What You Need to Know About the Johnson & Johnson COVID-19 Viral Vector Vaccine

April 9, 2021

INTRODUCTION

The FDA authorized the COVID-19 vaccine made by the Janssen unit of Johnson & Johnson on February 27, 2021, under Emergency Use Authorization (EUA). It was authorized for use in persons 18 years of age and older and was the third COVID-19 vaccine authorized in the U.S.

The other two vaccines are made by Pfizer-BioNTech and Moderna and both use an mRNA platform that requires two doses. The Johnson & Johnson (J&J) vaccine, on the other hand, uses a viral vector vaccine platform and is administered in a single dose. Use the talking points in this document to talk with health care providers, the media, and other stakeholders about this vaccine.

If you have more questions about viral vector vaccines after reading this document, please contact Jasmine Berry (jberry@immunizationmanagers.org). You can also direct media requests to the Association of Immunization Managers (AIM).

For talking points that providers can use to answer patient questions about the J&J vaccine, see page 22 of this document.

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VACCINE DEVELOPMENT & SAFETY

How does the J&J viral vector vaccine work?

Key message: The J&J viral vector vaccine uses a modified version of an adenovirus (the vector) to carry genetic codes into the body. These codes teach the body to make the spike protein that is on the COVID-19 virus. Once the immune system recognizes the spike proteins, it creates antibodies to fight off what it believes to be the SARS-CoV-2 virus. The body can now respond faster and stronger when faced with the actual COVID-19 virus.

Because the adenovirus is modified, it will not make copies of itself once in the body—which is how viruses typically cause infection. That's why the vaccine will not make people sick from either COVID-19 or the adenovirus.

Additional talking points

- Viruses cause infection in your body by replicating. The COVID-19 virus (SARS-CoV-2) contains spike proteins on its surface. The spike protein allows the virus to get into human cells and cause an infection.
- In developing COVID-19 vaccines, scientists have found that viruses can be used to help carry genetic codes that tell the body to make the spike proteins needed to cause the necessary immune response.
- Rather than using live viruses in COVID-19 vaccines, scientists identified the gene that codes for the spike protein in the coronavirus and put the gene into a "carrier." Once in our bodies, the genetic code instructs our bodies to make the SARS-CoV-2 spike protein. The immune system sees these spike proteins as foreign, and creates antibodies to kill them and prevent infection. If someone is infected in the future by the real COVID-19 virus, the body has built up memory antibodies against the spike protein and can now respond faster and stronger to the actual virus.
- The J&J vaccine uses a vector virus that is modified so it will not replicate and will not cause disease in our bodies. This is called a non-replicating vector virus. The vector virus is only a carrier of the genetic code that tells the body to make the necessary spike proteins.
- Different viruses can be used as viral vectors. J&J uses a human adenovirus vector called adenovirus 26 (Ad26). Astra Zeneca used a chimpanzee adenovirus in its viral vector vaccine, which also does not cause disease in people.
- mRNA technology, which is used in the other two authorized COVID-19 vaccines, uses synthetic mRNA (messenger RNA) as the carrier to deliver a message to cells.

More Information

- (CDC) Different COVID-19 Vaccines
- (Hopkins Medicine) COVID-19 Vaccines: Infographic

Why were adenoviruses chosen for the J&J vaccine?

Key message: Adenoviruses were chosen for the J&J vaccine for several reasons. First, because they are a group of viruses that cause the common cold, scientists knew they were suitable for transporting things to humans. And because the common cold is a mild illness that spreads so quickly between people, they also knew they would produce a robust immune response.

Second, scientists have studied adenoviruses since the 1970s and understand how to use them in vaccines. Third, vaccines using adenovirus vectors are easy to design and easy to develop in large quantities. That made them a good choice for a vaccine needed to respond to a pandemic.

Additional talking points:

- The vaccine development process can be accelerated when using viral vector technology. All that is needed to start the process is to find the genetic code for the protein you want the body to fight.
- Once this genetic code is identified, scientists can add the code to a vector virus and vaccine production can begin. Researchers can develop these vaccines in large quantities quickly.

More information

- (CDC) Understanding and Explaining Viral Vector COVID-19 Vaccines

How do you know the vector virus will not cause disease?

Key message: When making the vaccine, scientists did not want the adenovirus to keep on replicating and cause disease in a person. So they altered it so it could no longer make copies of itself or spread in a person's body.

Also, the COVID-19 spike proteins made in the body after vaccination are not actual COVID-19 viruses. Instead, they are a piece of the virus, so they will not by themselves cause disease in the body. Their role is only to trick the body into thinking it is the actual disease. That's why scientists know the vaccine does not cause infections from either COVID-19 or the adenovirus.

