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Editorial

The 2019 immunization schedules for children, adolescents and adults. What's New?

Each year, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention updates the recommended immunization schedules for children, adolescents, and adults [1,2]. These schedules describe the routine immunizations recommended based on age and medical history and include new recommendations adopted by the ACIP in the previous 12 months. They are endorsed by the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Physicians, the American College of Nurse-Midwives, and the American College of Obstetricians and Gynecologists. In addition to new vaccine recommendations, the 2019 ACIP schedules incorporated numerous formatting changes based on user feedback, which has resulted in improved readability and clarity.

The key updates to vaccine recommendations that clinicians should be aware of in 2019 are as follows.

Influenza:

(a) LAIV an option for flu vaccination:

In June 2018, the ACIP updated the influenza vaccine recommendations to allow for the use of the live attenuated influenza vaccine (LAIV) in healthy persons aged 2–49 years [3]. The ACIP recommended that LAIV not be used in the 2016–17 and 2017–18 flu seasons due to data suggesting lower efficacy. The reversal of this decision was based on review of previous seasons' data on LAIV effectiveness in children aged 2–17 years and newer data from the manufacturer on replicative fitness of the virus strains in LAIV. This data showed that while LAIV was much less effective than injectable influenza vaccine (IIV) against influenza A (H1N1) pdm09-like viruses, LAIV was as effective against influenza B and influenza A (H3N2) viruses as IIV. Additionally, manufacturer data showed that the more recent H1N1pdm09-like virus (A/Slovenia/2903/2015 HIN1) in LAIV had improved replicative fitness over previous H1N1pdm09-like viruses included in LAIV. Based on this data, LAIV was deemed to be an option for use in the 2018–19 season. LAIV remains contraindicated for immunosuppressed individuals, pregnant women, and for those who have the following conditions: an absent or non-functional spleen; a cerebrospinal fluid leak or a cochlear implant; a diagnosis of active influenza and those who have recently (within prior 48 h) received antiviral medications active against influenza. End-stage renal disease, heart or lung disease, chronic liver disease, or diabetes are listed as precautions for LAIV.

(b) Guidance for flu vaccine use in persons who are egg-allergic:

ACIP updated its guidance on the use of influenza vaccines in persons who report that they are allergic to eggs, as follows:

- Only hives after egg exposure: Any age-appropriate influenza vaccine may be administered.
- More severe reactions to egg including angioedema: Any age-appropriate influenza vaccine may be administered, but the vaccine should be given in a medical setting supervised by a healthcare provider who can manage severe allergic reactions.

(c) Labeling changes, expanded age indications for influenza vaccine formulations:

- The age indication for Afluria Quadrivalent was expanded from ≥18 years to ≥5 years.
- The age indication for Fluarix Quadrivalent was expanded from ≥3 years to ≥6 months.
- Use of the Fluarix Quadrivalent at the same 0.5 mL per dose (containing 15 μg of hemagglutinin [HA] per dose) as is used for older children and adults was approved for children 6 months to 3 years, obviating the need to acquire and store the 0.25 mL dose.

Hepatitis A:

Homelessness has been added as an indication for routine hepatitis A vaccination [4]. A 2-dose hepatitis A vaccine series has been part of the routine childhood vaccination schedule since 2006. In addition, the vaccine is recommended for anyone over the age of one year who is at increased risk of hepatitis A. This includes travelers to countries with high rates of hepatitis A, men who have sex with men, drug users, and researchers who work with the hepatitis A virus. The vaccine is also recommended for those with chronic liver disease, as they are at increased risk of complications from hepatitis A infection. After the introduction of the vaccine, cases of hepatitis A in the United States dropped precipitously, and cases that did occur were generally due to infection acquired by international travelers or outbreaks related to food imported from overseas. However, in 2017 and 2018, several large outbreaks of hepatitis A occurred among the homeless in the United States. In 2017, 1521 outbreak-associated cases were reported from California, Kentucky, Michigan, and Utah. This outbreak was characterized by higher than usual hospitalization and mortality rates (71% and 3% mortality, respectively). The outbreak continued in

