ICSI
Institute for Clinical Systems Improvement

Health Care Guideline:

Immunizations Update

The Immunization Update is designed to provide you with current information and prevention recommendations on Immunizations as released by the Centers for Disease Control that come in between the full revision of the guideline. Below is a list of the updates currently published and the affected immunizations.

Immunization Update May 2013

The ICSI Immunizations work group has created new recommendations for the Tdap vaccination and has re-written Annotation #9. In addition, the recommendations for the meningococcal vaccine have been modified. Therefore, Annotations #19 and 23 have been updated.

As a result of the new meningococcal combined vaccine, Annotation #10 for Hib has also been revised.

ICSI Institute for Clinical Systems Improvement

Health Care Guideline
Immunizations

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Immunization Administration Algorithm

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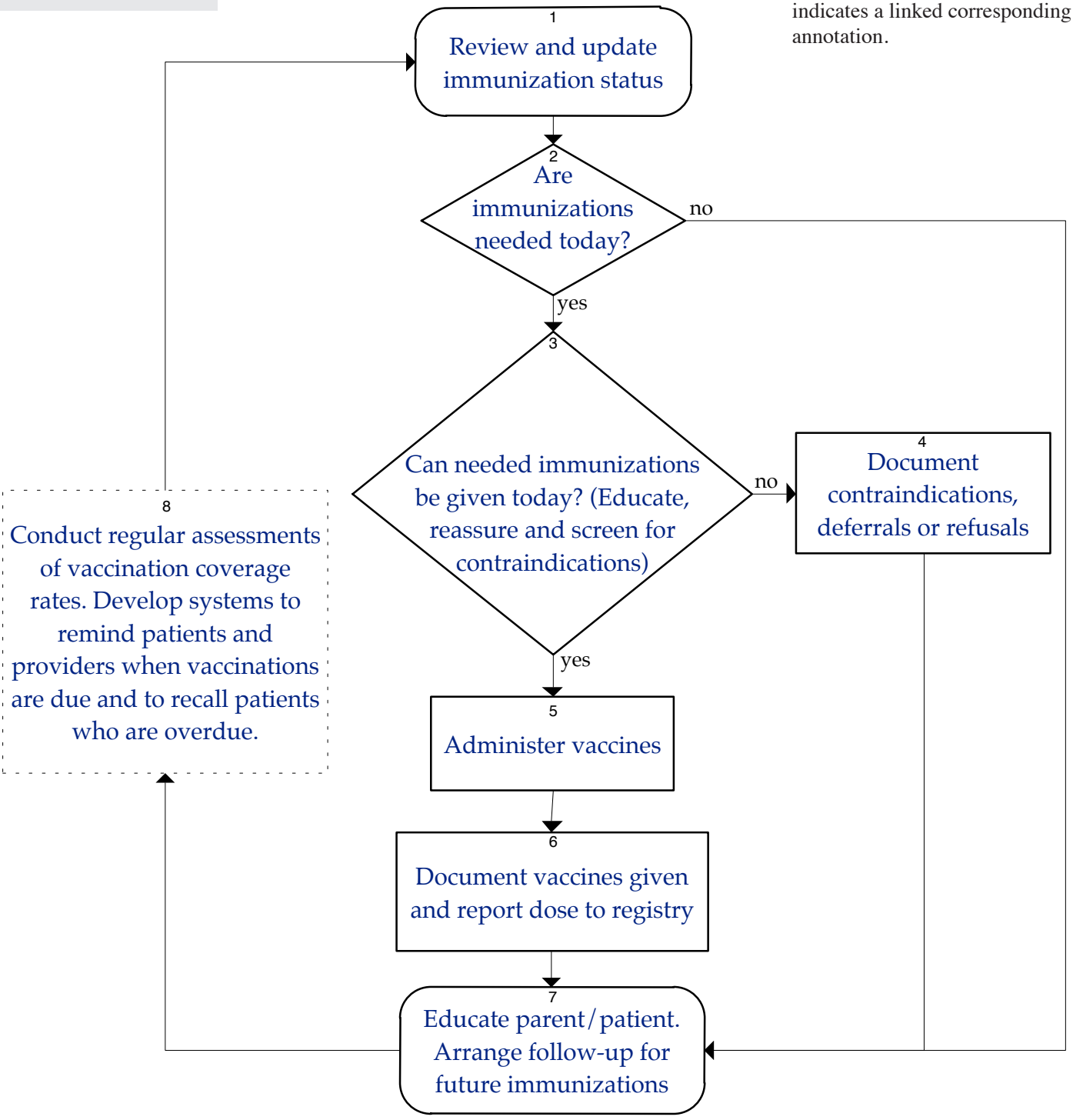
Text in blue in this algorithm indicates a linked corresponding annotation.



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Recommended and Minimum Ages and Intervals Between Doses of Routinely Recommended Vaccines