Additional talking points

- Viral vectors are safe because they are modified not to cause disease once they get into the body. They only deliver the genetic code.
- Because vector viruses are non-replicating, they will not create additional viruses or viral vectors in the body.

More information

- (CDC) Understanding and Explaining Viral Vector COVID-19 Vaccines
- (CHOP) Questions and Answers about COVID-19 Vaccines

What happens to the genetic code and the viral vector once it has done its job?

Key message: The genetic code is broken down in our cells after our bodies make the spike protein. The viral vector, in this case the adenovirus, cannot replicate because it is weakened. That means it will not create additional viruses or viral vectors in the body. They are removed by specific cells in our bodies and eliminated within weeks.

Additional talking points

- The genetic code delivered by the viral vector is broken down in cells after a person's body makes the necessary protein. Both the genetic code and the viral vector disintegrate, and the body gets rid of them.
- Also, the genetic material delivered by the viral vector does not integrate into a person's DNA.

More information

- (Janssen) The Janssen COVID-19 Vaccine: How It's Designed
- (CDC) Understanding and Explaining Viral Vector COVID-19 Vaccines
- (CHOP) Questions and Answers about COVID-19 Vaccines

Are viral vector vaccines new technology?

Key message: J&J's Janssen unit developed the J&J COVID-19 vaccine using ***existing*** viral vector vaccine technology called the AdVac® vaccine platform, and a human adenovirus vector called adenovirus 26 (Ad26).

Scientists have conducted clinical trials in humans for viral vector vaccines against various diseases, including Zika virus, influenza viruses, respiratory syncytial virus (R.S.V.), HIV, and malaria. Two Ebola vaccines using this viral vector method were utilized in Ebola outbreaks in West Africa and the Democratic Republic of the Congo.

Additional talking points:

- The J&J Ebola vaccine is currently being used in Africa to help stop the 2021 Ebola outbreak. It was approved by the European Commission in July 2020 for those age one and older.
- During the Ebola vaccine trial, the vaccine using the Ad26-based platform was studied in over 193,000 participants of various races and ethnicities, including healthy adults, adults over the age of 65, breastfeeding and pregnant women, infants, children, and those with HIV.
- South Africa approved the J&J COVID-19 vaccine in February 2021 for use in its general population.
- The AstraZeneca vaccine also uses viral vector technology. This vaccine has been used in Europe since January 2021 and is still undergoing trials in the United States. As of April 8, 2021, it has not been authorized for use in the United States.

More information

- (CDC) Understanding and Explaining Viral Vector COVID-19 Vaccines
- (CDC) Overview of Janssen's Single-Dose COVID-19 Vaccine, Ad26.COV2.S
- (Jannsen) Vaccine Technology
- (WHO) Ebola vaccination starts in Guinea to curb new outbreak

What ingredients are in the J&J vaccine?

Key message: The J&J vaccine includes weakened, non-replicating adenoviral 26 particles containing the genetic code for the spike protein of COVID-19. It also contains a buffer of commonly used, inactive ingredients: sodium chloride (table salt), sodium hydroxide, hydrochloric acid, citric acid monohydrate, trisodium citrate dihydrate, polysorbate-80, 2-hydroxypropyl-B-cyclodextrin, ethanol, and water for injection.

It does ***not*** contain adjuvants (ingredients used to strengthen the effectiveness of a vaccine), antibiotics or preservatives.

Additional talking points

- The J&J vaccine cell line grows in a medium that is free of animal components.
- None of the three currently authorized COVID-19 vaccines (Pfizer-BioNTech, Moderna, and J&J) contain eggs, gelatin, latex, or preservatives.

More information

- (CDC) Overview of Janssen's Single-Dose COVID-19 Vaccine, Ad26.COV2.S
- (CDC) Appendix C: Ingredients included in COVID-19 vaccines
- (CHOP) Vaccine Ingredients — DNA

Were fetal cells used in making the vaccine?

Key message: The J&J vaccine development process uses cells initially isolated from fetal tissue (often referred to as fetal cells), but the vaccine does not contain fetal tissue. Fetal cells were used because viruses used to make vaccines need cells to grow, and cells grow better in human cells.

The special cells for this process were isolated decades ago from one of two terminated fetuses and later adapted for the adenovirus reproduction process. This is ***not*** an ongoing process. The two cell lines used have been maintained in the laboratory, and no additional fetuses are needed to produce adenovirus vector vaccines.

