14. IMMUNIZATIONS
Mark Schuster, M.D., Ph.D.

The United States Public Health Service Immunization Practice Advisory Committee (ACIP) and the American Academy of Pediatrics (AAP) Committee on Infectious Diseases traditionally provide recommendations for immunization schedules and procedures in the United States (Centers for Disease Control [CDC], 1995). These organizations publish their recommendations primarily in the Morbidity and Mortality Weekly Report (MMWR) and the Red Book, respectively; their recommendations usually agree (Dennehy et al., in Feigin and Cherry, 1992). This review draws heavily on these recommendations.

In January 1995, the ACIP and the AAP, along with the American Academy of Family Physicians (AAFP), released a joint set of recommendations (CDC, 1995).¹ These organizations developed this immunization schedule in collaboration with representatives from the Food and Drug Administration and the National Institutes of Health. State immunization programs, the Maternal and Child Health Bureau; vaccine manufacturers also provided advice (Hall, 1995).

Additional sources include textbooks on pediatrics (Wilson in Oski et al., 1994), primary care pediatrics (Rennels in Dershewitz, 1993), and pediatric infectious disease (Dennehy et al., in Feigin and Cherry, 1992). Several articles were also identified from the bibliographies of the previously described sources and from a MEDLINE search of English-language articles on missed opportunities (the common term for episodes of clinical interaction in which children who could have been immunized were not) published between January 1990 and March 1995.

IMPORTANCE

Immunizations are the primary method of preventing many communicable diseases. They work both by inducing immunity in the

¹Clinicians who have not adapted to the new immunization schedule from the ACIP's prior schedule (released in the fall, 1993) will not be placed at a disadvantage because the new one only lengthens the time period during which several immunizations are recommended.
recipient and by creating herd immunity in a community that is well-immunized (if more than a threshold percentage of a community is immunized, the disease cannot get enough of a foothold to spread). Thus, there are personal and public health reasons for children to be immunized.

Most (if not all) public school districts require children to have received the full immunization schedule to start school, so the United States has high immunization rates for school-aged children. For example, in the early 1980s, more than 95 percent of school-aged children were completely immunized (Cutts et al., 1992). By contrast, the United States has a poor record for two-year olds, who should have received the primary series for all childhood immunizations. A median of 46 percent of children among various studied populations had completed immunizations by their second birthday (Cutts et al., 1992).\(^1\)

All diseases for which immunizations are routinely recommended can cause serious illness. Hepatitis B is the only disease that is not traditionally associated with childhood. Immunization of children for hepatitis B is recommended primarily because targeted immunization of high-risk adolescents and adults has failed; therefore, the AAP decided to recommend immunization of all infants as well (AAP, 1992).

GENERAL ISSUES PERTINENT TO ALL IMMUNIZATIONS

Contraindications to Immunization

Contraindications specific to individual vaccines are described in the discussions of those vaccines. The following list covers contraindications that apply to all vaccines:

1. Anaphylactic reaction to a vaccine (AAP in Peter, 1994; CDC, 1993b). Clinicians should ask about prior reactions to vaccines.

2. Anaphylactic reaction to a vaccine constituent (AAP in Peter, 1994; CDC, 1993b). Known allergies to specific vaccine

---

\(^1\)These data exclude immunizations for *Haemophilus influenzae* type b (Hib), which were not yet included in most states' school entry requirements.
constituents are rare, so it would be difficult to incorporate clinician inquiries about them into quality indicators.

3. Moderate or severe illnesses with or without a fever (AAP in Peter, 1994; CDC, 1993b). The ACIP/AAP recommendations do not define the distinction between mild vs. moderate/severe illnesses. Even when the ACIP provides an example of a mild illness--a mild upper respiratory infection (URI) with or without low-grade fever (CDC, 1989)--it does not specify what temperature and what thermometer site constitute the cut off for a fever that is higher than low grade. Clinicians are given wide discretion in deciding when to delay immunizations. Researchers conducting studies of missed opportunities (which uniformly show that physicians frequently delay immunizations for mild illnesses) have developed their own criteria for symptoms that warrant immunization delay (Farizo et al., 1992; Szilagyi et al., 1993; McConnochie and Roghmann, 1992), but their protocols have not been widely disseminated and have not become standards for the profession. Thus, there are no published guidelines or professional standards to incorporate into quality indicators for immunization delay. One solution to this problem is to select quality indicators that allow a sufficient grace period so that most children who miss an immunization because of a moderate/severe illness would have had enough time to catch up. The number who do not catch-up because of prolonged or chronic illnesses would be small and so should have little impact on the overall quality score. More comprehensive approaches to measuring quality could be added in the future.