Vaccine and dose number	Recommended age for this dose	Minimum age for this dose	Recommended interval to next dose	Minimum interval to next dose
Hepatitis B (HepB)-1[3]	Birth	Birth	1-4 months	4 weeks
HepB-2	1-2 months	4 weeks	2-17 months	8 weeks
HepB-3[4]	6-18 months	24 weeks	—	—
Diphtheria-tetanus-acellular pertussis (DTaP)-1[3]	2 months	6 weeks	2 months	4 weeks
DTaP-2	4 months	10 weeks	2 months	4 weeks
DTaP-3	6 months	14 weeks	6-12 months	6 months[5,6]
DTaP-4	15-18 months	12 months	3 years	6 months[5]
DTaP-5	4-6 years	4 years	—	—
Haemophilus influenzae type b (Hib)-1[3,7]	2 months	6 weeks	2 months	4 weeks
Hib-2	4 months	10 weeks	2 months	4 weeks
Hib-3[8]	6 months	14 weeks	6-9 months	8 weeks
Hib-4	12-15 months	12 months	—	—
Inactivated poliovirus (IPV)-1[3]	2 months	6 weeks	2 months	4 weeks
IPV-2	4 months	10 weeks	2-14 months	4 weeks
IPV-3	6-18 months	14 weeks	3-5 years	6 months
IPV-4[9]	4-6 years	4 years	—	—
Pneumococcal conjugate (PCV)-1[7]	2 months	6 weeks	8 weeks	4 weeks
PCV-2	4 months	10 weeks	8 weeks	4 weeks
PCV-3	6 months	14 weeks	6 months	8 weeks
PCV-4	12-15 months	12 months	—	—
Measles-mumps-rubella (MMR)-1[10]	12-15 months	12 months	3-5 years	4 weeks
MMR-2[10]	4-6 years	13 months	—	—
Varicella (Var)-1[10]	12-15 months	12 months	3-5 years	12 weeks[11]
Var-2[10]	4-6 years	15 months	—	—
Hepatitis A (HepA)-1	12-23 months	12 months	6-18 months[5]	6 months[5]
HepA-2	≥18 months	18 months	—	—
Influenza, inactivated (TIV)[12]	≥6 months	6 months[13]	1 month	4 weeks
Influenza, live attenuated (LAIV)[12]	2-49 years	2 years	1 month	4 weeks
Meningococcal conjugate (MCV4)-1[14]	11-12 years	2 years	4-5 years	8 weeks
MCV4-2	16 years	11 years (+ 8 weeks)	—	—
Meningococcal polysaccharide (MPSV4)-1[14]	—	2 years[15]	5 years	5 years
MPSV4-2	—	7 years	—	—
Tetanus-diphtheria (Td)	11-12 years	7 years	10 years	5 years
Tetanus-diphtheria-acellular pertussis (Tdap)[16]	≥11 years	7 years	—	—
Pneumococcal polysaccharide (PPSV)-1	—	2 years	5 years	5 years
PPSV-2[17]	—	7 years	—	—
Human papillomavirus (HPV)-1[18]	11-12 years	9 years	2 months	4 weeks
HPV-2	11-12 years (+ 2 months)	9 years (+ 4 weeks)	4 months	12 weeks[19]
HPV-3[19]	11-12 years (+ 6 months)	9 years (+24 weeks)	—	—
Rotavirus (RV)-1[21]	2 months	6 weeks	2 months	4 weeks
RV-2	4 months	10 weeks	2 months	4 weeks
RV-3[21]	6 months	14 weeks	—	—
Herpes zoster[22]	≥60 years	60 years	—	—

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1 Combination vaccines are available. Use of licensed combination vaccines is generally preferred to separate injections of their equivalent component vaccines. When administering combination vaccines, the minimum age for administration is the oldest age for any of the individual components; the minimum interval between doses is equal to the greatest interval of any of the individual components.

2 Information on travel vaccines including typhoid, Japanese encephalitis, and yellow fever, is available at www.cdc.gov/travel. Information on other vaccines that are licensed in the US but not distributed, including anthrax and smallpox, is available at www.bt.cdc.gov.

3 Combination vaccines containing a hepatitis B component (Comvax, Pediarix, and Twinrix) are available. These vaccines should not be administered to infants younger than 6 weeks because of the other components (i.e., Hib, DTaP, HepA, and IPV).

4 HepB-3 should be administered at least 8 weeks after HepB-2 and at least 16 weeks after HepB-1, and should not be administered before age 24 weeks.

5 Calendar months.

6 The minimum recommended interval between DTaP-3 and DTaP-4 is 6 months. However, DTaP-4 need not be repeated if administered at least 4 months after DTaP-3.

7 Children receiving the first dose of Hib or PCV vaccine at age 7 months or older require fewer doses to complete the series.

8 If PRP-OMP (Pedvax-Hib) was administered at ages 2 and 4 months, a dose at age 6 months is not required.

9 A fourth dose is not needed if the third dose was administered on or after the 4th birthday and at least 6 months after the previous dose.

10 Combination measles-mumps-rubella-varicella (MMRV) vaccine can be used for children aged 12 months through 12 years. (See CDC. General recommendations on Immunization: recommendations of the ACIP. *MMWR* 2011;60[No. RR-2],7.)

11 For persons beginning the series on or after the 13th birthday, the minimum interval from varicella-1 to varicella-2 is 4 weeks.

12 One dose of influenza vaccine per season is recommended for most people. Children younger than 9 years of age who are receiving influenza vaccine for the first time should receive 2 doses this season. See current influenza recommendations for other factors affecting the decision to administer one vs. two doses to children younger than 9 years.

13 The minimum age for inactivated influenza vaccine varies by vaccine manufacturer and formulation. See package inserts for vaccine-specific minimum ages.

14 Revaccination with meningococcal vaccine is recommended for previously vaccinated persons who remain at high risk for meningococcal disease. (See CDC. Updated recommendations from the ACIP for vaccination of persons at prolonged increased risk for meningococcal disease. *MMWR* 2009;58:[1042-3])

15 Menactra may be given as young as 9 months for high-risk children.

16 Only one dose of Tdap is recommended. Subsequent doses should be given as Td. For one brand of Tdap (Adacel), the minimum age is 11 years. For management of a tetanus-prone wound in a person who has received a primary series of a tetanus-toxoid containing vaccine, there is no minimum interval between a previous dose of any tetanus-containing vaccine and Tdap.

17 A second dose of PPSV 5 years after the first dose is recommended for persons ≤65 years of age at highest risk for serious pneumococcal infection, and for those who are likely to have a rapid decline in pneumococcal antibody concentration. (See CDC. Prevention of pneumococcal disease: recommendations of the ACIP. *MMWR* 1997;46[No. RR-8].)

18 Bivalent HPV vaccine (Cervarix) is approved for females 10 through 25 years of age. Quadravalent HPV vaccine (Gardasil) is approved for males and females 9 through 26 years of age.

19 The minimum age for HPV-3 is based on the baseline minimum age for the first dose (108 months) and the minimum interval of 24 weeks between the first and third doses. Dose 3 need not be repeated if it is given at least 16 weeks after the first dose (and if the intervals between doses 1 and 2 and doses 2 and 3 are maintained at 4 weeks and 12 weeks, respectively).

20 The first dose of rotavirus must be administered between 6 weeks 0 days and 14 weeks 6 days. The vaccine series should not be started after age 15 weeks 0 days. Rotavirus should not be administered to children older than 8 months 0 days, regardless of the number of doses received before that age.

