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Position Paper

Adolescent immunizations: A position paper of the Society for Adolescent Medicine

Abstract: New vaccines are being targeted to help protect the adolescent population from disease. The Society for Adolescent Medicine strongly urges compliance with adolescent vaccination recommendations provided by the Advisory Committee on Immunization Practices. These vaccines will significantly impact the health and well-being of the adolescent population. To enhance vaccination compliance and access to prevention health care and promotion, the Society supports linking vaccination to the three distinct comprehensive preventive health care visits already recommended by multiple organizations during early, middle, and late adolescence. In addition, multiple provider strategies should be used to increase vaccination rates among adolescents.

Positions

The Society for Adolescent Medicine (SAM) endorses the following positions:

- The use of all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines and vaccination schedules in the adolescent age group, without prejudice against the type of infection or mode of disease transmission targeted by the vaccine.
- The development of three distinct adolescent vaccination visits/platforms for adolescents (11–12-year visit, 14–15-year visit, and a 17–18-year visit) to integrate and emphasize the role of vaccination in already recommended comprehensive health care screening and provision visits. The 11–12-year platform is the primary immunization platform promulgated by ACIP. We endorse emphasizing a 14–15-year visit/platform as a time to catch up on missed vaccines or complete multiple-dose vaccination regimens, and a 17–18-year visit/platform as an opportunity to update all vaccinations that may have been missed or are newly recommended while the patient is still covered by third party payers, including the Vaccine for Children program.
- The use of standing immunization orders, immunization screening tools, immunization registries, immunization reminder systems (for both provider and patient) and recall systems, whenever available, to increase rates of vaccination among this age group.
- The simultaneous administration of multiple vaccines to increase vaccination rates and utilize/capitalize on currently required and mandated vaccination regimens.
- The use of "non-comprehensive" visits (e.g., minor illness visits, camp/sports physical visits, pre-college visits) and qualified "alternative" vaccination sites (e.g., pharmacies, schools) for adolescents unable to access comprehensive preventive care. SAM urges the alternative vaccination sites to provide adolescent clients with referral lists of adolescent care providers in their area as well as appropriate adolescent health education materials.
- The continued and increased education of health care providers, parents and teens regarding the health promotion benefits of immunization against vaccine-preventable disease.

Background information

The development of multiple vaccines against childhood illnesses has been one of the most significant contributions to the health of children in the 20th century. Rates of disease have decreased dramatically in this country over the past 100 years; most recently, rates of hepatitis B infection in this country have gone from an estimated 300,000 to an

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estimated 79,000 cases per year in 20 years with use of the three-dose vaccine [1]. Immunization is inextricably related to preventive health care strategies for all ages, but most notably for infants and children. Immunization is one of the hallmarks of pediatric preventive health care, and pediatric preventive health care visit patterns for infants and children have been structured around vaccination schedules.

Recently, meningococcal, acellular pertussis, and human papillomavirus (HPV) vaccines have been developed and targeted for the adolescent age group. The meningococcal and pertussis vaccines, in particular, have current Food and Drug Administration (FDA) approval.

Statement of the problem: immunizing the adolescent population

Multiple factors contribute to difficulties immunizing adolescents, and many of these factors may be remediable. One of the most commonly cited difficulties is that adolescents do not seek preventive health care despite recommendations from multiple national organizations encouraging annual preventive health care visits for this population, thus decreasing the likelihood that they will be immunized using these new vaccines. In fact, 92% of adolescents report having a source of primary care [2], indicating an existing infrastructure for vaccine administration as part of preventive care for this age group. According to Centers for Disease Control (CDC) data for 2001–2002 [3], over 85% of all children aged 6–17 years in the United States had visited a doctor or clinic within the past 12 months. Although all of these visits may not have been specifically designated for preventive care per se, adolescents are clearly accessing services that could integrate immunization, and potentially other pieces of preventive health care strategies, as part of the visit.

