbate) have a precaution to mRNA COVID-19 ccines.*
•	Persons with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 vaccine.*		
•	In persons who received one mRNA COVID-19 dose but are contraindicated to receive the 2 nd dose, consideration may be given to vaccination with Janssen COVID-19 vaccine (at least 28 days after mRNA dose).*		

*In patients with these precautions, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the

management of severe allergic reactions. Consider referral to allergist-immunologist.

Note: Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur.

No contraindication or precaution:

There are allergies that do not constitute a contraindication or precaution to vaccination, including:

- History of food, pet, insect, venom, environmental/seasonal, latex, or other allergies not related to vaccines or injectable therapies
- History of allergy to oral medications (including the oral equivalent of an injectable medication)
- Family history of anaphylaxis
- Any other history of anaphylaxis that is not related to a vaccine or injectable therapy

For rare instances when individuals experience immediate allergic reactions, appropriate medical treatments are available (and are mandatory on site) to manage the symptoms. Clinical considerations are available here: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

(See figure on next page for triage of individuals presenting for COVID-19 vaccination.)

Triage of Individuals Presenting for COVID-19 Vaccination:

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
 History of the following: Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine† Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine† 	 Among people without a contraindication, a history of: Any immediate allergic reaction* to other vaccines or injectable therapies‡ Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.# 	 Among people without a contraindication or precaution, a history of: Allergy to oral medications (including the oral equivalent of an injectable medication) History of food, pet, insect, venom, environmental, latex, etc., allergies Family history of allergies
 Actions: Do not vaccinate. Consider referral to allergist- immunologist. Consider other vaccine alternative.† 	 Actions: Risk assessment Consider referral to allergist- immunologist 30-minute observation period if vaccinated 	 Actions: 30-minute observation period: people with history of anaphylaxis (due to any cause) 15-minute observation period: all other people

† See <u>Appendix C</u> for a list of ingredients. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).

* Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

‡Includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction.

#Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among people who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). People with a contraindication to Janssen COVID-19 vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. For people with these precautions, referral to an allergistimmunologist should be considered. Healthcare providers and health departments may also request a consultation from the <u>Clinical Immunization Safety Assessment COVIDvax</u> project. In patients with these precautions, vaccination should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions.

The above figure is available at <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-</u> considerations.html#Appendix-C

Full clinical guidance is available here: https://www.cdc.gov/vaccines/covid-19/clinical-

considerations/managing-

anaphylaxis.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-byproduct%2Fpfizer%2Fanaphylaxis-management.html

Are children and adolescents recommended to receive COVID-19 vaccines?

Children/adolescents under age 16.

COVID-19 vaccines are not recommended for children/teens under age 16 (Pfizer) or under age 18 (Moderna or Johnson & Johnson/Janssen) at this time. In early clinical trials for various COVID-19 vaccines, only adults who were not pregnant participated. Older children (12 and up) were added in later trials. However, clinical trials continue to expand and include other groups, so these recommendations may change in the future.

Adolescents age 16 and older.

Individuals aged 16-17 years are eligible to receive the Pfizer-BioNTech COVID-19 vaccines (but **not** the Moderna or Johnson & Johnson/Janssen COVID-19 vaccine at this time). No safety concerns were identified in this group during Pfizer-BioNTech COVID-19 clinical trials. Although vaccine safety and efficacy data in this age group are somewhat limited, there is no medical reason to believe that responses from this group would be different from those who are 18 years of age and older. Adolescents aged 16-17 years who are part of a group recommended to receive a COVID-19 vaccine may be vaccinated with the Pfizer-BioNTech vaccine.

Should I take a COVID-19 vaccine if I am pregnant?

Based on current knowledge, experts believe that COVID-19 vaccines are unlikely to pose a risk for people who are pregnant. Currently, however, there are no data on the safety and efficacy of COVID-19 vaccines in pregnant women. Yet, people who are pregnant and become infected with COVID-19 can have an increased risk of severe illness or negative pregnancy outcomes, such as preterm birth. Reputable sources, such as the American College of Obstetricians and Gynecologists, have advised that the benefit of vaccination may outweigh the risk of severe COVID-19 disease. For this reason, if a person who is pregnant is part of a group who is recommended to receive a COVID-19 vaccine, **they may choose to be vaccinated.** A discussion with a health care provider can help make an informed decision. Although a conversation with a healthcare provider may be helpful, it is not required prior to vaccination.

Should I take the vaccine if I am breastfeeding?

If someone who is breastfeeding is part of a group who is recommended to receive a COVID-19 vaccine, **they may choose to be vaccinated.** Currently, there is no data on the safety and efficacy of COVID-19 vaccines in breastfeeding women as they were excluded from clinical trials. However, COVID-19 vaccines are not thought to be a risk to breastfeeding infants. A discussion with a health care provider can help to make an informed decision. Although a conversation with a healthcare provider may be helpful, it is not required prior to vaccination.

Are the COVID-19 vaccines safe for people who want to become pregnant?

There is no evidence the COVID-19 vaccine affects fertility. People who are trying to become pregnant or who are pregnant and for whom the vaccine is recommended may choose to be vaccinated. A discussion with a health care provider can help to make an informed decision.

More information from the American Society for Reproductive Medicine is available here: https://www.asrm.org/news-and-publications/news-and-research/press-releases-and-bulletins/asrmissues-statement-on-covid-19-vaccines-joins-other-obgyn-groups-on-community-wide-statement/

If I have dermal fillers (e.g., face/lip enhancements), are there other possible side effects from COVID-19 vaccination?

