COVID-19 Vaccine Administration Guide

	Pfizer	Moderna	J&J (Janssen)	
Age Approved	≥ 5 years old	≥ 18 years old	≥ 18 years old	
Full Dose	30 µg–0.3 сс	100 µg–0.5 сс	5 x 10 ¹⁰ viral particles – 0.5 cc	
1st Dose	Any time	Any time	Any time (single dose only)	
2nd Dose	≥ 21 days from 1st, no max interval	≥ 28 days from 1st, no max interval	N/A	
3rd Dose*	Approved for moderate to severe immunocompromised individuals 5 and older.	Moderate to severe immunocompromised individuals ≥ 4 weeks after 2nd dose	N/A	
Booster**	≥ 5 months after 2nd dose if ≥ 12 yrs old: Full dose	≥ 5 months after 2nd dose: Half dose (50 μg)	Full dose of Pfizer/Moderna > 28 days after JNJ dose, 2 months later can receive a booster dose N/A Yes Can receive Janssen (J&J), Pfizer or Moderna	
Second Booster	 ≥ 4 months after first booster dose if ≥ 50 years old OR ≥ 12 years old AND severely immunocompromised 	 ≥ 4 months after first booster dose if ≥ 50 years old OR ≥ 18 years old AND severely immunocompromised 		
Booster Mix and Match (Ages18+)	Yes Can receive Pfizer, Moderna or Janssen	Yes Can receive Moderna, Pfizer or Janssen		
Ages 12–15	1st, 2nd, 3rd dose or booster dose recommendations same as adults	Not FDA, ACIP or CDC approved	Not FDA, ACIP or CDC approved	
Ages 5–11***	Approved for all children ages 5–11, regardless of underlying medical condition 1st and 2nd dose are 1/3 the adult dose (10 micrograms), 2nd dose ≥ 21 days. 3rd dose approved for moderate to severe immunocompromised No Booster	Not FDA, ACIP or CDC approved	Not FDA, ACIP or CDC approved	

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

* Third dose candidate individuals include active cancer treatment, history of organ transplant or taking medications to suppress the immune system, primary immunodeficiency, advanced or untreated HIV, active treatment with high-dose steroids. These individuals who received three total mRNA vaccine doses ARE eligible for a single booster dose at least 5 months (Pfizer or Moderna) after their third mRNA vaccine dose.

** Individuals who qualify for a booster but did not qualify for third dose:

- For Pfizer-BioNTech COVID-19 vaccines, a single COVID-19 vaccine booster dose is recommended 5 months after completion of an mRNA primary series.
- For Moderna COVID-19 vaccines, a single COVID-19 vaccine booster dose is recommended 5 months after completion of an mRNA primary series.
- Moderately-severely immunocompromised individuals that received a 3rd dose can schedule a booster at 3 months after the 3rd dose.
- Individuals that received a J&J as the primary vaccine, can now get an mRNA full dose at 28 days past J&J primary and then another mRNA full dose 2 months later.

Individuals who qualify for a second booster:

- For Pfizer and Moderna second booster to individuals 50 years of age and older, 4 months after first booster.
- For those 12 and older who are severely immunocompromised can receive a second booster of Pfizer 4 months after first booster.
- For Moderna second booster for individuals 18 and older who are severely immunocompromised can receive it 4 months after the first booster dose of any type of vaccine.
- *** The dosage should be based on the child's age on the day of vaccination. If a child turns from 11 to 12 years of age in between their first and second dose and receives 5–11 years 10 µg (orange cap) for their second dose, they do not need to repeat the dose and this is not considered an error per the EUA.

It's preferred to stay with homologous (same) vaccines. However, heterologous (mixed) is accepted if no other product is available for individuals 18 and older.









COVID-19 Vaccine FAQ





About the COVID-19 Vaccine

1. What is a COVID-19 vaccine?

It is a new type of vaccine designed to protect against COVID-19.

2. How do vaccines work?

Vaccines stimulate the immune response of the recipient to produce proteins (antibodies) to fight infection. In the past, vaccines used either viruses that were inactivated or viruses that were made less infectious or "attenuated." However, many newer vaccines, including those developed for COVID-19, do not contain the virus itself. There are four types of vaccine production platforms—attenuated, protein-based, viral vector and mRNA.

