Guidelines for Quality Standards for Immunization


This is an update of the 1997 Quality Standards for Immunization, which is one of a series of guidelines commissioned by the Infectious Diseases Society of America (IDSA) through its Practice Guidelines Committee. This information is presented as a standard-of-care rather than practice guidelines because the evidence for following these recommendations is so strong that they should be implemented with rare exceptions. The purpose of these standard-of-care guidelines is to provide assistance to clinicians who make decisions on providing immunizations to infants, children, adolescents, and adults. This document is a summary of evidence-based guidelines previously developed by national organizations. A standard ranking system was used to determine the strength of the recommendations, and the quality of evidence cited in the literature was reviewed for each guideline. The targeted health care professionals are pediatricians, family practitioners, internists (including specialists), obstetricians, and others who provide immunizations. The panel members are experts in the field of adult and pediatric infectious diseases. The document has been subjected to external review by peer reviewers as well as by the Practice Guidelines Committee, and it was approved by the IDSA Council. Indicators for measuring compliance with the standards are included. The document will be posted on the IDSA home page at http://www.idsociety.org/.

The Infectious Diseases Society of America (IDSA) endorses use of the following immunizations on the basis of current immunization recommendations in the United States for healthy infants, children, adolescents, and adults. Immunizations for people beginning at birth through 18 years of age include hepatitis B; diphtheria and tetanus toxoids and pertussis; Haemophilus influenzae type b; inactivated poliovirus; measles, mumps, and rubella; varicella; pneumococcal conjugate; hepatitis A, in selected states and regions and for high-risk groups; and influenza, for people with certain risk factors [1, 2]. All adults should be immune to measles, mumps, rubella, tetanus, and diphtheria; people ≥50 years of age or in groups at high risk for infection should receive annual influenza immunizations; and people ≥65 years of age or in high-risk groups should receive pneumococcal vaccine [3–5]. Adults who are susceptible to hepatitis A, hepatitis B, varicella, and/or meningococcal disease should be given appropriate immunizations if they are at special risk for exposure to these agents [6–8].

STATEMENT OF PURPOSE

The purpose of this document is to aid in the achievement of higher immunization rates among children and adults and, as a result, to reduce the incidence and public health burden of vaccine-preventable diseases [9]. Members of the IDSA endorse the following stan-
dards for implementation of the current immunization recommendations for healthy infants, children, adolescents, and adults. These standards pertain to the routine use of universally recommended vaccines [2, 3, 6–8, 10–17]. More-comprehensive sources [3, 11, 12, 18–22] are available for recommendations regarding immunization of persons who belong to specific groups (e.g., international travelers, health care providers, veterinarians, and prison inmates) or who have medical conditions (e.g., asplenia; HIV infection, cancer, or other immunosuppressive conditions; diabetes mellitus; renal failure; or compromised cardiac or pulmonary function).

BACKGROUND INFORMATION

The national goals of Healthy People 2010 [23] include the reduction of disease and death due to infectious diseases, including vaccine-preventable diseases. Achievement of these goals requires implementation of current guidelines for the universally recommended vaccines for children and adults and implementation of standards for child and adolescent and for adult immunization practices. The guidelines and standards have been developed and/or endorsed by other major organizations in both the public and private sectors of medicine (as relevant to their constituencies), including the US Department of Health and Human Services, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Physicians/American Society for Internal Medicine.

Information on costs and benefits, recent immunization coverage rates for various vaccines and age groups, and Healthy People 2010 goals are shown in table 1 [24–33]. Table 2 compares the maximum number of cases and number of provisional cases of selected vaccine-preventable diseases that occurred in the year 2000. Strong evidence of disease prevention supports the benefit of vaccines for prevention of these infectious diseases [9].

The delivery and acceptance of recommended immunizations is an ongoing challenge for health care professionals and health care and public health systems. Barriers to successful immunization of children and adults include inadequate access; the high out-of-pocket cost of and low reimbursement for vaccines and their administration; misconceptions of health care professionals, patients, and parents about the severity of vaccine-preventable diseases, the safety of current vaccines, current vaccination recommendations, and valid precautions and contraindications to vaccination; and the fragility of the vaccine supply. Also important are the missed opportunities for administering vaccines during all patient visits, including ambulatory care visits and hospitalizations. These missed opportunities often reflect the lack of organized practice-based and hospital-based programs to promote immunization.