It is possible, although infrequent, for persons who have received dermal fillers to develop swelling at or near the site of filler injection (usually face or lips) following administration of a dose of a COVID-19 vaccine. This appears to be temporary and can resolve with medical treatment, including corticosteroid therapy. The COVID-19 vaccines may be administered to people who have received injectable dermal fillers (and who have no contraindications to vaccination). Anyone with a dermal filler who experiences swelling at or near the site of the filler injection should contact a healthcare provider for evaluation.

Should I take the vaccine if I am immunocompromised?

CDC recommends immunocompromised individuals receive the vaccine upon discussion with a healthcare provider. Currently, there is no data on the safety and efficacy of COVID-19 vaccines in immunocompromised people. However, persons with immunocompromising conditions or who take immunosuppressive medications or therapies might be at increased risk for severe disease if they get COVID-19. Therefore, the CDC recommends these individuals receive the COVID-19 vaccine. Immunocompromised individuals should discuss this with a healthcare provider. It is important to note that the COVID-19 vaccines do not contain live virus; so, it is not possible to develop COVID-19 from vaccination.

Are COVID-19 vaccines safe for people with autoimmune disease?

People with autoimmune disease may receive COVID-19 vaccination. Experts say there is no reason to believe that the currently approved COVID-19 vaccines will be unsafe for people with autoimmune disease. Additionally, authorized vaccines are expected to be safe for immunocompromised patients and those on immunosuppressant drugs. However, it is yet unconfirmed whether immunosuppressant medications or unchecked disease activity may reduce vaccine effectiveness. Persons with autoimmune conditions who have no contraindications to vaccination may receive a COVID-19 vaccine. A discussion with a health care provider can help to make an informed decision.

Should I take the vaccine if I've had Guillain-Barré syndrome?

People with a history of Guillain-Barré syndrome (GBS) may receive COVID-19 vaccination. No cases of Guillain-Barré syndrome (GBS) have been reported following vaccination among participants in the mRNA COVID-19 vaccines clinical trials. One case of GBS was reported in a participant in the vaccine group in the J&J/Janssen COVID-19 vaccine clinical trial, compared to one GBS case among those who received placebo. With few exceptions, Advisory Committee on Immunization Practices (ACIP) general best practice guidelines for immunization does not include history of GBS as a contraindication or precaution to vaccination. Persons with a history of GBS may receive an COVID-19 vaccine unless they have a contraindication to vaccination. Any occurrence of GBS following COVID-19 vaccination should be reported to VAERS.

Should I take the vaccine if I have a history of Bell's palsy?

People with a history of Bell's palsy may receive COVID-19 vaccination Cases of Bell's palsy were reported following vaccination in participants in the COVID-19 vaccines' clinical trials. However, the FDA does not consider these to be above the frequency expected in the general population and has not concluded that these cases were causally related to vaccination. The FDA and CDC will continue to monitor the vaccines' safety. In the absence of such evidence, persons with a history of Bell's palsy may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination. Any occurrence of Bell's palsy following mRNA COVID-19 vaccination should be reported to VAERS.

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

The Advisory Committee on Immunization Practices (ACIP) recommends that vaccination should be deferred until 90 days after receiving convalescent plasma or monoclonal antibodies. Currently, there are no data on the safety and efficacy of COVID-19 vaccines in people who received convalescent

plasma or monoclonal antibody therapy. This is to avoid interference of these treatments with vaccineinduced immune responses. The risks and benefits of vaccination based upon the underlying risk factors, including living in a nursing home, could be considered. A discussion with a health care provider can help make an informed decision.

Should I take the vaccine if I already had COVID-19 and recovered?

Yes. Data from clinical trials indicate that COVID-19 vaccines are safe in persons with evidence of a prior SARS-CoV-2 infection. Vaccination should be offered to individuals regardless of history of COVID-19 (symptomatic or asymptomatic). The length of immunity after recovering from COVID-19 disease is unknown; early studies show that immunity after disease recovery is not long lasting and rare cases of reinfection have been reported.

Testing specifically to determine whether a person has active or prior COVID-19 infection is not recommended solely for the purpose of vaccine decision-making.

How long after recovering from COVID-19 should I take the vaccine?

While there is no recommended minimum interval between infection and vaccination, current evidence suggests that the risk of COVID-19 reinfection is low within 90 days after initial infection, but risk may increase with time due to waning immunity. Thus vaccination *could* be deferred during that timeframe; however, given initially limited supply of vaccines, it is not certain when another opportunity for vaccination will be available.

Should I take the vaccine if I currently am infected with COVID-19?

No. Those infected should wait until they have recovered from the acute illness (if the person had symptoms) and criteria have been met for them to end their isolation. This waiting period is essential to avoid exposing healthcare personnel (HCP) or other persons during the vaccination visit. Getting the vaccine while infected is not expected to harm you, but leaving isolation will put others in danger of getting COVID-19. This recommendation applies to persons who get COVID-19 before receiving any vaccine doses as well as those who get COVID-19 after the first dose but before taking the second dose.

Should I get a COVID-19 vaccine if I am in quarantine?

<u>Individuals in a community or outpatient setting</u> should defer vaccination until quarantine period has ended to avoid exposing healthcare personnel (HCP) or other persons during the vaccination visit.

