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Addendum: Effectiveness of mRNA COVID-19 Vaccines

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A reader of our article on the 2024-2025 formulations of the mRNA COVID-19 vaccines manufactured by Pfizer/BioNTech *(Comirnaty)* and Moderna *(Spikevax)*[1] asked us to provide more information on the data that supported their licensure.

The vaccines were initially licensed by the FDA in 2021 (Pfizer) and 2022 (Moderna) based on the results of large, double-blind trials in SARS-CoV-2-naive adolescents and adults. Both vaccines significantly decreased the risk of symptomatic and severe SARS-CoV-2 infection compared to placebo.[2-4] Issuance of the FDA Emergency Use Authorizations (EUAs) allowing use of the vaccines in younger children was initially based primarily on the results of immunogenicity studies. Titer levels of anti-SARS-CoV-2 neutralizing antibodies following vaccination were at least as high in persons 6 months through 11 years old as they were in comparator adult cohorts.[5,6]

As with the influenza vaccine, efficacy trials are no longer required by the FDA for licensure of new COVID-19 vaccine formulations that only significantly differ from previous formulations in the virus strain that they target. Licensure is based on the immunogenicity, efficacy, and safety of previous formulations, and on the likelihood of the new formulations to protect against currently circulating SARS-CoV-2 variants.[7-9]

Observational studies suggest that all of the COVID-19 vaccine formulations available in the US in 2023-2024 were effective in reducing the incidence of COVID-19. In a case-control analysis of 14,860 COVID-19 nucleic acid amplification tests administered at community pharmacies to immunocompetent adults with COVID-like symptoms between September 2023 and May 2024, receipt of any 2023-2024 COVID-19 vaccine at least 7 days before the test was associated with a decreased incidence of SARS-CoV-2 infection. The estimated adjusted vaccine efficacy was 45%; it was 58% for infections likely caused by the XBB.1.5 variant, which the 2023-2024 vaccines targeted, and 37% for infections likely caused by the JN.1 variant.[10,11]

In similar analyses of tests administered to adults with COVID-like illness within 10 days before or 3 days after an emergency department/urgent care visit (n=245,504) or a hospitalization (n=77,103) between September 2023 and May 2024, receipt of any 2023-2024 COVID-19 vaccine at least 7 days before the test was associated with a decreased incidence of COVID-19 requiring an emergency department/urgent care visit (estimated adjusted vaccine efficacy 36%) or hospitalization (estimated adjusted vaccine efficacy 41%). Among hospitalized immunocompetent persons, the estimated adjusted vaccine efficacy against critical illness was 58%.[10,12]

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