21 If two doses of Rotarix are administered as age appropriate, a third dose is not necessary.

22 Herpes zoster vaccine is recommended as a single dose for persons 60 years of age and older.

Adapted from Table 1, ACIP General Recommendations on Immunization. February 2012

Vaccines Routinely Administered in the United States

Abbreviation	Vaccine	Trade Name	Manufacturer	Comments
DT	Diphtheria, Tetanus	Generic	Sanofi Pasteur	6 weeks through 6 years
DTaP	Diphtheria, Tetanus, acellular Pertussis	Daptacel®	Sanofi Pasteur	
		Infanrix®	GlaxoSmithKline	
DTaP-HepB-IPV	Diphtheria, Tetanus, acellular Pertussis, Hepatitis B, Polio	Pediarix®	GlaxoSmithKline	
DTaP-IPV	Diphtheria, Tetanus, acellular Pertussis, Polio	Kinrix®	GlaxoSmithKline	5th DTaP and 4th IPV at 4 through 6 years
DTaP-IPV/Hib	Diphtheria, Tetanus, acellular Pertussis, Polio, Hib	Pentacel®	Sanofi Pasteur	
Hib	*Haemophilus Influenzae* Type B	ActHIB®	Sanofi Pasteur	PRP-T
		Hiberix®	GlaxoSmithKline	PRP-T, booster only
		PedvaxHIB®	Merck	PRP-OMP
Hib-HepB	*Haemophilus Influenzae* Type B, Hepatitis B	Comvax®	Merck	PRP-OMP and HepB
HepA	Hepatitis A	Havrix®	GlaxoSmithKline	Pediatric formulation, 1 through 18 years, 0.5 mL Adult formulation, 19 years and older, 1 mL
		Vaqta®	Merck	
HepB	Hepatitis B	Engerix-B®	GlaxoSmithKline	Pediaric formulation, 0 through 19 years, 0.5 mL Adult formulation, 20 years and older, 1 mL
		Recombivax HB®	Merck	
HepA-HepB	Hepatitis A, Hepatitis B	Twinrix®	GlaxoSmithKline	18 years and older
HPV2	Human Papillomavirus (bivalent)	Cervarix®	GlaxoSmithKline	Types 16, 18; females, 10 through 26 years
HPV4	Human Papillomavirus (quadrivalent)	Gardasil®	Merck	Types 6, 11, 16, 18; males and females, 9 through 26 years

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Abbreviation	Vaccine	Trade Name	Manufacturer	Comments
TIV	Influenza (injectable)	Afluria®	CSL	5 years and older
		Fluarix®	GlaxoSmithKline	3 years and older
		FluLaval®	GlaxoSmithKline	18 years and older
		Fluvirin®	Novartis	4 years and older
		Fluzone®	Sanofi Pasteur	6 months and older
TIV HD	Influenza High-Dose (injectable)	Fluzone HD®	Sanofi Pasteur	65 years and older
TIV ID	Influenza (intradermal)	Fluzone ID®	Sanofi Pasteur	18 through 64 years
LAIV	Influenza (intranasal)	FluMist®	MedImmune	2 through 49 years
MMR	Measles, Mumps, Rubella	M-M-R® II	Merck	
MMRV	Measles, Mumps, Rubella, Varicella	ProQuad®	Merck	1 through 12 years
MCV4-D	Meningococcal conjugate	Menactra®	Sanofi Pasteur	9 months through 55 years
MCV4-CRM	Meningococcal conjugate	Menveo®	Novartis	2 through 55 years
MPSV4	Meningococcal polysaccharide	Menomune®	Sanofi Pasteur	2 years and older
PCV13	Pneumococcal conjugate	Prevnar 13®	Wyeth	
PPSV23	Pneumococcal polysaccharide	PNEUMOVAX® 23	Merck	2 years and older
IPV	Polio	Ipol®	Sanofi Pasteur	
RV1	Rotavirus (monovalent)	Rotarix®	GlaxoSmithKline	
RV5	Rotavirus (pentavalent)	RotaTeq®	Merck	
Td	Tetanus, Diphtheria	Tenivac	Sanofi Pasteur	7 years and older
		Generic	Massachusetts Biological Labs	
Tdap	Tetanus, Diphtheria, Acellular Pertussis	Adacel®	Sanofi Pasteur	
		Boostrix®	GlaxoSmithKline	
VAR	Varicella	Varivax®	Merck	
ZOS	Herpes Zoster (Shingles)	Zostavax	Merck	50 years and older

Refer to **Current Vaccine Shortages and Delays (CDC)** for information about vaccine supplies, shortages or delays.

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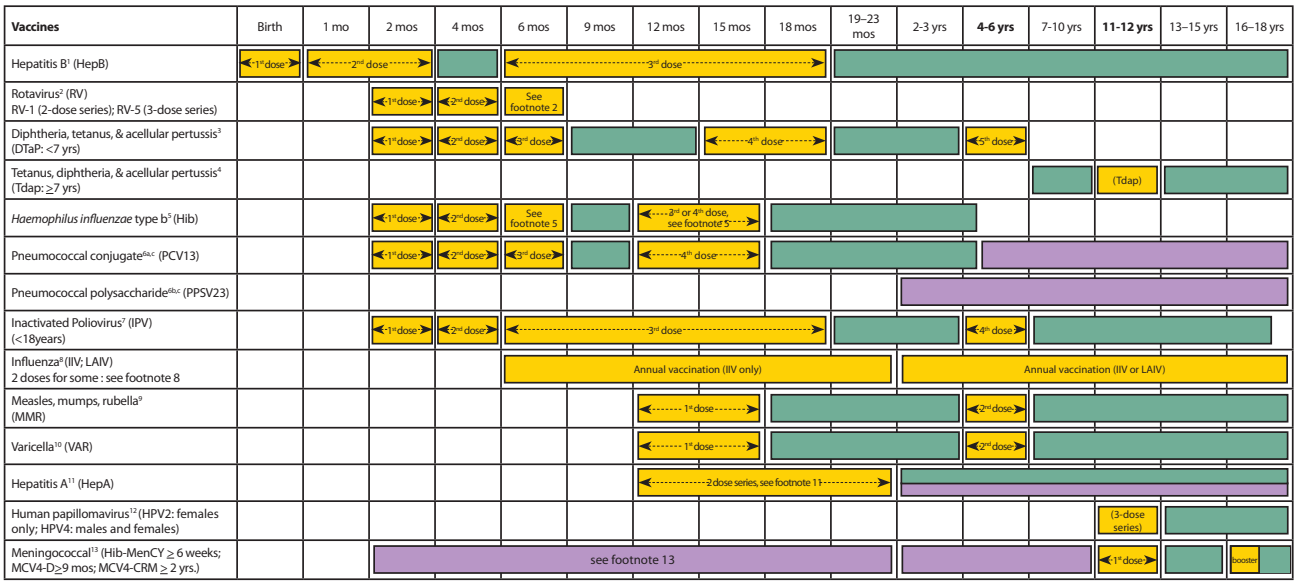
Figure 1. Recommended immunization schedule for persons aged 0 through 18 years – 2013.