<u>Residents of congregate healthcare settings</u> (e.g., long-term care facilities) may be vaccinated, as this likely would not result in any additional exposures. HCP are already in close contact with residents and should employ appropriate infection prevention and control procedures.

<u>Residents of other congregate settings</u> (e.g., correctional facilities, homeless shelters, residential settings) may be vaccinated, in order to avoid delays and missed opportunities for vaccination. Where possible, precautions should be taken to limit mixing of these individuals with other residents or non-essential staff.

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

Given the lack of data on the safety and efficacy of COVID-19 vaccines administered simultaneously with other vaccines, the vaccine series should routinely be administered alone, with a minimum interval of 14 days before or after administration with any other vaccine. However, COVID-19 and other vaccines may be administered within a shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine co-administration (e.g., tetanus toxoid-containing vaccination as part of wound management, measles or hepatitis A vaccination during an outbreak) or to avoid barriers or delays to COVID-19 vaccination (e.g., in long-term care facility residents or healthcare personnel who received influenza or other vaccinations prior to/upon admission or onboarding). If COVID-19 vaccines are administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

Could getting a COVID-19 vaccine affect the results of a mammogram?

Possibly. Some people who receive a COVID-19 vaccine may experience swollen lymph nodes on the same side of the body where they received the injection. This lymph node enlargement is a normal reaction to a COVID-19 vaccine and a sign that the body is responding to the vaccine to build immunity. Some health care professionals are concerned that having a mammogram soon after vaccination may cause unnecessary worry about swollen lymph nodes.

For routine mammograms (i.e., regular screenings with no symptoms), some medical societies have recommended either completing a mammogram prior to vaccination or waiting 4-6 weeks after completing the vaccination series (two doses for mRNA vaccines, one dose for viral vector). However, no person should cancel a mammogram appointment without consulting the healthcare provider. Any person who gets a mammogram within 4-6 weeks of COVID-19 vaccination should let the clinician know about when and which arm the vaccine was administered. It is important not to put off cancer screenings—or the opportunity to get a COVID-19 vaccine. Talk to a healthcare professional to ask for guidance.

Should premedication be given prior to vaccination?

Taking medications such as acetaminophen or ibuprofen before receiving the vaccine to try to prevent symptoms like fever or pain is not recommended at this time. This is because there is not enough information on how pain-relieving medications will impact immune responses. These medications may be taken after receiving the vaccine for the treatment of symptoms.

What is the Vaccine Administration Management System (VAMS)?

The Vaccine Administration Management System (VAMS) is a secure online tool to manage vaccine administration from the time the vaccine arrives at a clinic to when it is administered to a person.

For more information on VAMS: <u>https://www.cdc.gov/vaccines/covid-19/reporting/vams/faqs.html</u>

VAMS is different from the WV COVID-19 Vaccine Registration System, which enables West Virginians to pre-register for COVID-19 vaccine appointment offerings and notifications.

For more information on the Registration System: <u>https://www.vaccinate.wv.gov</u>

When will I get the vaccine?

After receiving FDA authorization for use in the U.S., Pfizer-BioNTech and Moderna vaccines began arriving in West Virginia in early-mid December. In February 2021, Johnson & Johnson's Janssen also received FDA authorization and entered the state. Vaccines remain in limited supply nationally. West Virginia is dedicated to ensuring that all West Virginians have access to a COVID-19 vaccination as soon as possible. The guiding principles in decision making for getting COVID-19 vaccines to our higher-risk groups include: protecting our most vulnerable, reducing deaths, reducing hospitalizations, and maintaining our critical services and acute care.

As vaccine availability increases over the coming months, the state will able to reach more and more of the general public to offer COVID-19 vaccines as the national supply can meet demand.

Decisions regarding overlapping phased distribution of limited vaccine supplies will remain flexible to ensure West Virginians are offered access as quickly, efficiently, and equitably as possible. It is not necessary to fully complete vaccination in one phase before beginning the next phase.

To view the state's overlapping phased allocation plan and more details regarding particular age groups and high-risk settings: vaccinate.wv.gov

How is the COVID-19 vaccine administered?

COVID-19 vaccines are given through injections into the muscle, typically of the upper arm (i.e., intramuscular), as either a two-dose series or single dose. Each person receives the recommended dose set forth by the manufacturer.

Who will administer the COVID-19 vaccine?

The vaccine will be administered by a health care professional trained in giving an injection into the muscle.

How long between the 2-dose vaccines? What happens if I'm late for the second dose?

Pfizer-BioNTech. The Pfizer product requires a 2-dose vaccination series administered three weeks (21 days) apart. Administration of second dose is allowed within a 4-day grace period (meaning days 17-

21) or after. If more than 21 days have passed since the first dose, the second dose should be administered at the earliest opportunity. There is no need to restart the series.

Moderna. The Moderna vaccine requires a 2-dose vaccination series administered one month (28 days) apart. Administration of second dose is allowed within a 4-day grace period (meaning days 24-28) or after. If more than 28 days have passed since the first dose, the second dose should be administered at the earliest opportunity. There is no need to restart the series.

Any individual who is late to receive their second dose will still mount an immune response upon receipt of the second dose. However, in the meantime between first and second doses, the individual will not have maximum protection against COVID-19. Further, the longer one waits after the recommended dosage period (3-4 weeks after the first dose), it is unknown how protected they will be. Thus it is advised for the second dose to be administered as close to the recommended time period as possible.