4. Guardian refusal. Guardian refusal (for religious or other reasons) should be documented for legal reasons and so that other clinicians will know the context in which they are offering immunizations at future visits.
Documentation

One component of quality is the quality of documentation. It is important to document specific details such as lot number in case a vaccine lot is recalled later. Documentation standards are set by federal law in the United States. The National Childhood Vaccine Injury Act of 1986, which went into effect in 1988, requires that health care providers record in the child's permanent medical record the date of administration of all childhood-mandated vaccines, the manufacturer, the lot number, and the name of the health care provider administering the vaccine (Dennehy et al., in Feigin and Cherry, 1992).^1^1

POLIO

The standard vaccine is oral polio vaccine (OPV), which is a live virus vaccine. An alternative is the inactivated polio vaccine (IPV).

Recommendations

The recommendation is to give OPV at 2 months, 4 months, 6 to 18 months, and 4 to 6 years (CDC, 1995). The first dose can be administered as early as 6 weeks (CDC, 1994).

Children with HIV infection or a known altered immunodeficiency (hematologic and solid tumors, congenital immunodeficiency, and long-term immunosuppressive therapy) (AAP in Peter, 1994; CDC, 1993b) should not receive OPV; instead, they should receive IPV (AAP in Peter, 1994; CDC, 1993b). Elsewhere, the CDC (1993a) provides a more expansive list of immunosuppressive conditions, including congenital immunodeficiency, leukemia, lymphoma, generalized malignancy or therapy with alkylating agents, antimetabolites, radiation, or large amounts of corticosteroids. Pregnancy is a questionable contraindication (AAP in Peter, 1994; CDC, 1993b) but is unlikely to turn up for this population (since most pregnant adolescents would have received the complete polio series in order to attend school). If a pregnant adolescent is at high risk for

^1^ While Hib (Haemophilus influenza type b) and HBV (Hepatitis b vaccination) were not mandated at the time of this Act, it is safe to assume that they are covered by it now or that it would be viewed as reasonable for a quality indicator to apply the same standards to them that it applies to vaccines that were mandated at the time.
exposure to the against polio virus, OPV rather than IPV should be given (AAP in Peter, 1994; CDC, 1993b). Corticosteroid therapy does not contraindicate live virus vaccination when it is less than two weeks duration, low to moderate dose, long-term alternative day treatment with short-acting preparations, maintenance physiologic doses (replacement therapy), or administered topically (skin or eyes), by aerosol, or by intra-articular, bursal, or tendon injection.

IPV should be given to anyone with a household contact who is immunosuppressed (AAP in Peter, 1994; CDC, 1993b; see list of conditions qualifying as immunosuppression in preceding paragraph). Therefore, an inquiry must be made at each visit about possible immunosuppressed contacts. Some families may not want the household contact's immunosuppression listed in the child's chart for privacy reasons, so administration of IPV should be interpreted as presumptive evidence of an immunosuppressed child or contact.

Contraindications to IPV include anaphylactic reaction to neomycin or streptomycin (AAP in Peter, 1994; CDC, 1993b).

**DIPHTHERIA-TETANUS-PERTUSSIS**

The standard formulation is a combination of diphtheria and tetanus toxoids and pertussis vaccine (DTP). A formulation with acellular pertussis vaccine is also available (DTaP). Other formulations include Td (with a smaller amount of diphtheria toxoid) and DT.

DTP should be given at 2 months, 4 months, 6 months, 12-18 months, and 4-6 years. If the child is at least 15 months old, the fourth (and fifth) dose can be given as either DTaP or DTP (CDC, 1995). The first dose can be administered as early as 6 weeks (CDC, 1994). There must be at least 6 months between the third and fourth doses (CDC, 1995). As of the seventh birthday, a child should only receive formulations that do not contain the pertussis vaccine.

Td should be given between 11 and 16 years of age (CDC, 1995). However, the CDC used to recommend and the Guidelines for Adolescent Preventive Services (Elster and Kuznets, 1994) recommend that adolescents receive Td 10 years after the last DTP (due, but not necessarily given, between 4 and 6 years). Therefore, an indicator
should reflect that a person who received a DTP between 7 and 10 years old would not need to be revaccinated until 10 years later when he or she would be 17 to 20 years old.

DTP should not be given if the patient has had encephalopathy within seven days of administration of a previous dose of DTP (AAP in Peter, 1994; CDC, 1993b). It is also acceptable (but not necessary) to withhold DTP/DTaP when, within 48 hours of receiving a prior DTP vaccine, the patient has experienced fever greater than or equal to 40.5°C (105°F), collapse or shock-like state (hypotonic-hyporesponsive episode), persistent, inconsolable crying lasting at least three hours; within 72 hours of receiving a prior DTP vaccine, the child has a seizure; and if the child has a proven or suspected underlying neurologic disorder (AAP in Peter, 1994; CDC, 1993).

