

Guidance Date 09/15/21

COVID-19 VACCINES FOR STAFF/PHYSICIANS FREQUENTLY ASKED QUESTIONS

GENERAL QUESTIONS (SIDE EFFECTS, ADMINISTRATION, ETC)

1. Who is eligible to receive the COVID vaccine?

The Pfizer/BioNTech vaccine is currently FDA licensed to administer to people age 16 years and older, and is authorized to be administered to teens 12 years -15 years old under Emergency Use Authorization (EUA). Moderna and Johnson & Johnson (J&J) vaccines are available under EUA for people 18 years and older.

2. How many doses are required? How is it administered?

The Pfizer-BioNTech and Moderna COVID-19 vaccines are administered intramuscularly as a two-dose series. The Pfizer vaccine doses are spaced a minimum of 21 days apart, and the Moderna doses are spaced a minimum of 28 days apart. The J&J vaccine is a single dose administered intramuscularly.

3. Specifically, what is the vaccine made of?

The Pfizer and Moderna vaccines are based on the SARS-CoV-2 spike glycoprotein (S) antigen encoded by mRNA, and packaged in lipid nanoparticles (LNP) for effective delivery to your cells for an immune response. The J&J vaccine utilizes DNA encoding for the spike protein, and then packages it with an Adenovirus vector delivery system. The Adenovirus vector is made incapable of replication; therefore, it is just a delivery system for the spike protein DNA to be able to enter the cell.

The other components of the vaccines are stabilizers, sugars and salts. The COVID vaccines are preservative free, and do not contain egg, gelatin, metals, or adjuvants.

The SARS-CoV-2 spike protein on the virus is what allows the virus to bind to and infect your cells, making it an excellent target for the vaccines.

4. Can I get COVID infection from the vaccine? Will COVID-19 vaccines cause me to test positive on COVID-19 viral tests?

No. These vaccines will not give you COVID and will not cause a false positive result on the COVID-19 tests (used to identify if you have a COVID infection). The Pfizer vaccine only uses a small piece of messenger RNA from the virus.

5. What is the long-term effect of the COVID vaccine?

In general, vaccines do not have long-term side effects. Vaccine side effects usually occur within the first 42 days after vaccination.

6. Are there microchips embedded in the vaccine?

No, there are no microchips in any of the COVID vaccines, and it is technologically impossible for a

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microchip or magnet to be in a vaccine.

7. Will the vaccine magnetize me?

No, it will not cause you to become magnetized.

8. As a QHS/QMG employee, will I be required to get a COVID-19 vaccine?

Starting October 1st, 2021, all QHS employees and affiliated providers are required to receive the COVID vaccine or undergo weekly COVID testing.

9. How long will it take for the vaccine to begin protecting me?

Overall, the COVID vaccines begin to create immune memory about 7-14 days after the vaccine. After completing the vaccine series, you are considered fully protected 2 weeks later. During this time and afterward, it will be important to continue to wear your PPE, in particular your mask, wash your hands and social distance to fully protect yourself.

10. Is this vaccine safe for children?

The Pfizer vaccine is safe and has EUA for children age 12 – 15 years old, and is fully licensed for teens 16 years old and above. Currently, there are large clinical studies looking at the safety and effectiveness of the Pfizer and Moderna vaccines in younger age groups.

11. What if I miss my second dose? Is the vaccine still effective?

The Pfizer and Moderna vaccines are not *as* effective if you receive only one dose. However, initial data suggest that efficacy against **severe** COVID-19 occurring after the first dose was 88.9%, but this evaluation is based on limited data. It is advised to get vaccinated as close to the 21-day Pfizer or 28-day Moderna timeframe as possible.

12. How will I know when and where to get the immunization?

Please refer to the Queen's COVID internet website for locations and times for receiving the vaccine.

13. Will the vaccine be available to non-employed medical staff?

Yes. Any QHS credentialed provider regardless of whether they are employed or not are eligible to receive the vaccine.

14. Will we administer the vaccine to our QHS patients?

Yes, ambulatory and hospitalized patients are all eligible for vaccination if they have not previously completed their vaccines and do not have a contra-indication.

15. Do I have to continue wearing a mask after I get the vaccine?

Yes. We must continue to wear face masks, practice excellent hand hygiene and social distancing until the numbers of active COVID infections have significantly decreased and herd immunity is expected.

