U.S. FOOD & DRUG ADMINISTRATION

Recommendation for the 2023-2024 Formula of COVID-19 vaccines in the U.S.

The Vaccines and Related Biological Products Advisory Committee (VRBPAC) periodically convenes in open session to discuss and make recommendations on the selection of strain(s) to be included in updated COVID-19 vaccines. At the January 26, 2023, VRBPAC meeting on COVID-19 vaccines, FDA stated that they anticipate assessing SARS-CoV-2 evolution at least annually (review of data to commence in the Spring of each year) and to convene the VRBPAC in June of each year regarding strain selection for a fall vaccination.

Data on SARS-CoV-2 evolution indicated that XBB sublineages accounted for more than 95% of the circulating virus variants in the U.S. as of early June 2023. While XBB.1.5 has declined to less than 40% of presumed circulating virus in the U.S., XBB.1.16 is on the rise and XBB.2.3 is slowly increasing in proportion (CDC COVID Data Tracker: Variant Proportions). The current trajectory of virus evolution suggests that XBB.1.16 could be dominant by fall 2023. XBB.2.3 and other XBB sublineages could also continue to increase in proportion as the virus evolves. Although SARS-CoV-2 continues to evolve, the protein sequences of XBB.1.5, XBB.1.16, and XBB.2.3 Spike protein appear similar, with few amino acid differences. Available evidence suggests little to no further immune evasion from these new substitutions in the XBB.1.16 Spike protein compared to XBB.1.5. By several measures, including escape from antibody neutralization and waning protection, the currently available bivalent COVID-19 (Original plus Omicron BA.4/BA.5) vaccines appear less effective against currently circulating variants (e.g., XBB-lineage viruses) than against previous strains of virus. The totality of available evidence suggests that a monovalent XBB-lineage vaccine is warranted for the 2023–2024 update.

The VRBPAC met on June 15, 2023, to discuss the strain composition for the 2023-2024 Formula of COVID-19 vaccines in the U.S. Sublineages considered by the VRBPAC included XBB.1.5, XBB.1.16, and XBB.2.3. Evidence influencing strain selection discussed by the Committee included virus surveillance and genomic analyses, antigenic characterization of viruses, human serology studies from current vaccines, pre-clinical immunogenicity studies evaluating immune responses generated by candidate vaccines. The Committee also reviewed manufacturing timelines.

For the 2023-2024 Formula of COVID-19 vaccines in the U.S., the committee unanimously voted (21/0) on recommending a 2023-2024 Formula update of the current vaccine composition to a monovalent XBB-lineage. Based on the evidence and other considerations presented, there was a preference for selection of XBB.1.5.

Based on the totality of the evidence, for the 2023-2024 Formula of COVID-19 vaccines in the U.S., FDA has advised manufacturers seeking to update their COVID-19 vaccines that they should develop vaccines with a monovalent XBB.1.5 composition.

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