(FOR THOSE WHO FALL BEHIND OR START LATE, SEE THE CATCH-UP SCHEDULE [FIGURE 2]).

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are in bold.



This schedule includes recommendations in effect as of January 1, 2013. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at http://www.cdc.gov/vaccines/pubs/acip-list.htm. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (http://www.vaers.hhs.gov) or by telephone (800-822-7967).Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (http://www.cdc.gov/vaccines) or by telephone (800-CDC-INFO [800-232-4636]).

This schedule is approved by the Advisory Committee on Immunization Practices (http://www.cdc.gov/vaccines/acip/index.html), the American Academy of Pediatrics (http://www.aap.org), the American Academy of Family Physicians (http://www.aafp.org), and the American College of Obstetricians and Gynecologists (http://www.acog.org).

NOTE: The above recommendations must be read along with the footnotes of this schedule.

Footnotes — Recommended immunization schedule for persons aged 0 through 18 years—United States, 2013

For further guidance on the use of the vaccines mentioned below, see: http://www.cdc.gov/vaccines/pubs/acip-list.htm.

1. **Hepatitis B (HepB) vaccine. (Minimum age: birth)**
   Routine vaccination:
   At birth
   - Administer monovalent HepB vaccine to all newborns before hospital discharge.
   - For infants born to hepatitis B surface antigen (HBsAg)–positive mothers, administer HepB vaccine and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth. These infants should be tested for HBsAg and antibody to HBsAg (anti-HBs) 1 to 2 months after completion of the HepB series, at age 9 through 18 months (preferably at the next well-child visit).
   - If mother's HBsAg status is unknown, within 12 hours of birth administer HepB vaccine to all infants regardless of birth weight. For infants weighing <2,000 grams, administer HBIG in addition to HepB within 12 hours of birth. Determine mother's HBsAg status as soon as possible and, if she is HBsAg-positive, also administer HBIG for infants weighing ≥2,000 grams (no later than age 1 week).

   Doses following the birth dose
   - The second dose should be administered at age 1 or 2 months. Monovalent HepB vaccine should be used for doses administered before age 6 weeks.
   - Infants who did not receive a birth dose should receive 3 doses of a HepB-containing vaccine on a schedule of 0, 1 to 2 months, and 6 months starting as soon as feasible. See Figure 2.
   - The minimum interval between dose 1 and dose 2 is 4 weeks and between dose 2 and 3 is 8 weeks. The final (third or fourth) dose in the HepB vaccine series should be administered no earlier than age 24 weeks, and at least 16 weeks after the first dose.
   - Administration of a total of 4 doses of HepB vaccine is recommended when a combination vaccine containing HepB is administered after the birth dose.

   Catch-up vaccination:
   - Unvaccinated persons should complete a 3-dose series.
   - A 2-dose series (doses separated by at least 4 months) of adult formulation Recombivax HB is licensed for use in children aged 11 through 15 years.
   - For other catch-up issues, see Figure 2.
2. **Rotavirus (RV) vaccines. (Minimum age: 6 weeks for both RV-1 [Rotarix] and RV-5 [RotaTeq]).**
   Routine vaccination:
   - Administer a series of RV vaccine to all infants as follows:
     1. If RV-1 is used, administer a 2-dose series at 2 and 4 months of age.
     2. If RV-5 is used, administer a 3-dose series at ages 2, 4, and 6 months.
     3. If any dose in series was RV-5 or vaccine product is unknown for any dose in the series, a total of 3 doses of RV vaccine should be administered.

   Catch-up vaccination:
   - The maximum age for the first dose in the series is 14 weeks, 6 days.
   - Vaccination should not be initiated for infants aged 15 weeks 0 days or older.
   - The maximum age for the final dose in the series is 8 months, 0 days.
   - If RV-1(Rotarix) is administered for the first and second doses, a third dose is not indicated.
   - For other catch-up issues, see Figure 2.
3. **Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine. (Minimum age: 6 weeks)**
   Routine vaccination:
   - Administer a 5-dose series of DTaP vaccine at ages 2, 4, 6, 15–18 months, and 4 through 6 years. The fourth dose may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose.

   Catch-up vaccination:
   - The fifth (booster) dose of DTaP vaccine is not necessary if the fourth dose was administered at age 4 years or older.
   - For other catch-up issues, see Figure 2.
4. **Tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine. (Minimum age: 10 years for Boostrix, 11 years for Adacel).**
   Routine vaccination:
   - Administer 1 dose of Tdap vaccine to all adolescents aged 11 through 12 years.
   - Tdap can be administered regardless of the interval since the last tetanus and diphtheria toxoid-containing vaccine.
   - Administer one dose of Tdap vaccine to pregnant adolescents during each pregnancy (preferred during 27 through 36 weeks gestation) regardless of number of years from prior Td or Tdap vaccination.

   Catch-up vaccination:
   - Persons aged 7 through 10 years who are not fully immunized with the childhood DTaP vaccine series, should receive Tdap vaccine as the first dose in the catch-up series; if additional doses are needed, use Td vaccine. For these children, an adolescent Tdap vaccine should not be given.
   - Persons aged 11 through 18 years who have not received Tdap vaccine should receive a dose followed by tetanus and diphtheria toxoids (Td) booster doses every 10 years thereafter.
   - An inadvertent dose of DTaP vaccine administered to children aged 7 through 10 years can count as part of the catch-up series. This dose can count as the adolescent Tdap dose, or the child can later receive a Tdap booster dose at age 11–12 years.
   - For other catch-up issues, see Figure 2.
5. ***Haemophilus influenzae* type b (Hib) conjugate vaccine. (Minimum age: 6 weeks)**
   Routine vaccination:
   - Administer a Hib vaccine primary series and a booster dose to all infants. The primary series doses should be administered at 2, 4, and 6 months of age; however, if PRP-OMP (PedvaxHib or Comvax) is administered at 2 and 4 months of age, a dose at age 6 months is not indicated. One booster dose should be administered at age 12 through15 months.
   - Hiberix (PRP-T) should only be used for the booster (final) dose in children aged 12 months through 4 years, who have received at least 1 dose of Hib.