The Task Force on Community Preventive Services conducted systematic reviews of 17 interventions designed to increase vaccine coverage rates, and they made evidence-based recommendations regarding these interventions [5]. Listed below are these specific interventions, all of which have the potential to increase levels of immunization coverage in children, adolescents, and adults [5, 35, 36]: client reminder/recall systems; multicomponent interventions that include education; vaccination requirements for child care, school, and college attendance; community-wide education; clinic-based education; client or family incentives; client-held medical records; reduction of out-of-pocket costs; expansion of access in medical or public health clinical settings; vaccination programs in Women, Infants, and Children (WIC) settings; home visits; vaccination programs in schools; vaccination programs in child care centers; provider reminder or recall systems; assessment and feedback for vaccination providers; standing orders; and provider education.

In addition, vaccination programs in nontraditional sites (e.g., pharmacies and shopping centers) have increased vaccine delivery to adolescents and adults, especially delivery of influenza vaccine.

VACCINE STANDARDS

Children. The standard for immunization of children and adolescents is the “Recommended Childhood Immunization Schedule, United States,” approved each year by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics, and the American Academy of Family Physicians (figure 1) [2]. Immunizations that should be given routinely are those against hepatitis B; diphtheria, tetanus, and pertussis; H. influenzae type b; poliomyelitis; measles, mumps, and rubella; varicella; and Streptococcus pneumoniae. In addition, hepatitis A vaccine is recommended for use in selected states and regions, and influenza vaccine is recommended for children with certain high-risk conditions. The specific goal for Healthy People 2010 is ≥90% immunization rates for persons aged 2 years for the recommended vaccines in the schedule. Approximately 80% of immunizations recommended for children are scheduled in the first 2 years of life. For adolescents, vaccines should be given at 11–12 years of age, in accordance with recommendations shown in figure 1 [2, 11]. Children and adolescents who are at increased risk for influenza, hepatitis A, invasive pneumococcal infection, and invasive meningococcal infection should be given appropriate immunizations [4, 7, 16, 37, 38].

Adults. The standards for adult immunization practices are based on recommendations currently being developed by the ACIP of the CDC, the American College of Physicians/
American Society for Internal Medicine, the American Academy of Family Physicians, and other national organizations (figure 2) [12, 45].

All adults should be immune to measles, mumps, rubella, tetanus, and diphtheria. All adults ≥65 years of age and younger persons in high-risk groups should receive the pneumococcal vaccine [38], and people ≥50 years of age and younger people in high-risk groups should receive annual influenza immunization [4]. The goals of Healthy People 2010 for pneumococcal and influenza vaccine are to achieve immunization rates of ≥90% among all adults aged ≥65 years. Adults who are susceptible to hepatitis A, hepatitis B, varicella, and/or meningitis should receive the hepatitis A and B vaccines. All adults should be immune to mumps and rubella. All adults ≥65 years of age and younger persons in high-risk groups should receive the pneumococcal vaccine [38], and people ≥50 years of age and younger people in high-risk groups should receive annual influenza immunization [4].

Table 2. Comparison of annual morbidity before vaccine availability with current morbidity.

<table>
<thead>
<tr>
<th>Vaccine-preventable disease</th>
<th>No. of annual cases before vaccination¹</th>
<th>Reported cases, 2000</th>
<th>Decrease, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measles</td>
<td>503,282</td>
<td>86</td>
<td>100</td>
</tr>
<tr>
<td>Mumps</td>
<td>152,209</td>
<td>338</td>
<td>99.8</td>
</tr>
<tr>
<td>Polio (paralytic)ᵇ</td>
<td>16,316</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Rubella</td>
<td>47,745</td>
<td>176</td>
<td>99.6</td>
</tr>
<tr>
<td>Diphtheria</td>
<td>175,885</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Tetanus</td>
<td>1314</td>
<td>35</td>
<td>97.3</td>
</tr>
<tr>
<td>Pertussis</td>
<td>147,271</td>
<td>786</td>
<td>94.7</td>
</tr>
<tr>
<td><em>Haemophilus influenzae</em> type b and unknown (&lt;5 years)ᶜ</td>
<td>20,000</td>
<td>121</td>
<td>99.4</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>22,339ᵈ</td>
<td>8036</td>
<td>64</td>
</tr>
<tr>
<td>Invasive pneumococcal disease (&lt;5 years)</td>
<td>15,933ᵉ</td>
<td>14,382ᵉ</td>
<td>9.7</td>
</tr>
</tbody>
</table>