Additional talking points

- The two non-replicating viral vector vaccines by J&J and AstraZeneca use cell lines initially isolated from fetal tissue (often referred to as fetal cells). These cells are used to grow the vaccine virus. The vaccines themselves do not contain fetal tissue.
- The fetal cell lines are: the HEK-293, a kidney cell line that was isolated from a terminated fetus in 1972, and PER.C6, a retinal cell line isolated from a terminated fetus in 1985.
- Even though fetal cells are used to grow vaccine viruses, vaccines do not contain these cells or pieces of DNA that are recognizable as human DNA. Once the vaccine virus is grown, it is purified so that cellular debris and growth reagents are removed. During this purification process, any remaining cellular DNA is also broken down.

- Some religious organizations have assured their congregants that they may be vaccinated with vaccines whose components were grown in fetal cells.
- Reviews by both the Vatican's Pontifical Academy for Life and the National Catholic Bioethics Center have determined that vaccines grown in these cell lines do not go against the religion's doctrine, and using these vaccines are the best way to protect people from serious vaccine-preventable diseases.

More information

- (CHOP) Vaccine Ingredients – Fetal Cells
- (Vaccinate Your Family) Vaccine Ingredients
- (Academy for Life) Note on Italian vaccine issue
- (The National Catholic Bioethics Center) FAQ: On the Use of Vaccines
- (Immunization Action Coalition) MORAL REFLECTIONS ON VACCINES PREPARED FROM CELLS DERIVED FROM ABORTED HUMAN FOETUSES
- (United States Conference of Catholic Bishops) MORAL CONSIDERATIONS REGARDING THE NEW COVID-19 VACCINES
- (The Vatican) Note on the morality of using some anti-Covid-19 vaccines

Is there a concern that some people may already have immunity to adenoviruses?

Key message: As humans, we develop an immune response after exposure to a virus. Since some of us have already been exposed to adenoviruses used in the J&J vaccine, it is possible some people may already have some immunity, and the vaccines might not work for everyone. However, the human adenovirus used in the J&J Ebola vaccines did ***not*** find this to be an issue.

Additional talking points

- Scientists used the chimpanzee adenovirus as the viral vector in the AstraZeneca vaccine because most people have never come into contact with this virus and so will not already have immunity.
- Remember that the vector virus, whether from human adenovirus or chimpanzee adenovirus, is modified so it will not cause disease in the body. It is only a messenger to take the genetic code to the body's cells.

More information

- (CDC) Understanding and Explaining Viral Vector COVID-19 Vaccines
- (CHOP) Questions and Answers about COVID-19 Vaccines

What are the side effects?

Key message: Side effects noted during the clinical trial were common within seven days of getting vaccinated but were mostly mild to moderate and lasted for 1 to 3 days. Side effects were more common in people 18 to 59 years old than in people 60 years and older. Study participants will be followed for up to two years to assess safety and efficacy and, like the other COVID-19 vaccines, the J&J vaccine will continue to be rigorously evaluated for safety.

Additional talking points

- Side effects may occur, and as seen in the clinical trials, they are expected to be mild and minor, including both local reactions (pain at the injection site, redness, swelling) and systemic reactions (headache, fever, fatigue). These side effects are expected, and are a sign our immune system is working.
- Most local reactions occurred within two days of vaccination and lasted 2-3 days. Most systemic reactions occurred within two days of vaccination and lasted 1-2 days.
- No safety concerns were seen in people of different races, those with underlying medical conditions, or those who previously had COVID-19 infection.
- The FDA requires vaccination providers to report vaccination administration errors, serious adverse events, cases of the multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death after administration of COVID-19 vaccine under EUA.
- Adverse events that occur after receipt of any COVID-19 vaccine should be reported to the Vaccine Adverse Events Reporting System (VAERS). Information on how to submit a report is available at https://vaers.hhs.gov/index.html or by calling 800-822-7967. Anyone who administers or receives a COVID-19 vaccine is encouraged to report any clinically significant adverse event, whether or not it is clear that a vaccine caused the adverse event.
- The CDC has developed a new, voluntary smartphone-based online tool (v-safe) that uses text messaging and online surveys to provide near real-time health check-ins after receipt of a COVID-19 vaccine. The v-safe call center follows up on reports of possible medically significant health events to collect additional information for completion of a VAERS report.