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2018, with over 7000 outbreak-associated cases reported from 12 states by October 2018. Hepatitis A is spread by the fecal-oral route, and person-to-person transmission is amplified in the homeless due to poor living conditions. The vaccine is safe, highly immunogenic, and even a single dose of the vaccine is highly protective, with protection persisting for several years [5], making vaccination an effective strategy to curb outbreaks.

Hepatitis B:

In February 2018, ACIP recommended a new recombinant hepatitis B vaccine with a novel cytosine-phosphate-guanine 1018 oligodeoxynucleotide adjuvant (Heplisav-B, Dynavax Technologies Corporation) as an option for prevention of hepatitis B virus infection in adults aged ≥18 years [6]. Heplisav-B is given as a two-dose series, with the doses separated by at least 4 weeks. Heplisav-B can be substituted for any dose in the traditional three-dose Hepatitis B vaccination series. There is no available information on safety of the vaccine in pregnancy; therefore, the ACIP recommends against its use during pregnancy. In clinical studies, the two-dose series of Heplisav-B produced protective levels of antibodies in 90–100% of recipients compared to 71–90% of those who received the three-dose series of Engerix-B (GlaxoSmithKline Biologicals) [7]. Side-effects were similar in the two groups. The improved immunogenicity and the shorter duration needed to complete the series makes this an attractive option for vaccination of at-risk adults. The cost of the two-dose Heplisav-B series is roughly 40% more expensive than the traditional three-dose series [8]. There have been no changes to the groups for whom Hepatitis B vaccination is recommended [9].

In addition to the new recommendations summarized above, the 2019 immunization schedules were reorganized based on usability studies performed over the previous two years that included in-depth interviews and internet surveys of medical practitioners. This has made the schedules easier to read and use. The language in the child and adolescent schedule is consistent with that in the adult schedule. The notes section lists vaccines in alphabetical order and in larger font than previous versions. Vaccines that are contraindicated due to certain medical conditions are very clearly labeled. A minor criticism of the schedules has to do with the color coding in Table 2 of the adult schedule [10]—specifically, the "grey areas." The key indicates that grey is used when there is no recommendation. The use of pneumococcal conjugate vaccine and the hemophilus influenzae type B vaccine in pregnancy is labeled as grey. While there is limited data on the safety of these vaccines in pregnancy, the data on the meningitis B vaccine is similarly limited and is marked as orange, which is used to indicate "Precaution" or "use if benefits from vaccination outweigh the risk." Similarly, the use of the recombinant zoster vaccine (RZV) in immunocompromised individuals remains a "grey area"—although most clinicians currently administer RZV if vaccine is available.

Vaccines are life-saving and health-protecting. The ACIP vaccine schedules are evidence-based and represent the best available guidelines for the use of vaccines in the United States. For this reason, every health care provider should be familiar with them, use them, and promote vaccines to the patients they are privileged to care for. These schedules represent the standard of care and therefore should be implemented in all clinical care settings.

Disclosures

Dr. Poland is the chair of a Safety Evaluation Committee for novel investigational vaccine trials being conducted by Merck Research Laboratories. Dr. Poland offers consultative advice on vaccine development to Merck & Co. Inc., Avianax, Adjuvance, Valneva, Medicago, Sanofi Pasteur, GlaxoSmithKline, and Emergent Biosolutions. Dr. Poland holds patents related to vaccinia and measles peptide vaccines. These activities have been reviewed by the Mayo Clinic Conflict of Interest Review Board and are conducted in compliance with Mayo Clinic Conflict of Interest policies.

Dr. Sampathkumar serves as a member of a Data Monitoring Committee for a vaccine trial conducted by Merck.

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