On August 12th, the FDA authorized that a third dose of COVID-19 mRNA vaccines (Pfizer and Moderna) may be given to patients who are moderately or severely immunocompromised. Pfizer is approved for ages 12 years and older and Moderna for 18 years and older. Effective August 16, VUMC will begin administering 3rd dose COVID-19 mRNA vaccinations with the following guidelines:

Patient Eligibility:

Patients have already received 2 doses of a mRNA COVID-19 vaccine (e.g., Pfizer or Moderna) with the 2nd dose at least 8 weeks ago <u>AND</u>

Patient has moderate or severe immunocompromise. The CDC's Advisory Committee on Immunization Practices (ACIP) and VUMC define moderately or severely immunocompromised patients as patients who have any of these conditions:

- Under active treatment for solid tumor or hematologic malignancy
- Solid organ transplant patient on immunosuppressive therapy
- Hematopoietic stem cell transplant in last 2 years or otherwise on immunosuppression therapy after stem cell transplant
- Receipt of CART-cell therapy in last 2 years
- Primary immunodeficiency syndrome (Common Variable Immune Deficiency, DiGeorge Syndrome, Wiskott-Aldrich syndrome)
- Advanced (CD4<200) or untreated HIV infection
 - Active treatment in last month with one of the following immunosuppressing drugs:
 - High dose corticosteroids (≥20mg prednisone or equivalent per day for ≥14 days)
 - o Alkylating agents (ex: cyclophosphamide, temozolomide, chlorambucil, carboplatin, cisplatin)
 - Antimetabolites (ex: methotrexate, hydroxyurea, gemcitabine, fludarabine)
 - TNF alpha inhibitors (ex: adalimumab, etanercept, infliximab)
 - Other biologic agents that are immunosuppressive or immunomodulatory (e.g., rituximab, anakinra, golimumab, natalizumab)

Additionally, chronic medical conditions such as End Stage Renal Disease may be associated with varying degrees of immune deficit. The patient's provider and clinical team are best able to assess the degree of immune suppression and determine whether the patient may need a 3rd dose of vaccination.

Patients who have received a single dose of the Johnson & Johnson vaccine are not recommended to receive additional doses of vaccine at this time.

Studies are underway to determine if other groups of patients who do not meet the criteria above (e.g. older patients) may ultimately need an additional dose of a COVID-19 mRNA vaccine. A third dose is not currently recommended due to age alone (e.g., for those 65 years and older without conditions noted above).

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SARS-CoV-2 antibody tests should not be used to determine whether a patient is eligible for a third dose of a COVID-19 mRNA vaccine. For more information, please refer to the recent U.S. Food and Drug Administration's (FDA) advisory against the use of antibody testing to assess immunity: <u>https://www.fda.gov/medical-devices/safety-</u> communications/antibody-testing-not-currently-recommended-assess-immunity-after-covid-19-vaccination-fda-safety

Administration Guidelines:

VMG providers can identify eligible patients within their practice and provide direction for those patients to receive 3rd dose of a COVID-19 mRNA vaccination.

Patient Identification

- 1. Providers can identify or patients can self-identify as being eligible for a 3rd dose of a COVID-19 mRNA vaccine. If a patient self-identifies, Vanderbilt Health will provide a 3rd dose without requiring further proof of eligibility.
- 2. If providers reach out to patients, they can use My Health at Vanderbilt to let them know about their eligibility and share instructions on how to get the 3rd dose. This is a suggested MHAV message:

"Based on your medical history and CDC guidelines, (need link) you're eligible for a 3rd dose of a COVID-19 mRNA vaccine. Getting a 3rd shot will improve your protection against COVID-19.

We recommend that you get the same brand of vaccine (Pfizer or Moderna) that you had for your first 2 doses. But, if the same brand isn't available, it's OK for you to get the other brand.

- Wait for least 28 days after your 2nd shot before you get the 3rd shot.
- If possible, get your shot at least 2 weeks before you start any immunosuppressive therapy.