(Note: Johnson & Johnson's Janssen vaccine only requires ONE dose.)

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 for maximum protection.

Can I get one dose of one mRNA vaccine (e.g., Pfizer) and the second dose of another mRNA vaccine (e.g., Moderna)?

Individuals should receive the second dose of the COVID-19 vaccine from the same manufacturer as the first dose. The COVID-19 vaccine products are not interchangeable. The safety and efficacy of mixing products in the vaccination series have not been evaluated. However, if two doses of different mRNA COVID-19 vaccine products are *inadvertently* administered, no additional doses of either product are recommended at this time. In certain rare situations, such as when the first-dose vaccine product cannot be determined, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series. Again, COVID-19 vaccines are not interchangeable. In extremely rare situations, some people simply may not have documentation or know which vaccine they got for their first dose.

Recommendations may be updated as further information becomes available or other vaccine types (e.g., viral vector, protein subunit vaccines) are authorized. As further information becomes available and other vaccine types are authorized, recommendations may be updated.

Please note: **The Johnson & Johnson's Janssen** COVID-19 vaccine **should not** be used in place of the second dose for any mRNA vaccine. (However, if an individual experiences a contraindication with the first mRNa dose, in rare cases they may re-start vaccination with the single J&J/Janssen dose with guidance from a healthcare provider—see "Contraindications" and "Precautions" question).

Which COVID-19 vaccine should I receive?

All authorized COVID-19 vaccines are lifesaving vaccines. It is recommended to receive the first vaccine an individual is eligible to receive and that is offered in their community. If someone chooses to delay getting a COVID-19 vaccine when offered, that person would be left open to infection for a longer period of time and be at greater risk of serious illness and death.

Research trials have shown all three vaccines are highly effective against severe COVID-19 illness, hospitalization, and death. Each was developed and evaluated at different points in time against different strains of COVID-19 within distinct geographic regions and populations. The CDC offers no preference among the authorized vaccines.

How will second dose appointments be offered?

Those who have received a first dose of a two-dose mRNA COVID-19 vaccine (i.e., Pfizer or Moderna) will be contacted through the location that administered the first dose and/or receive a notification from the West Virginia COVID-19 Vaccine Registration System.

Is taking the COVID-19 vaccine mandatory?

The vaccine is not mandatory.

After Getting Vaccinated

What are common side effects or immune responses after receiving COVID-19 vaccines?

Short-Term: The majority of short-term effects reported in clinical trials were mild to moderate and occurred within the first few days of receiving a COVID-19 vaccine. Examples of common mild to moderate immune responses include pain, redness, and swelling in the arm of the injection, along with possible tiredness, headache, muscle pain, chills, fever, and nausea.

It is also worth noting that clinical trials for the mRNA vaccines (Pfizer and Moderna) showed stronger immune responses (and reported short-term side effects) after the second dose. The second dose remains essential for maximum protection for mRNA vaccines.

One particular short-term effect reported as possible for all COVID-19 vaccines is a localized rash (usually red in color) that occurs up to one week after vaccination on the arm at which the vaccine was administered. The reddened skin has been described as being red and may feel warm to the touch. In addition, some say that they feel a "knot" or hard area where the skin is red. This appears to be a delayed-onset local immune response and is not systemic (a full-body response). Therefore, individuals who experience this effect are still advised to take the second dose using the same vaccine product as the first dose and at the recommended interval, and preferably in the opposite arm.

Antibiotics are not advised for this particular reaction. Those who experience this reaction could talk to a healthcare provider and consider taking an antihistamine for itching and/or taking their preferred over-the-counter medications to treat pain symptoms (assuming no contrary allergies/conditions precluding use of those medications).

Long-Term: Historically, long-term side effects from vaccines have been rare and most side effects have been seen within the first 60 days of receiving vaccines.

Before vaccination, COVID-19 vaccine recipients should be counseled about expected local (e.g., pain, redness, swelling at the injection site) and systemic (e.g., tiredness, headache, muscle pain, chills, fever, nausea) post-vaccination symptoms.

Anaphylaxis from COVID-19 vaccines is rare, at about 4.5 cases per million doses. This rate is similar to other adult vaccines. Effective treatments for anaphylaxis exist and are on site at the location where vaccines are administered.

What is the V-safe after vaccination health checker?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after a person receives a COVID-19 vaccination. Through V-safe, a person can quickly tell the CDC if they experience side effects after getting the COVID-19 vaccine. Depending on the person's responses, a CDC staff member may call for additional information. V-safe also sends reminders to get the second COVID-19 vaccine dose. Participation in the CDC's V-safe initiative makes a difference — it helps keep COVID-19 vaccines safe.

For more information on V-safe: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html</u>

Should side effects from COVID-19 vaccines be reported? What is VAERS?

Individuals concerned about their health after getting vaccinated should talk with a health care provider, who will determine the appropriate treatment and reporting requirements. Anyone also can choose to report a side effect. Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event.

Vaccination providers are required by the FDA to report the following occurring after COVID-19 vaccination:

- Vaccine administration errors
- Serious adverse events
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

For information on how to submit a report to VAERS: <u>https://vaers.hhs.gov/</u> or call 1-800-822-7967.

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

Yes. It typically takes a few weeks for the body to build immunity after the second dose of the vaccine. 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 as the vaccine has not had enough time to provide protection for disease.

Individuals who have COVID-19 virus symptoms after getting the vaccine or at any time should contact a health care provider and consider getting tested for COVID-19.

