

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

- On June 5 2024, the FDA's <u>Vaccine and Related Biological Products Advisory Committee</u>
 (<u>VRBPAC</u>) unanimously voted for the 2024-2025 formula of COVID-19 vaccines in the U.S to include a monovalent JN.1-lineage.
- All viruses currently circulating are Omicron viruses with <u>JN.1 lineages</u> (KP.2-like lineages and KP.3 lineages are increasing) being predominant. The virus is continuing to evolve over time.
 VRBPAC felt that JN.1 containing vaccines are needed because:
 - XBB-containing vaccines from 2023-2024 had robust effectiveness against XBB lineages, but declining effectiveness against JN.1 lineages
 - Current XBB vaccines maintain effectiveness but show signs of waning, and immunity is likely to be further reduced by fall.
- VRBPAC also discussed selection of a KP.2 or KP.3 lineage for inclusion in the 2024-2025 formula of COVID-19 vaccines in the U.S.
 - JN.1 is preferred because the neutralization for each of the lineages is similar and JN.1 has the most data from the manufacturers.
 - Cross protection is good between the JN.1 lineages and future sub lineages.
 - It is also important to have uniformity across the manufacturers because Novavax can currently only produce a JN.1 lineage vaccine.

What's Next?

- The FDA will review VRBPAC's recommendations and approve final composition for the 2024-2025 COVID-19 vaccines.
- The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) will meet on <u>June 27, 2024</u> to discuss and make recommendations on FDA's approvals.
- The new vaccines are expected to be available in the August 2024 timeframe.



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