# **FAQs and Talking Points**



**Purpose:** Internal use only. Penn Medicine providers and staff should reference this document for more information about the COVID Delta variant, third doses of the COVID-19 vaccine for severely immunocompromised patients, and the booster shot.

#### **Delta Overview**

- The dominant strain of COVID-19 in the United States is now the Delta variant:
  - The Delta variant is highly contagious, more than 2x contagious as previous variants.
  - Some data suggest that the Delta variant might cause more severe illness than previous strains in unvaccinated persons.
  - Unvaccinated people remain the greatest concern. Although breakthrough infections happen much less often than infections in unvaccinated people, individuals infected with the Delta variant, including fully vaccinated people with symptomatic breakthrough infections, can transmit it to others.
  - Fully vaccinated people with Delta variant breakthrough infections can spread the virus to others. However, vaccinated people appear to be infectious for a shorter period. Previous variants typically produced less virus in the body of infected fully vaccinated people (breakthrough infections) than in unvaccinated people. In contrast, the Delta variant seems to produce the same high amount of virus in both unvaccinated and fully vaccinated people.

#### **Vaccine Effectiveness and Third Doses for Immunocompromised Patients**

- Vaccines are highly effective against the Delta variant.
  - Although vaccines are highly effective, some fully vaccinated people will become infected (called a breakthrough infection) and experience illness. For such people, the vaccine still provides them strong protection against serious illness and death.
  - In response to the Delta variant, the FDA extended its emergency use authorizations (EUA) for both the Pfizer-BioNTech COVID-19 vaccine and the Moderna COVID-19 vaccine to allow an additional dose for certain people who are immunocompromised. Information about vaccine boosters for immunocompromised patients is available on the <a href="COVID-19 vaccine">COVID-19 vaccine</a> <a href="page">page</a> (pennmedicine.org/coronavirus/vaccine).

#### **Third-Dose Vaccine Appointments for Immunocompromised Patients**

- As of Wednesday, August 25, Penn Medicine is scheduling third doses of the Pfizer-BioNTech
  COVID-19 vaccine for severely immunocompromised patients ages 16 and older and the Moderna
  COVID-19 vaccine for severely immunocompromised patients ages 18 and older. Information about
  step-by-step patient scheduling is available <a href="here">here</a>.
  - Appointments will only be made for patients with severely compromised immune systems and who received the 2<sup>nd</sup> dose of a COVID-19 vaccine at least 28 days prior. Patients should check with their providers to determine if they are severely immunocompromised.



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- "Severely immunocompromised" includes people who have received an organ transplant and are taking therapies that suppress their immune systems, and people who are in active treatment, such as chemotherapy or a daily radiation therapy for cancer.
- We are starting with third-dose vaccines for patients with severely weakened immune systems and will open up third vaccine dose scheduling to moderately immunocompromised patients in the near future.
- Patients who receive a third-dose vaccine should notify their care team so the information can be updated in their medical record.
- A third dose of the vaccine is recommended for patients who are moderately to severely immunocompromised. The third dose can be administered 28 days after a person's second dose. People who do not have severely weakened or compromised immune systems may be eligible for a third dose "booster shot" of the Pfizer or Moderna vaccines this fall and winter, pending final recommendation and approval by the CDC.
- Unlike last winter, there is ample supply of the vaccines. We are confident in our area pharmacies' ability to provide your COVID booster shots, safely and conveniently, just like they do with flu shots ever year. When a booster shot is authorized and available to you, we recommend that you take it.
- Patients are encouraged to utilize <u>vaccines.gov</u> as a resource to find COVID-19 vaccines locally.
- Currently, there is not data to support the use of an additional vaccine dose after a primary Johnson & Johnson vaccine in people with severely weakened immune systems. The FDA and CDC are working to provide guidance on this issue.
- Penn Medicine <u>is not administering</u> booster vaccines at this time. Patients who do not have severely weakened or compromised immune systems may be eligible for a third dose "booster shot" of the Pfizer or Moderna vaccines this fall and winter, pending final recommendation and approval by the CDC.