Table 1. Local reactions in persons aged 18-59 years and persons aged ≥60 years, Janssen COVID-19 vaccine and placebo[a]

	18-59 years		≥60 years	
	Janssen Vaccine N=2036	Placebo N=2049	Janssen Vaccine N=1320	Placebo N=1331
Any Local, n (%)				
Any	1218 (59.8)	413 (20.2)	467 (35.4)	244 (18.3)
Grade 3	18 (0.9)	4 (0.2)	5 (0.4)	2 (0.2)
Pain[b], n (%)				
Any	1193 (58.6)	357 (17.4)	439 (33.3)	207 (15.6)
Grade 3	8 (0.4)	0 (0.0)	3 (0.2)	2 (0.2)
Erythema[c], n (%)				
Any	184 (9.0)	89 (4.3)	61 (4.6)	42 (3.2)
Grade 3	6 (0.3)	2 (0.1)	1 (0.1)	0 (0.0)
Swelling[c], n (%)				
Any	142 (7.0)	32 (1.6)	36 (2.7)	21 (1.6)
Grade 3	5 (0.2)	2 (0.1)	2 (0.2)	0 (0.0)

[a] Solicited local and systemic adverse reactions collected for participants in a safety subset (N=6,736)

[b] Pain – Grade 3: any use of prescription pain reliever or prevented daily activity

[c] Erythema and Swelling – Grade 3: >100mm

Note: No grade 4 local reactions were reported.

Table 2. Systemic reactions in persons aged 18-59 years and persons aged ≥60 years, Janssen COVID-19 vaccine and placebo[a]

	18-59 years		≥60 years	
	Janssen Vaccine N=2036	Placebo N=2049	Janssen Vaccine N=1320	Placebo N=1331
Any systemic, n (%)				
Any	1252 (61.5)	745 (36.4)	598 (45.3)	440 (33.1)
Grade 3	47 (2.3)	12 (0.6)	14 (1.1)	9 (0.7)
Fatigue[b], n (%)				
Any	891 (43.8)	451 (22.0)	392 (29.7)	277 (20.8)
Grade 3	25 (1.2)	4 (0.2)	10 (0.8)	5 (0.4)
Headache[b], n (%)				
Any	905 (44.4)	508 (24.8)	401 (30.4)	294 (22.1)
Grade 3	18 (0.9)	5 (0.2)	5 (0.4)	4 (0.3)
Myalgia[b], n (%)				
Any	796 (39.1)	248 (12.1)	317 (24.0)	182 (13.7)
Grade 3	29 (1.4)	1 (<0.1)	3 (0.2)	5 (0.4)
Nausea[c], n (%)				
Any	315 (15.5)	183 (8.9)	162 (12.3)	144 (10.8)
Grade 3	3 (0.1)	3 (0.1)	3 (0.2)	3 (0.2)
Fever[d], n (%)				
Any	261 (12.8)	14 (0.7)	41 (3.1)	6 (0.5)
Grade 3	7 (0.3)	0 (0.0)	1 (0.1)	0 (0.0)

[a] Solicited local and systemic adverse reactions collected for participants in a safety subset (N=6,736)

[b] Fatigue, Headache, Myalgia – Grade 3: use of prescription pain reliever or prevented daily activity

[c] Nausea – Grade 3: prevented daily activity

[d] Fever – Grade 3: ≥39.0 – ≤40.0°C or ≥102.1 – ≤104.0°F

Note: No grade 4 systemic reactions were reported.

More information

- (CDC) Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events: Janssen COVID-19 Vaccine
- (CDC) The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021
- (CDC) V-safe After Vaccination Health Checker
- Local Reactions, Systemic Reactions, Adverse Events, And Serious Adverse Events: Janssen COVID-19 Vaccine

Can the J&J vaccine be given to pregnant and breastfeeding women?

Key message: Yes, any of the currently authorized COVID-19 vaccines can be offered to people who are pregnant or breastfeeding. The FDA has not found any contraindication (a specific situation in which a drug, procedure, or surgery should not be used because it may be harmful to the person) for pregnant or breastfeeding women.

The vaccine trials did not choose to include pregnant or breastfeeding individuals, so it is recommended these women speak with their doctor before getting the vaccine. Side effects can occur with COVID-19 vaccine use in pregnant people that are similar to those expected among non-pregnant people. There is no reason to believe the vaccine itself is responsible for any risks to pregnant women greater than the virus itself.

Additional talking points

- The modified adenovirus used in the J&J vaccine can't replicate or cause illness. The body quickly clears it from the injection site, so it's unlikely to reach or cross the placenta.
- Vaccines similar to the J&J vector vaccine have been studied in humans for HIV, Ebola, and Zika virus. Trials that enrolled pregnant women reported no harmful pregnancy outcomes.

More information

- (CDC) Information about COVID-19 Vaccines for People who Are Pregnant or Breastfeeding
- (CDC) Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States
- (FDA) Janssen COVID-19 Vaccine Frequently Asked Questions

Does the vaccine affect fertility?