**NOTE.** Data are from [34]. Provisional data for 2001 can be obtained at http://wonder.cdc.gov/mmwr/mmwr/morb.asp/.

¹ Annual cases reported (passive surveillance) 1–5 years before vaccine implementation.
² Caused by wild-type virus.
³ Reporting began in 1991; 2000 data include 66 cases that were not serotyped.
⁴ Average number of reported cases before routine childhood immunization (1987–1991). Role of vaccines in reduction in reported cases is unclear. Most vaccination efforts have focused on young children and health care workers. Most cases occur in adolescents and young adults in areas where information on vaccine coverage is limited. Thus, factors other than vaccine may have contributed to disease reduction.
⁵ Projected cases.
Figure 1. Recommended childhood immunization schedule, United States, 2002. Schedule indicates recommended ages for routine administration of currently licensed childhood vaccines, as of 1 December 2001, for children through the age of 18 years. Any dose not given at the recommended age should be given at any subsequent visit when indicated and feasible. Diagonal hatching indicates age groups that warrant special effort to administer those vaccines not previously given. Additional vaccines may be licensed and recommended during the year. Licensed combination vaccines may be used whenever any components of combination are indicated and the vaccine’s other components are not contraindicated. Providers should consult the manufacturers’ package inserts for detailed recommendations. Approved by Advisory Committee on Immunization Practices (www.cdc.gov/nip/acip), American Academy of Pediatrics (www.aap.org), and American Academy of Family Physicians (www.aafp.org). Additional information about vaccines, vaccine supply, and contraindications for immunization is available at the National Immunization Program Web site at www.cdc.gov/nip or at the National Immunization Hotline, 800-232-2522 (in English) or 800-232-0233 (in Spanish).

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Age (months)</th>
<th>Range of recommended ages</th>
<th>Catch-up vaccination</th>
<th>Preadolescent assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B *</td>
<td>Birth</td>
<td>1 month</td>
<td>2 months</td>
<td>4 months</td>
</tr>
<tr>
<td>Diphtheria, tetanus, pertussis b</td>
<td>Birth</td>
<td>1 month</td>
<td>2 months</td>
<td>4 months</td>
</tr>
<tr>
<td>Haemophilus influenzae type b c</td>
<td>Birth</td>
<td>1 month</td>
<td>2 months</td>
<td>4 months</td>
</tr>
<tr>
<td>Inactivated polio d</td>
<td>Birth</td>
<td>1 month</td>
<td>2 months</td>
<td>4 months</td>
</tr>
<tr>
<td>Measles-mumps-rubella e</td>
<td>Birth</td>
<td>1 month</td>
<td>2 months</td>
<td>4 months</td>
</tr>
<tr>
<td>Varicella f</td>
<td>Birth</td>
<td>1 month</td>
<td>2 months</td>
<td>4 months</td>
</tr>
<tr>
<td>Pneumococcal g</td>
<td>Birth</td>
<td>1 month</td>
<td>2 months</td>
<td>4 months</td>
</tr>
<tr>
<td>Hepatitis A h</td>
<td>Birth</td>
<td>1 month</td>
<td>2 months</td>
<td>4 months</td>
</tr>
<tr>
<td>Influenza i</td>
<td>Birth</td>
<td>1 month</td>
<td>2 months</td>
<td>4 months</td>
</tr>
</tbody>
</table>

Hepatitis B vaccine (Hep B). All infants should receive the first dose soon after birth and before hospital discharge; the first dose also may be given by the age of 2 months if the infant’s mother is negative for hepatitis B surface antigen (HBsAg). Only monovalent Hep B can be used for the birth dose. Monovalent or combination vaccine containing Hep B may be used to complete the series; 4 doses may be administered if combination vaccine is used. The second dose should be given ≥4 weeks after the first dose, except for Haemophilus influenzae type b–containing vaccine, which cannot be administered before the age of 6 weeks. The third dose should be given ≥16 weeks after the first dose and ≥8 weeks after the second dose. The last dose in the series (third or fourth dose) should not be administered before the age of 6 months. Infants born to HBsAg-positive mothers should receive Hep B and 0.5 mL of hepatitis B immunoglobulin (HBIG) at separate injection sites within 12 h of birth. The second vaccine dose is recommended at the age of 1–2 months, and the vaccination series should be completed (third or fourth dose) at the age of 6 months. Infants born to mothers with unknown HBsAg status should receive the first dose of Hep B within 12 h of birth. Maternal blood samples should be obtained at delivery to determine the mother’s HBsAg status; if the test result is positive, the infant should receive HBIG as soon as possible (no later than the age of 1 week).

Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP). The fourth dose may be administered as early as the age of 12 months, provided that 6 months have elapsed since the third dose was administered and the child is unlikely to return at the age of 15–18 months. Tetanus and diphtheria toxoids vaccine (Td) is recommended at age 11–12 years if ≥5 years have elapsed since the last dose of Td-containing vaccine was administered. Subsequent routine Td boosters are recommended every 10 years.