Do I need to quarantine if I am exposed between doses?

Quarantine is used to keep someone who might have been exposed to COVID-19 away from others. Quarantine helps prevent spread of disease that can occur before a person knows they are sick or if they are infected with the virus without feeling symptoms.

If exposure occurs between doses, follow quarantine guidance as advised by the local health department. Specifically:

Quarantine Guidance Following 1st Dose Vaccination (Partial Vaccination): Standard quarantine is recommended if individuals are possibly exposed between doses of COVID-19 vaccine. It could take up one to two weeks after the last dose of the vaccine to have maximum protection.

A shortened quarantine is an acceptable option: after day 10 without testing or after day 7 after receiving a negative test (test must occur on day 5 or later). After stopping quarantine, individuals should continue to watch for symptoms until 14 days of exposure, wear a face covering, stay at least 6 ft from others, and take other steps to prevent the spread of COVID-19.

Quarantine Guidance Following 2nd Dose Vaccination for mRNA vaccines (full Vaccination for Pfizer and Moderna): It could take up to 1-2 weeks after your last dose of the vaccine to have maximum protection. After that time, vaccinated persons with an exposure to someone with suspected or confirmed COVID-19 are NOT required to <u>quarantine</u> if they meet ALL of the following criteria:

- Are fully vaccinated (i.e., 2 or more weeks following receipt of the second dose in a 2-dose series, or 2 or more weeks following receipt of one dose of a single-dose vaccine)
- Are within 3 months following receipt of the last dose in the series
- Have remained asymptomatic since the current COVID-19 exposure

Persons who do not meet all 3 of the above criteria should continue to follow guidance after exposure to someone with suspected or confirmed COVID-19.

Quarantine Guidance for Vaccinated Healthcare Personnel, Patients, and Residents in Healthcare Settings: The above criteria can be applied for fully vaccinated healthcare personnel. However, vaccinated inpatients and residents in healthcare settings should continue to quarantine following exposure to someone with confirmed COVID-19.

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.

If I had one type of COVID-19 vaccine (e.g., mRNA) could/should I get another type (e.g., viral vector) too?

A single, valid vaccination series (i.e., either a two-dose mRNA COVID-19 vaccine series or a single dose of J&J/Janssen COVID-19 vaccine) should be administered. People are not recommended to receive more than one complete COVID-19 vaccination series.

Please note that for vaccines that are a two-dose series, individuals should get the first and second dose from the same manufacturer (for example, anyone receiving Moderna for the first dose should receive Moderna for the second dose).

Further, the safety and efficacy of J&J/Janssen COVID-19 vaccine administered after an mRNA COVID-19 vaccine (Pfizer or Moderna) has not been established.

Do I still need to wear a mask and take other COVID-19 precautions after I get the vaccine?

Yes, in public settings and when visiting with unvaccinated people who are, or who have a household member who is, at increased risk for severe COVID-19 disease, vaccinated individuals should continue to wear masks, stay 6+ feet away from others, wash hands frequently, and avoid medium- and large-sized in-person gatherings.

However, there are some exceptions to mask-wearing for those who are fully vaccinated. Beginning at least two weeks after being fully vaccinated ("fully vaccinated" means two doses of Pfizer or Moderna vaccines; one dose of Johnson and Johnson's Janssen vaccine), those who have been vaccinated can visit with other fully vaccinated people indoors without wearing masks or physical distancing and can also visit with unvaccinated people from a single household who are at low risk for severe COVID-19 disease indoors without wearing masks or physical distancing.

For more details about the CDC's Recommendations for Fully Vaccinated People, visit <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html</u>

How many people need to get the vaccine for community immunity (herd immunity)?

Vaccination is the safest path to community or "herd" immunity. These terms describe when enough people have protection, either from previous infection or vaccination, making it unlikely an infection can spread in the population and cause disease. As a result, everyone within the community is protected, even if some people have not received the vaccination. The percentage of people who need to have protection in order to achieve community immunity varies by disease and with the use of other measures to limit spread like social distancing and mask use. The number, or percentage of population, that need to be immune in order to reach community immunity for COVID-19 is not yet known but is thought to begin at around at least 70%.

References

- Advisory Committee on Immunization Practices Meeting Webcast. December 12, 2020.
- 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-biontechconclude-phase-3-study-covid-19-vaccine
- Centers for Disease Control and Prevention Clinical Partner Call: What Clinicians need to know about the Pfizer-BioNTech COVID-19 Vaccine. December 13, 2020.
- Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine. Available from https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html. February 11, 2021.
- Centers for Disease Control and Prevention. Frequently asked questions about vaccination. Available from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html
- Centers for Disease Control and Prevention. Vaccines & Immunizations. Vaccination Communication Toolkit. Available from https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html
- Centers for Disease Control and Prevention. Ensuring the safety of COVID-19 vaccines in the United States. Available from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html COVID-19
- Food and Drug Administration. COVID-19 Vaccines. Available from https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
- Mbaeyi, S. ACIP COVID-19 Vaccines Work Group. Use of mRNA COVID-19 Vaccines: Interim Clinical Considerations. Available from: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-19/06-COVID-Mbaeyi.pdf
- Mehta M, Reece R. WVU Medicine COVID-19 Vaccine Frequently Asked Questions. Updated 3/1/21.
- Vaccine and Related Biological Products Advisory Committee Meeting. December 10, 2020.
- US Department of Health and Human Services. Vaccine side effects. Available from https://www.vaccines.gov/basics/safety/side_effects
- Vaccine Management System. Deloitte. Available from
 <u>https://www2.deloitte.com/us/en/pages/publicsector/solutions/vaccine-management-system.html</u>
- Zhang et al. Advances in mRNA vaccine for infectious diseases. Front. Immunol. March 2019; 10:594
- Also see links provided within answers to particular questions above.

