Immunization Update and ACIP Highlights – October 2023

Nov. 1, 2023

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) met on October 25, 26 for its regular triennial vaccine meeting. For archives of minutes and slides, go to the ACIP meeting website and click on "Meeting Materials." COVID vaccine recommendations are available on the CDC's Clinical Considerations website. Below are the key highlights:

- **Meningococcal Vaccine – Vote**
  - ACIP recommended Pentavalent Meningococcal ABCWY vaccine (PENBRAYA™: Pfizer) may be used when both MenACWY and MenB are indicated at the same visit.
- **Mpox Vaccine – Vote**
  - The two-dose series of mpox vaccine (JYNNEOS®: Bavarian Nordic A/S) is recommended for persons ages 18 and older at risk for mpox. This is an interim recommendation that will be reevaluated in 2 to 3 years.
- **Combined Immunization Schedule – Vote**
  - The proposed 2024 Child and Adolescent Immunization Schedule and Adult Immunization Schedule were approved. They will be published on-line in November 2023, earlier than in previous years.
- **Influenza Vaccines**
  - Presentations on safety in pregnancy and coadministration included studies showing recombinant influenza vaccine (RIV4, Flublok) and cell culture influenza vaccine (ccIIV, Flucelvax) to be safe when administered during pregnancy compared to standard dose influenza vaccine (SD-IIV4). Reactogenicity of COVID-19 and influenza vaccine was comparable when given either simultaneously or sequentially. Local or systemic reaction and adverse reactions were similar when either adjuvanted influenza vaccine (aIIV4, Fluad) or high-dose inactivated influenza vaccine (HD-IIV4, High-dose Fluzone) were coadministered with dose 1 recombinant zoster vaccine (RZV: SHINGRIX).
  - Presentation of the first U.S. study showing that maternal vaccination was associated with reduced odds of influenza hospitalization and emergency department (ED) visits in infants less than 6 months of age, particularly when administered during the third trimester of pregnancy was presented.
  - Due to an absence of cases caused by B/Yamagata lineage viruses, the World Health Organization (WHO) recommends that the inclusion of that antigen is no

longer warranted and manufacturers should move to exclude it, leading to influenza vaccines becoming trivalent rather than quadrivalent.

- **Respiratory Syncytial Virus (RSV) Vaccine – Adult 50-59**
    - Immunobridging study of RSV Vaccine (Arexvy:GSK) showed non-inferiority of immune response in adults ages 50-59 compared to adults ages 60 and older with a similar safety profile in both cohorts.
- **COVID-19 Vaccines**
    - Implementation is progressing on shifting from publicly provided to commercially provided COVID-19 vaccine. Recent clinical considerations were reviewed.
- **Pneumococcal Vaccines**
    - Pneumococcal vaccines of higher valences are currently being studied.
- **Other Topics**
    - Evidence to recommend **Chikungunya** vaccine was presented. Takeda TAK-003 **Dengue** vaccine has been withdrawn from consideration by the FDA

Meningococcal Vaccines

The ACIP voted to recommend the newly approved pentavalent meningococcal ABCWY vaccine (Pfizer: PENBRAYA™) which may be used when both MenACWY and MenB are indicated at the same visit. This may apply for healthy individuals ages 16 through 23 years during their routine MenACWY schedule when shared clinical decision-making favors administration of MenB vaccine. It also applies for individuals ages 10 years and older at increased risk of meningococcal disease due to conditions, such as persistent complement deficiencies, complement inhibitor use or functional or anatomic asplenia when the person is due for both vaccines.

The minimum interval for MenABCWY vaccine is 6 months. Individual at increased risk of meningococcal disease who should receive additional doses of MenACWY and Men B less than 6 months after MenABCWY vaccine should instead receive separate MenACWY and Pfizer's MenB-FHbp vaccine (Trumenba®). Data are not available regarding safety or immunogenicity of dosing intervals of greater than 12 months for repeat doses of MenABCWY vaccine. The licensed B component vaccines are not interchangeable by manufacturer. Therefore, when Pfizer's MenABCWY vaccine is used, Pfizer's Trumenba® must be the prior or subsequent MenB component vaccine used.