**HAEMOPHILUS INFLUENZAE TYPE B**

There are two schedules for Haemophilus influenzae type b vaccine (Hib), depending on which vaccine formulation is used (CDC, 1995):

- HbOC (HibTITER®), PRP–T (ActHib™ and OmniHIB™), or DTP/HbOC (TETRAMUNE™) are due at 2, 4, 6, and 12–15 months.
- PRP-OMP (PedvaxHIB®) are due at 2, 4, and 12–15 months. The guidelines imply but do not directly state that if either of the first two are not PRP-OMP, then there should be a 6-month vaccine. This formulation is also known as the Meningococcal Protein Conjugate.

Either type can be given at 12–15 months, regardless of which were used for the first year. The first Hib can be given as early as the sixth week (CDC, 1994a).

A recent study comparing various sequences and substitutions of the different Hib formulations suggests that the immune response to using PRP-OMP alone during the first year is inferior to the response when at least one HbOC is given and also inferior to a sequence of three HbOC shots (Anderson et al., 1995). While the study's authors draw the conclusion that changing vaccines during the primary sequences is acceptable, they recommend further study rather than advise against using only PRP-OMP.
MEASLES-MUMPS-RUBELLA

Measles, mumps, and rubella (German measles) vaccines are generally combined (MMR).

The first MMR is due at 12 to 15 months. The second shot is due at 4 to 6 years or 11 to 12 years (CDC, 1995), and is generally dictated by the requirements of local school districts. Though the recommendations specify either time period for the second shot, but not the time in between, it seems most reasonable for an indicator to allow the second vaccine to be given during the full range of time between these two time periods. For example, if an eight-year-old child not yet immunized with a second MMR moved to a school district that requires the second MMR, he or she would need to be immunized and would have no reason to get a repeat MMR at 11 to 12 years old.

The second shot should not be given within a month of the first. This would probably only come up as an issue if a child of at least 4 years old has had no MMRs and is presently catching up.

During measles outbreaks in preschool children, vaccination may be recommended for children as young as 6 months old; these children should still have a vaccination after they reach 12 months.

Reasons not to be vaccinated specific to MMR (AAP in Peter, 1994; CDC, 1993b) include anaphylactic reaction to neomycin, pregnancy (for theoretical reasons (CDC, 1994)), and known altered immunodeficiency other than HIV (hematologic and solid tumors, congenital immunodeficiency, and long term immunosuppressive therapy). Anaphylactic reaction to egg ingestion is also an acceptable contraindication, though protocols exist for immunizing people with such histories (Greenberg and Birx, 1988; Herman et al., 1983). If a child has had immunoglobulin administered within the prior three months, it is acceptable to delay MMR if one has done a risk-benefit analysis for the individual patient.

HEPATITIS B VACCINE

The Hepatitis B vaccine is referred to as HBV. Though not a vaccine, Hepatitis B Immune Globulin (HBIG) will also be discussed below because it is sometimes used in tandem with HBV.
In the United States, 200,000 to 300,000 acute Hepatitis B infections occur each year. More than one million people in the U.S. have chronic Hepatitis B infection, and about 4,000 to 5,000 people die each year from chronic liver disease and hepatocellular carcinoma resulting from Hepatitis B. Depending on region, gender, and race, between 3.3 percent and 25 percent of the population have had Hepatitis B. The likelihood of becoming chronically infected with Hepatitis B varies inversely with the age at which infection occurs. Newborns who become infected from Hepatitis B surface antigen (HBsAg)-positive mothers have a 90 percent probability of becoming chronic carriers. It is estimated that more than 25 percent of infants who are chronic carriers will die from primary hepatocellular carcinoma or cirrhosis of the liver, generally while adults (AAP, 1992).

All pregnant women should be screened for HBsAg during an early prenatal visit (CDC, 1995) (See Chapter 16).

If the mother is HBsAg-negative, the child should receive HBV at birth to 2 months, 1 to 4 months, and 6 to 18 months with at least one month between the first two doses (CDC, 1995; AAP, 1992; AAP in Peter, 1994).

If the mother is HBsAg-positive, a newborn should receive HBIG within 12 hours of birth, and the initial dose of HBV should be given concurrently at a different site. (Because of differences in different manufacturer's formulations, this initial dose should be either Merck Sharpe & Dohme's Recombivax HB® or SmithKline Beecham's Engerix-B®.) The second and third HBV doses should be given at 1 and 6 months of age (CDC, 1995; AAP, 1992; AAP in Green, 1994).

If the mother's HBsAg status is not known, a newborn should receive HBV within 12 hours of birth in the dose recommended for children whose mothers are HBsAg-positive. The mother should be tested immediately. Though not specifically recommended, it seems clear that a mother who was not screened perinatally should be screened soon enough to allow administration of HBIG to the child before he/she is one week old. If the mother is found to be HBsAg-positive, the child should receive HBIG as soon as possible and within seven days of birth. The recommendations for the second and third dose of HBV follow the guidelines according to
whether the mother is positive or negative (AAP, 1992; AAP in Peter, 1994). Although the recommendations do not address what should occur if the mother's status remains unknown, one might argue that the child should be treated as if the mother were positive.

