Vaccine 31 (2013) 4689–4693

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Editorial

Immunization guidelines in the United States: New vaccines and new recommendations for children, adolescents, and adults

When meditating over a disease, I never think of finding a remedy for it, but, instead, a means of preventing it.

– Louis Pasteur

It is increasingly apparent that prevention, rather than treatment, of infectious diseases offers significant health and economic benefits to individuals and populations. Combined with the increasing virulence of some pathogens, and the increasing rates of antimicrobial resistance, as well as the tremendous costs associated with treating disease once it has occurred, vaccines are a highly cost-effective public health strategy.

Despite this, and the widespread availability of vaccines in the US, an estimated annual average of 50,000 Americans die of potentially vaccine-preventable diseases each year, with more than 99% of these deaths occurring in adults. This means that at the start of each year, 1 out of every 7000 Americans will die of a disease that might be prevented by already existing and available vaccines.

Several factors commonly conspire to prevent routine immunization, including cost, lack of knowledge and awareness, missed opportunities, and the lack of a systems-level approach to providing vaccines. Excellent resources are available for setting up an immunization program and are available from the American College of Physicians at http://www.acponline.org/aii/index.html and from the CDC at http://www.cdc.gov/vaccines/. In addition, a free and very helpful smart phone app is available through the iTunes store (ACP Immunization Advisor).

The purpose of the annual immunization guidelines is to provide an evidence-based schedule of routine immunizations demonstrated to be safe and effective, based on age and concurrent medical conditions. This is the approved official schedule for use in the US, and allows all clinicians to provide vaccines in a harmonious manner regardless of geographic location. The schedule is developed by a federal advisory committee (the Advisory Committee on Immunization Practices – ACIP), which consists of experts in vaccinology, public health, infectious diseases, and related disciplines.

These new recommendations describe each vaccine, its use, indications and contraindications, background data, and other information, and can be accessed at http://www.immunize.org/catg.d/p2010.pdf. The full adult immunization schedule is available at http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-schedule-bw.pdf. These schedules can be found in Appendix A.

Below we provide brief commentary on the major changes clinicians should be aware of:

Immunization of persons 0–18 years

New vaccines:

- A new vaccine that provides protection against invasive disease caused by *Haemophilus influenzae type B* and meningococcal Groups C and Y was licensed for use in infants and children. Finding a role for this combined vaccine has been somewhat challenging because although the ACIP has long recommended universal infant protection against *H. influenzae B* infections, it has no comparable recommendation for the use of meningococcal vaccine in this age group. Nevertheless, certain infants are at increased risk for meningococcal infections, including those with recognized persistent complement pathway deficiencies and infants who have anatomic or functional asplenia, including sickle cell disease. The ACIP noted that the new vaccine (Hib-MenCY) could be used to vaccinate these infants (a four-dose series at 2, 4, 6 and 12–15 months). The vaccine also could be used in infants ages 2 months through 18 months who are in communities that are experiencing outbreaks of disease caused by meningococcal serogroups C or Y.
- No other new vaccines have been added to the schedule for use in children and adolescents at the present time [January, 2013]; however, quadrivalent LAIV has been approved and is expected to be available for the 2013–2014 influenza vaccination season. Quadrivalent inactivated influenza vaccines are also expected to be available in limited quantities. The nomenclature for inactivated influenza vaccines has been changed in the 2013 schedule to 'IIV' from 'TIV' to minimize potential confusion for readers as this transition occurs.

New recommendations for existing vaccines:

- The structure of the vaccine schedule for children 0–18 years of age has been modified significantly to place recommendations for all children on a single schedule. The new table highlights recommended vaccine intervals, catch-up and risk-factor based immunization in a single pediatric schedule, and is followed by reformatted and clarified footnotes for each vaccine product.
- *Rotavirus vaccines*: The vaccine footnote has been revised to detail the recommendations for the RV-1 and RV-5 vaccines separately.
- *HiB vaccine*: Only one dose of HiB vaccine is recommended after 15 months of age. This vaccine is not routinely recommended in persons older than 5 years; however, one dose should be

0264-410X/$ – see front matter
http://dx.doi.org/10.1016/j.vaccine.2013.03.031

administered to unvaccinated or partially vaccinated persons with severe immune compromise, as detailed in the adult recommendations below.

- *Pneumococcal vaccines*: Vaccination recommendations for persons with high-risk conditions have been clarified. Specific guidance for pneumococcal polysaccharide 23 vaccine after age 2 and following completion of a pneumococcal conjugate 13 vaccine series is provided for high risk children. This includes a recommendation for a single booster dose of pneumococcal polysaccharide 23 vaccine five years later.
- *Meningococcal vaccines*: Recommendations for meningococcal vaccines in children with high-risk conditions have been expanded and clarified.