It will be of great benefit to strengthen the already existing infrastructure supporting early (11–12 years), middle (14–15 years), and late (17–18 years) adolescent comprehensive preventive care visits by incorporating vaccination platforms into the visits. The 11–12-year platform is the primary immunization platform promulgated by ACIP. The 14–15-year visit/platform would serve as a time to catch up on missed vaccines or complete multiple-dose vaccination regimens, and the 17–18-year visit/platform would serve as an opportunity to update all vaccinations that may have been missed or have been recommended since the last vaccination visit. Assuring a visit prior to the potential loss of parental health insurance coverage or coverage of cost by the Vaccine for Children program also increases the likelihood of vaccination among this age group. The preventive benefit of vaccines is substantial, and by establishing vaccination as a key component of the health care visit, adolescents will have increased opportunity to become fully protected against vaccine-preventable diseases. Of course, it will be critical to the optimal success of adolescent immunization for providers to take advantage of all vaccination opportunities—these established visits as well as non-comprehensive or non-traditional health care visits. In addition, it is recommended that providers vaccinate adolescents despite mild illnesses that should not contraindicate vaccination.

Research also indicates that parents play an important role in guiding adolescents on the issue of immunization [4,5]. Parental involvement is clearly an important influence in decision-making and also provides more concrete support such as transportation, insurance coverage, and authorization for vaccination to take place (although adolescents are often able to consent to vaccination related to sexually transmitted infections). Data suggest that the rate of adolescents presenting for care is higher among younger teens, with diminishing rates as adolescents age and become young adults. In addition, research supports that physicians are more likely to screen for and provide vaccination to younger adolescents [6]. Promoting and reinforcing a primary immunization platform at the 11–12-year visit with catch-up opportunities later during adolescence will clearly affect the largest number of youth. On a basic level, providers must be creative with efficiently educating, obtaining consent from, and providing Vaccine Information Sheets to parents for adolescent immunizations so the process can progress as patients present to clinic for preventive and other health care visits.

Provider and parent support are important components of vaccine acceptance and compliance. For example, data indicate that parents will support the use of a vaccine to prevent sexually transmitted infections (STIs) including HPV, especially after receiving education and an understanding of the potential outcomes of the disease [7–10]. In addition, provider acceptability is important to parents and their adolescent children [5]. Thus, health care professionals need to educate themselves, parents and patients with the goal of promoting the health and well-being of patients regardless of the transmission routes of infection and disease. Vaccination does not preclude the use of other methods to prevent disease, including significant educational initiatives. Even with significant educational efforts aimed at behavioral change, adolescents still engage in health-risk behaviors. Just as with any other health prevention strategy, it makes the most sense to protect all youth—including our most vulnerable youth—with all prevention strategies available, including education and vaccination.

An additional potential barrier for vaccination may be the need for multiple doses (HPV vaccine, for example). Further study will be needed to determine efficacy of the newer multiple-dose vaccines when given using varying dosing schedules more likely to be consistent with adolescent behavior. For example, hepatitis B vaccine was found to be equally, if not more effective when given on a 0-, 12- and 24-month dosing schedule, which represents annual visits often acceptable to adolescent patients and their parents [11]. Again, by missing fewer opportunities for vaccination during more acute illness and camp/sport physical visits, complete vaccination with multiple-dose vaccination regimens is an achievable goal. Vaccination platforms at

14–15 and 17–18 years of age will also help strengthen compliance with immunizations among this age group.

Despite the access to health care that the majority of teens have, experience with the hepatitis B vaccine has also shown us that immunization rates among teens can be significantly and positively affected by school entry mandates from state governments [12,13]. States may not specifically mandate vaccination for all of the newer adolescent-targeted vaccines. Many states, however, currently mandate completion of the Td (ACIP now recommends Tdap) for school entry at either age 12 or 14 years. By administering multiple adolescent vaccines simultaneously, providers can capitalize on currently existing mandates and significantly increase rates of vaccination without requiring additional health care visits or additional state mandates. Standing orders, phone/postcard/e-mail reminders to families, and the utilization of immunization registries may help increase rates of vaccination among this age group [14,15].