The AAP recommends vaccinating adolescents who have sexually transmitted infections, have had more than one sexual partner in the previous six months, are injection drug users, are males who are sexually active with other males, have sexual contacts with individuals at high risk, or have tasks as employees, volunteers, or trainees that involve contact with blood or blood-contaminated body fluids (AAP in Peter, 1994). Some of this information would not necessarily be recorded in the chart because of privacy concerns and the last risk factor would not be asked routinely, but when such risk factors appear in the chart, delivery (or an offer) of the vaccine should be noted as well.

Children or adolescents who are Alaskan Natives or Pacific Islanders or whose parents are immigrants from countries with high rates of HBV infection should be vaccinated as well (AAP in Peter, 1994). It would be difficult to incorporate countries with high rates of HBV into an indicator, but the list would be available from the CDC if desired.

**CATCHING UP FOR LATE IMMUNIZATIONS**

Patients who are behind on immunizations are supposed to follow an accelerated schedule to catch-up. The general approach is not to delay age-appropriate immunizations while catching up on missed immunizations (e.g., a thirteen-month-old can receive the first MMR while catching up on missed DTPs). If the child is at least 4 months old but less than 7 years old and has not begun any of the initial series, the interval between the first, second, and third DTPs and Hib should be reduced to one month. Except in special circumstances, Hib should not be given after the fifth birthday. Additional Hib recommendations vary with the particular manufacturer and are detailed in CDC (1994b). The second OPV is given 2 months after the first, and the third 6 weeks after the second. The second HBV is given 1 month after the first, and the third is given 6 months after the second. The fourth DTP/DTaP is given at
least 6 months after the third one; likewise for the fourth Hib. If the child reaches his/her 7th birthday during this catch-up sequence, remaining DTPs should be given as Td (CDC, 1994b).

A child who is at least 7 years but less than 18 years of age and has never been vaccinated should receive on the first visit, Td, OPV, MMR; 6-8 weeks after the first visit, the same set should be given again. Six months after the second visit, Td and OPV are given. DTP/DTaP is not given to people who are 7 or older. OPV is not given to people who are 18 or older. Hepatitis B vaccination generally depends on risk factors (CDC 1994b). Additional details appear in CDC (1994b).

**UNKNOWN PRIOR IMMUNIZATION RECORD**

There are no guidelines for how quickly a physician should track down a new patient's immunization history from other clinicians if the guardian does not know it. However, given that there are no adverse reactions to being reimmunized with MMR, OPV/IPV, Hib, HBV, a child whose immunization record cannot be obtained should be reimmunized (CDC 1994b).
## RECOMMENDED QUALITY INDICATORS FOR CHILDHOOD IMMUNIZATIONS

The following criteria apply to routine immunizations for infants, children, and adolescents.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Quality of Evidence</th>
<th>Literature</th>
<th>Benefits</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Polio</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. All children should have had two OPV/IPV between six weeks and the first birthday. *</td>
<td>I, III</td>
<td>CDC, 1995; CDC, 1994a; Cherry in Feigin and Cherry, 1992; CDC, 1991</td>
<td>Prevent polio. *</td>
<td>OPV and IPV both help prevent individuals from contracting polio and help decrease the chances of polio spreading through a community.</td>
</tr>
<tr>
<td>2. All children should have had three OPV/IPV between six weeks and the second birthday. *</td>
<td>I, III</td>
<td>CDC, 1995; CDC, 1994a; Cherry in Feigin and Cherry, 1992; CDC, 1991</td>
<td>Prevent polio. *</td>
<td>OPV and IPV both help prevent individuals from contracting polio and help decrease the chances of polio spreading through a community.</td>
</tr>
<tr>
<td>3. All children should have had four OPV/IPV between six weeks and the seventh birthday. *</td>
<td>I, III</td>
<td>CDC, 1995; CDC, 1994a; Cherry in Feigin and Cherry, 1992; CDC, 1991</td>
<td>Prevent polio. *</td>
<td>OPV and IPV both help prevent individuals from contracting polio and help decrease the chances of polio spreading through a community.</td>
</tr>
<tr>
<td>4. Children with immunocompromise (hematologic and solid tumors, congenital immunodeficiency, and long-term immunosuppressive therapy) or HIV infection should receive IPV rather than OPV (at the same ages as OPV).</td>
<td>III</td>
<td>AAP in Peter, 1994; CDC, 1993b</td>
<td>Prevent polio. * Prevent polio transmission from the vaccine.</td>
<td>OPV can cause polio in an immunocompromised person.</td>
</tr>
<tr>
<td>5. Before each OPV, guardians should be questioned about the presence of an immunocompromised contact in the household.</td>
<td>III</td>
<td>Inferred from AAP in Peter, 1994; CDC, 1993b</td>
<td>Prevent spreading polio to an immunocompromised contact of a recipient of OPV. *</td>
<td>OPV can cause polio in an immunodeficient contact of the recipient. Many people probably do not document this; however, it is quite important to ask. An expectation of documentation increases the likelihood that it is really done, allows for quality review, and provides some legal protection. One might argue that if the parent signs a consent that says to tell the clinician about immunosuppressed household contacts, that is adequate. Such consents should be in the chart for documentation. A physician who takes care of the whole household might argue that he or she knows everyone’s immune status and doesn’t need to ask again or to document in the child’s chart that no one is immunosuppressed.</td>
</tr>
<tr>
<td>6. If there is a household contact with immunocompromise, children should receive IPV instead of OPV.</td>
<td>III</td>
<td>AAP in Peter, 1994; CDC, 1993b</td>
<td>Prevent polio. *</td>
<td>The live virus presents a risk for infection among immunocompromised persons.</td>
</tr>
</tbody>
</table>

