

COVID-19 vaccines – VRBPAC makes recommendations for new monovalent vaccine composition

- On June 15, 2023, the FDA's [Vaccines and Related Biological Products Advisory Committee \(VRBPAC\)](#) unanimously voted for the 2023-2024 formula of COVID-19 vaccines in the U.S to include a periodic update of the current vaccine composition to a monovalent XBB-lineage.
 - Because there are no currently circulating Wuhan and BA4/BA5 virus variants, VRBPAC felt that these strains no longer need to be included in a vaccine for the Fall.
- All viruses currently circulating are Omicron viruses with [XBB variants](#) being predominant. The virus is continuing to evolve over time. VRBPAC felt that XBB containing vaccines are needed because:
 - Better-matched vaccines improve protection
 - Current bivalent vaccines maintain effectiveness but show signs of waning and immunity is likely be further reduced by fall.
- Risk factors for severe COVID-19 illness continue to remain the same with different virus strains:
 - Unvaccinated people at higher risk of severe illness compared with vaccinated people
 - Most (75%) vaccinated people who develop severe COVID-19 illness have multiple risk factors:
 - Older age (most ≥ 65 years, but with risk increasing with age)
 - Underlying medical conditions (with risk increasing with number of underlying conditions): immunosuppression, diabetes mellitus, chronic kidney disease, chronic lung disease, chronic cardiovascular disease, and chronic neurologic disease.
- VRBPAC also discussed selection of a specific XBB lineage (eg, XBB.1.5 or XBB.1.16 or XBB.2.3) for inclusion in the 2023-2024 formula of COVID-19 vaccines in the U.S.
 - XBB.1.5 is preferred because the neutralization for each of the lineages is similar and XBB.1.5 has the most data from the manufacturers.
 - It is also important to have uniformity across the manufacturers.

What's Next?

- The FDA will review VRBPAC's recommendations and approve final composition for the 2023-2024 COVID-19 vaccines.
- The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) will meet on [June 23, 2023](#) to discuss and make recommendations on FDA's approvals.
- The new vaccines are expected to be available in the September 2023 timeframe.