H. influenzae type b (Hib) conjugate vaccine. Three Hib conjugate vaccines are licensed for infant use. If PRP-OMP (PedvaxHIB or ComVax [Merck]) is administered at the ages of 2 and 4 months, receipt of a dose at 6 months is not required. DTaP-Hib combination products should not be used for primary immunization of infants at the ages of 2, 4, or 6 months but can be used as boosters after any Hib vaccine.

Inactivated poliovirus vaccine (IPV). All-IPV schedule is recommended for routine childhood vaccination in the United States. All children should receive 4 doses of IPV at the ages of 2 months, 4 months, 6–18 months, and 4–6 years.
gococcal disease should be immunized appropriately if they are at high risk for exposure to these agents.

IMPLEMENTATION STANDARDS

The following implementation standards apply to children and adolescents and to adults [45, 46]. These standards summarize guidelines that previously were developed by other national committees and organizations and pertain to the use of universally recommended vaccines.

Children and adolescents
1. Vaccinations services are readily available.
2. Vaccinations are coordinated with other health care services and provided in a medical home when possible [47].
3. Barriers to vaccination are identified and minimized.
4. Patient costs are minimized. Information about the Vaccines for Children program is available at www.cdc.gov/nip/vfc/.
5. Health care professionals review the vaccination and health status of patients at every encounter to determine which vaccines are indicated.
6. Health care professionals assess for and follow only medically accepted contraindications, as specified by the ACIP. For additional information, see www.cdc.gov/nip/recs/contraindications.pdf.
7. Parents or guardians and patients are educated about the risks and benefits of vaccination in a culturally appropriate manner and in easy-to-understand language. For additional information, see www.cdc.gov/nip/vacsafe/.
8. Health care professionals follow appropriate procedures for vaccine storage and handling.
9. Up-to-date, written vaccination protocols are accessible at all locations where vaccines are administered.
10. Persons who administer vaccines and staff who manage or support vaccine administration are knowledgeable and receive ongoing education. A list of CDC-sponsored training and education opportunities for health care professionals is available at www.cdc.gov/nip/ed/.
11. Health care professionals simultaneously administer as many doses of the indicated vaccine as possible.
12. Vaccination records for patients are accurate, complete, and easily accessible.
13. Health care professionals report adverse events that occur after vaccination promptly and accurately to the Vaccine Adverse Event Reporting System (www.vaers.org) and are aware of the National Vaccine Injury Compensation Program (www.hrsa.gov/bhpr/vicp/).
14. All personnel who have contact with patients are appropriately vaccinated.
15. Systems are used to remind parents or guardians, patients, and health care professionals when vaccinations are due and to recall those who are overdue.
16. Office- or clinic-based patient record reviews and vaccination coverage assessments are performed annually.

Adults
1. Adult vaccination services are readily available.
2. Barriers to receiving vaccines are identified and minimized.
3. Patient out-of-pocket vaccination costs are minimized.
4. Health care professionals routinely review the vaccination status of patients.
5. Health care professionals assess for valid contraindications. For information on contraindications, see www.cdc.gov/nip/.
6. Patients are educated about the risks and benefits of vaccination in easy-to-understand language.
7. Written vaccination protocols are available at all locations where vaccines are administered.
8. Persons who administer vaccines are properly trained.

Figure 1. (Continued.) *Measles, mumps, and rubella vaccine (MMR). The second dose of MMR is recommended routinely at the age of 4–6 years but may be administered during any visit, provided ≥4 weeks have elapsed since the first dose was administered and that both doses are administered beginning at or after the age of 12 months. Those who have not previously received their second dose should complete schedule by the visit made at the age of 11–12 years.

Varicella vaccine. Recommended at any visit at or after the age of 12 months for susceptible children (those who lack reliable history of chickenpox). Susceptible persons aged ≥13 years should receive 2 doses, given ≥4 weeks apart.

Pneumococcal vaccine. Heptavalent pneumococcal conjugate vaccine (PCV) is recommended for all children aged 2–23 months and for certain children aged 24–59 months. Pneumococcal polysaccharide vaccine (PPV) is recommended in addition to PCV for certain high-risk groups. See [16].

Hepatitis A vaccine. Recommended for use in selected states and regions and for certain high-risk groups; consult the local public health authority. See [7].