Key message: Some people have falsely claimed that the same antibodies created by the vaccine to teach the body to fight against COVID-19 will also attack the proteins on the placenta, leading to infertility.

There's no evidence that COVID-19 antibodies will lead to infertility**.** While there are similarities between the COVID-19 spike proteins and the proteins needed to form a placenta, medical experts have proven there are no similarities between the amino acid sequences of the spike protein and placental synctin-1. With no relation between them, there is no reason to believe the COVID-19 vaccine will cause COVID-19 antibodies to react with a healthy placenta.

Furthermore, there has been no evidence of infertility from COVID-19, and if the virus itself does not cause infertility, then the antibodies cannot.

Additional talking point

- While those placental proteins are similar to the coronavirus spike proteins, they are not the same – and our bodies know that. Our antibodies know what they're looking for, and the two proteins aren't similar enough to confuse them.

More information

- (CDC) Myths and Facts about COVID-19 Vaccines
- (Vaccinate Your Family) Questions and Answers About COVID-19 Vaccines

TESTING & EFFICACY

How was the J&J vaccine tested?

Key message: The J&J vaccine followed the same rigorous, transparent, three-phased testing process as every other vaccine. This process prioritizes safety.

Phase 3 clinical trials to determine whether the J&J vaccine was safe and effective included 43,783 participants. The trials took place in eight (8) countries and three (3) regions globally, including the U.S., Latin America and South Africa, where scientists identified some of the more recent coronavirus strains.

Additional talking points

- The phase 3 clinical trials began in September 2020 and participants ranged from 18 to 100 years old, with 29% over the age of 65. Half of those participating received the J&J vaccine. Half received a saline placebo.
- The goal of the Phase 3 study was to determine whether the J&J vaccine prevented moderate to severe COVID-19 disease in persons whose blood tests show no evidence of having had COVID-19 in the past.
- After getting the vaccine or placebo, these participants were evaluated at two weeks and a month after vaccination, followed for eight weeks after vaccination, and will continue to be followed for two years after vaccination.
- Racial/ethnic breakdowns in the U.S. arm of the study in both vaccine and placebo groups were as follows:
- 1% American Indian or Alaska Native
- 6-7% Asian
- 13% Black or African American
- 0.4-0.5% Native Hawaiian or other Pacific islander
- 74% White
- 14-15% Hispanic or Latino
- People with comorbidities (or underlying medical conditions) that could put them at increased risk for severe disease from COVID-19 were included in the study in both vaccine and placebo groups:
- ≥ 1 risk factor: 43.8-44%

- Obesity > 30 kg/m^2: 31.7-32%
- Hypertension: 11.8-12.1%
- Type 2 Diabetes Mellitus: 7.6-7.7%

- Serious heart conditions: 3-3.2%
- Asthma: 1.7-2.1%

More information

- (CDC) Overview of Janssen's Single-Dose COVID-19 Vaccine, Ad26.COV2.S
- (CDC) Information About Johnson & Johnson's Janssen COVID-19 Vaccine

How effective is the J&J vaccine?

Key message: The J&J vaccine was 74% effective in preventing symptomatic COVID-19 disease in the U.S. trial, and 85% effective in preventing severe COVID-19 disease. The vaccine also showed 93% efficacy in preventing people from being hospitalized due to COVID-19 illness. No deaths occurred during the trial in those who had received the vaccine.

In addition, preliminary data suggests that the J&J COVID-19 vaccine might also protect against asymptomatic infection.

Additional talking points

- The efficacy of a vaccine refers to how well it protects people against disease during a clinical trial, looking at a specific question: does the vaccine protect against all disease, mild disease, moderate disease, and severe disease?
- Real-world effectiveness of a vaccine can sometimes be less than what is seen during the trials. One reason is that vaccine trials often do not include people whose immune response may be slightly weaker, such as those with underlying health conditions, those on certain medications, older individuals, or pregnant women.
- Scientists continue to observe and study people in real-world conditions who got the vaccine.
- In the Phase 3 clinical trial, 28 days after vaccination, efficacy was 66% in preventing symptomatic COVID-19 disease across all eight countries represented in the trials.
- There was a difference in efficacy across regions: 74% in the United States, 65% in Latin America, and 52% in South Africa. Experts believe that the circulation of variant strains of the COVID-19 virus worldwide may have led to this difference.
- There was some evidence that the vaccine may also help prevent asymptomatic infection, and scientists continue to study this question.

