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IN BRIEF

Third Dose of mRNA-based COVID-19 Vaccines for Immunocompromised Persons

The FDA has expanded the Emergency Use Authorizations (EUAs) for the mRNA-based COVID-19 vaccines manufactured by Pfizer/BioNTech *(Comirnaty)* and Moderna *(Spikevax)* to include administration of a third dose in persons ≥12 years old (Pfizer/BioNTech) or ≥18 years old (Moderna) who have undergone solid organ transplantation or have a condition that compromises the immune system to a similar extent (see Table 1).[1]

Immunocompromised persons are more likely than healthy individuals to have an inadequate antibody response to COVID-19 vaccination, breakthrough SARS-CoV-2 infection, and severe COVID-19 requiring hospitalization. About 2.7% of adults in the US are considered immunocompromised, but 40-44% of hospitalizations for breakthrough COVID-19 cases have occurred in such persons.[2] In a study in 658 solid organ transplant recipients who received 2 doses of an mRNA-based vaccine, anti-SARS-CoV-2 antibodies were detectable in only 54% of persons 28-31 days after the second dose.[3]

Several clinical studies have demonstrated that the immunogenicity of mRNA-based COVID-19 vaccines in immunocompromised persons is increased with administration of a third dose. In a double-blind trial in 120 organ transplant recipients, median antibody, T-cell, and virus neutralization levels were significantly higher in persons who received 3 doses of the Moderna vaccine (at 0, 1, and 3 months) than in those who received 2 doses.[4] In 5 cohort studies, administration of a third dose of an mRNA-based vaccine to a total of 112 organ transplant recipients or hemodialysis patients who tested negative for anti-SARS-CoV-2 antibodies following their second dose resulted in seroconversion rates ranging from 33% to 50%.[2] Adverse effects with a third vaccine dose in immunocompromised persons have been similar to those observed with the first two doses.[5]

Immunocompromised persons who have received two doses of the Pfizer/BioNTech or Moderna vaccine can now receive a third dose of the same vaccine at least ≥28 days after their second dose.[6,7] The FDA has not authorized to date the use of additional doses of any COVID-19 vaccine in immunocompromised persons who received the Johnson & Johnson (Janssen) adenovirus-based vaccine. ■

Table 1. Some Immunocompromising Conditions[1]

- Active or recent treatment for a solid tumor or hematologic malignancy
- Receipt of a solid-organ or hematopoietic stem cell transplant
- Severe primary immunodeficiency
- Advanced or untreated HIV infection
- Active immunosuppressive or immunomodulatory treatment (e.g., high-dose corticosteroids, antimetabolites, alkylating agents, tumor necrosis factor inhibitors)
- Chronic renal disease (especially requiring hemodialysis)
- Anatomical or functional asplenia

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