3. What is different about COVID-19 vaccines?

In late 2020, a type of vaccine known as mRNA (messenger RNA) vaccine for COVID-19 was introduced. Two similar vaccines are now available, made by Pfizer-BioNTech (fully approved) and Moderna (full approved). The mRNA vaccines have been studied for the past decade for other viruses and for cancer treatment. They were ready to go with the Zika virus, but not needed by the time the vaccine was developed. On Feb. 27, 2021, the Food and Drug Administration (FDA) approved emergency use of a third vaccine in the United States, a DNA single dose vaccine made by Janssen, a division of Johnson & Johnson. On Nov. 30, 2021, Novavax filed an application with the FDA for emergency use.

4. What are the ingredients in the COVID-19 vaccines?

Pfizer:

	Genetic material:	nucleoside-modified messenger RNA encoding the viral spike glycoprotein (S) of SA CoV-2	
	Lipids:	((4-hydroxybutyl)azanediyl))bis (hexane -6,1-diyl)bis (ALC-3015); (2- hexyldecanoate),2- [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) 1,2-distearoyl- snglycero-3-phosphocholine (DPSC), Cholesterol	
	Salts:	Potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate	
	Other:	Sucrose	
Moderna:			
	Genetic material:	nucleoside-modified messenger RNA encoding the viral spike glycoprotein (S) of SARS-CoV-2	
	Lipids:	SM-102 (heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate); PEG2000-DMG 1,2-dimyristoyl-rac-glycerol-3-methoxypolyethylene glycol-2000; 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), Cholesterol	
Salts: Saline (salt)		Saline (salt) solution	
	The liquid buffer:	Tromethamine (tris), Sodium acetate, Sucrose (sugar), Water	
	J & J:		
	Active ingredient:	recombinant, replication-incompetent adenovirus type 26 expressing the vector encoding a stabilized variant of the SARS-CoV-2 spike protein.	
	Salts:	citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-	

cyclodextrin (HBCD), polysorbate-80, sodium chloride.

5. Do the two mRNA vaccines for COVID-19 have the same protein sequence genetic material?

 No. Both vaccines contain the genetic code for the SARS-CoV-2 spike protein. The mRNA in the two vaccines is slightly different. Each company made slight changes to the genetic sequence of the mRNA they used so the vaccines would produce a stronger immune response.

About the COVID-19 Vaccine-cont.

6. How does mRNA vaccination for COVID-19 work?

The technology duplicates the coding sequence for the intended viral protein. For COVID-19, the surface protein on the low glycoprotein spike has genetic information that is encoded into messenger RNA. It is then packaged in a lipid nanoparticle for delivery purposes. There is no infectious material in the COVID-19 vaccine. The lipid nanoparticle will be recognized and transcribed into the host cell's ribosomal RNA to make proteins, namely antibodies against the SARS-CoV-2 spike protein.

7. Why develop a new type of vaccine?

• Efficiency. Instead of the time-consuming and costly process of creating a vaccine with inactivated virus, we can manufacture large quantities of synthetic RNA sequences in a more efficient way.

8. Is the vaccine FDA-approved?

 The FDA has approved the Pfizer and Moderna vaccines. The Janssen (J & J) vaccine has FDA-approved Emergency Use Authorization (EUA).

9. What is a EUA?

It is a license granted to manufacturers to produce a product for a condition during a public health emergency when there are no adequate, approved or available alternatives.

10. How is the one-dose or single-dose vaccine by Janssen (Johnson & Johnson) different?

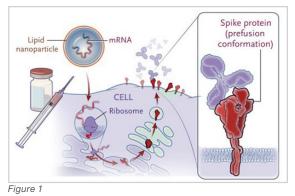
It is an adenovector vaccine, a double-stranded DNA vaccine. This is not an mRNA vaccine (single-stranded RNA). The COVID-19 spike protein sequence is added into another virus (Adenovirus 26) to piggyback onto the person's respiratory cells. Adenovirus commonly causes cold symptoms; however, this vaccine was made so the adenovirus can enter the cell, but cannot replicate to cause cold symptoms because the adenovirus is attenuated (weakened). The adenovirus puts the DNA from the spike protein into the cell where it is then copied ("translated") into mRNA.

11. Will having a COVID-19 vaccine affect any future COVID-19 testing?

 No. It will not affect the results for any nasal or nasopharyngeal swab for molecular, polymerase chain reaction (PCR) or antigen tests.