Here's how to get your 3rd shot:

- If you have an upcoming visit with us, ask your provider during your visit.
- Go to our website VUMC.org/Coronavirus/GetVaccines and make an appointment.
- Go to any place that's giving COVID-19 vaccines, such as your local health department or a retail pharmacy.

The COVID-19 vaccines help prevent severe illness and death. A 3rd dose can keep or improve your immune response if you're exposed to COVID-19. Along with the vaccine, you should continue to wear a mask in public and practice social distancing."

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Vaccine Scheduling or walk-up instructions

- 1. Patients have the option to receive the 3rd dose at VUMC or any other locations where COVID-19 mRNA vaccinations are being provided.
- 2. As of Monday, August 16, the following clinics can administer in clinic (NOTE: more locations are being added so please check with your clinic leadership if vaccine will become available to administer within your practice):
 - a. The Vanderbilt Clinic
 - i. Medical Specialties (accepting walk-ins from other areas; Pfizer and Moderna vaccines available at this site)
 - ii. Vanderbilt-Ingram Cancer Center
 - b. One Hundred Oaks
 - i. Vanderbilt Primary Care North (accepting walk-ins from other areas; Pfizer and Moderna vaccines available at this site)
 - ii. University Pediatrics
 - iii. Adolescent Health/Pediatric Allergy
 - c. Monroe Carell Jr. Children's Hospital at Vanderbilt
 - i. DOT 8
 - ii. Vanderbilt Children's Diabetes Program at MCE
 - iii. Walk-in Clinics
 - d. Vanderbilt Asthma, Sinus & Allergy Program (VASAP)
 - e. Walk-in Clinics (schedule at <u>https://www.vumc.org/coronavirus/GetVaccines</u>)
 - i. Vanderbilt Health Walk-In Clinic Bellevue
 - ii. Vanderbilt Health Walk-In Clinic Hendersonville
 - iii. Vanderbilt Health Walk-In Clinic Melrose
 - iv. Vanderbilt Health Walk-In Clinic Belcourt
 - v. Vanderbilt Health Walk-In Clinic Mt. Juliet
 - vi. Vanderbilt Health Walk-In Clinic Belle Meade
 - vii. Vanderbilt Health and Williamson Medical Center Walk-In Clinic Franklin
 - viii. Vanderbilt Health and Williamson Medical Center Walk-In Clinic Spring Hill
 - ix. Vanderbilt Health and Williamson Medical Center Walk-In Clinic Nolensville
 - x. Vanderbilt Health and Williamson Medical Center Walk-In Clinic Brentwood
 - xi. Vanderbilt Health and Williamson Medical Center Walk-In Clinic Cool Springs
 - f. Regional Clinics
 - i. Vanderbilt Children's Primary Care Smyrna
 - ii. Vanderbilt Children's Primary Care Lebanon
 - iii. Vanderbilt Integrated Primary Care Shelbyville (N. Main Street)
 - iv. Vanderbilt Integrated Urgent Care Shelbyville (N. Main Street)
 - v. Vanderbilt Integrated Primary Care Madison Street (Shelbyville)
 - vi. Vanderbilt Integrated Primary Care North (Frank Martin Road, Shelbyville)
 - vii. Vanderbilt Integrated Primary Care Wartrace
 - viii. Vanderbilt Integrated Primary Care Unionville

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3rd dose COVID-19 mRNA vaccination guidelines

- The COVID-19 3rd dose mRNA vaccination should be administered at least 28 days after the 2nd dose. The patient should ideally get the same brand of mRNA COVID-19 vaccine as they received for the 1st and 2nd doses, however, if unavailable, then another COVID-19 mRNA vaccine brand may be used. When possible, mRNA COVID-19 vaccine doses should be given at least two weeks before initiation of immunosuppressive therapies.
- 2. Currently there are no data to support the use of an additional mRNA COVID-19 vaccine dose after a primary Janssen (Johnson & Johnson) COVID-19 vaccination in immunocompromised people. FDA and CDC are actively working to provide further guidance on this issue.