**Diphtheria/Tetanus/Pertussis**
<table>
<thead>
<tr>
<th></th>
<th>All children should have had three DTP between six weeks and the first birthday.*</th>
<th>I, III</th>
<th>CDC, 1995; CDC, 1994a; Dennehy et al., in Feigin and Cherry, 1992; CDC, 1991</th>
<th>Prevent diphtheria.(^b) Prevent tetanus.(^c) Prevent pertussis.(^d)</th>
<th>DTP helps prevent individuals from contracting diphtheria, tetanus, and pertussis.</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>All children should have had four DTP between six weeks and the second birthday, with at least six months between the third and fourth dose (the fourth may be DTaP if given after 15 months old).*</td>
<td>I, III</td>
<td>CDC, 1995; CDC, 1994a; Dennehy et al., in Feigin and Cherry, 1992; CDC, 1991</td>
<td>Prevent diphtheria.(^b) Prevent tetanus.(^c) Prevent pertussis.(^d)</td>
<td>DTP/DTaP helps prevent individuals from contracting diphtheria, tetanus, and pertussis.</td>
</tr>
<tr>
<td>9</td>
<td>All children should have had five DTP/DTaP between six weeks and the seventh birthday, with at least six weeks between the third and fourth doses (the fourth and fifth may be DTaP if given after 15 months).*</td>
<td>I, III</td>
<td>CDC, 1995; CDC, 1994a; Dennehy et al., in Feigin and Cherry, 1992; CDC, 1991</td>
<td>Prevent diphtheria.(^b) Prevent tetanus.(^c) Prevent pertussis.(^d)</td>
<td>DTP/DTaP helps prevent individuals from contracting diphtheria, tetanus, and pertussis.</td>
</tr>
<tr>
<td>10</td>
<td>By age 17, all children should have had one Td between age 7 and 17. A formulation that includes pertussis is acceptable.</td>
<td>I, III</td>
<td>CDC, 1995; Dennehy et al., in Feigin and Cherry, 1992; CDC, 1991</td>
<td>Prevent diphtheria.(^b) Prevent tetanus.(^c)</td>
<td>Booster vaccines for tetanus are indicated every 10 years. Though the pertussis vaccine has generally not been given to patients over 7 years old because of concerns about increased side effects, there is growing concern that adults are spreading the disease to children. Though official recommendations have not emerged, an infectious disease expert has indicated that some clinicians are now giving the pertussis vaccine to persons older than 7.</td>
</tr>
<tr>
<td>11</td>
<td>Children who have had encephalopathy within 7 days of a prior dose of DTP should not receive any further vaccination with DTP.</td>
<td>III</td>
<td>AAP in Peter, 1994; CDC, 1993b</td>
<td>Prevent recurrent encephalopathy. Prevent neurologic defects.</td>
<td>Risk of encephalopathy due to DTP is higher in people with a prior episode of encephalopathy associated with DTP.</td>
</tr>
<tr>
<td>12</td>
<td>All children should have had two PHP-OMP Hib or three Hib (any combination of formulations) between six weeks and the first birthday.*</td>
<td>I, III</td>
<td>CDC, 1995; CDC, 1994a; Dennehy et al., in Feigin and Cherry, 1992; CDC, 1991b</td>
<td>Prevent infection with Haemophilus influenzae type B.(^e)</td>
<td>Hib helps prevent individuals from contracting Haemophilus influenzae type B and helps decrease the chances of it spreading through a community.</td>
</tr>
<tr>
<td>13</td>
<td>Between the ages of six weeks and 2 years, all children should have had either: – four Hib vaccinations, or – three Hib vaccinations if the first two were PRP-OMP Hib.*</td>
<td>I, III</td>
<td>CDC, 1995; CDC, 1994a; Dennehy et al., in Feigin and Cherry, 1992; CDC, 1991b</td>
<td>Prevent infection with Haemophilus influenzae type B.(^e)</td>
<td>Hib helps prevent individuals from contracting Haemophilus influenzae type B and helps decrease the chances of it spreading through a community.</td>
</tr>
<tr>
<td>14</td>
<td>All children should have had one MMR between their first and second birthdays.*</td>
<td>I, III</td>
<td>CDC, 1995; Dennehy et al., in Feigin and Cherry, 1992; Cherry in Feigin and Cherry, 1992a, 1992b; Brunell in Feigin and Cherry, 1992; CDC, 1990a; CDC, 1989a</td>
<td>Prevent measles.(^f) Prevent mumps.(^g) Prevent rubella.(^h)</td>
<td>MMR helps prevent individuals from contracting measles, mumps, and rubella and helps decrease the chances of it spreading through a community.</td>
</tr>
<tr>
<td>15.</td>
<td>All children should have had an MMR between their fourth and thirteenth birthdays.*</td>
<td>I, III</td>
<td>CDC, 1995; Dennehy et al., in Feigin and Cherry, 1992; Cherry in Feigin and Cherry, 1992; Brunell in Feigin and Cherry, 1992; CDC, 1990; CDC, 1989a</td>
<td>Prevent measles.¹ Prevent mumps.⁰ Prevent rubella.²</td>