Recently approved vaccines

Meningococcal vaccine

A number of surveillance systems indicate that the peak incidence of meningococcal disease including both meningococcemia and meningitis occurs among young children and infants, with a second peak among adolescents [16]. Incidence rates are relatively low; the incidence of meningococcal disease in 2004 was .5–1.1/100,000 population [17]. The sequelae of this disease, however, can be devastating and include limb loss and amputations, hearing loss, stroke, hemiplegia, spastic quadriplegia, seizures, and death. For reasons that are not clear, adolescents and young adults have higher rates of mortality from meningococcal disease than younger children [18]. There are multiple serogroups of *N. meningitidis*, and the incidence of these serogroups varies by population. Serogroup B, against which there is currently no reliable vaccine available in the United States, primarily affects younger children and infants. Serogroup C, and increasingly, serogroups Y and W-135, are more common among adolescents and adults (serogroup A is uncommon in the United States). It is estimated that approximately 80% of the meningococcal disease among adolescents and young adults is vaccine-preventable with the quadrivalent product [18]. The quadrivalent vaccines available in the United States protect against serogroups A, C, Y, and W-135. The two vaccines available include Menomune (sanofi-pasteur), a polysaccharide vaccine, and Menactra (sanofi-pasteur), the new conjugate vaccine approved for use among 11–55 year olds.

The Advisory Committee on Immunization Practices (ACIP), the body that advises the Centers for Disease Control and Prevention (CDC) regarding immunization policy, has recently recommended the universal use of the new conjugate meningococcal vaccine for adolescents aged 11–12 years, with an interim policy including the immunization of those entering high school (~15 years old) and all of those who will be freshmen in college living in a dormitory [17]. Vaccination is also recommended for those wishing to decrease the risk of disease and other special groups. The interim recommendation for 15-year-olds and college entry will most likely be phased out in 2008, as already-immunized 11–12-year-olds and 15-year-olds move into these age ranges and as further data accumulate regarding length of immunity from the vaccine. The conjugate vaccine, unlike the previously used polysaccharide vaccine, uses an attached protein (diphtheria toxoid) to engender a T cell response (resulting in cell-mediated immunity) to the antigen rather than a solely B cell response (resulting in only humoral immunity). The T cell response to the antigen confers many advantages over the solely B cell response, including lack of hyporesponsiveness (which refers to a diminished response to repeat vaccination), booster effect, longer term immunity, elimination of the carrier state, and herd immunity. Assuming the vaccine behaves as other conjugate vaccines in the past, the persistence of protection could be much longer than that occurring from the polysaccharide vaccine [19].

Recent reports have caused concern regarding possible safety issues associated with this new vaccine. Further research is required to determine any true associations; updated safety information regarding any vaccine is available at www.cdc.gov.

Pertussis vaccine

Pertussis, also known as whooping cough, is the only vaccine-preventable childhood illness for which incidence rates are currently rising in this country. The highest increases in incidence rates have occurred in the adolescent age group 10–19 years [20]. Thirty-eight percent of reported cases in 2004 were among the 10–19-year age group [21]. The most likely explanation for this rising incidence during the early teen years is that immunity from vaccination wanes approximately 5–8 years after a booster exposure [22]. Other possible contributing factors to the increase include improved surveillance and reporting, poor vaccination compliance among children, questions of vaccine efficacy at varying times in the 1980s, and genetic variations of disease in circulation. Data collected by the CDC reveal that the number of reported U.S. cases of pertussis increased from the overall nadir in 1976 to 25,827 cases in 2004. It is believed that this represents a small fraction of the true burden of disease, which is estimated at approximately one million cases per year in the United States [23].