12. For more information regarding the mechanism of the COVID-19 vaccine, watch this video:

- youtube.com/watch?v=8Vra-Nmnaug
 - 1. Identified RNA spike protein sequence.
 - 2. Synthetic RNA protein is combined with a lipid carrier coating to make it stable.
 - 3. Vaccination—the mRNA protein with lipid carrier travels and presents itself.
 - 4. Dendritic cells grab the protein and through the process of phagocytosis, endocytosis and ribosomal translation, the RNA protein is then encoded and displayed on the cell membrane.



- 5. These cells travel throughout the body, including lymph nodes, where B cells recognize the new protein on the cell membrane.
- 6. Plasma cells make antibodies and antigen-binding regions that will recognize the spike protein on the coronavirus if exposed. The antigen-binding regions then bind to the spikes. Therefore, the SARS-CoV-2 protein has less opportunity to bind to any new host cells because of the attached antibodies.
- nejm.org/doi/full/10.1056/NEJMoa2034577
- assets.acponline.org/coronavirus/scormcontent/?& ga=2.21864123.1674164449.1608676594-94631438.1560890673#/cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

About the COVID-19 Vaccine-cont.

13. Can an immunocompromised patient receive the vaccine?

Yes. During phase 3 development, almost 5,000 patients had an illness or medication that classified the participant as immunocompromised. Since then, millions of immunocompromised persons have received a COVID-19 vaccine. In general, the response is excellent, but in a few studies the antibody development after vaccination is lower among the immunocompromised patients than in the general population. It is recommended to have an informed discussion regarding the COVID-19 vaccine risks vs. benefits with your provider. It is likely more important for the immunocompromised patient to receive the vaccine because of possible high-risk complications from COVID-19. No specific ill effects among immunocompromised recipients of the vaccine have been reported. Because of a potentially weak immune response, a third dose of vaccine 2 months after the first series should be given.

14. To see the latest FDA status of COVID-19 vaccines, visit:

fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

15. Learn more about how mRNA vaccines work at:

- cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html
- <u>cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html</u>
- cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html?CDC_AA_ refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-manufacturer%2Fpfizer% 2Freactogenicity.html
- <u>nejm.org/covid-vaccine</u>
- nytimes.com/interactive/2021/health/how-covid-19-vaccines-work.html
- Specific American College of Obstetrics and Gynecology (ACOG) guidelines can be found at: acog.org/en/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-Pregnant-and-Lactating-Patients-Against-COVID-19

COVID-19 Vaccine Availability and Distribution

16. Where can I find vaccine/booster administration sites?

- Please check the IDPH vaccine administration data on their website for the latest information: <u>dph.illinois.gov/covid19/vaccinedata?county=Illinois</u>
- vaccinefinder.org
- For Sangamon County's latest vaccine information, please also check the vaccination dashboard on the county health department's website: <u>co.sangamon.il.us/departments/a-c/county-board/covid-19/covid-19-vaccination-information</u>.
- There are several locations in Springfield for vaccine administration—including HSHS, Springfield Clinic, Memorial Care on South Sixth, Sangamon County Department of Public Health and many pharmacies. Vaccine administration is available in many physicians' offices. You may also visit <u>coronavirus.illinois.gov</u> to find the nearest vaccination location.

17. Will vaccination for residents in long-term care facilities be performed at the health department?

 Most are already vaccinated. Group homes and assisted living facilities may schedule vaccinations and boosters at the Sangamon County Department of Public Health.

Administration of COVID-19 Vaccine

18 The mRNA COVID-19 vaccines require two doses. When is the second dose?

The mRNA COVID-19 vaccines require two doses for the primary series.

19. What is the difference between a third dose of COVID-19 vaccine and a booster shot?

- The Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) have issued recommendations about who should receive third doses or booster shots of the COVID-19 vaccine.
 - Immuno competent patients (about 97% of the population) should receive two doses of the
 Pfizer vaccine or two doses of the Moderna vaccine followed five months later by a booster.
 Immunosuppressed patients (about 3% of the total population) should receive three doses, each 4
 weeks apart, to establish their immunity, with a fourth dose to be given five months after the third dose.
 - Individuals that received a J&J as the primary vaccine, can receive an mRNA FULL dose at 28 days past J&J primary and then a mRNA BOOSTER STRENGTH dose 2 months later. CDC prefers mRNA over Johnson & Johnson if able.
- Note that the third dose recommended for people with specific health conditions is not the same as a booster dose. Because immunocompromised individuals have weakened immune responses, they need three doses of the vaccine to achieve adequate levels of protection.
- The booster dose is an additional dose intended to extend protection for individuals who had a strong immune response to their first dose(s) but may need additional protection.