Nimenrix® is the MenACWY component of PENBRAYA vaccine. When it was coadministered with DTap/IPV/Hib/HepB combination vaccine, the MenA, MenC and MenW135 titers were decreased. When it was administered with Tdap, the PT, FHA and PRN pertussis antigens were decreased. Clinical relevance of these findings is unknown.

Pfizer committed to a $210 price per dose if ACIP were to vote for two doses of MenABCWY, but since ACIP only voted for one dose to be administered for the during the adolescent series, Pfizer is planning to increase the price per dose.

Mpox Vaccine

Modeling suggests that without vaccination, transmission of mpox will continue with sporadic outbreaks. The WHO is trying to eradicate mpox and vaccinating at-risk persons prior to an outbreak will assist with that goal. Less than 25% of the eligible population is fully vaccinated with 2 doses. Overall coverage needs to be improved.

The ACIP voted to change preexposure recommendation for those at risk from just during an outbreak to anytime. It recommends the two-dose series of mpox vaccine (JYNNEOS®: Bavarian Nordic A/S) for persons ages 18 and older at risk for mpox. Those considered to be at risk include gay, bisexual, and other men who have sex with men, and transgender or nonbinary people who in the past 6 months have had one of the following:

- A new diagnosis of one or more sexually transmitted diseases
- More than one sex partner
- Sex at a commercial sex venue
- Sex in association with a large public event in a geographic area where mpox transmission is occurring

Sexual partners of persons with the risks described above or persons who anticipate experiencing any of the above are also deemed to be at risk.

This is an interim recommendation that will be reevaluated in 2 to 3 years. ACIP voted to add mpox vaccine to the Vaccines for Children (VFC) program for persons aged 18 years. It is anticipated that the vaccine will transition to commercialization with a wholesale average cost of $200 to $270/dose.

Clinical considerations include:

- Pregnant or breastfeeding persons at risk for mpox may receive the JYNNEOS vaccine before an exposure
- JYNNEOS is not recommended as a routine vaccination for healthcare personnel unless sexual risk factors are present
- There is no minimum interval between receiving any COVID-19 vaccine and JYNNEOS vaccine regardless of which vaccine is administered first.
- Young adult males who are recommended to receive both vaccines might consider waiting 4 weeks between vaccines. This is because of the observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopox virus vaccine and COVID -19 vaccines and the hypothetical risk for myocarditis and pericarditis after JYNNEOS vaccine. However, if a patient's risk for mpox or severe disease due to COVID-19 is increased, administration of JYNNEOS and COVID-19 vaccines should not be delayed.

Completion of the 2-dose series should be encouraged. As much as possible, the second dose of JYNNEOS should be administered approximately 28 days after the first dose. Unintentional delays in receiving the second dose do not require restarting the series; the second dose should be administered as soon as possible even if greater than 1 year has elapsed.

Combined Immunization Schedule

To achieve more timely insurance reimbursement, provide vaccine information to providers and allow pharmacists in some states to administer, the Child and Adolescent and the Adult Immunization schedules will now be published earlier than in previous years. Throughout the year, new recommendations will be placed in the Addendum to facilitate keeping the schedule up to date on a more frequent basis than yearly. The schedules will be published on the web and CDC app in November 2023 and will be published in MMWR in January 2024.

The title page now refers to "Vaccines and other Immunizing agents" to allow for the inclusion of Nirsevimab RSV monoclonal.

Nirsevimab, mpox vaccine, COVID-19 20223-2024 formulation, RSV vaccine, MenABCWY and PCV20 have been added to the schedule. PCV13, Menactra, DT and bivalent COVID-19 vaccines have been removed from the schedule. PPSV23 has been removed from the Child and Adolescent schedule.

Influenza Vaccines

Studies showing recombinant influenza vaccine (RIV4, Flublok) and cell culture influenza vaccine (ccIIV, Flucelvax) to be safe when administered during pregnancy compared to standard dose influenza vaccine (SD-IIV4) were presented. Reactogenicity of COVID-19 and influenza vaccine was comparable when given either simultaneously or sequentially. Local or systemic reaction and adverse reactions were similar when adjuvanted influenza vaccine (aIIV4. Fluad) or high-dose inactivated influenza vaccine (HD-IIV4, High-dose Fluzone) is coadministered with dose 1 recombinant zoster vaccine (RZV: SHINGRIX).