COVID-19 Vaccine Key Messages

Recommended Use:

These messages are meant for internal use by staff or providers to use as points of reference when talking about COVID-19 vaccination with others.

Main Message: COVID-19 vaccination is safe, effective, and trusted.

Key Message 1 (Safety)

COVID-19 vaccination will help protect us and save lives.

- COVID-19 can have <u>serious</u>, <u>life-threatening complications</u>, and there is no way to know how COVID-19 will affect you. Getting vaccinated not only protects you, but also helps protect the people around you particularly those at risk of severe COVID-19.
- The FDA-authorized COVID-19 vaccines have been scientifically tested to ensure that they meet rigorous safety requirements. Independent experts advising the FDA, scientists and researchers, and West Virginia health care leaders trust the safety and effectiveness of COVID-19 vaccines.
- COVID-19 vaccine development was built on more than a decade of cutting-edge technology and large, rigorous clinical trials. At the same time, manufacturing facilities were established and planning for distribution began. The top minds in vaccination science and supply logistics worked together to bring safe, quality, and effective vaccines quickly to the public.

Key Message 2 (Access)

West Virginia is dedicated to offering COVID-19 vaccines to every West Virginian as quickly, efficiently, and equitably as possible.

- All West Virginians 16 years of age and older can pre-register for a COVID-19 vaccine through the West Virginia COVID-19 Vaccine Registration System at <u>www.vaccinate.wv.gov</u>. By pre-registering, you will be contacted about vaccine updates and appointment scheduling via your preferred methods—email, text, or phone.
 - Vaccine supplies are limited, so pre-registration does not mean immediate access to vaccination. It may take days, weeks, or months before an appointment is scheduled.
 - However, all West Virginians considering vaccination should pre-register immediately to reserve a space in line and receive a vaccination appointment as soon as is possible.
- Vaccine supply is limited nationally, so the state is taking an overlapping phased approach to get vaccines to higher-risk groups first.
- Four statewide principles drive decisions about which high-risk groups receive the vaccine while it is in limited supply. The principles are: (1) protect the most vulnerable, (2) reduce deaths, (3) reduce hospitalizations, and (4) maintain critical services and acute care.
- Based on the state's driving principles, groups such as healthcare workers, first responders, residents and staff
 of long-term care facilities, many people over the age of 65, and K-12 and higher education faculty and staff
 personnel have been getting vaccinated. As vaccine supply has begun to increase, vaccines have started to be
 offered to West Virginians age 50 and older, educational personnel age 40 and older, West Virginians age 16 and
 older with certain chronic diseases (e.g., obesity BMI >35, cystic fibrosis, congenital heart disease, sickle cell
 anemia, Down syndrome, organ transplant) and people who are pregnant.
- Cost should not be a barrier for West Virginians to get vaccinated.

Key Message 3 (Community Immunity)

Community immunity begins with each one of us doing our part to prevent the spread of the virus.

- Stopping a pandemic requires using all the public health tools we have available, and vaccination is likely to be our strongest tool yet. Using all our tools gives us the best chance at living life with our families, communities, schools, and workplaces.
- The safest path toward community immunity is vaccination.
- Vaccination, continuing to wear a mask, staying at least 6 feet apart, washing your hands frequently, and avoiding crowds or indoor gatherings are together the best way to disrupt virus spread.

Key Message 4 (Side Effects)

Based on months of clinical trials with tens of thousands of people the FDA determined that COVID-19 vaccination is highly effective in preventing COVID-19 and causes no serious safety concerns.

- Reactions to the COVID-19 vaccines are similar to reactions to vaccinations in general. Common responses to the COVID-19 vaccines include pain, redness, and swelling in the arm where you got the shot, along with possible tiredness, headache, muscle pain, chills, fever, and nausea. These side effects are a sign that your immune system is doing exactly what it is supposed to do. It is working and building up protection to disease.
- Historically, long-term side effects from vaccines have been rare and most side effects have been seen within
 the first 60 days of being vaccinated. Participants in clinical trials for COVID-19 vaccines were monitored for 2
 months after vaccination, with no serious long-term side effects observed. Although long-term side effects are
 not anticipated, additional clinical trials are ongoing, and it will take more people getting vaccinated before we
 learn whether there are very rare or long-term side effects.
- COVID-19 vaccines <u>will not give anyone COVID-19</u>. None of the current COVID-19 vaccines in the U.S. use the live virus that causes COVID-19.

Draft Social Media Posts

The first two versions of the toolkit provided sample social media content. Due to the growing amount of content and array of information needs, previous and NEW social media content are now located in the **Community Immunity WV Social Press Kit (link below).**

The social media content can be directly shared from this platform. Printable and electronic materials for local partners to use are also regularly updated. We hope you will find this new platform helpful in answering your community members' questions about COVID-19 vaccination.