20. Who is considered moderately to severely immunocompromised?

- A three-dose regimen of the Pfizer or Moderna vaccines is recommended for moderately to severely immunocompromised individuals. If any of the following statements apply to you, you should get a third dose. If you aren't sure if you qualify, talk to your doctor.
 - I am receiving active cancer treatment for tumors or cancers of the blood.
 - I have received an organ transplant and am taking medicine to suppress my immune system.
 - I have received a stem cell transplant within the last two years.
 - I have moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome).
 - I have advanced or untreated HIV infection.
 - I am undergoing active treatment with high-dose corticosteroids or other drugs that may suppress my immune response.

21. Who should receive a booster dose?

 Booster doses are approved for ages 12 and above for Pfizer booster and approved for ages 18 and above for Moderna. (See vaccine grid.)

22. Does my booster dose have to be the same type of vaccine as my first dose(s)?

No. While the CDC recommends that you get a booster dose of the same type of vaccine you already received, it is not required if it is more convenient for you to get another type. So far, research hasn't shown any medical advantage to getting the same type of booster as your original series.

Administration of COVID-19 Vaccine-cont.

23. Is there a specific timeframe in which I should get an additional dose of vaccine if I qualify?

- If you qualify to receive a booster dose of Pfizer or Moderna, at least five months must have passed since your second dose.
- If you qualify for a three-dose regimen of Pfizer or Moderna because you are immunocompromised, at least 28 days must have passed since your second dose.
- Individuals that received a JNJ as the primary vaccine, can receive an mRNA FULL dose at 28 days past JNJ primary and then a mRNA BOOSTER STRENGTH dose 2 months later. CDC prefers mRNA over Johnson & Johnson if able.

24. Who is eligible for a second booster shot?

- People 50 and older may choose to get a second booster dose of either Pfizer or Moderna if at least 4 months have passed since their first booster dose.
- A second booster dose of the Pfizer vaccine may be administered to immunocompromised individuals 12 and older at least 4 months after their first booster dose. A second booster dose of the Moderna vaccine may be administered to immunocompromised individuals who are 18 and older at least 4 months after their first booster dose.

25. Can I get my seasonal flu shot or another vaccination at the same time as an additional dose of COVID-19 vaccine?

Yes, although the original studies advised spacing vaccines, subsequent studies led the CDC to remove the restriction on May 13, 2021. Therefore, routine vaccinations may be given with the COVID-19 vaccine (e.g., Tdap). Wait for four weeks with live virus vaccines (for example: MMR, yellow fever).

26. How long do I need to be monitored after my vaccine?

 Recommended time is 15 minutes, extended to 30 minutes if recipient has a history of any significant allergies (vaccines or medications). Immediate reactions have been quite rare.

27. Can the vaccine cause cough, sore throat, nasal congestion or shortness of breath?

 Unlikely. The vaccine causes local injection site reactions and generalized systemic side effects, such as low-grade fevers and headache, but not specific respiratory side effects.

28. Can I take Tylenol or ibuprofen if I have pain or fever from my COVID-19 vaccination?

Yes. While these analgesics are commonly used to ameliorate vaccine adverse reactions, their use prophylactically may blunt the vaccine immune responses. Therefore, you should not take Tylenol (acetaminophen) or ibuprofen "just in case" you have a side effect, but it is OK if you take these medications if you are having pain or fever.

29 Should you plan to take a day off after the vaccination?

 Only 26% of individuals reported any side effect with Pfizer vaccine, compared to 13% with placebo. The side effects are generally mild. It is not recommended to schedule a day off. However, it may be beneficial to schedule the vaccination on a day before a day off of work.

30. If I miss the 21 or 28 day mark for the second dose of Pfizer or Moderna, do I need to start over with two vaccinations?

No. There is no maximum interval between the first and second dose for either vaccine. However, the next dose should be given as soon as possible. In the initial studies, some doses were given as late as 42 days after the first dose. Although three weeks is recommended, recipients received the second dose 19–42 days after the first dose (Pfizer package insert).

Administration of COVID-19 Vaccine-cont.

31. What is the grace period for the second dose?

- A grace period beginning four days earlier than the recommended date for the second dose is considered valid. Although 21 or 28 days is recommended, there is no maximum interval between the first and second dose for either vaccine. Therefore, if the second dose is administered >3 weeks after the first Pfizer vaccine dose or >1 month after the first Moderna vaccine dose, there is no need to restart the series.
- 32. What if I get COVID-19 after my first vaccination or before my booster, do I still need to get the next vaccine as scheduled?
 - Yes, you must wait until you are out of isolation and feeling better. On average, it is recommended to wait two weeks to receive a vaccine after a natural infection. After having COVID-19, it is likely you will have some natural immunity for 180 days. Even if you have developed natural immunity from COVID-19, the vaccine will not harm you.