The first U.S. study showing maternal vaccination was associated with reduced odds of influenza hospitalization and ED visits in infants less than 6 months of age, particularly when administered during the third trimester of pregnancy, was presented.

Due to an absence of cases caused by B/Yamagata lineage viruses, the WHO recommends that the inclusion of that antigen is no longer justified and manufacturers should move to exclude it, leading to influenza vaccines becoming trivalent rather than quadrivalent.

Respiratory Syncytial Virus (RSV) Vaccine – Adult 50-59

GSK presented data from their immunobridging study of RSV vaccine administered to adults ages 50 to 59 compared to adults ages 60 and older. One dose of RSV vaccine is currently recommended for persons ages 60 years and older after a shared clinical decision-making discussion between patient and licensed provider. There is no established immunologic correlation of protection against RSV. GSK demonstrated that the humoral immune response to a single dose of RSVPreF3 vaccine in adults ages 50 through 59 years in two cohorts is non-inferior to that in adults ages 60 years and older. The cohorts include those ages 50 through 59 who are healthy and another ages 50 through 59 with conditions associated with increased risk of severe RSV disease. The safety profile of RSVPreF3 vaccine in adults ages 50 through 59 years was similar to the safety profile in persons ages 60 years and older.

COVID-19 Vaccines Implementation

With the transition to commercialization of COVID-19 vaccine and the shift from federal distribution to private distribution, there have been delays in vaccine delivery. The Bridge Access Program which provides vaccine at no cost for uninsured and underinsured adults has administered >380,000 doses at >24,000 contracted pharmacies.

Since September, 7.2% of adults and 2.1% of children have received the updated 2023-2024 formulation. ACIP plans to discuss additional doses for older adults in the February 2024 meeting and future formulations in the June 2024 meeting.

Clinical guidance has been updated for children to receive the age-appropriate vaccine dose based on their age on the day of vaccine administration as they transition from age 4 to 5 years during the initial vaccination series, and for immunocompromised children who transition from age 11 to 12 years. COVID vaccine doses from the same manufacturer should be administered for multiple dose series in children ages 4 years and younger. In the following circumstances, an age-appropriate COVID-19 vaccine from a different manufacturer may be administered:

- When the same vaccine is not available at the vaccination site at the time of the clinic visit
- If the previous dose is unknown
- If the person would otherwise not receive a recommended vaccine dose
- If the person starts but is unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication.

Note: A Vaccine Adverse Event Reporting System (VAERS) report is not indicated in these circumstances.

For the latest CDC COVID vaccine recommendations, visit the CDC's Clinical Considerations website

Pneumococcal Vaccines

Prior to the COVID-19 pandemic, each year pneumococcal infections caused approximately 100,000 non-invasive pneumococcal pneumonia hospitalizations, 30,000 invasive pneumococcal disease (IPD) cases, and 3,000 deaths. Approximately 40% of IPD cases in adults ages 65 years and older were caused by serotypes not contained in currently recommended vaccines. FDA approval of Merck's 21-valent pneumococcal conjugate vaccine for adults is anticipated in the first half of 2024. Two 24 -valent pneumococcal conjugate vaccines are currently in phase 1/2 studies.

Other Topics

Chikungunya – Valenva's chikungunya vaccine is expected to be licensed in November 2023. No chikungunya vaccine has ever been licensed in the U.S or globally. Policy options are under development for the use among U.S persons at risk including travelers, laboratory workers and residents of U.S. territories and states with, or at risk of, transmission. ACIP reviewed EtR with anticipated vote to recommend in February 2024 if licensed.

Dengue – The Takeda TAK-003 dengue vaccine was voluntarily withdrawn from consideration by the FDA. The dengue workgroup will be paused until TAK-003 is re-submitted to FDA or a new vaccine is submitted for approval.

If you have any questions regarding immunization, feel free to contact Tamara Sheffield, MD, MPA, MPH, Senior Medical Director, Preventive Medicine, Intermountain Healthcare, at 801-442-3946.