   Catch-up vaccination:
   - If dose 1 was administered at ages 12-14 months, administer booster (as final dose) at least 8 weeks after dose 1.
   - If the first 2 doses were PRP-OMP (PedvaxHIB or Comvax), and were administered at age 11 months or younger, the third (and final) dose should be administered at age 12 through 15 months and at least 8 weeks after the second dose.
   - If the first dose was administered at age 7 through 11 months, administer the second dose at least 4 weeks later and a final dose at age 12 through 15 months, regardless of Hib vaccine (PRP-T or PRP-OMP) used for first dose.
   - For unvaccinated children aged 15 months or older, administer only 1 dose.

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For further guidance on the use of the vaccines mentioned below, see: http://www.cdc.gov/vaccines/pubs/acip-list.htm.

- For other catch-up issues, see Figure 2.

Vaccination of persons with high-risk conditions:

- Hib vaccine is not routinely recommended for patients older than 5 years of age. However one dose of Hib vaccine should be administered to unvaccinated or partially vaccinated persons aged 5 years or older who have leukemia, malignant neoplasms, anatomic or functional asplenia (including sickle cell disease), human immunodeficiency virus (HIV) infection, or other immunocompromising conditions.

6a. Pneumococcal conjugate vaccine (PCV). (Minimum age: 6 weeks)

Routine vaccination:

- Administer a series of PCV13 vaccine at ages 2, 4, 6 months with a booster at age 12 through 15 months.
- For children aged 14 through 59 months who have received an age-appropriate series of 7-valent PCV (PCV7), administer a single supplemental dose of 13-valent PCV (PCV13).

Catch-up vaccination:

- Administer 1 dose of PCV13 to all healthy children aged 24 through 59 months who are not completely vaccinated for their age.
- For other catch-up issues, see Figure 2.

Vaccination of persons with high-risk conditions:

- For children aged 24 through 71 months with certain underlying medical conditions (see footnote 6c), administer 1 dose of PCV13 if 3 doses of PCV were received previously, or administer 2 doses of PCV13 at least 8 weeks apart if fewer than 3 doses of PCV were received previously.
- A single dose of PCV13 may be administered to previously unvaccinated children aged 6 through 18 years who have anatomic or functional asplenia (including sickle cell disease), HIV infection or an immunocompromising condition, cochlear implant or cerebrospinal fluid leak. See MMWR 2010;59 (No. RR-11), available at http://www.cdc.gov/mmwr/pdf/rr/rr5911.pdf.
- Administer PPSV23 at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions (see footnotes 6b and 6c).

6b. Pneumococcal polysaccharide vaccine (PPSV23). (Minimum age: 2 years)

Vaccination of persons with high-risk conditions:

- Administer PPSV23 at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions (see footnote 6c). A single revaccination with PPSV should be administered after 5 years to children with anatomic or functional asplenia (including sickle cell disease) or an immunocompromising condition.

6c. Medical conditions for which PPSV23 is indicated in children aged 2 years and older and for which use of PCV13 is indicated in children aged 24 through 71 months:

- Immunocompetent children with chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy), diabetes mellitus; cerebrospinal fluid leaks; or cochlear implant.
- Children with anatomic or functional asplenia (including sickle cell disease and other hemoglobinopathies, congenital or acquired asplenia, or splenic dysfunction);
- Children with immunocompromising conditions: HIV infection, chronic renal failure and nephrotic syndrome, diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas and Hodgkin disease; or solid organ transplantation, congenital immunodeficiency.

7. Inactivated poliovirus vaccine (IPV). (Minimum age: 6 weeks)

Routine vaccination:

- Administer a series of IPV at ages 2, 4, 6–18 months, with a booster at age 4–6 years. The final dose in the series should be administered on or after the fourth birthday and at least 6 months after the previous dose.

Catch-up vaccination:

- In the first 6 months of life, minimum age and minimum intervals are only recommended if the person is at risk for imminent exposure to circulating poliovirus (i.e., travel to a polio-endemic region or during an outbreak).
- If 4 or more doses are administered before age 4 years, an additional dose should be administered at age 4 through 6 years.
- A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.
- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.
- IPV is not routinely recommended for U.S. residents aged 18 years or older.
- For other catch-up issues, see Figure 2.

8. Influenza vaccines. (Minimum age: 6 months for inactivated influenza vaccine [IIV]; 2 years for live, attenuated influenza vaccine [LAIV])

Routine vaccination:

- Administer influenza vaccine annually to all children beginning at age 6 months. For most healthy, nonpregnant persons aged 2 through 49 years, either LAIV or IIV may be used. However, LAIV should NOT be administered to some persons, including 1) those with asthma, 2) children 2 through 4 years who had wheezing in the past 12 months, or 3) those who have any other underlying medical conditions that predispose them to influenza complications. For all other contraindications to use of LAIV see MMWR 2010; 59 (No. RR-8), available at http://www.cdc.gov/mmwr/pdf/rr/rr5908.pdf.
- Administer 1 dose to persons aged 9 years and older.

For children aged 6 months through 8 years:

- For the 2012–13 season, administer 2 doses (separated by at least 4 weeks) to children who are receiving influenza vaccine for the first time. For additional guidance, follow dosing guidelines in the 2012 ACIP influenza vaccine recommendations, MMWR 2012; 61: 613–618, available at http://www.cdc.gov/mmwr/pdf/wk/mm6132.pdf.
- For the 2013–14 season, follow dosing guidelines in the 2013 ACIP influenza vaccine recommendations.

9. Measles, mumps, and rubella (MMR) vaccine. (Minimum age: 12 months for routine vaccination)

Routine vaccination:

- Administer the first dose of MMR vaccine at age 12 through 15 months, and the second dose at age 4 through 6 years. The second dose may be administered before age 4 years, provided at least 4 weeks have elapsed since the first dose.
- Administer 1 dose of MMR vaccine to infants aged 6 through 11 months before departure from the United States for international travel. These children should be revaccinated with 2 doses of MMR vaccine, the first at age 12 through 15 months (12 months if the child remains in an area where disease risk is high), and the second dose at least 4 weeks later.
- Administer 2 doses of MMR vaccine to children aged 12 months and older, before departure from the United States for international travel. The first dose should be administered on or after age 12 months and the second dose at least 4 weeks later.

Catch-up vaccination:

- Ensure that all school-aged children and adolescents have had 2 doses of MMR vaccine; the minimum interval between the 2 doses is 4 weeks.