Immunization of persons 19 and older:

New vaccines

- *Pneumococcal conjugate 13 vaccine*: The traditional pneumococcal polysaccharide 23 vaccine is designed to prevent the invasive complications of pneumococcal infection. Limitations of the vaccine include the uncertain protection against pneumococcal pneumonia and poor induction of long-term immune memory. Nevertheless, it remains the mainstay of protection against invasive pneumococcal disease in adults. This past year pneumococcal conjugate 13 vaccine was licensed for use in adults age 50 and older. To date, the ACIP has limited its recommendation for the use of this vaccine in adults to immunocompromised persons, including those with anatomic or functional asplenia, and persons who have CSF leaks or cochlear implants. A single dose of PCV13 is recommended, followed at least eight weeks later with a dose of PPSV23. Depending upon prior receipt of PPSV23, additional doses of PPSV23 at recommended intervals are recommended.
- *Quadrivalent influenza vaccine*: Starting with the 2013–2014 season, quadrivalent live attenuated influenza vaccine (LAIV) will become available in the US, along with limited supplies of quadrivalent inactivated influenza vaccines.
- *Baculovirus-produced influenza vaccine*: In January 2012, a new trivalent inactivated influenza vaccine was granted FDA approval. The vaccine contains 45 micrograms of each influenza strain antigen (3 times the dose contained in other IIV vaccines) and is composed of recombinant hemagglutinin – with no neuraminidase component. The vaccine is licensed for use in adults 18–49 years of age, and has no egg proteins as it is not produced in eggs.
- *Cell-culture derived inactivated influenza vaccine*: In November 2012, a new trivalent inactivated influenza vaccine was granted FDA approval. The vaccine contains 15 micrograms of each influenza strain antigen, and is propagated in a continuous MDCK (Madin Darby Canine Kidney) cell line. As such it does not contain egg proteins, preservatives, or antibiotics. The vaccine is licensed for use in adults age 18 years and older.

New recommendations for existing vaccines:

- *Inactivated influenza vaccines*: Persons who experience hives, but not anaphylactic allergic reactions, can receive inactivated influenza vaccines. However, such persons should not receive LAIV. Inactivated influenza vaccine options include both IM and ID preparations.
- *Tdap vaccines*: Recommendations have now been expanded to routinely immunize all adults 65 years of age and older with a single dose of Tdap; and to administer a booster dose of Tdap with each pregnancy, regardless of interval between pregnancies, ideally after the 20th week of gestation.
- *Pneumococcal polysaccharide 23 vaccine (PPSV23)*: Individuals with certain medical conditions (asplenia, chronic renal failure, immunocomprised) have long been recommended to receive two doses of PPSV23 before the age of 65 as long as five or more years have elapsed since the last dose. The ACIP has clarified that, even for these individuals, another dose of PPSV23 is recommended at age 65 years if the last dose received was at least five years earlier.
- *Hepatitis A*: Vaccination is recommended for persons with injection or non-injection illicit drug use and travelers to areas of the world endemic for hepatitis A. Pregnancy is no longer a precaution for use of this vaccine.
- *Hepatitis B*: Due to documented elevated rates of hepatitis B, all individuals with diabetes younger than age 60 were recommended last year to receive the HBV vaccine series. Individuals with diabetes older than age 60 may receive HBV vaccine based on the risk of acquiring HBV through assisted blood glucose monitoring in assisted care type settings, or other risk factors. Although not, strictly speaking, a new recommendation, we emphasize it because knowledge of this new recommendation seems not yet to have penetrated very effectively among either those who provide medical care to persons with diabetes or to persons with diabetes themselves.
- *H. influenzae type B vaccine*: A single dose of Hib vaccine can be considered for those individuals with functional or anatomic asplenia, sickle cell anemia, HIV infection, or leukemia.

As VACCINE did last year, we plan to publish these recommendations on an annual basis for readers. We do so with the goals of providing widespread visibility for these schedules, and to insure that our readers have access to the latest recommendations and the rationale for changes in the schedules. In addition, as we stated in a previous editorial, we hope that publishing this schedule might stimulate consideration of global harmonization of immunization schedules, and interest from every country in engaging in a process similar to what the ACIP process entails.

Routine immunization of all persons should be considered a quality of care and patient safety issue. Anywhere medical care is rendered, systems and procedures should be in place to screen patients for needed vaccines, with facilities or policies to administer needed vaccines, or to refer such persons to another facility where vaccines can be administered. No other single medical maneuver is as effective in the prevention of the morbidity and mortality due to infectious diseases. Immunization is an important standard of medical care and it is the duty of every physician, and every nurse, to be both knowledgeable and supportive of the goal to fully immunize the patients for whom we are privileged to care.

Disclosures:

- Gregory A. Poland, MD: 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., CSL Biotherapies, Avianax, Sanofi Pasteur, Dynavax, Novartis Vaccines and Therapeutics, and PAXVAX Inc. 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.
- William Schaffner, MD. Dr. Schaffner is a member of a Safety Evaluation Committee for novel investigational vaccine trials by Merck Research Laboratories and has provided consultative advice to Sanofi-Pasteur, Pfizer, GlaxoSmithKline and Dynavax.
- Robert H. Hopkins, Jr, MD. Dr. Hopkins reports no disclosures.