Immunization Update and ACIP Highlights – February 2019

March 12, 2019

The Advisory Committee on Immunization Practices (ACIP) of the CDC met on February 27-28 to provide guidance on vaccines. Below are the key highlights which discuss the influenza vaccine, a new hexavalent childhood vaccine (DTaP5, IPV, Hep B, Hib), approval of a booster dose for children receiving Japanese Encephalitis (JE) Vaccine and an accelerated schedule for adults receiving JE vaccine, and considerations and evidence surrounding anticipated future recommendations to be voted on in the June 2019 ACIP meeting.

- Influenza
    - The interim vaccine effectiveness (VE) for the 2018-2019 influenza season is 47% during this moderate severity year predominated by H1N1 with increasing levels of H3N2 as the season has progressed.
    - Three of the four candidate strain components of 2019-2020 influenza vaccine have been determined. The two Influenza B types will be the same as last season's vaccine. The two Influenza A types will be new. The A/H3N2 type determination has been delayed until March 21. Hopefully, this delay will not cause a delay in the production and delivery of vaccine in the fall.
    - The CDC influenza website is now providing stats on disease averted through influenza immunization. In the 2017-2018 season, 7 million illnesses, 109,000 hospitalizations and 8,000 deaths were averted due to the influenza vaccine.
    - In a study published in October 2017, the Vaccine Safety Datalink (VSD) had found an association with spontaneous abortion (SAB) in the first 28 days after vaccination with an influenza vaccine when an H1N1pmd09-containing vaccine had also been received in the previous season. An expanded VSD study was presented which added data from three more influenza seasons with a much larger study population. This study has found no significant association between influenza vaccine receipt and SAB, regardless of prior season vaccination status, supporting the safety of influenza vaccine in early pregnancy.
- Hexavalent vaccine (DTaP5, IPV, Hep B, Hib PRP-OMP reduced amount)
    - VAXELIS™ hexavalent vaccine (HV) produced as a joint venture between Merck and Sanofi was licensed 12/21/18 for three primary series doses ages 2, 4, and 6 months. It is approved up to age 4 years. The vaccine contains the same DTaP5 as Sanofi's DAPTACEL®, IPOL®, adult dose RECOMBIVAX HB® and only 3 micrograms of Hib PRP-OMP. Merck's PedvaxHIB® contains 7.5 micrograms of Hib PRP-OMP. HV will not be on the market until 2020.
    - A vote to approve the use of HV for the VFC program is anticipated in June 2019. Non-inferiority was demonstrated for all antigens with the exception of GMC for one pertussis antigen post dose 3 and for one pneumococcal antigen post dose 3 when given concomitantly with PCV13. Safety of the vaccine was demonstrated with some increased rates of pyrexia compared to control, but no febrile convulsions.
    - The amount of Hib PRP-OMP was reduced to avoid reactogenicity. Because of this reduced level of antigen, ACIP will not give a preferential recommendation for its use in

the American Indian/Alaska Native (AI/AN) population unless more evidence is provided on post-1st dose immunogenicity

- Japanese Encephalitis (JE) Vaccine
    - ACIP voted to approve an accelerated dosing schedule for adults who may receive the second dose anytime 7 to 28 days after the first dose
    - Booster doses of JE vaccine had previously been approved in adults. ACIP voted to expand the recommendation of a booster dose of JE vaccine down to age 14 months through 65 years for those at continued risk with at least 12 months separation from a previous dose.
- Future recommendations – evidence was provided regarding HPV, PCV13, Men B, and Hep A that will inform ACIP votes anticipated in June 2019, including:
    - HPV for male and female adults up to age 45 years has been approved by the FDA. The ACIP will most likely harmonize gender by recommending catch-up vaccination for both males and females up to either age 26 or 30 years. It is anticipated that the recommendation up to 45 years would be for informed decision-making (formerly known as a category B recommendation) rather than a full recommendation
    - Possible removal of PCV13 recommendation for average risk adults age ≥65 years due to the indirect beneficial herd effects of vaccinating children. The majority of the work group is favoring removing the recommendation or changing it to an informed decision-making recommendation, but there are enough dissenting opinions that it is not certain what direction the ACIP will go when it is put to a vote, possibly in June 2019. There is added uncertainty whether to remove the recommendation with new PCV15 and PCV20 vaccines looming on the horizon.
    - The Meningococcal work group recommended to the ACIP a booster dose of Meningococcal B vaccine for those at high-risk age ≥10 years such as persons with asplenia, complement component deficiency, using a complement inhibitor medication and microbiologists, or during an outbreak. Booster to be given 1 year after primary series followed by repeat doses every 2-3 years as long as risk continues. Vote anticipated June 2019
    - The Hepatitis work group recommended to the ACIP adding adult persons with HIV as a risk group for receiving 2 doses of Hep A vaccine. Vote anticipated June 2019
    - Tdap was approved by FDA in January 2019 as a repeat tetanus dose in ages 10 through 64 years as long as there has been an 8-year separation between doses or at least 5 years between doses for wound management. In its October 2018 meeting, the ACIP said it would discuss the removal of “single use” language for Tdap, allowing it to be given for tetanus boosters or wound management, during its February 2019 meeting, but that discussion did not occur.

If you have any questions regarding immunization, feel free to contact Tamara Sheffield, MD, MPA, MPH, Medical Director, Community Health and Prevention, Intermountain Healthcare, at **(801) 442-3946.**