10. Varicella (VAR) vaccine. (Minimum age: 12 months)

Routine vaccination:

- Administer the first dose of VAR vaccine at age 12 through 15 months, and the second dose at age 4 through 6 years. The second dose may be administered before age 4 years, provided at least 3 months have elapsed since the first dose. If the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.

Catch-up vaccination:

- Ensure that all persons aged 7 through 18 years without evidence of immunity (see MMWR 2007;56 [No. RR-4], available at http://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf) have 2 doses of varicella vaccine. For children aged 7 through 12 years the recommended minimum interval between doses is 3 months (if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid); for persons aged 13 years and older, the minimum interval between doses is 4 weeks.

11. Hepatitis A vaccine (HepA). (Minimum age: 12 months)

Routine vaccination:

- Initiate the 2-dose HepA vaccine series for children aged 12 through 23 months; separate the 2 doses by 6 to 18 months.
- Children who have received 1 dose of HepA vaccine before age 24 months, should receive a second dose 6 to 18 months after the first dose.
- For any person aged 2 years and older who has not already received the HepA vaccine series, 2 doses of HepA vaccine separated by 6 to 18 months may be administered if immunity against hepatitis A virus infection is desired.

Catch-up vaccination:

- The minimum interval between the two doses is 6 months.

Special populations:

- Administer 2 doses of Hep A vaccine at least 6 months apart to previously unvaccinated persons who live in areas where vaccination programs target older children, or who are at increased risk for infection.

12. Human papillomavirus (HPV) vaccines. (HPV4 [Gardasil] and HPV2 [Cervarix]). (Minimum age: 9 years)

Routine vaccination:

- Administer a 3-dose series of HPV vaccine on a schedule of 0, 1-2, and 6 months to all adolescents aged 11-12 years. Either HPV4 or HPV2 may be used for females, and only HPV4 may be used for males.
- The vaccine series can be started beginning at age 9 years.
- Administer the second dose 1 to 2 months after the **first** dose and the third dose 6 months after the **first** dose (at least 24 weeks after the first dose).

Catch-up vaccination:

- Administer the vaccine series to females (either HPV2 or HPV4) and males (HPV4) at age 13 through 18 years if not previously vaccinated.
- Use recommended routine dosing intervals (see above) for vaccine series catch-up.

13. Meningococcal conjugate vaccines (MCV). (Minimum age: 6 weeks for Hib-MenCY, 9 months for Menactra [MCV4-D], 2 years for Menveo [MCV4-CRM]).

Routine vaccination:

- Administer MCV4 vaccine at age 11–12 years, with a booster dose at age 16 years.
- Adolescents aged 11 through 18 years with human immunodeficiency virus (HIV) infection should receive a 2-dose primary series of MCV4, with at least 8 weeks between doses. See MMWR 2011; 60:1018–1019 available at: http://www.cdc.gov/mmwr/pdf/wk/mm6030.pdf.
- For children aged 9 months through 10 years with high-risk conditions, see below.

Catch-up vaccination:

- Administer MCV4 vaccine at age 13 through 18 years if not previously vaccinated.
- If the first dose is administered at age 13 through 15 years, a booster dose should be administered at age 16 through 18 years with a minimum interval of at least 8 weeks between doses.
- If the first dose is administered at age 16 years or older, a booster dose is not needed.
- For other catch-up issues, see Figure 2.

Vaccination of persons with high-risk conditions:

- For children younger than 19 months of age with anatomic or functional asplenia (including sickle cell disease), administer an infant series of Hib-MenCY at 2, 4, 6, and 12-15 months.
- For children aged 2 through 18 months with persistent complement component deficiency, administer either an infant series of Hib-MenCY at 2, 4, 6, and 12 through 15 months or a 2-dose primary series of MCV4-D starting at 9 months, with at least 8 weeks between doses. For children aged 19 through 23 months with persistent complement component deficiency who have not received a complete series of Hib-MenCY or MCV4-D, administer 2 primary doses of MCV4-D at least 8 weeks apart.
- For children aged 24 months and older with persistent complement component deficiency or anatomic or functional asplenia (including sickle cell disease), who have not received a complete series of Hib-MenCY or MCV4-D, administer 2 primary doses of either MCV4-D or MCV4-CRM. If MCV4-D (Menactra) is administered to a child with asplenia (including sickle cell disease), do not administer MCV4-D until 2 years of age and at least 4 weeks after the completion of all PCV13 doses. See MMWR 2011;60:1391–2, available at http://www.cdc.gov/mmwr/pdf/wk/mm6040.pdf.
- For children aged 9 months and older who are residents of or travelers to countries in the African meningitis belt or to the Hajj, administer an age appropriate formulation and series of MCV4 for protection against serogroups A and W-135. Prior receipt of Hib-MenCY is not sufficient for children traveling to the meningitis belt or the Hajj. See MMWR 2011;60:1391–2, available at http://www.cdc.gov/mmwr/pdf/wk/mm6040.pdf.
- For children who are present during outbreaks caused by a vaccine serogroup, administer or complete an age and formulation-appropriate series of Hib-MenCY or MCV4.
- For booster doses among persons with high-risk conditions refer to http://www.cdc.gov/vaccines/pubs/acip-list.htm#mening.

Additional information

- For contraindications and precautions to use of a vaccine and for additional information regarding that vaccine, vaccination providers should consult the relevant ACIP statement available online at http://www.cdc.gov/vaccines/pubs/acip-list.htm.
- For the purposes of calculating intervals between doses, 4 weeks = 28 days. Intervals of 4 months or greater are determined by calendar months.
- Information on travel vaccine requirements and recommendations is available at http://wwwnc.cdc.gov/travel/page/vaccinations.htm.
- For vaccination of persons with primary and secondary immunodeficiencies, see Table 13, "Vaccination of persons with primary and secondary immunodeficiencies," in General Recommendations on Immunization (ACIP), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm; and American Academy of Pediatrics. Passive immunization. In: Pickering LK, Baker CJ, Kimberlin DW, Long SS eds. Red book: 2012 report of the Committee on Infectious Diseases. 29th ed. Elk Grove Village, IL: American Academy of Pediatrics.

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FIGURE 2. Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind —United States • 2013

The figure below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. Always use this table in conjunction with Figure 1 and the footnotes that follow.