- In comparison, during the phase 3 clinical trials, scientists did not evaluate the Pfizer vaccine for the prevention of asymptomatic infection, while data for the Moderna vaccine was insufficient to decide whether the vaccine prevents asymptomatic infection.
- Because we are not sure whether any of the vaccines prevent asymptomatic infection, the CDC currently recommends that anyone who was vaccinated continue to follow precautions to prevent the spread of COVID-19, including wearing masks, practicing physical distancing and maintaining good hand hygiene.

More information

- (GAVI) What is the difference between efficacy and effectiveness?
- (CDC) Ensuring COVID-19 Vaccines Work
- (CDC) The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021
- (CDC) Information About Johnson & Johnson's Janssen COVID-19 Vaccine
- (NCBI) Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine
- (New England Journal of Medicine) Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine

Is one type of COVID-19 vaccine recommended over another?

Key message: The CDC and ACIP (Advisory Committee on Immunization Practices) do not state a preference of any of the three currently authorized COVID-19 vaccines. The three vaccines were never compared directly in head-to-head clinical trials. Each one was tested against a placebo. Also, each of the vaccines was tested at various times during the pandemic and in different regions of the world.

You should receive the first authorized vaccine made available to you. People who want to complete their vaccination schedule quickly or might have difficulty returning for a second dose might prefer the J&J single-dose vaccine.

Additional talking points

- Because the J&J vaccine only requires one dose and is stable at refrigerator temperatures for transportation and storage, it is feasible (when more widely available) for use in most community settings and mobile sites.
- The study design differed for the three vaccines. The J&J study design looked at how many people were protected from moderate to severe illness (having to be hospitalized, admitted to the ICU, or be on a ventilator). The two mRNA vaccine study designs looked at how many people were protected from symptomatic disease.

- Scientists stress that we should look at how well all three vaccines prevent severe disease from COVID-19, including hospitalizations and deaths. During clinical trials, all three currently approved vaccines showed over 85% efficacy in preventing severe disease.
- The J&J vaccine clinical trials occurred when the South African (B.1.351) and Brazil (P.2) variants were widely circulating in the respective regions.
- Scientists are continuing to look at how well all three vaccines are doing in the real world in preventing the virus and new variants. These studies will let us know how effective these vaccines are in the real world.

More information

- (CDC) The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021
- (CDC) Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States
- (CDC) The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021
- (FDA) Emergency Use Authorization for Vaccines to Prevent COVID-19
- (CDC) Overview of Janssen's Single-Dose COVID-19 Vaccine, Ad26.COV2.S
- (CDC) Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Janssen COVID-19 Vaccine
- (NCBI) Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine
- (NCBI) Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine
- (AIM) ACIP Meeting Information and Presentations

Does it protect against the new viral strains?

Key message: Viruses constantly mutate to survive. Currently there are three variants of COVID-19: B.1.351, P.2, and B.1.1.7. Scientists continue to monitor these variants to learn more about how easily they spread, whether they could cause more severe illness and whether currently authorized vaccines will protect people against them.

The J&J Phase 3 clinical trials were conducted in South Africa and Brazil when the variant strains were predominant in those countries. The vaccine showed efficacy against these strains.

Additional talking points:

- COVID-19 can mutate by changing the spike proteins. A new virus variant emerges when the virus develops one or more mutations that differentiate it from the predominant virus variants already circulating in a population.
- Sometimes new variants emerge and then disappear; sometimes they persist. Scientists monitor these changes to see how strains spread, what happens when someone is infected with a new strain and whether the current vaccines will work against them.
- The three strains of concern found in the U.S. are the U.K. variant, called B.1.1.7, the South Africa variant, called B. 1.351, and the Brazil variant called P.1. The concern is that because these variants spread more easily and quickly, they may lead to more cases of COVID-19 and potentially lead to more hospitalizations and deaths.
- All three vaccines are expected to provide at least some protection against new variants because they elicit a broad immune response involving a range of antibodies and cells. Therefore, changes or mutations in the virus should not make vaccines completely ineffective.
- If any of these vaccines prove to be less effective against one or more variants, it will be possible to change the composition of the vaccines to protect against these variants.

More information

- (WHO) The effects of virus variants on COVID-19 vaccine
- (CDC) About Variants of the Virus that Causes COVID-19
- (Medscape) Viral Variants and Vaccines
- (bioRxiv) Neutralization of viruses with European, South African, and United States SARS-CoV-2 variant spike proteins by convalescent sera and BNT162b2 mRNA vaccine-elicited antibodies
- (Moderna) Moderna Announces it has Shipped Variant-Specific Vaccine Candidate, mRNA-1273.351, to NIH for Clinical Study
- (GAVI) COVID-19 variants are not going away, but vaccines may help make that OK

What does the difference in efficacy between the different vaccines mean?

