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Pediatric Vaccines:

What's New for 2022

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Abstract

Childhood immunizations have proven to be tremendously successful in eradicating diseases that have previously been considered to be fatal. Though current immunizations are generally well tolerated, it is important to constantly evaluate existing methods and be amenable to changes when they present. Newer formulations of products have been in development to improve vaccine completion, vaccine efficacy, and protection against emerging diseases. Growing interest in health economics has led to production of new vaccines that promote healthier outcomes in all populations, especially those vulnerable to infectious disease, children.

New vaccines

Childhood immunizations have had a profound impact on rates of communicable diseases worldwide. It continues to be important to invest in this global health domain. Recently, multiple new vaccines were approved and made available for use in children. These include Vaxelis, Flucelvax, Pfizer-BioTech COVID-19 vaccine, and Moquirix.

Vaxelis, the hexavalent vaccine for diphtheria, tetanus, acellular pertussis, inactivated poliovirus, *Haemophilus influenzae* type b, and hepatitis B from Merck and Sanofi, was made available for use in the United States and included in the pediatric vaccination schedule update for 2022. Vaccination compliance and completion rates increase with administration of combination vaccines. Studies suggest this is due to reduced distress experienced visits when a single injection is offered.[1] The new vaccine combined diphtheria, tetanus, acellular pertussis, and inactivated poliovirus from Sanofi with *Haemophilus influenzae* type b and hepatitis B from Merck reduces the quantity of needle sticks required for pediatric vaccine series. The series is recommended at 2, 4, and 6 months as a 3-dose series. The Food and Drug Administration (FDA) approved the vaccine for children 6 weeks to 4 years of age in 2018, and it became available in the United States in 2021.[2]

Flucelvax, the quadrivalent cell-based influenza vaccine from Seqirus, was approved by the FDA for use in children 6 months and older in 2021 (previously approved for use in children 2 years and older). Approval occurred following a Phase 3 study demonstrating safety and noninferiority immunogenicity of the cell-based vaccine when compared with other quadrivalent influenza vaccines currently on the market.[3] Flucelvax remains the only cell-based quadrivalent inactivated influenza vaccine approved for use by the FDA. This vaccine is grown in mammalian cultured cells in order to avoid risk of mutations of influenza virus that occurs with egg-based production. Preparation in this way promotes fewer instances of antigenic mismatch, raising vaccine efficacy.[4]

The Pfizer-BioNTech (BNT162b2) COVID-19 vaccine was also approved for use in pediatric patients 5 to 18 years of age in 2021. Trials are still ongoing for pediatric patients 6 months through 4 years of age. BNT162b2 remains the only vaccine approved for use in children in the

United States. Children 5 to 11 years of age receive a pediatric dose of the vaccine, while adolescents 12 years of age and older receive the adult dose.[5] The recommended series for an immunocompetent child is a 2-dose series separated by three weeks with a booster available for children 12 years of age and older (see updates to vaccine schedule and special considerations for immunocompromised children below).[6] In patients 12-18 years of age, vaccination with BNT162b2 has been shown to be protective against sequelae including multisystem inflammatory syndrome in children. Acute myocarditis is rare but has been reported as a severe adverse effect of the vaccine in this age range.[7]

Outside of the United States, Moquirix (RTS,S/AS01), the malaria vaccine from GlaskoSmithKline, has been recommended by the World Health Organization (WHO) in 2021 for vaccination for children at risk for *P. falciparum* malaria in Africa and Asia.[8] It is recommended as a 4-dose series in children five months of age and older. The vaccine is currently available in Ghana, Kenya, and Malawi and production will increase to make it more widely available.[9]

Emerging Vaccines

In addition to newly approved vaccines, there are numerous emerging vaccines currently undergoing further testing and clinical trials. These include the Ebola, Chikungunya, Lyme, and Middle Eastern Respiratory Syndrome (MERS) vaccines. Zabdeno (Ad26.ZEBOV) and Mvabea (MVA-BN-Filo) is the 2-dose Ebola vaccine regimen in development from Johnson & Johnson, has received European Commission authorization in 2020 and WHO prequalification in 2021[10] following a Phase 3 trial including children 1-17 years of age,[11] though has not yet been approved for use by the FDA. Currently, there is only one FDA approved vaccine for protection against Ebola, Ervebo, which is only approved for ages 18 and up. VLA1553, the Chikungunya vaccine candidate from Valneva, is currently undergoing Phase 3 trial with a plan to move forward with regulatory approval in 2022.[12] VLA15, the Lyme disease vaccine candidate from Pfizer has recently completed a Phase 2 trial with a plan to move forward to a Phase 3 trial in 2022.[13] INO-4700, the MERS vaccine candidate from Inovio, is currently undergoing a Phase 2 trial.[14]

Pediatric Vaccination Schedule for 2022

The Advisory Committee on Immunization Practices released its newest recommendations for 2022 on the Center for Disease Control and Prevention (CDC) website (https://www.cdc.gov/vaccines/acip). This updated schedule has been reviewed and approved by multiple advisory committees including the CDC, the American Academy of Pediatrics, and the National Association of Pediatric Nurse Practitioners. Changes included addition of vaccines to the schedule, clarification to the existing vaccines on the schedule, and an appendix with contraindication and precautions for all of the vaccines. Additions include dengue and COVID. Dengue is recommended as a 3-dose series for children 9-16 years old who have had previous Dengue infection and live in endemic areas.[15] Recommendations for the 2-dose COVID vaccine series were also included (3 dose for moderately to severely immunocompromised children) as well as the booster 5 months after series completion for children 12 years and older (3 months after for moderately to severely immunocompromised children 12 years and older).[6] Clarifications were made regarding *Haemophilus influenzae* type b, hepatitis A, hepatitis B, human papillomavirus, varicella, and the measles, mumps, and rubella vaccines. *Haemophilus*

influenzae type b vaccination with the Vaxelis combination vaccine was clarified for use only in the primary series and not as a booster at age 12-15 months. Hepatitis A vaccination was clarified to be recommended at age 12-23 months. Hepatitis B revaccination was clarified to be recommended for infants of hepatitis B surface antigen positive moms, hemodialysis patients, and immunocompromised patients with post vaccination serology demonstrating insufficient immunity. Human papillomavirus vaccination was recommended to be a 3-dose series for immunocompromised patients (including patients with HIV) regardless of age at series initiation. Varicella and the measles, mumps, and rubella vaccines were recommended to be administered separately for dose 1 for children ages 12- 47 months.[15]

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