



Continued Monitoring of COVID-19 Vaccines, Seasonal Immunization Schedules, and More

Updated: November 13, 2020

CDC's Advisory Committee on Immunization Practices (ACIP) continues to hold monthly emergency meetings to assist in accelerated COVID-19 vaccine development.

ACIP recently held a 3-day meeting to include additional vaccine topics and voted to approve the pediatric/adolescent and adult immunization schedules for 2021. These schedules include minor changes and edits to recommendations due to factors including the unavailability of Zostavax for shingles prevention (RZV will be the remaining shingles vaccine) in 2021 and the addition of MenQuadfi for Meningitis-A, C, Y and W in adolescents and people at increased risk.

In February 2021, ACIP will discuss and consider the following:

- A recommendation for the use of Flucelvax, a cell-derived quadrivalent influenza vaccine, in children 2-18 years of age.
- A final assessment of laboratory tests for pre-vaccine screening and vaccine recommendations for the implementation of the Sanofi Pasteur dengue vaccine in Puerto Rico.
- A recommendation for the use of Pfizer's tick-borne encephalitis vaccine.
- A vote on policy changes related to pre-exposure prophylaxis for rabies.

Additionally, ACIP has formed a new group to evaluate the safety and immunogenicity of Vaxchora for cholera in children 2-17 years of age, expecting that FDA licensure could occur in the 2nd quarter of 2021 with a possible ACIP vote following in October.

ACIP spent the entirety of day 3 focused on COVID-19 vaccines, of which there are four in Phase 3 development:

- AZD1222 (AstraZeneca; hold removed by FDA on 10/23)
- Ad26.COV2.S (Janssen; hold removed by FDA on 10/23)
- BNT162b2 (Pfizer/BioNtech)
- mRNA-1273 (Moderna)

A summary of the recent Vaccines and Related Biological Products Advisory Committee (VRBPAC) revealed that issuance of an emergency use authorization (EUA) would be contingent upon the ability to conduct active follow-up of recipients, passive monitoring for clinically significant adverse reactions, observational studies, and continuation of blinded, placebo-controlled follow-up in ongoing clinical trials for as long as feasible.

Importantly, **FDA does not consider issuance of an EUA to necessitate immediate un-blinding or offering vaccine to placebo recipients.**

CDC is working toward a jurisdictional readiness date of Nov. 15, 2020 for vaccine implementation. This includes identifying and enrolling provider sites, augmenting state capacity through federal pharmacy partnerships, and planning for various vaccine products and allocations for readiness across different scenarios. The vaccine will be

administered at no cost to providers or recipients. While providers can charge administration fees, CDC requires that providers administer vaccine regardless of a recipient's ability to pay.

There were slight revisions to the ethical principles for phased allocation of vaccine, which are as follows:

- Maximize benefits and minimize harms;
- Promote justice and fairness; and
- Mitigate health inequities and promote transparency.

IDSA will continue to monitor ACIP activities. Please contact Haley Payne, Public Health Policy Manager, at hpayne@idsociety.org with any questions.