Pertussis evolves in distinct stages. The catarrhal stage (1–2 weeks) is indistinguishable from the common cold. Unfortunately, this is the most contagious stage of the disease. The paroxysmal stage can last for six weeks and includes the paroxysms of coughing. Although the spectrum of disease ranges from mild to severe, whooping is often present as patients try to catch their breath while coughing. Patients may also experience post-tussive gagging and vomiting, difficulty sleeping, scleral hemorrhages, pneumonia, broken ribs, apnea, cyanosis, and, primarily among infants, death. The final, convalescent stage can persist for months with waxing and waning

episodes of cough and fatigue. The psychological development of adolescents may be disrupted by the length and severity of disease; however, it is partially and fully unimmunized infants that represent the majority of hospitalizations and deaths. Adolescents and young adults serve as a dangerous reservoir of disease—often unrecognized disease—and may unwittingly transmit disease to vulnerable young infants.

Treatment for pertussis rarely affects the course of the disease unless initiated within days of disease acquisition, yet treatment may be helpful to prevent transmission. Again, because the disease is often not recognized in its earliest and most contagious stages, and because treatment is not helpful for those with the disease, prevention through immunization is the only truly effective strategy for disease control. There are currently two Tdap vaccines available: Adacel (sanofi-pasteur, Swiftwater, Pennsylvania), approved for use among 11–64-year-olds, and Boostrix (GlaxoSmithKline Biologicals, Rixensart, Belgium), approved for use among 10–18-year-olds.

In June 2005, ACIP recommended that the Tdap vaccine be administered in place of Td for adolescents through the 18th year of life. It will be given to those eligible for the 11–12-year Td booster, children 10 years of age or older requiring wound management who have not received the Tdap previously, and "catch-up" for those 13–18-year-olds who received the Td more than five years ago. In settings with increased risk of pertussis or complications, intervals less than five years can be used. In October, 2005, ACIP further recommended replacing Td boosters with Tdap for persons age 19–54 years who have not yet received Tdap, who have increased exposure to infants, or who wish to decrease the risk of pertussis. For those who have no documentation of the primary DPT series, one of the three catch-up vaccinations given at a zero, one, and six to 12 months should be a Tdap. It is important to recognize that the current FDA licensure is for one-time use of Tdap only.

There is a relatively small concern that the diphtheria toxoid component in the meningococcal conjugate vaccine, which is thought to be approximately four times the amount contained in a Td or Tdap vaccine, may induce local or other reactions for those receiving the meningococcal and Td/Tdap vaccines within a short time interval. Data from vaccine immunogenicity and safety trials indicate that the meningococcal conjugate vaccine can be given safely even one month after the Td, but there are no safety data regarding Td or Tdap vaccination given after meningococcal conjugate vaccine. Ideally, the Tdap and meningococcal conjugate vaccine should be given simultaneously at the 11–12-year health care visit or whenever possible. If simultaneous administration is not possible, individual administration of each vaccine when available is recommended. Due to the complexity of the issue created by the diphtheria toxoid in the newer vaccines for adolescents, the encouragement of a five-year interval between Td boosters (now including Tdap) stands; however, data indicate safety with a minimum two-year interval [24]. As the interim period during which meningococcal vaccine and Tdap are administered using schedules other than simultaneous administration at age 11–12 years passes, the concern regarding the risk of reactions will become less relevant.

Cost effectiveness of new vaccines

In general, vaccination is a very cost-effective health prevention strategy. Most childhood vaccines are either cost-saving or cost approximately $20,000 per QALY (quality adjusted life year) saved. "Cost per QALY" refers to estimates of cost per life year gained as a result of immunization. Clearly, the cost per QALY is of use only as a comparison of cost; it cannot begin to estimate the true value of a life lost or changed as the result of acquiring a vaccine-preventable disease.

The societal cost per quality adjusted life year (QALY) saved for the conjugate meningococcal vaccine is higher than for other recommended vaccines. Some cost-effectiveness studies place the cost per QALY of the conjugate vaccine at approximately $121,000 [25]. Despite the relatively high cost, because meningococcal disease is often initially mistaken for a viral illness (making timely treatment difficult) and results in high mortality, prevention is truly the only effective defense against the disease.