Persons aged 4 months through 6 years					
Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to dose 2	Dose 2 to dose 3	Dose 3 to dose 4	Dose 4 to dose 5
Hepatitis B[1]	Birth	4 weeks	8 weeks and at least 16 weeks after first dose; minimum age for the final dose is 24 weeks		
Rotavirus[2]	6 weeks	4 weeks	4 weeks[2]		
Diphtheria, tetanus, pertussis[3]	6 weeks	4 weeks	4 weeks	6 months	6 months[3]
Haemophilus influenzae type b[5]	6 weeks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose) if first dose administered at age 12–14 months No further doses needed if first dose administered at age 15 months or older	4 weeks[5] if current age is younger than 12 months 8 weeks (as final dose)[5] if current age is 12 months or older and first dose administered at younger than age 12 months and second dose administered at younger than 15 months No further doses needed if previous dose administered at age 15 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 through 59 months who received 3 doses before age 12 months	
Pneumococcal[6]	6 weeks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose for healthy children) if first dose administered at age 12 months or older or current age 24 through 59 months No further doses needed for healthy children if first dose administered at age 24 months or older	4 weeks if current age is younger than 12 months 8 weeks (as final dose for healthy children) if current age is 12 months or older No further doses needed for healthy children if previous dose administered at age 24 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 through 59 months who received 3 doses before age 12 months or for children at high risk who received 3 doses at any age	
Inactivated poliovirus[7]	6 weeks	4 weeks	4 weeks	6 months[7] minimum age 4 years for final dose	
Meningococcal[13]	6 weeks	8 weeks[13]	see footnote 13	see footnote 13	
Measles, mumps, rubella[9]	12 months	4 weeks			
Varicella[10]	12 months	3 months			
Hepatitis A[11]	12 months	6 months			
Persons aged 7 through 18 years					
Tetanus, diphtheria; tetanus, diphtheria, pertussis[4]	7 years[4]	4 weeks	4 weeks if first dose administered at younger than age 12 months 6 months if first dose administered at 12 months or older	6 months if first dose administered at younger than age 12 months	
Human papillomavirus[12]	9 years	Routine dosing intervals are recommended[12]			
Hepatitis A[11]	12 months	6 months			
Hepatitis B[1]	Birth	4 weeks	8 weeks (and at least 16 weeks after first dose)		
Inactivated poliovirus[7]	6 weeks	4 weeks	4 weeks[7]	6 months[7]	
Meningococcal[13]	6 weeks	8 weeks[13]			
Measles, mumps, rubella[9]	12 months	4 weeks			
Varicella[10]	12 months	3 months if person is younger than age 13 years 4 weeks if person is aged 13 years or older			

NOTE: The above recommendations must be read along with the footnotes of this schedule.

Footnotes — Recommended immunization schedule for persons aged 0 through 18 years—United States, 2013

For further guidance on the use of the vaccines mentioned below, see: http://www.cdc.gov/vaccines/pubs/acip-list.htm.

1. **Hepatitis B (HepB) vaccine. (Minimum age: birth)**
   Routine vaccination:
   At birth
   - Administer monovalent HepB vaccine to all newborns before hospital discharge.
   - For infants born to hepatitis B surface antigen (HBsAg)–positive mothers, administer HepB vaccine and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth. These infants should be tested for HBsAg and antibody to HBsAg (anti-HBs) 1 to 2 months after completion of the HepB series, at age 9 through 18 months (preferably at the next well-child visit).
   - If mother's HBsAg status is unknown, within 12 hours of birth administer HepB vaccine to all infants regardless of birth weight. For infants weighing <2,000 grams, administer HBIG in addition to HepB within 12 hours of birth. Determine mother's HBsAg status as soon as possible and, if she is HBsAg-positive, also administer HBIG for infants weighing ≥2,000 grams (no later than age 1 week).

   Doses following the birth dose
   - The second dose should be administered at age 1 or 2 months. Monovalent HepB vaccine should be used for doses administered before age 6 weeks.
   - Infants who did not receive a birth dose should receive 3 doses of a HepB-containing vaccine on a schedule of 0, 1 to 2 months, and 6 months starting as soon as feasible. See Figure 2.
   - The minimum interval between dose 1 and dose 2 is 4 weeks and between dose 2 and 3 is 8 weeks. The final (third or fourth) dose in the HepB vaccine series should be administered no earlier than age 24 weeks, and at least 16 weeks after the first dose.
   - Administration of a total of 4 doses of HepB vaccine is recommended when a combination vaccine containing HepB is administered after the birth dose.

   Catch-up vaccination:
   - Unvaccinated persons should complete a 3-dose series.
   - A 2-dose series (doses separated by at least 4 months) of adult formulation Recombivax HB is licensed for use in children aged 11 through 15 years.
   - For other catch-up issues, see Figure 2.

2. **Rotavirus (RV) vaccines. (Minimum age: 6 weeks for both RV-1 [Rotarix] and RV-5 [RotaTeq]).**
   Routine vaccination:
   - Administer a series of RV vaccine to all infants as follows:
     1. If RV-1 is used, administer a 2-dose series at 2 and 4 months of age.
     2. If RV-5 is used, administer a 3-dose series at ages 2, 4, and 6 months.
     3. If any dose in series was RV-5 or vaccine product is unknown for any dose in the series, a total of 3 doses of RV vaccine should be administered.

   Catch-up vaccination:
   - The maximum age for the first dose in the series is 14 weeks, 6 days.
   - Vaccination should not be initiated for infants aged 15 weeks 0 days or older.
   - The maximum age for the final dose in the series is 8 months, 0 days.
   - If RV-1 (Rotarix) is administered for the first and second doses, a third dose is not indicated.
   - For other catch-up issues, see Figure 2.

3. **Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine. (Minimum age: 6 weeks)**
   Routine vaccination:
   - Administer a 5-dose series of DTaP vaccine at ages 2, 4, 6, 15–18 months, and 4 through 6 years. The fourth dose may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose.

   Catch-up vaccination:
   - The fifth (booster) dose of DTaP vaccine is not necessary if the fourth dose was administered at age 4 years or older.
   - For other catch-up issues, see Figure 2.

4. **Tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine. (Minimum age: 10 years for Boostrix, 11 years for Adacel).**
   Routine vaccination:
   - Administer 1 dose of Tdap vaccine to all adolescents aged 11 through 12 years.
   - Tdap can be administered regardless of the interval since the last tetanus and diphtheria toxoid-containing vaccine.