Influenza vaccine. Recommended annually for children aged ≥6 months with certain risk factors (including but not limited to asthma, cardiac disease, sickle cell disease, HIV, and diabetes; see [4]) and can be administered to all others wishing to obtain immunity. Children aged ≤12 years should receive vaccine in a dose appropriate for their age (6–35 months, 0.25 mL; ≥3 years, 0.5 mL). Children aged ≥8 years who are receiving influenza vaccine for the first time should receive 2 doses separated by ≥4 weeks.
Figure 2. Recommended adult immunization schedule, United States, 2002. Schedule indicates the recommended age groups for routine administration of currently licensed vaccines for persons aged ≥19 years. Licensed combination vaccines may be used whenever any component of combination is indicated and vaccine’s other components are not contraindicated. Providers should consult the manufacturers’ package inserts for detailed recommendations. Please report all significant postvaccination reactions to Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing VAERS reports are available at 800-822-7967 or from the VAERS Web site at www.vaers.org. Approved by Advisory Committee on Immunization Practices and accepted by American College of Obstetricians and Gynecologists. Additional information about the vaccines listed here and contraindications for immunization is available at the National Immunization Program Web site at www.cdc.gov/nip or at the National Immunization Hotline, 800-232-2522 (in English) or 800-232-0233 (in Spanish).

*Covered by Vaccine Injury Compensation Program. Information on how to file a claim is available at 800-338-2382 or from www.hrsa.gov/osp/vicp/*.

+Tetanus and diphtheria vaccine (Td). Primary series for adults in 3 doses; doses 1 and 2 are given ≥4 weeks apart, and the third dose is given 6–12 months after the second. Administer 1 dose if the person had received the primary series and the last vaccination was ≥10 years earlier (the Guide for Adult Immunization [3] provides the following as an alternative booster policy: completion of primary immunization series with Td followed by single booster at the age of 50 years for persons who have completed full pediatric series, including teenage and young adult boosters [39].

+Influenza vaccine. Medical indications: patients with chronic disorders of cardiovascular or pulmonary systems including asthma, chronic metabolic diseases including diabetes mellitus, renal dysfunction, hemoglobinopathies, and immunosuppression (including that caused by medications or HIV); those requiring regular medical follow-up or hospitalization during preceding year; and women who will be in the second or third trimester of pregnancy during influenza season. Occupational indications: health care workers and community service workers. Other indications: residents of nursing homes and other long-term care facilities, persons likely to transmit influenza (in-home care givers to persons with medical indications, household contacts and out-of-home care givers of children <23 months of age or children with asthma or other indicator conditions for influenza vaccination, and household members and care givers of elderly persons and persons with high-risk conditions), and anyone who wishes to be vaccinated.

+Pneumococcal polysaccharide vaccine. Medical indications: chronic disorders of pulmonary system (excluding asthma), cardiovascular diseases, diabetes mellitus, chronic liver diseases including liver disease as result of alcohol abuse (e.g., cirrhosis), chronic renal failure or nephrotic syndrome, functional or anatomic asplenia (e.g., sickle cell disease or splenectomy), immunosuppressive conditions (e.g., congenital immunodeficiency, HIV infection, leukemia, lymphoma, multiple myeloma, Hodgkin disease, generalized malignancy, and organ or bone marrow transplantation), and chemotherapy with alkylating agents, antimetabolites, or long-term systemic corticosteroids. Geographic or other indications: Alaska natives and certain American Indian populations. Other indications: residents of nursing homes and other long-term care facilities [40].
9. Health care professionals recommend simultaneous administration of all indicated vaccine doses.
10. Vaccination records for patients are accurate and easily accessible.
11. All personnel who have contact with patients are appropriately immunized.
12. Systems are developed and used to remind patients and health care professionals when vaccinations are due and to recall patients who are overdue. Information about reminder or recall interventions can be found at www.atpm.org/immunization/whatworks.html.
13. Standing orders for vaccinations are used in hospitals, nursing homes, and other appropriate settings.
14. Regular assessments of vaccination coverage rates are conducted in a provider’s practice.

INDICATORS

Health care professionals are urged to audit their patient records on a regular basis to determine whether these guidelines for immunization are being implemented. The following indicators are suggested for review: for children, receipt of the entire series of 11 vaccines by the age of 2 years and receipt of 2 doses of measles-mumps-rubella vaccine by the age of 4–5 years; for adults, receipt of pneumococcal vaccine for those aged ≥65 years [48] and annual influenza vaccination for those aged ≥50 years. Receipt of these vaccines may be viewed as an indication that a given population has been immunized successfully.
References

36. Centers for Disease Control and Prevention. Use of standing orders