Because the true incidence of pertussis is not known, cost-effectiveness analyses for the new vaccine produce variable results [26]. The cost of one-time pertussis vaccination among adolescents has been estimated to be between cost-saving and $23,000 per QALY [27,28]. In a recent cost-benefit analysis, Purdy et al [27] determined that the most cost-effective immunization strategy would be the immunization of 10–19-year-olds against pertussis, which would save .6–1.6 billion dollars of direct and indirect costs associated with pertussis over 10 years (not including immunization costs) [27].

Past and future

In addition to these recently approved vaccines, adolescent "catch-up" vaccination is recommended against hepatitis B, hepatitis A when indicated, measles/mumps/rubella, and varicella. Vaccination against influenza is actually an annual recommendation for those who have chronic illness and for those who wish to reduce their risk of acquiring the disease. Please refer to the Adolescent Immunization Schedule provided at the end of this article and available in color at www.adolescenthealth.org/positionpapers.htm for details. This vaccination schedule specifically addresses the recommendations for 11–21-year-olds. When questions arise regarding immunization recommendations, the CDC website (www.CDC.gov) serves as the ultimate resource for immunization information and updates.

Further vaccines targeted for administration during the adolescent years are under development and warrant mention. These include vaccines against serogroup B meningococcus,

cytomegalovirus, genital herpes, and other sexually transmitted infections. The vaccine closest to FDA approval is the vaccine against Human Papillomavirus, the sexually transmitted infection associated with the development of cervical cancer.

Human papillomavirus (HPV) vaccine

HPV has more than 100 genotypes, over 30 of which infect the genital tract. Visible genital warts are caused by HPV types 6 and 11. The genotypes that account for over 70% of cervical cancers in women, with very little geographic variability, are types 16 and 18. HPV is thought to be responsible for nearly all cases of cervical cancer. By age 50 years, it is estimated that 80% of U.S. women will have acquired HPV in the genital tract. It is believed that after acquiring HPV, most commonly within the first few years of initiating sexual activity, most infections are cleared by the host's immune system; 91% are cleared within two years [29]. The increased screening with Pap smears in developed countries such as the U.S. has significantly decreased rates of cervical cancer; however, less developed countries continue to lose hundreds of thousands of women each year to cervical cancer.

Two pharmaceutical companies currently have HPV vaccines in phase III clinical trials. GlaxoSmithKline (GSK) has developed a vaccine addressing types 16 and 18, and the dosing schedule for this product is zero, one, and six months. Merck & Co., Inc. (West Point, Pennsylvania) has developed a vaccine against types 6, 11, 16, 18; the dosing schedule is zero, two, and six months. Merck hopes to further appeal to males by targeting genital warts in addition to cervical cancer with its vaccine. Safety and efficacy data on these vaccines thus far are extremely encouraging [30]. Studies of cytologic and pathologic endpoints of infection with HPV 16 and 18 reveal that efficacy against ASC-US or higher grade pathology is 93% (GSK) and efficacy against CIN 2/3 is 100% (Merck) [31,32].

Cost-effectiveness data pertaining to the HPV vaccine are encouraging. One model demonstrates that the cost effectiveness of a vaccine with 90% efficacy, assuming conservatively that vaccination does not change current screening practices, was determined to be approximately $24,300 per QALY. The model did not take into account transmission issues or the impact of HPV types 6 and 11, potentially underestimating the true cost effectiveness of the vaccine [33].

Summary

To promote and preserve the health and well-being of adolescents through immunization, we must reinforce vaccination compliance as part of already existing early, middle and late adolescent preventive care visits (GAPS, Bright Futures). The 11–12-year visit serves as the primary vaccination platform at this time, and the middle and late adolescent visits would serve as "catch-up" vaccination visits/platforms. This concept of "catch-up" vaccination for hepatitis B vaccination was very successful in more definitively establishing the 11–12-year-old immunization visit for the Td booster as a vaccination platform. Now, while the meningococcal interim recommendations exist for 15-year-olds as well as those 17–18-year-olds leaving for college, we have the opportunity to develop and support new vaccination platforms during both middle and late adolescence. These new vaccination platforms would allow for "catch-up" of any of the currently recommended vaccines targeted to adolescents in addition to those that may be recommended after adolescents have had their 11–12 year visit. Further visits will also increase completion rates for multiple-dose vaccination series. A visit specifically for the 17–18-year age group will allow for immunization completion while patients are more likely to have third party payment coverage, including the Vaccine for Children program. We need to utilize all possible resources to immunize and protect adolescents against vaccine-preventable diseases.