33. How many people need to be vaccinated in order to have herd immunity?

- For COVID-19, various scientists have estimated, herd immunity occurs when 70 to 80% of people in a population are immune to the disease either because of natural immunity or because they have received a vaccine. Immunity to one type of SARS-CoV-2 may not protect against other types or variants.
- 34. There has been talk about decreasing the vaccine to a "half dose" or a "single dose" in order for more people to get the vaccine. Is this recommended?
 - No. We now have sufficient supplies to give the full series to all who desire the vaccine.

35. How much will it cost to get vaccinated?

The federal government provides the COVID-19 vaccine free of charge to all individuals. Insurance companies are committed to not charging out-of-pocket fees or copays related to the administration of the COVID-19 vaccine.

36. If I received one dose of vaccine on a vacation, should I return to that city for my second dose?

You should receive both doses in the same location. Try to schedule travel accordingly. If emergencies preclude a return within the desired interval between doses, contact your physician for advice. Keep the vaccine information with you until you have received both doses and the details have been entered in to the national vaccine registry.

37. What is the Countermeasures Injury Compensation Program (CICP)?

It is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including the COVID-19 vaccine. Generally, a claim must be submitted to the CICP within one year of receiving the vaccine. To learn more, visit https://www.hrsa.gov/CICP or call 855–266–2427.

Efficacy of the COVID-19 Vaccine

38. How long will the vaccine last?

We currently don't know. Studies are in progress to see how long it lasts. You will need a booster and possibly an annual vaccine to "jump start" your immune system.

39. Does immunity caused by getting COVID-19 last longer than protection from COVID-19 vaccination?

 The duration of the natural immunity varies depending on the person and disease course. Vaccines add to the natural immunity produced by natural infection.

Efficacy of the COVID-19 Vaccine-cont.

40. Influenza vaccines change yearly based on rotating strain; will the COVID-19 vaccine also need to change yearly?

We have seen various mutations in the virus (D to G substitution in the spike protein, cluster 5 variant from Denmark; the Alpha B.1.1.7 strain from the United Kingdom). Other variants include the Beta.1.351 strain from South Africa, the Epsilon B.1427/429 from California, Gamma P.1 discovered in Brazil and B1.617.2 (the delta variant) in India. The current COVID-19 vaccines appear to protect against these variants, although they are less effective against the B.1.1.529 (omicron variant from South Africa).

41. If you had dose one of a COVID-19 vaccine, can you still get COVID-19?

Yes. There is 52% protection after Pfizer dose #1 and 94% protection after Pfizer dose #2. Full protection begins about two weeks after dose #2. Protection after the Janssen (J&J) vaccine 76.7% was starting 14 days after the dose and 85.4% starting 28 days after the single injection. It was 100% effective at preventing death from COVID-19 infection. The Moderna vaccine offers 94% protection after two doses. All three vaccines offer protection against the delta variant, about 90% for Pfizer and Moderna and 67% for J & J. They still offer good protection against the omicron variant, but require boosting.

42. Have there been any differences noted in efficacy of the vaccine with different racial and ethnic groups?

• No. There are no differences in efficacy of the vaccine between different racial and ethnic groups.

The clinical trials for all the approved vaccines in the United States recruited a racially and ethnically diverse population. The vaccine was efficacious in all groups.

COVID-19 Vaccine Side Effects

42. What are the COVID-19 vaccination side effects or "reactogenicity" concerns?

Side effects tend to be more frequent after the second dose. Fatigue, headache, chills, muscle pain, joint pain and diarrhea were some of the side effects reported with the Pfizer vaccine. Those older than 55 reported fewer side effects. The Moderna and Janssen (J & J) vaccine produced similar side effects, including arm swelling, fever and pain requiring an OTC pain reliever. See chart below for further details.