<td>MMR helps prevent individuals from contracting measles, mumps, and rubella and helps decrease the chances of it spreading through a community. The recommendation is to give the second MMR between 4-6 years or 11-12 years, with local school requirements having a major impact on the choice. For our purposes, it will be easiest to make sure a second has been given between 4-12 years. Thus the acceptable range ends on the thirteenth birthday.</td>
</tr>
<tr>
<td>16.</td>
<td>Children who are immunocompromised (with the exception of children with HIV infection) (hematologic and solid tumors, congenital immunodeficiency, and long-term immunosuppressive therapy) should not receive MMR.</td>
<td>III</td>
<td>AAP in Peter, 1994; CDC, 1993b</td>
<td>Prevent contraction of measles from the vaccine.³</td>
<td></td>
</tr>
<tr>
<td><strong>Hepatitis B</strong></td>
<td>17.</td>
<td>The mother's HBsAg status should be documented in the child's chart within one week of birth.</td>
<td>III</td>
<td>Inferred from AAP, 1992</td>
<td>Prevent perinatal transmission of Hepatitis B. Prevent liver disease from Hepatitis B. If a mother is HBsAg positive, the infant should receive immune globulin within 12 hours to prevent development of Hepatitis B.</td>
</tr>
<tr>
<td>18.</td>
<td>All children whose mothers are known to be HBsAg-Negative should have had at least two HBV by the first birthday with at least one month between the first two doses.*</td>
<td>I, III</td>
<td>CDC, 1995; Dennehy et al., in Feigin and Cherry, 1992; CDC, 1990a</td>
<td>Prevent Hepatitis B infection and subsequent liver disease. HBV helps prevent individuals from contracting Hepatitis B and helps decrease the chances of it spreading through a community.</td>
<td></td>
</tr>
<tr>
<td>19.</td>
<td>All children whose mothers are known to be HBsAg-Negative should have had three HBV by the second birthday with at least one month between the first two doses.*</td>
<td>I, III</td>
<td>CDC, 1995; Dennehy et al., in Feigin and Cherry, 1992; CDC, 1990a</td>
<td>Prevent Hepatitis B infection and subsequent liver disease. HBV helps prevent individuals from contracting Hepatitis B and helps decrease the chances of it spreading through a community.</td>
<td></td>
</tr>
<tr>
<td>20.</td>
<td>All children whose mothers are known to be HBsAg-Positive at birth should receive HBIG and HBV by the beginning of the twelfth hour of life.</td>
<td>I, III</td>
<td>CDC, 1995; AAP, 1992 and 1994; Dennehy et al., in Feigin and Cherry, 1992; CDC, 1990a</td>
<td>Prevent perinatal or subsequent transmission of Hepatitis B from the mother. Prevent liver disease from Hepatitis B. HBV helps prevent individuals from contracting Hepatitis B and helps decrease the chances of it spreading through a community. HBIG helps prevent the child from contracting Hepatitis B over the short run.</td>
<td></td>
</tr>
<tr>
<td>21.</td>
<td>All children whose mothers are known to be HBsAg-Positive should have had three HBV by the beginning of the ninth month of life.*</td>
<td>I, III</td>
<td>CDC, 1995; AAP, 1992 and 1994; Dennehy et al., in Feigin and Cherry, 1992; CDC, 1990a</td>
<td>Prevent perinatal or subsequent transmission of Hepatitis B from the mother. Prevent liver disease from Hepatitis B. HBV helps prevent individuals from contracting Hepatitis B and helps decrease the chances of it spreading through a community. Given that the child has a known risk of becoming infected with Hepatitis B, it seems reasonable to provide a narrower grace period for vaccination.</td>
<td></td>
</tr>
<tr>
<td>22.</td>
<td>All children whose mother’s HBsAg status is not known should receive HBV by the beginning of the twelfth hour of life.</td>
<td>I, III</td>
<td>CDC, 1995; AAP, 1992; AAP in Peter, 1994; Dennehy et al., in Feigin and Cherry, 1992; CDC, 1990a</td>
<td>Prevent perinatal or subsequent transmission of Hepatitis B from the mother. Prevent liver disease from Hepatitis B. HBV helps prevent individuals from contracting Hepatitis B and helps decrease the chances of it spreading through a community.</td>
<td></td>
</tr>
</tbody>
</table>
23. All children whose mother's HBsAg status is not known by the end of the first week of life should receive HBIG.  
   I, III Inferred from CDC, 1995; AAP, 1992; AAP in Peter, 1994; Dennehy et al., in Feigin and Cherry, 1992; CDC, 1990a  
   Prevent perinatal or subsequent transmission of Hepatitis B from the mother. Prevent liver disease from Hepatitis B.  
   While this is not specifically recommended, it seems to flow logically from the recommendation that mothers of unknown Hepatitis B status be checked in time for the child to receive HBIG by the end of the first week of life. HBIG helps prevent the child from contracting Hepatitis B over the short run.