#### **Masking Guidance**

- In response to the rapid spread of the Delta variant, Penn Medicine announced changes to the masking guidance. Effective immediately:
  - Masks should be worn at all times when indoors in all Penn buildings, regardless of whether the building is clinical or nonclinical, and regardless of individual vaccination status.
  - o Individuals should avoid large crowds.
  - Masks should be worn during meetings, even when all attendees are known to be fully vaccinated, and regardless of whether the meeting is in a clinical or nonclinical space/building.
  - Meals should no longer be served at educational conferences and meetings; even if all attendees are vaccinated. Masks should stay on at all times in these group settings.



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#### **Pre-Procedure Testing**

 Penn Medicine is requiring pre-procedure testing for all procedures with sedation and/or anesthesia (general, MAC, and regional). This decision by the UPHS COVID-19 Clinical Testing Oversight and the UPHS Epidemiology Committees is effective Monday, August 23. For all other procedures, testing is not required but may be ordered at the discretion of the provider.

#### **Classifying SARS-CoV-2 Variants**

- The Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO)
  have classified SARS-CoV-2 variants by letters of the Greek alphabet, and have subdivided the
  variants by clinical importance.
- Variants of Interest (VOI) are those that carry genetic markers that have been associated with
  changes to the receptor binding, reduced neutralization by antibodies, reduced efficacy of
  treatments, potential diagnostic impact, or predicted increase in transmissibility or disease severity.
  Many of these are under study by CDC.
- Variants of Concern (VOC) are those for which there is solid evidence of increased transmissibility, more severe disease, a significant reduction in neutralization by antibodies, reduced effectiveness of treatments or vaccines, or diagnostic detection failures. The table below outlines the current list of VOC:

WHO designation	Other names	Country/region of origin
Alpha	B.1.1.7	U.K.
Beta	B.1.351, B.1.351.2, B.1.351.3	South Africa
Gamma	P.1, P.1.1, P.1.2	Brazil
Delta	B.1.617.2, AY.1, AY.2, AY.3	India
Epsilon	B.1.427, B.1.429	California

 Variants of High Consequence (VOHC) are those with clear evidence that prevention measures or medical countermeasures have significantly reduced effectiveness compared to prior variants.
 Fortunately, there are no SARS-CoV-2 VOHC that have been identified.

#### **Responding to Patient Questions**

**Question:** What is the Delta variant?

**Response:** The Delta variant, which was first discovered in India during the summer and spread rapidly around the globe, is the predominant strain of COVID-19 in the U.S. This new variant is far more contagious than all prior SARS-CoV-2 strains. The Delta variant is associated with a two-fold increased risk of hospitalization compared to prior variants. Although uncommon, the Delta variant has demonstrated the ability to infect and be transmitted by persons that have been fully vaccinated. Illness caused by the Delta variant in vaccinated persons, however, tends to be mild. Nonetheless, the rising rate of U.S. cases due to the Delta variant has resulted in a CDC recommendation to return to indoor masking as an added mitigation step irrespective of vaccination status.



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**Question:** What about the Delta-plus and Lambda variants?

**Response:** The Delta-plus variant has an additional mutation that enhances the ability to enter cells. It also arose in India, and currently makes up a small percentage of U.S. SARS-CoV-2 strains. The Lambda variant developed in Peru, where it now causes the vast majority of infections in that and surrounding countries. It has not, however, gained a foothold in the U.S. The CDC currently considers both of these variants to be VOI, and they are being carefully tracked.

Question: I am immunocompromised. Why do I need to get an additional dose of vaccine?

**Response:** People with severely weakened immune systems have a harder time fighting infections and are especially vulnerable to viruses like COVID. The FDA evaluated information on the use of a third dose of the Pfizer-BioNTech or Moderna vaccines in these individuals and determined that a third vaccine dose may increase their protection against COVID.