Side Effect	Pfizer (%)	Moderna (%)		Janssen (J & J) (%)		
	16–55	>55	18–64	>65	18–59	>60
Arm swelling	6.3	7.5	12.6	10.8	7.0	2.7
Arm erythema	5.9	7.2	9	7.4	9.0	4.6
Arm pain	83.1	66.1	90.1	83.4	58.6	33.3
Fatigue	59.4	50.5	67.6	58.4	43.8	29.7
Headache	51.7	39	62.8	46.4	44.4	30.4
Myalgia	37.3	28.7	61.3	46.9	39.1	24.0
Chills	35.1	22.7	48.3	30.6		
Arthralgia	21.9	18.9	45.2	34.9		
Fever	15.8	10.9	17.4	10.2	12.8	3.1
Use of pain or fever- reducing medication	45	37.7	—	—	26.4	9.8

43. What is the chance of a severe allergy?

Among the first 11 million recipients of the Pfizer vaccine, the rate of anaphylaxis was only 5 per million. Three quarters of them had a previous history of anaphylaxis. However, none of the 189 patients who have developed severe reactions to their first dose had problems after the second dose.

44. If I have symptoms or some side effects from the vaccine, will I be contagious during this time?

No.

COVID-19 Vaccine Side Effects-cont.

45. What are the contraindications to the vaccine?

Severe allergic reaction to a previous dose of mRNA COVID-19 vaccine, or to any component in the vaccine, polysorbate or polyethylene glycol are contraindications. Previous severe allergic reaction or anaphylactic reaction to a different vaccination is considered a precaution, not a contraindication. People with a "significant history of allergic reactions" or anaphylaxis from other vaccines or medications may want to have the vaccination performed in a controlled environment with medication available if needed. Individuals who have had prior reactions to viral vector vaccines should be evaluated by their provider before receiving the Janssen (J&J) vaccine.

46. Will my family need to quarantine if I develop side effects after the vaccination?

No.

47. Can I still work or attend school if I have side effects?

Yes, if you feel well enough and you have typical reactogenicity symptoms. However, if you have COVID-19-like symptoms (sore throat, congestion, shortness of breath or temperature > 100.4) further evaluation may be needed.

48. What if a fever lasts longer than two days?

Another cause should be sought for the etiology of the fever, including COVID-19 infection. Exposure may have occurred prior to the vaccination. Start isolation until COVID-19 results are known or another cause is determined for the temperature.

49. How does a patient report any side effects or adverse events?

The CDC offers a smartphone-based tool, known as V-safe, for all vaccine recipients. It will guide the individual through questions daily after the vaccine. The Vaccine Adverse Event Reporting System (VAERS) is used by providers and pharmacists to report moderate to severe adverse effects from the vaccine (vaers.hhs.gov).

50. Should I be concerned about getting Bell's palsy or Guillain-Barré syndrome?

Bell's palsy is a drooping of the face that lasts weeks to months and rarely longer. The rate of Bell's palsy in the clinical trials is similar to the overall rate in the general population (15–20 per 100,000 annual incidence). Four of 30,000 participants in the Moderna clinical trial had Bell's palsy, including three participants who received the vaccine instead of the placebo. Similarly, four out of 43,000 participants in the Pfizer clinical trial had Bell's palsy, and all four received the vaccine. The paralysis onset was three days to 32 days after the vaccine. The rate is also low for Guillain-Barré syndrome, which is a paralysis starting in the feet and rising up the legs or higher. Vaccines do not increase the risk of either condition.

51. What other reactogenicity side effects have you personally encountered?

Swollen lymph nodes on the side of the vaccine, jitters, feeling in a "fog," headaches, light-headedness, hand tingling, lip tingling and, rarely, chest tightness. All of these symptoms have been short-lived. Delaying a mammogram after a COVID-19 vaccine by a couple of weeks may be recommended to avoid any misinterpretation from swollen lymph nodes.

52. If I have lip fillers or facial fillers, is the vaccine contraindicated?

 Rarely, patients with lip or face fillers will get swelling after vaccines. This is not a contraindication. Swelling should subside spontaneously but may require anti-inflammatories and/or antihistamines. Steroids should be reserved only for significant swelling.

COVID-19 Vaccine Side Effects-cont.

53. Do COVID-19 vaccines cause myocarditis (inflammation of the heart muscle)?

In June 2021, the CDC raised awareness of myocarditis after vaccination. The country saw 275 cases of myocarditis from December 2020 to May 2021 among more than 5 million vaccinated people. Most of these patients spent fewer than four days in the hospital and 95% of cases were classified as mild. The association appeared strongest among males ages 16 to 19 and was more common after the second dose. Health regulators have not yet confirmed a causal link between COVID-19 mRNA vaccines and myocarditis.