Community Immunity WV Social Press Kit:

https://thesocialpresskit.com/communityimmunitywv

Resource Page

COVID-19 Vaccine Information Websites/pages:

- CDC: Pfizer-BioNTech COVID-19 Vaccine: <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html</u>
- CDC: Moderna COVID-19 Vaccine: <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html</u>
- Pfizer-BioNTech Fact Sheet for Vaccine Recipients and Caregivers: <u>https://www.fda.gov/media/144414/download</u>
- Moderna Fact Sheet for Vaccine Recipients and Caregivers: <u>https://www.fda.gov/media/144638/download</u>
- WV Coronavirus Website: <u>https://dhhr.wv.gov/COVID-19/Pages/Vaccine.aspx</u>
- COVID-19 Vaccination Communication Toolkit For Medical Centers, Clinics, and Clinicians: https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html
- CDC's COVID-19 Vaccine websection for patients/general public: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html
- CDC's COVID-19 Vaccine websection for healthcare workers: https://www.cdc.gov/coronavirus/2019-ncov/hcp/vaccination.html
- CDC: COVID-19 Vaccines: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html
- HHS: Fact Sheet: Explaining Operation Warp Speed: <u>https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html</u>
- U.S. Food & Drug Administration: COVID-19 Vaccines webpage: <u>https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines</u>
- Oliver SE, Gargano JW, Scobie H, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021. MMWR Morb Mortal Wkly Rep. ePub: 2 March 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7009e4external icon.
- Operation Warp Speed: <u>https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/</u>
- AVAC: Cheat Sheet: COVID-19 vaccine pipeline: <u>https://www.avac.org/resource/cheat-sheet-covid-19-vaccine-pipeline</u>
- CDC: Busting Myths and Misconceptions about COVID-19 Vaccination: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits/facts.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fvaccines%2Fabout-vaccines%2Fvaccine-myths.html
- CMS: Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and Cost Sharing under Medicaid, the Children's Health Insurance Program, and Basic Health Program: <u>https://www.medicaid.gov/state-resourcecenter/downloads/covid-19-vaccine-toolkit.pdf</u>
- The Office of Minority Health (OMH) at the U.S. Department of Health and Human Services (HHS) has created the sample social media messages in English and Spanish to share with your audiences, and promote the latest CDC recommendations, information about vaccine planning, guidance on how healthcare providers can address their patients, and the benefits of COVID-19 vaccination. https://www.minorityhealth.hhs.gov/assets/pdf/OMH Prepare for COVID-19 Vaccination_One_Pager.pdf?utm_medium=email&utm_source=govdelivery.
- The Vaccine Education Center at Children's Hospital of Philadelphia: *Questions and Answers about COVID-19* Vaccines: <u>https://www.chop.edu/centers-programs/vaccine-education-center/making-vaccines/prevent-covid</u>

Appendices

Appendix A: West Virginia COVID-19 Vaccine Registration System How-To Sheet

Please see the appended document for a brief how-to on the new West Virginia COVID-19 Vaccine Registration System in West Virginia.

Appendix B: West Virginia COVID-19 Vaccine Registration System How-To Sheet in Spanish

Please see the appended document for a brief how-to on the new West Virginia COVID-19 Vaccine Registration System in West Virginia in Spanish.

Appendix C: West Virginia COVID-19 Vaccine Registration System Printable Flyer

Please see the appended flyer about pre-registration in the West Virginia COVID-19 Vaccine Registration System for printing and distribution needs.

Appendix A: West Virginia COVID-19 Vaccine Registration System How-To Sheet

(on following page)

WV COVID-19 Vaccine Registration System

All West Virginians age 16 and older are encouraged to pre-register for COVID-19 vaccination by creating a WV COVID-19 Vaccine Registration System account at vaccinate.wv.gov or by calling the WV COVID-19 Vaccine Info Line at 1-833-734-0965.

By creating an account, you can pre-register, opt-in to receive updates on COVID-19 vaccine availability, and be contacted about appointment scheduling to get your first and second dose when supplies allow. The pre-registration process takes less than 10 minutes to complete. Follow the steps below.

Pre-registration

STEP 1—Sign Up: Create Your Account

Log on to any web browser and go to: <u>vaccinate.wv.gov</u>. On this site, you will see a "Sign Up Here" button. Click that button, and it will take you to the pre-registration portal. There, enter your:

- Name
- Username
- Password
- Security question
- Location information (verify your address)
- Communication contact information (email, text, or phone/TTY)

Note: After you set up this account, you can use your username and password to login to make edits to your information, change your preferences, or delete your account.

STEP 2—Complete Your Profile

Once you create your account, you will be asked to give additional demographic information in any of 50+ available languages. Your entries allow the system to identify you for vaccination opportunities as supplies allow. The system will take you step-by-step through the process to:

- Verify name and contact information are correct
- Verify location, or provide additional relevant location (optional)
- Add additional contact information (e.g., other phone number, email, TTY)
- Provide required demographic information (e.g., age, ethnicity, gender, occupation, race)
- Provide optional demographic information (e.g., insurance, relevant medical information, information on whether you have received your first dose)

Note: Providing demographic information helps the state serve West Virginians equitably.

STEP 3—Review and Finish

Select "Finish" to complete your pre-registration. Next:

- Review your information for accuracy
- You may edit any section now or later by clicking the "Edit" button(s)
- You will receive confirmation of your successful account setup and pre-registration within 24 hours. If not, you may contact the COVID-19 Vaccine Info Line at 1-833-734-0965 to verify your account information.

What's Next?

