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Volume 64 (Issue 1648)

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COVID-19 UPDATES

Second Booster Vaccine Dose for Older and Immunocompromised Persons

The FDA has expanded the Emergency Use Authorizations (EUAs) for the mRNA COVID-19 vaccines manufactured by Pfizer-BioNTech (*Comirnaty*) and Moderna (*Spikevax*) to allow for their use as a second booster dose ≥ 4 months after a first booster dose in adults ≥ 50 years old and in persons aged ≥ 12 years (Pfizer) or ≥ 18 years (Moderna) who have undergone solid organ transplantation or have a condition that compromises the immune system to a similar extent.^{1,2}

EFFICACY – Expansion of the EUAs was based on the results of a cohort study in healthcare workers in Israel who had received two primary doses and one booster dose of the Pfizer COVID-19 vaccine ≥ 4 months previously. A total of 274 persons were boosted again with either the Pfizer vaccine (n=154) or the Moderna vaccine (n=120) and then compared with age-matched controls over ~ 34 days (Pfizer) or ~ 25 days (Moderna). Geometric mean titers of neutralizing anti-SARS-CoV-2 antibodies 2 weeks after a second booster dose were significantly higher than those in the control group (by 10.4-fold with Pfizer and by 14.3-fold with Moderna) and slightly higher than those observed 2 weeks after the first booster dose (by 1.4-fold with Pfizer and by 2.0-fold with Moderna). The rate of symptomatic COVID-19 from day 8 was lower in persons who received a second booster dose than in those who did not (by 43% [95% CI 7% to 65%] with Pfizer and by 31% [95% CI -18% to 60%] with Moderna).³

In a 40-day retrospective cohort study in 563,735 persons 60-100 years old in Israel, the rate of death due to COVID-19 was significantly lower in persons who received a second COVID-19 vaccine booster dose during the study period than in eligible persons who did not (28 vs 99 deaths per 100,000 persons; adjusted HR 0.22 [95% CI 0.17-0.28]).⁴

SAFETY – In the cohort study in healthcare workers, adverse effects with a second booster dose were similar to those with previous vaccine doses.² According to the FDA, a surveillance study (not published) of $\sim 700,000$ persons in Israel who received a fourth dose of the Pfizer vaccine did not generate new safety concerns.¹

DOSAGE – The recommended second booster doses of the mRNA vaccines are the same as the initial booster doses (30 mcg for Pfizer; 50 mcg for Moderna). A second booster dose can be given ≥ 4 months after an initial booster dose of any FDA-authorized or approved COVID-19 vaccine (Pfizer, Moderna, or Johnson & Johnson/Janssen).^{5,6} ■

1. FDA News Release. Coronavirus (COVID-19) update: FDA authorizes second booster dose of two COVID-19 Vaccines for older and immunocompromised individuals. March 29, 2022. Available at: <https://bit.ly/38bToLQ>. Accessed March 31, 2022.
2. CDC. COVID-19 vaccines for moderately or severely immunocompromised people. March 24, 2022. Available at: <https://bit.ly/3iREJYo>. Accessed March 31, 2022.
3. G Regev-Yochay et al. Efficacy of a fourth dose of Covid-19 mRNA vaccine against Omicron. N Engl J Med 2022 March 16 (epub).
4. R Arbel et al. Second booster vaccine and Covid-19 mortality in adults 60 to 100 years old. Research Square 2022 March 24 (preprint). Available at: <https://bit.ly/3uKhzbY>. Accessed March 31, 2022.
5. FDA. Fact sheet for healthcare providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). For 12 years of age and older. March 29, 2022. Available at: <https://bit.ly/3bBH5GV>. Accessed March 31, 2022.
6. FDA. Fact sheet for healthcare providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Moderna COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). Booster dose only presentation. March 29, 2022. Available at: <https://bit.ly/3wQC8WO>. Accessed March 31, 2022.

Additional Content Available Online: COVID-19 Tables/Charts

Please check our website for the latest information on COVID-19, including our continuously updated tables/charts on treatments, vaccines, and dosing recommendations. Available at: www.medicalletter.org/drugs-for-covid-19.

FDA Restricts Use of Sotrovimab

The FDA has begun to restrict use of the anti-SARS-CoV-2 monoclonal antibody sotrovimab in US regions with a high relative prevalence of the BA.2 (Omicron) variant of the virus.¹ Sotrovimab, which is available under an Emergency Use Authorization (EUA) for treatment of mild to moderate COVID-19 in high-risk patients ≥ 12 years old who weigh ≥ 40 kg,² is unlikely to be effective for treatment of COVID-19 caused by BA.2; it has significantly less neutralizing activity *in vitro* against BA.2 than against other variants.³

Sotrovimab is no longer authorized for use in regions where the BA.2 variant of SARS-CoV-2 causes $>50\%$ of COVID-19 cases. At the time of publication (March 31, 2022), this was the case in HHS Regions 1 (New England), 2 (NJ, NY, Puerto Rico, Virgin Islands), 5 (Upper Midwest), 9 (AZ, CA, HI, NV, Pacific islands), and 10 (AK, ID,

OR, WA).¹ BA.2 is likely to become the predominant strain of SARS-CoV-2 in all regions of the US in the coming weeks⁴; announcements of further restrictions on use of sotrovimab will be published at: <https://bit.ly/3wGZNc9>.¹ Alternative treatments for mild to moderate COVID-19 that retain efficacy against the BA.2 variant include nirmatrelvir/ritonavir (*Paxlovid*), remdesivir (*Veklury*), bebtelovimab, and molnupiravir (*Lagevrio*).⁵ ■

1. FDA Drug Safety and Availability. FDA updates sotrovimab emergency use authorization. March 25, 2022. Available at: <https://bit.ly/3wGZNc9>. March 31, 2022.
2. An EUA for sotrovimab for treatment of COVID-19. *Med Lett Drugs Ther* 2021; 63:97.
3. FDA. Fact sheet for health care providers. Emergency Use Authorization (EUA) of sotrovimab. March 2022. Available at: <https://bit.ly/2TfoomJ>. Accessed March 31, 2022.
4. CDC. COVID data tracker. Variant proportions. Available at: <https://bit.ly/3Ka3HhH>. Accessed March 31, 2022.
5. Treatment of COVID-19 in high-risk outpatients. *Med Lett Drugs Ther* 2022 March 3 (epub). Available at: https://secure.medicalletter.org/downloads/1643f_table.pdf.

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