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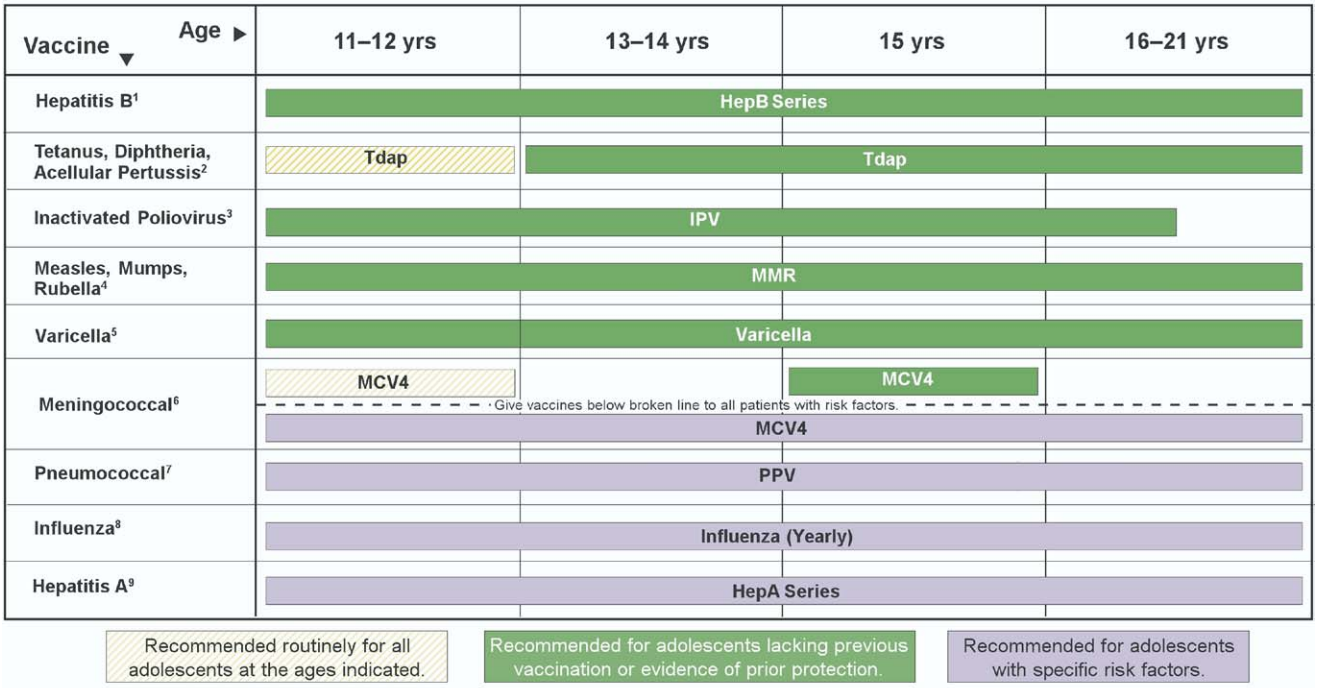
Recommended Adolescent Immunization Schedule



This schedule indicates the recommended ages for routine administration of currently licensed vaccines for adolescents ages 11–21 years. Any dose not given at the recommended age should be given at any subsequent visit when indicated and feasible. Providers should consult the manufacturers' package inserts for detailed recommendations. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at www.vaers.hhs.gov or by telephone, 800-822-7967.