Key message: All three COVID-19 vaccines currently authorized in the United States have been found to be safe and effective. And each exceeded efficacy criteria set by the World Health Organization.

Various factors may lead to efficacy differences. These include when it was tested, among which populations it was tested, whether or not new viral strains were present, and whether it was studied using a different design than another vaccine.

Additional talking points

- Over 100 different vaccines are being developed around the world to protect against COVID-19. Some have reported different efficacy results in their clinical trials.
- Before the trial results of any COVID-19 vaccines were published, the FDA and the World Health Organization (WHO) said vaccines with greater than 50% efficacy would be worth approving.
- All authorized COVID-19 vaccinations surpassed WHO criteria and help prevent us from getting COVID-19 and protect us from being hospitalized or dying from COVID-19.
- Some of the COVID-19 vaccines currently being studied show lower efficacy in general but higher efficacy in preventing more severe illnesses. Some also work better in specific populations, such as older adults.

More information

- (GAVI) What is the difference between efficacy and effectiveness?
- (GAVI) Why even a low efficacy COVID-19 vaccine could still be extremely useful
- (CDC) Benefits of Getting a COVID-19 Vaccine
- (CDC) Ensuring COVID-19 Vaccines Work

DOSING, HANDLING, & STORAGE

What are the dosing, administration, and storage and handling guidelines of the J&J vaccine?

The J&J vaccine is recommended for people aged 18 years and older. It is administered as a single dose; no additional doses are recommended at this time. It is stored in a refrigerator at a temperature between 2°C and 8°C (36°F and 46°F).

Dosage

- The vaccine comes in a suspension in multi-dose vials.
- There are five (5) doses in each multi-dose vial.
- Each vaccine dose is 0.5ml. Administer the vaccine intramuscularly.
- The vial does not contain a preservative.

Storage and handling

- The vaccine will arrive at a refrigerated temperature of 2C to 8C (36°F and 46°F).
- Store ***unpunctured*** vials between 2°C and 8°C (36°F and 46°F) until the expiration date.
- After puncturing the multi-dose vial seal, store vaccine in the refrigerator (between 2°C and 8°C (36°F and 46°F) for up to six (6) hours or at room temperature (up to 25°C/77°F) for two (2) hours.
- Discard any unused vaccine if not used within these timeframes.

Clinical guidelines

- Before vaccination, provide the EUA Fact Sheet to recipients and caregivers.
- Providers should advise vaccine recipients of expected systemic and local side effects.
- Administer the vaccine immediately by intramuscular injection in the deltoid muscle.
- Observe recipients for 15 minutes after vaccination for an immediate adverse reaction.
- If recipients have a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy, or a history of anaphylaxis due to any cause, observe for 30 minutes after vaccination.
- COVID-19 vaccines should be administered alone, with a minimum interval of 14 days before or after administration of any other vaccine.
- According to the CDC, 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 coadministration (e.g., tetanus-toxoid-containing vaccination as part of wound management, rabies vaccination for post-exposure prophylaxis, measles, or hepatitis A vaccination during an outbreak) or to avoid barriers to or delays in COVID-19 vaccination (e.g., in long-term care facility residents or healthcare personnel who received influenza or other vaccinations before or 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.

More information

Additional clinical considerations are available at:

- (CDC) Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States
- (CDC) Interim Considerations for Phased Implementation of COVID-19 Vaccination and Sub-Prioritization Among Recommended Populations
- (CDC) Janssen COVID-19 Vaccine (Johnson & Johnson)
- (FDA) FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)
- (CDC) Janssen COVID-19 Vaccine (Johnson & Johnson) Storage and Handling Summary
- (CDC) Janssen COVID-19 Vaccine Storage and Handling Label
- (CDC) Janssen COVID-19 Vaccine (Johnson & Johnson) Transporting Vaccine for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations
- (CDC) Temperature Log when Transporting Vaccine at Refrigerated Temperatures
- (Immunization Action Coalition) Vaccines: COVID-19

Can I mix and match doses of the J&J vaccine with other COVID-19 vaccines?

Key message: COVID-19 vaccines are ***not*** interchangeable. The safety and efficacy of the J&J vaccine administered after an mRNA COVID-19 vaccine has not been established.

In ***limited, exceptional*** situations where a patient received the first dose of an mRNA vaccine but is unable to complete the series with either the same or different mRNA vaccine (e.g., due to contraindication), a single dose of the J&J vaccine may be considered at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose.

More information

- (CDC) Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States
- (CDC) Contraindications and precautions

EXPLAINING THE J&J VIRAL VECTOR VACCINE TO PATIENTS

Is the viral vector vaccine a new kind of vaccine?

