New Omicron Targeting Vaccine Formula Approved as Booster Dose for Individuals 12 years and Older

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On August 31, 2022, the US Food and Drug Administration (FDA) <u>amended</u> the previously issued emergency use authorizations (EUAs) for both the Moderna and the Pfizer-BioNTech (Pfizer) COVID-19 vaccines to authorize the use of bivalent formulations for boosters. The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) voted to recommend both the Moderna and Pfizer bivalent formulation boosters on September 1, 2022. This new formulation, which can be administered at least two months following the completion of a primary series or a previous booster dose, targets both the original virus and the current Omicron variants. During a monthly call with Tribal and urban Indian organization (UIO) leaders, the Indian Health Service (IHS) stated that it started shipping the bivalent formulation the week of Labor Day and that these boosters will replace all booster formulations once rolled out. Currently, Omicron variants make up more than 99% of COVID-19 cases within the US.

As it stands, the monovalent (original) COVID vaccine is no longer the recommended booster for people ages 12 and up. In order for an individual to be considered 'up to date' on their COVID vaccination, they must have received the bivalent booster, regardless of previous booster status. Individuals who have previously caught COVID-19 can be vaccinated up to three months after the infection.

Background

American Indians and Alaska Natives (AI/ANs) have been <u>disproportionately affected</u> by the COVID-19 pandemic. At the height of the pandemic, AI/ANs were 3.5 times more likely to test positive, 3.2 times more likely to be hospitalized, and 2.2 times more likely to die to due COIVD-19.

Indian Country has had highly successful vaccine rollouts and UIOs have been <u>instrumental in the</u> <u>success of vaccinating AI/AN populations in urban Areas</u>. As of August 2022, AI/ANs have the highest vaccination administration rates in the US with 74.5% of AI/ANs having received at least one dose of one of the three previously available COVID-19 vaccines, per <u>CDC data</u>.