24. Adolescents with any of the following risk factors should receive the full three-part HBV series within one year of the clinician becoming aware of the risk factor:  
   – have a history of sexually transmitted infection;  
   – have had more than one sexual partner in the previous six months;  
   – use injection drugs;  
   – are males who are sexually active with other males;  
   – are sexual contacts of high-risk individuals;  
   – have tasks as employees, volunteers, or trainees that involve contact with blood or blood-contaminated body fluids.  
   I, III AAP in Peter, 1994; Dennehy et al., in Feigin and Cherry, 1992; CDC, 1990a  
   Prevent infection with Hepatitis B. Prevent liver disease from Hepatitis B.  
   The AAP does not make this recommendation in as strong a manner as it makes other vaccine recommendations. There appears to be concern about the increased cost of the vaccine in adolescents compared to children (because of a larger dose). However, in an environment in which there is a risk of underuse, particularly of expensive therapies, Hepatitis B vaccine may be susceptible to omission. HBV helps prevent individuals from contracting Hepatitis B and helps decrease the chances of it spreading through a community.

### Influenza

25. Children with asthma and other chronic pulmonary diseases, hemodynamically significant cardiac disease, hemoglobinopathies (e.g., sickle cell disease) or undergoing immunosuppressive therapy should receive a yearly influenza vaccine. Other children at high risk may also benefit from an annual influenza vaccine, including those with: HIV infection, diabetes mellitus, chronic renal disease, and chronic metabolic diseases.  
   I-III CDC, 1994a; AAP, 1994; Dennehy et al., in Feigin and Cherry, 1992; CDC, 1991a  
   Prevent pneumonia. Prevent mortality from influenza.  
   The influenza vaccine has been shown to prevent influenza. Patients at risk for developing complications from influenza should be vaccinated.

### General Indicators

26. An inquiry should be made before each new set of immunizations (or after each prior set) about reactions to prior vaccines.  
   III Inferred from AAP in Peter, 1994; CDC, 1993b  
   Prevent potentially life-threatening immunization reactions.  
   If consent forms that mention prior reactions are used, these may substitute for a specific notation in the chart.

27. Children who have had an anaphylactic reaction to a prior vaccine should not receive that vaccine again.  
   III AAP in Peter, 1994; CDC, 1993b  
   Prevent potentially life-threatening immunization reactions.  
   It will usually be unclear which vaccine caused the reaction, so presumably all given just prior to the reaction will be discontinued.

28. Each immunization given at that institution should be documented with the date of administration, manufacturer, lot number, and name of health care provider administering the vaccine.  
   III Dennehy et al., in Feigin and Cherry, 1992  
   Prevent infectious diseases covered by vaccines.  
   Proper documentation enables reimmunization if a batch is subsequently found to be bad.

### Catch-Up Immunizations
| 29. | Children at least 8 months old but less than 5 years old who are behind on their immunizations should receive three OPV/IPV, four DTP/DTaP/Td, three Hib, three HBV, and one MMR within one year of the first visit with the managed care provider. | III | CDC, 1994 | Prevent infectious diseases covered by each vaccine. | The guidelines start at 4 months old, but most children less than 8 months should be able to catch up easily by one year. Depending on the type of Hib, either three or four would be required; therefore, the indicator requires three so that the brand of Hib does not need to be specified. |
| 30. | Children at least 5 years old but less than 7 years old who are behind on their immunizations should receive three OPV/IPV, four DTP/DTaP/Td, three HBV, and one MMR within one year of the first visit with the managed care provider. | III | CDC, 1994 | Prevent infectious diseases covered by each vaccine. | This guideline is separated from the prior one because children should not receive Hib after their fifth birthday. |
| 31. | Children who are at least 7 years old but less than 18 years old and who are behind on their immunizations should have had three OPV/IPV, three Td, and two MMR within one year of the first visit with the managed care provider. | III | CDC, 1994 | Prevent infectious diseases covered by each vaccine. | Though the pertussis vaccine is not usually given after the seventh birthday, a tetanus formulation that includes pertussis will be considered acceptable. |