Question: Am I eligible to receive an additional dose of the COVID-19 vaccine?

**Response:** Penn Medicine is currently helping severely immunocompromised patients schedule appointments for a third-dose vaccine. Only solid organ transplant recipients or those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise are authorized to receive a third dose of a COVID-19 vaccine. Anyone who is not severely immunocompromised, including caregivers of immunocompromised individuals, is not authorized and should not get an additional dose. If you are not sure whether or not you are severely immunocompromised, or whether you should receive a third dose, you should speak with your doctor. More information about conditions that are considered to have an equivalent level of immunocompromise is available on the <a href="COVID-19">COVID-19</a> vaccine page (pennmedicine.org/coronavirus/vaccine).

**Question:** How soon should I get an additional dose? How long should I wait until after my second dose? **Response:** The FDA authorizes individuals with severely weakened immune systems to receive a third dose at least 28 days following the second dose of the same vaccine. If you are severely immunocompromised and received your second dose more than 28 days ago, you can get a third dose.

**Question:** Where should I get my third dose?

**Response:** Penn Medicine can help you schedule an appointment to get your third dose. Note that appointments fill up quickly; if we are unable to find a time that works for you, please consider checking with your local pharmacy for availability. You can also use <u>vaccines.gov</u> to find a vaccination location near you.

**Question:** Can I get the third dose from my local pharmacy?

**Response:** Yes. We are confident in our area pharmacies to administer the vaccine and encourage you to get the third dose at a location convenient to you. Use <u>vaccines.gov</u> to find a vaccination location near you.

**Question:** What kind of vaccine should I get?

**Response:** You should get the same type of vaccine for your third dose as you did for your first and second doses. If you received the Pfizer vaccine, your third dose should be Pfizer. If you received the Moderna vaccine, your third dose should be Moderna.

**Question:** Can I get an additional dose if I'm immunocompromised and got the Johnson & Johnson COVID-19 vaccine?

**Response:** No, not yet. We are awaiting more data and guidance from the FDA and CDC on whether anyone should receive an additional dose after a primary Johnson & Johnson vaccine.



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**Question:** What is the difference between a third dose and a booster shot of the COVID-19 vaccine? **Response:** A third dose of the vaccine is recommended for patients who are moderately to severely immunocompromised. The third dose can be administered 28 days after a person's second dose. People who do not have severely weakened or compromised immune systems may be eligible for a third dose "booster shot" of the Pfizer or Moderna vaccines this fall and winter, pending final recommendation and approval by the CDC.

Question: Will there be enough vaccine available to meet the demand?

**Response:** Yes, there is ample supply of the vaccines. At Penn Medicine, we will be prioritizing our supply to vaccinate our sickest patients and healthcare workers first. However, we are confident in our area pharmacies' ability to provide your COVID booster shots, safely and conveniently, just like they do with flu shots every year.

**Question:** Should I have an antibody test before I get a third dose?

Response: An antibody test is not necessary. It would not change the decision to give you an additional dose.

**Question:** Do I need to provide proof of vaccination to get my third dose?

**Response:** Proof of vaccine is preferred, but it is not required when you present for your third dose. For scheduling purposes, patients need to report which vaccine they received for their first and second dose.

Question: What kind of side effects can I anticipate if I get an additional dose of vaccine?

**Response:** Based on preliminary studies, the side effects appear to be similar to the initial vaccine reactions, although they may be more pronounced. These include pain, redness and swelling at the injection site, as well as tiredness, headache, muscle pain, chills, fever and nausea. So far, there have not been serious side effects to additional dosing, but we will monitor patients closely.

**Question:** Should I let my care team know if I received the third dose outside of Penn Medicine? **Response:** Yes. Please let your care team know if you get an additional dose of the vaccine, so we have an accurate report of your vaccination status in your health records.

**Question:** I am not immunocompromised, but I would like to receive a booster vaccine to protect myself. Can I receive a booster shot?