The CDC continues to recommend vaccination for all individuals over age 5 and above. In children under 18 in the U.S., with more than 4 million COVID-19 cases diagnosed, 15,000 hospitalizations and 300 deaths, the benefits of vaccination exceed the risks of rare adverse events. More data will become available as more individuals in younger age groups are vaccinated.

COVID-19 Vaccinations and High-Risk Exposure

54. If it has been more than two weeks from the Janssen (J&J) vaccine or more than two weeks since my second Pfizer or Moderna vaccination, do I still need to complete a 14-day quarantine at home if I have a high-risk exposure (>15 minutes, < 6 feet)?

 No. The CDC and IDPH in late December 2021 adopted a 5-day quarantine followed by 5 days of wearing a mask that fits snugly against the face. However, if you notice a development of COVID-19-like symptom(s), contact your provider or go to your nearest testing location.

55. If I had a high-risk exposure, can I get the vaccine to limit the quarantine duration?

No. The full quarantine period must be completed. Protection requires up to six weeks after the first dose of an mRNA vaccine (two weeks after the second dose) and two weeks after the Janssen (J&J) vaccine. Also, COVID-19 vaccination cannot be given until the quarantine ends without the development of COVID-19 symptoms (except in congregate settings where there are repeat long-term exposures).

COVID-19 Positive Patients and the COVID-19 Vaccine

56. Do I need the vaccine if I already had COVID-19?

• Yes. It is still recommended because immunity after natural disease is not permanent, and variants have appeared. Wait until you have improved from your illness.

COVID-19 and Pregnancy

57. Should I be concerned about pregnancy?

The American College of Obstetricians and Gynecologists (ACOG) recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination. There are no reports of excess danger in the pregnant population. In fact, the risk of premature birth is lower for vaccinated mothers. The Janssen (J&J) vaccine has limited data in human pregnancy although it appears to be safe, even in very large doses, in pregnant animal studies. Pregnant women who receive the Janssen (J&J) vaccine should register at c-viper.pregistry.com. Specific ACOG guidelines can be found at: www.acog. org/en/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-Pregnant-and-Lactating-Pratients-Against-COVID-19

COVID-19 and Pregnancy-cont.

58. Does COVID-19 cause infertility and sterility?

• The vaccine does not cause infertility. There is no data that the antibodies against the spike proteins attack the placenta, as the structure of the proteins in the placenta and spike protein are different.

There was some concern about a protein called synectin-1 that is necessary for placental formation being targeted by mRNA vaccine due to structural similarity with the spike protein. This concern does not seem to have any scientific evidence. Synectin-1 is not contained in the viral protein and they are NOT similar.

Men and women can receive vaccine safely. Very early confusion arose because someone read that the vaccines were produced under "sterile conditions." This means that the vaccines are made to avoid contamination and not cause bacterial infection. They have no effect on reproduction.

59. What is the recommendation for breastfeeding moms and the vaccines?

COVID-19 vaccines should be offered to lactating individuals similar to non-lactating individuals. The American Academy of Pediatrics provides the following guidance: While these vaccines were not specifically tested in breastfeeding women, it is not likely (based on the mechanisms of action of the vaccines in U.S. trials) that there would be any risk to the child. There are no reports of any excess risk of COVID-19 vaccines in the lactating population. Specific ACOG guidelines can be found at: www.acog.org/en/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-Pregnantand-Lactating-Patients-Against-COVID-19

COVID-19 Vaccine and Children

60. Can my kids get vaccinated?

Yes, the COVID-19 vaccine is approved for individuals age 5 + (Pfizer) and age 18 + (Moderna and J&J). Although Pfizer phase 3 studies have included participants down to 2 years of age with no ill effect, no COVID-19 vaccine is currently approved for people under 5.

COVID-19 Vaccine and Flu Vaccines/Other Tests

61. Can I get a TB (tuberculosis) skin test if I recently had a COVID-19 vaccine?

Yes, you no longer need to wait 90 days from the infusion to get a COVID vaccine. You may get your vaccine once you are out of isolation (at least past day 10 from symptom onset) and feeling better.

Monoclonal Antibody Infusion Therapy

62. Can you receive a COVID-19 vaccine if you had a monoclonal antibody infusion (e.g., Regeneron, Bamlanivimab, etesevimab, sotrovimab)?