16. Will I be required to wear all other PPE when caring for patients as outlined in the infection prevention protocols?

Yes. It is vital that we all continue to follow proper infection prevention in all of our QHS facilities. To

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ensure that you are optimally protected, we ask that you continue to practice the same precautions mandated which are based on the available evidence.

17. When should COVID-19 vaccine be given in terms of timing from other vaccines (flu shot, tetanus booster, etc.)? What about if delaying COVID-19 vaccine until 14 days presents a barrier to immunization (like long-term care facility)?

COVID-19 vaccines may be given at the same time, or any time before or after any other vaccines.

18. What about the timing of tuberculosis testing (either Tuberculin Skin Test (TST)/PPD or interferon gamma release assay) and administration of COVID vaccine?

Although it is not specifically studied, current guidance is that you do not need to wait. The COVID vaccines can be given at the same time, or any time before or after TB skin testing or blood testing.

19. How does the vaccine for COVID-19 work?

Pfizer's vaccine uses novel messenger-RNA, or mRNA, technology, which contains genetic information about the pathogen (COVID-19). This information is designed to "train" the body to identify and block the virus spike protein or recognize a virus-infected cell. The immune system responds by attacking the virus.

20. What type of study was performed to evaluate the Pfizer/BNT vaccine?

Study number C4591001 is an ongoing, multi-center, multi-national Phase 1/2/3 randomized, blinded, placebo-controlled study looking at safety, immunogenicity and efficacy of the vaccine.

21. How many people were enrolled in the study to evaluate the Pfizer/BNT vaccine?

The Pfizer study has enrolled 43,538 participants through November 14, 2020 (data cut-off for EUA submission) and randomized to get either placebo or the vaccine candidate at 21-day intervals. This translates into 50% of the volunteers getting the vaccine (21720), while the other half got a placebo of saltwater (21728). The next step was to wait and evaluate the volunteers to see who would get sick with COVID. An independent board of experts looked at the placebo and vaccine participants and reported that the vaccine is 95% effective.

22. How safe was the vaccine in this group of patients?

All initial reports show the vaccine is both safe and effective at preventing COVID-19 infection. The frequency of serious adverse events was low (<0.5%) and as of November 14, 2020, 43.9% and 79.5% of vaccine recipients completed at least two months (>8 weeks) and at least one month (>4 weeks), respectively, of safety follow-up after Dose 2.

23. What were the most frequent side effects from the vaccine and how often did they occur?

Overall, side effects were not uncommon, with 42% of recipients reporting some type of reaction compared to 19% of placebo recipients. The most common adverse reactions were:

- Injection site reactions (pain, redness, soreness) (84.1%)
- Fatigue (62.9%)
- Headache (55.1%)

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- New or worsened muscle pain (38.3%)
- Chills (31.9%)
- New or worsened joint pain (23.6%)
- Fever (14.2%)

Of note, only 27.8% of study participants who had symptoms considered them severe enough to take over-the-counter pain medication (Tylenol, NSAID) to treat. Also, 84% of adverse reactions were described as mild to moderate. No participant sought medical care to treat adverse reactions. Side effects considered to be linked to vaccination generally start within 6 weeks of getting vaccine.

24. Were there any neurologic, chronic inflammatory, or blood clotting disorders identified in the vaccine group?

There were no notable patterns or differences between treatment groups for specific categories of neurologic, neuro-inflammatory, or thrombotic events during the clinical trials for the vaccine, however since broader utilization, there have been some very rare safety concerns regarding some of the COVID vaccines.

Guillain-Barre Syndrome: this is a rare neurologic condition that has been associated only with the J&J vaccine, occurring about 14 days after vaccination.

Myocarditis/Pericarditis: This is a rare inflammatory reaction of the heart muscle or the sac that surrounds the heart, and it has only been associated with the mRNA vaccines (Pfizer and Moderna), but has not been seen or associated with the J&J vaccine. This rare event appears within 1-7 days after vaccination, more often seen after the 2nd dose. The condition is mild, and the long term follow-up is currently ongoing. It appears to happen primarily in younger males aged 12-29 years, but has been reported in some females and adults up to age 50. The evidence to date shows it to be mild, and patients appear to fully recover. The risks of myocarditis from a COVID infection happen with greater frequency, and tend to be more severe, therefore making the risk of myocarditis from catching COVID higher than the risk of having milder myocarditis from a vaccine.