**Response:** Currently, the authorization for an additional vaccine dose does not apply to people who are not immunocompromised. Booster shots may be available to anyone who is not immunocompromised in late September, pending final recommendation and approval by the CDC. The FDA and CDC are advising that you wait at least eight months from the date of your second shot of the Pfizer or Moderna vaccines before getting a COVID-19 vaccine booster dose.

**Question:** How can I keep up with which variants are present in the U.S.?

**Response:** The CDC provides general information on SARS-CoV-2 variants <u>here</u>. In addition, the relative proportion of variants present in the U.S. based on whole genome sequencing data can be found <u>here</u>.

**Question:** Do our current tests for SARS-CoV-2 detect the new variants?

**Response:** Yes. All of the current diagnostic instrument platforms used throughout Penn Medicine can detect the circulating SARS-CoV-2 variants. This continues to be carefully studied by the laboratory at HUP.





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Question: What are the symptoms of a breakthrough infection in vaccinated people?

**Response:** Most patients with symptoms of a breakthrough infection will have the common symptoms associated with COVID-19, including new cough, fever, fatigue, or loss of taste or smell. There are anecdotal reports of breakthrough infections being associated with nasal congestion or runny nose, and headache. To date, there is no published evidence to definitively suggest that these symptoms are now being associated with breakthrough infections caused by the Delta variant. However, if you develop these types of symptoms, you should get tested.

**Question:** If I become infected with a COVID-19 variant strain, is there still treatment available? **Response:** Yes. Although some variants have demonstrated partial resistance to monoclonal antibody cocktails administered in the outpatient setting, medications and other therapeutics administered in the hospital are still effective against the new COVID-19 variants.

**Question:** Where can I get more information?

**Response:** Please visit the <u>COVID-19 vaccine webpage</u> (pennmedicine.org/coronavirus/vaccine) for the most up-to-date information and FAQs. You can also review the guidance from the <u>City of Philadelphia</u> (phila.gov), the <u>PA Department of Health</u> (health.pa.gov) or the <u>NJ Department of Health</u> (nj.gov), depending on where you live. If you need help locating a vaccination site, visit <u>vaccines.gov</u>.

#### **Employee Questions**

**Question:** How and why do new SARS-CoV-2 variants arise?

**Response:** Genetic variants of SARS-CoV-2 have been emerging and circulating around the world throughout the COVID-19 pandemic. Viral replication is an inefficient process that is prone to errors in copying the nucleotide sequence of RNA. These errors can result in changes to the amino acid sequence in proteins and thus a change in the three-dimensional structure of that protein. This is especially important in the spike protein of SARS-CoV-2, which is the critical attachment site for coronavirus infection of human cells. For SARS-CoV-2, mutations in the spike protein can significantly enhance the ability of the virus to enter cells and produce higher numbers of virus particles, which leads to the ability to more easily transmit infection to others. Such enhancements allow some viral strains (variants) to out-compete other strains as infection spreads through a population. Additional mutations can result in the ability of SARS-CoV-2 to resist destruction (neutralization) by antibodies. The evolutionary trend in SARS-CoV-2 has been both towards more contagious and more antibody-resistant variants.

**Question:** What are Penn Medicine's plans for a third dose of the vaccine?

**Response:** The FDA extended its emergency use authorizations (EUA) for both the Pfizer-BioNTech COVID-19 vaccine and the Moderna COVID-19 vaccine to allow an additional dose for certain people who have severely weakened immune systems. Currently, Penn Medicine is scheduling third-dose appointments for patients who are severely immunocompromised. [Click here to review more information about scheduling a severely immunocompromised patient for a third-dose vaccine.]

**Question:** I'm not immunocompromised, but I work in a clinical setting. Will non-immunocompromised staff be eligible for the booster?

**Response:** A third dose booster shot may be available to those who are not immunocompromised, including health care workers, in the fall and winter. If authorized, the FDA and CDC will recommend that you get a booster eight months after your second dose.

