

Bivalent mRNA COVID-19 vaccines – ACIP discusses transitioning to bivalent primary series

- On February 24, 2023, the Centers for Disease Control and Prevention's (CDC) <u>Advisory Committee on Immunization Practices (ACIP)</u> supported (they did not vote) harmonizing the vaccine strain composition for mRNA COVID-19 vaccines across both the <u>primary</u> series and booster doses.
 - The current recommendation for people ages 6 months and older is a primary series of two monovalent vaccines followed by a bivalent booster dose (in most ages). For children 6 months to 4 years of age who start a Pfizer/BioNTech primary series, the third dose in a 3-dose primary series is a bivalent dose.
 - The future proposed recommendation for people ages 6 months and older is a primary series of two <u>bivalent</u> vaccines followed by a bivalent booster dose (in most ages).
- The ACIP's discussion follows the recommendation of the FDA's <u>Vaccines and Related Biological Products Advisory Committee (VRBPAC)</u> on January 26, 2023. VRBPAC voted unanimously in favor of harmonizing the vaccine strain composition of primary series and booster doses used in the U.S. to a single composition, meaning that the composition for all vaccines would be a bivalent vaccine (ie, Original strain plus Omicron BA.4/BA.5 strain).
- The FDA still needs to authorize the change either by changing the current emergency use authorizations (EUAs) or by approving new biologic license applications (BLAs) for the vaccines.
 - Pfizer/BioNTech has already submitted for approval of their Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine as a primary series and booster dose(s) for individuals 12 years of age and older. The expected FDA approval date is still to be determined.
- ACIP also discussed the number of vaccines needed by different groups on a yearly basis. ACIP felt that one vaccine per year is still appropriate for all age groups and for immunocompromised individuals.



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