The technology used to make the J&J viral vector vaccine is not new. Scientists have studied viral vector vaccines against various diseases for years, including Zika virus, influenza viruses, HIV and malaria. Plus, two Ebola vaccines using this vaccine method were used in Ebola outbreaks in West Africa and also the Democratic Republic of the Congo.

How does the vaccine work?

Rather than carrying a live virus into the body, viral vector vaccines carry genetic codes that teach the body to make the spike protein that is on the COVID-19 virus. The codes are carried by a different virus than COVID-19, in this case an adenovirus.

Once the immune system recognizes the spike proteins, it creates antibodies to fight infections. Your body can now respond faster and stronger when faced with the actual COVID-19 virus.

Since it carries a virus, can it make me sick?

The vaccine cannot infect you with either COVID-19 or adenovirus. A vector virus is only there to carry the genetic code to your cells and does not replicate once it is in your body. Plus, the COVID-19 spike proteins your body makes after you are vaccinated are not actual COVID-19 viruses; they are only a piece of the COVID-19 virus. They are designed to trick your body into thinking this is the actual disease so that your body's immune system can fight it.

Does it change my DNA?

No, the genetic material delivered by the viral vector does not integrate into a person's DNA.

Do the genetic code and the viral vector stay in my body?

No, the genetic code is broken down after our bodies make the spike protein. And the adenovirus is modified so it will not create additional viruses in your body. They are eliminated from our bodies in weeks.

Who can get the vaccine?

It is recommended for people age 18 years and older.

How many doses of the J&J vaccine do I need?

Only one dose is needed. No additional doses are recommended at this time.

Does it have any dangerous ingredients?

It contains only the adenovirus—which has been weakened and changed so that it will not make copies of itself—and harmless buffers for your body. It has no adjuvants (ingredients that help some vaccine create a stronger immune response), antibiotics or preservatives. And it does not contain eggs, gelatin, latex, or preservatives.

How do I know it's safe?

The J&J vaccine followed the same rigorous, transparent, three-phased testing process as all vaccines, and after the clinical trials, scientists determined it to be both safe and effective. Over 40,000 people worldwide of different races, ethnicities, and underlying medical conditions participated in the studies.

What are the side effects?

A few people suffered side effects after vaccination, including soreness, redness and swelling at the injection site, and fever, headache, and fatigue. These side effects were mild to moderate, occurred within a day or two after vaccination, and lasted for 1 to 3 days after vaccination. Remember, side effects are a sign that your immune system is working.

How effective is it?

Seven out of 10 people who received the J&J vaccine in clinical trials were protected from getting symptoms of COVID-19. Moreover, the vaccine prevented hospitalization and death in 93% of people who got the disease. The CDC and FDA recommends all three currently authorized vaccines as safe and effective.

Is one vaccine better then another?

All three authorized vaccines are safe and effective, so public health experts recommend you get the one available to you now. This way, you lower your chances of getting COVID-19 and the risk of infecting other people in your family or community.

If you want to get vaccinated more quickly or might have difficulty returning for a second dose, you might prefer a single-dose vaccine.

Will the J&J vaccine protect me from the new strains of COVID-19?

There are three variants of COVID-19 that we are watching at this time: the U.K. variant, the South Africa variant and the Brazil variant. The J&J vaccine's Phase 3 clinical trials were conducted in South Africa and Brazil when the variant strains were predominant in those countries and proved effective against them.

Scientists continue to monitor these strains to learn more about how easily they spread, whether they could cause more severe illness and whether our vaccines will protect people against them.

Can the COVID-19 vaccines be given to pregnant and breastfeeding women?

Any of the currently authorized COVID-19 vaccines can be offered to people who are pregnant or breastfeeding, though It is recommended that pregnant and breastfeeding women speak with their doctor before getting the vaccine.

While vaccine trials for the three authorized vaccines chose not to include pregnant individuals, so far pregnant women appear to have only the same mild to moderate vaccine side effects as nonpregnant individuals.

Do the COVID-19 vaccines affect fertility?

There's no evidence that COVID-19 vaccination will lead to infertility. Questions were raised because of similarities between COVID-19 spike proteins and the proteins needed to form a placenta. But there are no similarities between the amino acid sequences of the COVID-19 spike protein and placental synctin-1, so there is no reason to believe the vaccine will cause COVID-19 antibodies to react with a healthy placenta.

Furthermore, there has been no evidence of infertility in people who have had the COVID-19 virus. And if the virus itself does not cause infertility, then the antibodies cannot.

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