Vaccine supplies are limited, so pre-registration does not mean immediate access to vaccination. This means that even if you pre-register, it might take several weeks or months before an appointment is scheduled and you receive your vaccination.

When a vaccine is available for you based on supply, your demographics and location, you will receive a notification through the preferred method you selected (email/text/phone/TTY). The notification will include information about an available vaccination appointment, including date, time, and location. You will be able to accept or decline the appointment based upon your availability. If you decline the appointment, you do not need to re-register as you will be put back into the queue for the next available appointment.

At this time, vaccine appointments will be offered to those ages 65 and older and certain priority groups based on occupation.

Note: West Virginia will never share or distribute your personal information unless required to do so by law. Additionally, the state will never use your information for any purpose other than to send notifications or information pertaining to COVID-19 pandemic response in West Virginia.



How-to Updated: 2/6/21

Appendix A: West Virginia COVID-19 Vaccine Registration System How-To Sheet

(on following page)

Sistema de Registro para la Vacuna contra la COVID-19 en WV

Invitamos a todos los residentes de West Virginia mayores de 16 años al pre-registro para la vacunación contra la COVID-19 mediante la creación de una cuenta en el Sistema de Registro para la Vacuna contra la COVID-19 en WV en vaccinate.wv.gov o llamando a la Línea de Información sobre la Vacuna contra la COVID-19 en WV en el 1-833-734-0965.

Al crear una cuenta obtiene su pre-registro, puede seleccionar si desea recibir actualizaciones sobre la disponibilidad de la vacuna contra la COVID-19, y que lo contacten para reservar una cita una vez que se cuente con el suministro para la primera y segunda dosis. El proceso de pre-registro toma menos de 10 minutos. Siga los pasos que se presentan a continuación.

Pre-registro

PASO 1—Registro: Crear una Cuenta

En cualquier buscador ingrese a <u>vaccinate.wv.gov</u>. En este sitio encontrará el botón "Sign Up Here" (Regístrese aquí). Al hacer clic en este botón, tendrá acceso al portal del pre-registro. En el portal podrá registrar lo siguiente:

- Nombre
- Nombre de Usuario
- Contraseña
- Pregunta de Seguridad
- Información de Ubicación (verificar su dirección)
- Datos de Contacto (correo electrónico, texto, o teléfono/TTY)

Nota: Después de registrar su cuenta, puede usar su nombre de usuario y contraseña para ingresar al portal y editar sus datos, cambiar sus preferencias, o eliminar su cuenta.

PASO 2—Ingrese su Perfil

Una vez que haya creado su cuenta se le solicitará información demográfica adicional, que puede proporcionar en cualquiera de los más de 50 idiomas disponibles. Su información permite que el sistema identifique las oportunidades de vacunación con base en el suministro. El sistema le indicará el proceso a seguir paso a paso:

- Verifique que su nombre y datos de contacto sean correctos
- Verifique su ubicación, o proporcione una ubicación adicional (opcional)
- Agregue datos de contacto adicionales (ej. otro teléfono, correo electrónico, TTY)
- Proporcione la información demográfica necesaria (ej. edad, origen étnico, género, ocupación, raza)
- Proporcione información demográfica opcional (ej. seguro, información médica relevante, información sobre la primera dosis si ya la recibió)

Nota: Proporcionar información demográfica ayuda al estado a brindar un servicio equitativo para todos los residentes de WV.

PASO 3—Revisar y Terminar

Seleccione "Finish" (Terminar) para completar su pre-registro. A continuación:

- Revise si sus datos son correctos
- Puede editar cualquier sección en este momento o posteriormente al hacer clic en el botón "Edit" (Editar)
- Recibirá confirmación sobre la creación de su cuenta y pre-registro dentro de 24 horas. Si no la recibe, puede contactar a la Línea de Información sobre la Vacuna contra la COVID-19 en el teléfono 1-833-734-0965 para verificar la información de su cuenta.

¿Cuál es el siguiente paso?

El suministro de vacunas es limitado, por lo tanto, el pre-registro no implica acceso inmediato a la vacuna. **Esto significa que, aunque realice su pre-registro, pueden pasar semanas o meses para recibir una cita y su vacuna.**

Cuando haya una vacuna disponible para usted considerando el suministro, su demografía y ubicación, recibirá una notificación mediante el medio de su preferencia (correo electrónico/texto/teléfono/TTY). La notificación incluirá información sobre la cita disponible para su vacunación, incluyendo fecha, hora y lugar. Si no acepta la cita, no es necesario que vuelva a registrarse; sus datos se pondrán en espera para la siguiente cita disponible.

En este momento se ofrecerán citas para vacunación a las personas mayores de 65 años y a algunos grupos prioritarios con base en su ocupación.

Nota: West Virginia no compartirá o distribuirá su información personal a menos que la ley lo requiera. Adicionalmente, el estado nunca utilizará su información para otros fines, con la excepción del envío de notificaciones o información relacionada con la respuesta ante la pandemia por COVID-19 en West Virginia.

Toda la comunidad puede combatir la COVID-19 con las herramientas disponibles:



- ••• Usar tapabocas
- ••• Mantener la distancia 6 pies
- ···· Lavarse las manos
- ••• Vacunarse contra la COVID-19

#ComunidadImunidadWV

Consulte a su médico para saber si la vacuna contra la COVID-19 es conveniente para usted.

Actualizado: 2/12/21

Appendix C: West Virginia COVID-19 Vaccine Registration System Printable Flyer

(on following page)