Yes. However, it is recommended you wait 90 days from the infusion. As per CDC, "Currently, there is no data on the safety and efficacy of mRNA COVID-19 vaccines in people who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Based on the estimated half-life of such therapies, as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days as a precautionary measure until additional information becomes available to avoid potential interference of the antibody therapy with vaccine-induced immune responses. This recommendation applies to persons who receive passive antibody therapy after the first dose but before the second dose, in which case the second dose should be deferred for at least 90 days following receipt of the antibody therapy." Refer to cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html. The same 90-day delay applies to the Janssen (J&J) vaccine.

Monoclonal Antibody Infusion Therapy-cont.

63. Can I receive a COVID-19 vaccine if I received an antibody therapy not specific to COVID-19?

Yes. You do not need to wait 90 days. As per CDC, "For persons receiving antibody therapies not specific to COVID-19 treatment (e.g., intravenous immunoglobulin, RhoGAM), administration of mRNA COVID-19 vaccines either simultaneously with or at any interval before or after receipt of an antibody-containing product is unlikely to substantially impair development of a protective antibody response. Thus, there is no recommended minimum interval between other antibody therapies (i.e., those that are not specific to COVID-19 treatment) and mRNA COVID-19 vaccination." Refer to <u>cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html</u>. The same recommendation applies to the Janssen (J&J) vaccine, no delay is required.

Because of breakthrough infections, some people are given monoclonal antibodies even after the vaccine. Individuals may receive a monoclonal antibody at any time after the vaccine, whether the vaccine series is complete or not.

COVID-19 Vaccine and Testing

- 64. Can the COVID-19 vaccine cause a nasopharyngeal (NP) swab (antigen or molecular) to be falsely positive?
 - No.

65. Can the COVID-19 vaccine cause an antibody test to be falsely positive - IgM or IgG?

- No. The test would be a true positive because it would reflect immunity. However, the antibody tests do not distinguish between immunity from disease and immunity from vaccine. Specific antibodies to the spike protein and to the nucleocapsid in the virus can help distinguish antibody effects from disease effects.
- 66. Should I get tested for COVID-19 a few days after getting the vaccine if I am having fever, myalgia and fatigue?
 - Yes. It is best to be safe and test. If symptoms seem more than a reactogenicity effect, consider testing. The vaccine does not cause a false positive test.

67. If the Janssen (J&J) vaccine is safe, why did the FDA and CDC pause the distribution in April 2021?

The vaccine meets the EUA 2021 based on its high effectiveness. On April 13, 2021, because of six cases of a rare blood clot in the brain associated with a low platelet count (thrombosis thrombocytopenia syndrome—TTS), the company and two agencies decided to pause its use pending future study. On April 23, 2021, distribution resumed because the risk of TTS was found to be quite low—15 case among 8 million doses. The presentation of the rare blood clots occurred in ages 18–59 within 6–15 days after vaccination. The risk is as low as 0.7–1.0 per million. Clots are commonly seen in COVID-19 illness, occurring in 39 per million. Therefore, J&J vaccine has been released to be used in the general population with no additional concerns raised. J&J was initially granted EUA in March 2021.

68. Should I travel abroad for my vaccines?

A large supply of mRNA vaccines and the Janssen vaccine is available locally and throughout the United States. Other vaccines are available, including the Oxford-AstraZeneca vaccine from the United Kingdom, four vaccines from China [CanSino, Sinopharm (Beijing), Sinopharm (Wuhan), Sinovac), Bharat from India and two vaccines from Russia (Gamaleya and Vector Institute). The Novavax vaccine, in phase 3 development in the United States, is undergoing FDA review for approval. Nearly 200 other vaccines are under study throughout the world.

Questions/answers subject to change as more information is gathered from community observation and data collection.

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References:

Figure 1. Polack, Fernando P., MD; Thomas, Stephen J., MD; Kitchin, Nicholas, MD; Absalo, Judith, MD; Gurtman, Alejandra, MD; Lockhart, Stephen, DM; Perez, John L., MD; Marc, Gonzalo Perez, MD; Moreira, Edson D., MD; Zerbini, Cristiano, MD; Bailey, Ruth, BSc; Swanson, Kena A., PhD. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine, New England Journal of Medicine, December 31, 2020, https://www.nejm.org/doi/full/10.1056/NEJMoa2034577. May 25, 2021.

Figure 2. Centers for Disease Control and Prevention. "Summary Document for Interim Clinical Considerations for Use of Covid-19 Vaccines Currently Authorized in the United States." Centers for Disease Control and Prevention, April 9, 2021, https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations-poster.pdf. May 25, 2021.