Vaccine-Induced Thrombosis with Thrombocytopenia (blood clotting concern): this very rare condition has only been associated with the J&J vaccine, and is not a concern with the mRNA vaccines (Pfizer and Moderna). The symptoms appear about 1-3 weeks after receipt of the J&J vaccine, and although very rare it appears to impact females age 50 years and younger.

25. Did different age, gender or racial groups react differently to the vaccine?

With the exception of more frequent, generally mild to moderate side effects in participants <55 years of age, the safety profile of the vaccine candidate was generally similar across age groups, genders, ethnic and racial groups.

FERTILITY, PREGNANCY, OR BREASTFEEDING QUESTIONS

26. What is the effect of the COVID vaccine on fertility?

None of the COVID vaccines impact male or female fertility. The vaccines do not target reproductive organs.

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27. Can I get the vaccine if I am pregnant?

Yes. The American College of Obstetricians and Gynecology (ACOG) and the CDC highly recommend COVID vaccination in pregnancy. Although it was not specifically studied during the clinical trials, a large number of vaccinations have safely been given to pregnant females. There is no associated risk of birth defects or miscarriage from the vaccines. This is an important strategy to prevent COVID infection in both mother and newborn.

28. Can I get the vaccine if I am breastfeeding?

Yes, breastfeeding females can safely receive a COVID vaccine if not already vaccinated during pregnancy. Again, this is an important strategy to prevent COVID infection in both mother and infant.

COVID-19 VARIANTS AND VACCINE PROTECTION

29. How effective is the vaccine in preventing COVID-19 infections?

Vaccine efficacy against confirmed COVID-19 after the second dose of the Pfizer-BioNTech COVID-19 vaccine was 95.0% with eight COVID-19 cases in the vaccine group compared to 162 COVID-19 cases in the placebo group. These studies were done when the original ancestral strains were prevalent.

30. Does the vaccine protect me against the Delta variant?

Yes, the vaccines do provide protection against the Delta variant, which is the dominant virus strain in the US. Studies on the Moderna and Pfizer vaccines are showing that there is a decline in vaccine protection from mild COVID infection, with protection between 39-84%. This decline is likely due to decline in protective antibody levels. The Pfizer and Moderna vaccines are also shown to continue to be highly protective from severe COVID disease, including hospitalization and death from COVID infection. Current studies are showing the vaccines provide 87% or greater protection from hospitalization or death due to COVID infection.

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PRIOR COVID-19 INFECTION AND VACCINATION

31. I already got COVID, why should I get the vaccine?

While previous COVID infection confers a robust natural immune response, there are numerous cases of individuals becoming re-infected after previously having COVID.

Fatigued Ravens quarterback Lamar Jackson has had COVID twice, yet remains noncommittal about vaccine

By Associated Press Updated August 9, 2021, 6:04 p.m.



Receiving the vaccine after getting COVID leads to a 30-time increase in antibody response, potentially conferring added protection against variants of concern such as Delta.

<https://www.nature.com/articles/s41586-021-03696-9>

The CDC currently advises vaccination in those previously infected with COVID.

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

Of note, previous SARS-CoV-2 infection, whether symptomatic or asymptomatic, is not considered a contraindication to vaccination and serologic testing for SARS-CoV-2 antibodies is not recommended prior to vaccination. Please see the QHS Pre-Vaccination Screening Form for detailed questions.

32. If I have had COVID-19, will I experience worse reactions to the vaccine?

There did not appear to be any difference in type or frequency of reactions between participants with or without evidence of prior SARS-CoV-2 infection at enrollment.

33. Can I get vaccinated after receiving Monoclonal Antibody treatment for COVID?

You must wait 90 days after receiving Monoclonal Antibody treatment before you can receive a COVID vaccine.

THIRD DOSE/BOOSTER DOSE QUESTIONS

34. Will this be an annual shot?

This is unknown at this time. Booster doses may be approved by the FDA after September 20th, 2021. Studies are ongoing and data will guide this once the vaccine is distributed and more data becomes available.