Advisory Commission on Childhood Vaccines (ACCV) update

(September to November 2022)

Jay E. Slater, MD
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
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Boostrix

7 October - approved Boostrix (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed [Tdap]) for immunization during the third trimester of pregnancy to prevent pertussis, commonly known as whooping cough, in infants younger than two months of age.

Boostrix was initially approved by the FDA in 2005 as a single dose for booster immunization against tetanus, diphtheria and pertussis in individuals 10 through 18 years of age. Subsequently, the FDA also approved Boostrix to include use in individuals 19 years of age and older and to include use of an additional dose 9 years or more after the initial dose of a Tdap vaccine. The FDA's approval of Boostrix has always included its use during pregnancy to protect the vaccinated individual. Today's approval is specific to use in pregnancy to prevent pertussis in infants younger than 2 months of age. Since 2012, the CDC has recommended the use of Tdap vaccines during the third trimester of each pregnancy.

Boostrix

7 October - The determination of effectiveness of Boostrix administered during the third trimester to prevent pertussis among infants younger than 2 months of age was based on a re-analysis of the Boostrix-relevant data from an observational case-control study of Tdap vaccine effectiveness. The FDA found these real-world data as providing real-world evidence to support this approval. In this re-analysis, data from 108 cases of pertussis in infants younger than 2 months of age (including four cases whose mothers received Boostrix during the third trimester) and 183 control infants who did not have pertussis (including 18 whose mothers received Boostrix during the third trimester) resulted in a preliminary estimate of Boostrix as 78% effective in preventing pertussis among infants younger than 2 months of age, when administered during the third trimester of pregnancy. This preliminary estimate of effectiveness was updated using data from published observational studies. These statistical analyses provided estimates of effectiveness that are consistent with the preliminary estimate of 78%.

Moderna and Pfizer-BioNTech COVID-19 Vaccines

12 October 2022 - amended the emergency use authorizations (EUAs) of the Moderna COVID-19 Vaccine, Bivalent and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to authorize their use as a single booster dose in younger age groups. The Moderna COVID-19 Vaccine, Bivalent is authorized for administration at least two months following completion of primary or booster vaccination in children down to six years of age. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for administration at least two months following completion of primary or booster vaccination in children down to five years of age.

Moderna and Pfizer-BioNTech COVID-19 Vaccines

12 October 2022 - These bivalent COVID-19 vaccines include an mRNA component corresponding to the original strain to provide an immune response that is broadly protective against COVID-19 and an mRNA component corresponding to the Omicron variant BA.4 and BA.5 lineages to provide better protection against COVID-19 caused by the Omicron variant. The mRNA in these vaccines is a specific piece of genetic material that instructs cells in the body to make the distinctive “spike” protein of the Original virus strain and the Omicron variant lineages BA.4 and BA.5. The spike proteins of BA.4 and BA.5 are identical.

Novavax COVID-19 Vaccine, Adjuvanted

19 October 2022 - Authorized for emergency use the Novavax COVID-19 Vaccine, Adjuvanted for use as a first booster dose to individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine. The booster dose may be administered at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine.

VRBPAC meetings

6 October - to discuss the Strain Selection for the Influenza Virus Vaccines for the 2023 Southern Hemisphere Influenza Season.

FDA COVID-19 Website

- FDA has a website dedicated to its COVID-19 activities, including FDA's pandemic response activities pertaining to vaccines, testing, therapeutics, and devices. The website is frequently updated and is a resource for the public, including healthcare providers and industry. https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19

Questions?

The opinions expressed herein – *especially in response to questions* – are an informal communication and represent my best judgment. These comments/responses do not bind or obligate FDA.