**Prior Immunization Record**

| 32. | For children less than five years old who are new to the practice, there should be a notation of prior immunization history or a notation of an effort to obtain such information (e.g., parent will call in or bring it to next visit, letter will be sent to prior provider) at the first visit. | III | Prevent infectious diseases covered by vaccines. | This indicator does not come directly from recommendations in standard immunization guidelines, but it follows from them. It would be reasonable to omit the age cap. It is included because almost all children become up-to-date on their immunizations shortly after starting school, so it seems reasonable for a physician to take school attendance as a proxy for a complete immunization record, particularly if the parent says it is complete. |
| 33. | If a prior immunization record for a child less than five years old has not been obtained within six months of the first visit, the child should be given catch-up immunizations. | III | Inferred from CDC, 1994 | Prevent infectious diseases covered by vaccines. | This indicator does not come directly from recommendations in standard immunization guidelines, but it seems reasonable. It would be reasonable to omit the age cap. It is included because almost all children become up-to-date on their immunizations shortly after starting school, so it seems reasonable for a physician to take school attendance as a proxy for a complete immunization record, particularly if the parent says it is complete. |

* Any of the following (if documented in the chart) can serve as adequate justification for not having given the particular immunization: Refusal by guardian or persistent contraindication to immunization (for all immunizations, anaphylaxis; for IPV, anaphylactic reaction to streptomycin or neomycin; for DTP, encephalopathy within 7 days of prior DTP, fever at least 40.5 C (105 F) within 48 hours of prior DTP, collapse or shocklike state within 48 hours of prior DTP, seizures within 3 days of prior DTP, at least three hours of persistent inconsolable crying within 48 hours of prior DTP, proven or suspected underlying neurologic disorders; for MMR, anaphylactic reaction to egg ingestion or neomycin, altered immune status other than HIV infection, immunoglobulin administration in the prior 3 months.)

<sup>a</sup>Polio can be asymptomatic or cause a minor illness, aseptic meningitis, asymmetric acute flaccid paralysis with areflexia of the involved limb, residual paralytic disease, bulbar paralysis, or respiratory muscle paralysis. A child who has recently received OPV can spread polio to an immunocompromised contact or become infected with polio if he/she is immunocompromised.
Diphtheria can cause membranous nasopharyngitis, obstructive laryngotracheitis, subcutaneous infection, vaginal infection, conjunctival infection, otic infection, thrombocytopenia, myocarditis, or neurologic problems such as vocal cord paralysis or ascending paralysis.

Tetanus can cause neurologic disease with severe muscle spasms, which generally last more than one week, and subside over 6 weeks if the person recovers.

Pertussis can cause mild upper respiratory symptoms, severe paroxysms of coughing, and vomiting. Symptoms can last 6-10 weeks. It can cause apnea in children less than 6 months old. Complications include seizures, pneumonia, encephalopathy, and death.

Haemophilus influenzae type B can cause meningitis, epiglottitis, septic arthritis, etc.

Complications of measles include otitis media, bronchopneumonia, laryngotraceobronchitis, croup, diarrhea, encephalitis (which can cause permanent brain damage), death, and subacute sclerosing panencephalitis (SSPE; causes behavioral and intellectual deterioration and convulsions).

Mumps causes swelling of salivary glands, meningeal signs, encephalitis, orchitis in post-pubescent males (which can cause sterility), other rare complications, and death.

Rubella can cause mild disease with rare complications. The major concern is that it can be spread to pregnant women (not previously infected) and cause serious congenital anomalies.

Quality of Evidence Codes:

I: RCT
II-1: Nonrandomized controlled trials
II-2: Cohort or case analysis
II-3: Multiple time series
III: Opinions or descriptive studies

Note: There are multiple legitimate reasons why a child might not have received immunizations for which he/she was due at a particular visit. However, these reasons should not vary by location and should be infrequent enough so that they should not have a major impact on quality indicators. The time period over which these indicators expect immunizations to have been given is broad enough that most children who had a high fever or other transient illness at any particular visit should have had ample opportunity to catch up.

Note: We will try to collect the exact date of immunization so that we can do a sensitivity analysis on the impact of having shorter or longer grace periods for giving immunizations after the recommended age and on the impact of creating a graded scale for the length of delay (e.g., one point off for a one month delay, ten points off for a one year delay).
REFERENCES - CHILDHOOD IMMUNIZATION


Greenberg MA, and DL Birx. September 1988. Safe administration of mumps-