1. Hepatitis B vaccine (HepB). All adolescents who have not completed a 3-dose schedule of HepB vaccine should begin (or complete) the series during any visit. The 2nd dose should be given no sooner than 4 weeks from the 1st dose and the 3rd dose no sooner than 8 weeks from the 2nd dose. Overall, there must be at least 4 months between the 1st and 3rd doses (e.g., 0, 1, 4 months; 0, 2, 4 months; or 0, 1, 6 months). If the schedule has been delayed, do not start the series over; continue from where you left off. Alternatively, unvaccinated adolescents 11–15 years of age may be given 2 doses of Recombivax HB 1.0 mL (adult formulation) spaced 4–6 months apart.

2. Tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap). Adolescents 11–12 years of age who have completed the recommended DTP/DTaP vaccination series and have not received a Td booster dose should be given a dose of Tdap. Adolescents 13–18 years who missed the 11–12-year Td/Tdap booster should receive a single dose of Tdap if they have completed the recommended childhood DTP/DTaP vaccination series. A 5-year interval between Td and Tdap is encouraged to reduce the risk of local or systemic reactions. Subsequent **tetanus and diphtheria (Td)** boosters are recommended every 10 years.

3. Inactivated poliovirus vaccine (IPV). Adolescents who previously received a combination of both oral poliovirus vaccine (OPV) and IPV but received fewer than 4 doses should complete the full 4-dose series with IPV. Other adolescents who have not completed an all-IPV schedule should begin (or complete) a series of 3 doses, spaced at least 4 weeks apart. Vaccine is not indicated for persons 18 years of age and older unless they have a risk factor (e.g., pending travel to a country where polio is endemic).

4. Measles, mumps, and rubella vaccine (MMR). Adolescents who have not received at least two doses of MMR should begin (or complete) the 2-dose schedule at any visit; the two doses must be given at least 4 weeks apart.

5. Varicella vaccine. All adolescents who lack a reliable history of chickenpox or previous varicella vaccination should be given varicella vaccine. If younger than 13 years of age, give 1 dose; if 13 years of age or older, give 2 doses at least 4 weeks apart.

6. Meningococcal conjugate vaccine (MCV4). MCV4 is recommended for all children at 11–12 years of age as well as unvaccinated adolescents at 15 years of age. Other adolescents who wish to decrease their risk for meningococcal disease may also be vaccinated. In addition, all college freshmen living in dormitories should be vaccinated, preferably with MCV, although **meningococcal polysaccharide vaccine (MPSV4)** is an acceptable alternative. Vaccination against invasive meningococcal disease is recommended for adolescents with terminal complement component deficiencies or anatomic or functional asplenia and certain other high risk groups (see *MMWR* 2005;54(RR-7):1-21); use MCV4, although MPSV4 is an acceptable alternative.

7. Pneumococcal polysaccharide vaccine (PPV). PPV is recommended for adolescents with certain risk factors (e.g., chronic cardiac or pulmonary disease, chronic liver disease, diabetes mellitus, CSF leaks, candidate for or recipient of cochlear implant) as well as adolescents living in special environments (e.g., Alaska Natives and certain American Indian populations). Give a one-time revaccination to those at highest risk of fatal pneumococcal infection (see *MMWR* 2000;49(RR-9):1-35.)

8. Influenza vaccine. Influenza vaccine is recommended annually for adolescents with certain risk factors (including but not limited to asthma, cardiac disease, sickle cell disease, HIV, and diabetes), healthcare workers, and other persons (including household members) in close contact with persons in groups at high risk. All other adolescents wishing to obtain immunity may also be vaccinated. For healthy adolescents, the intranasally administered **live, attenuated influenza vaccine (LAIV)** is an acceptable alternative to the intramuscular **trivalent inactivated influenza vaccine (TIV)**.

9. Hepatitis A vaccine (HepA). Hepatitis A vaccine is recommended for adolescents who lack previous vaccination or evidence of prior infection and who live in selected states and regions and for certain high-risk groups (see *MMWR* 1999;48(RR-12):1-37); consult your local public health authority. The 2 doses in the series should be given at least 6 months apart.

This "Recommended Adolescent Immunization Schedule" was adapted by the Immunization Action Coalition for the Society for Adolescent Medicine and is based on the "Recommended Childhood and Adolescent Immunization Schedule," approved by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians, December 2005.