For further guidance on the use of the vaccines mentioned below, see: http://www.cdc.gov/vaccines/pubs/acip-list.htm.

- Administer one dose of Tdap vaccine to pregnant adolescents during each pregnancy (preferred during 27 through 36 weeks gestation) regardless of number of years from prior Td or Tdap vaccination.

Catch-up vaccination:

- Persons aged 7 through 10 years who are not fully immunized with the childhood DTaP vaccine series, should receive Tdap vaccine as the first dose in the catch-up series; if additional doses are needed, use Td vaccine. For these children, an adolescent Tdap vaccine should not be given.
- Persons aged 11 through 18 years who have not received Tdap vaccine should receive a dose followed by tetanus and diphtheria toxoids (Td) booster doses every 10 years thereafter.
- An inadvertent dose of DTaP vaccine administered to children aged 7 through 10 years can count as part of the catch-up series. This dose can count as the adolescent Tdap dose, or the child can later receive a Tdap booster dose at age 11–12 years.
- For other catch-up issues, see Figure 2.

5. *Haemophilus influenzae* type b (Hib) conjugate vaccine. (Minimum age: 6 weeks)

Routine vaccination:

- Administer a Hib vaccine primary series and a booster dose to all infants. The primary series doses should be administered at 2, 4, and 6 months of age; however, if PRP-OMP (PedvaxHib or Comvax) is administered at 2 and 4 months of age, a dose at age 6 months is not indicated. One booster dose should be administered at age 12 through15 months.
- Hiberix (PRP-T) should only be used for the booster (final) dose in children aged 12 months through 4 years, who have received at least 1 dose of Hib.

Catch-up vaccination:

- If dose 1 was administered at ages 12-14 months, administer booster (as final dose) at least 8 weeks after dose 1.
- If the first 2 doses were PRP-OMP (PedvaxHIB or Comvax), and were administered at age 11 months or younger, the third (and final) dose should be administered at age 12 through 15 months and at least 8 weeks after the second dose.
- If the first dose was administered at age 7 through 11 months, administer the second dose at least 4 weeks later and a final dose at age 12 through 15 months, regardless of Hib vaccine (PRP-T or PRP-OMP) used for first dose.
- For unvaccinated children aged 15 months or older, administer only 1 dose.
- For other catch-up issues, see Figure 2.

Vaccination of persons with high-risk conditions:

- Hib vaccine is not routinely recommended for patients older than 5 years of age. However one dose of Hib vaccine should be administered to unvaccinated or partially vaccinated persons aged 5 years or older who have leukemia, malignant neoplasms, anatomic or functional asplenia (including sickle cell disease), human immunodeficiency virus (HIV) infection, or other immunocompromising conditions.

6a. Pneumococcal conjugate vaccine (PCV). (Minimum age: 6 weeks)

Routine vaccination:

- Administer a series of PCV13 vaccine at ages 2, 4, 6 months with a booster at age 12 through 15 months.
- For children aged 14 through 59 months who have received an age-appropriate series of 7-valent PCV (PCV7), administer a single supplemental dose of 13-valent PCV (PCV13).

Catch-up vaccination:

- Administer 1 dose of PCV13 to all healthy children aged 24 through 59 months who are not completely vaccinated for their age.
- For other catch-up issues, see Figure 2.

Vaccination of persons with high-risk conditions:

- For children aged 24 through 71 months with certain underlying medical conditions (see footnote 6c), administer 1 dose of PCV13 if 3 doses of PCV were received previously, or administer 2 doses of PCV13 at least 8 weeks apart if fewer than 3 doses of PCV were received previously.
- A single dose of PCV13 may be administered to previously unvaccinated children aged 6 through 18 years who have anatomic or functional asplenia (including sickle cell disease), HIV infection or an immunocompromising condition, cochlear implant or cerebrospinal fluid leak. See MMWR 2010;59 (No. RR-11), available at http://www.cdc.gov/mmwr/pdf/rr/rr5911.pdf.
- Administer PPSV23 at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions (see footnotes 6b and 6c).

6b. Pneumococcal polysaccharide vaccine (PPSV23). (Minimum age: 2 years)

Vaccination of persons with high-risk conditions:

- Administer PPSV23 at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions (see footnote 6c). A single revaccination with PPSV should be administered after 5 years to children with anatomic or functional asplenia (including sickle cell disease) or an immunocompromising condition.

6c. Medical conditions for which PPSV23 is indicated in children aged 2 years and older and for which use of PCV13 is indicated in children aged 24 through 71 months:

- Immunocompetent children with chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy), diabetes mellitus; cerebrospinal fluid leaks; or cochlear implant.
- Children with anatomic or functional asplenia (including sickle cell disease and other hemoglobinopathies, congenital or acquired asplenia, or splenic dysfunction);
- Children with immunocompromising conditions: HIV infection, chronic renal failure and nephrotic syndrome, diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas and Hodgkin disease; or solid organ transplantation, congenital immunodeficiency.

7. Inactivated poliovirus vaccine (IPV). (Minimum age: 6 weeks)

Routine vaccination:

- Administer a series of IPV at ages 2, 4, 6–18 months, with a booster at age 4–6 years. The final dose in the series should be administered on or after the fourth birthday and at least 6 months after the previous dose.

Catch-up vaccination:

- In the first 6 months of life, minimum age and minimum intervals are only recommended if the person is at risk for imminent exposure to circulating poliovirus (i.e., travel to a polio-endemic region or during an outbreak).
- If 4 or more doses are administered before age 4 years, an additional dose should be administered at age 4 through 6 years.
- A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.
- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.
- IPV is not routinely recommended for U.S. residents aged 18 years or older.
- For other catch-up issues, see Figure 2.

8. Influenza vaccines. (Minimum age: 6 months for inactivated influenza vaccine [IIV]; 2 years for live, attenuated influenza vaccine [LAIV])

Routine vaccination:

- Administer influenza vaccine annually to all children beginning at age 6 months. For most healthy, nonpregnant persons aged 2 through 49 years, either LAIV or IIV may be used. However, LAIV should NOT be administered to some persons, including 1) those with asthma, 2) children 2 through 4 years who had wheezing in the past 12 months, or 3) those who have any other underlying medical conditions that predispose them to influenza complications. For all other contraindications to use of LAIV see MMWR 2010; 59 (No. RR-8), available at http://www.cdc.gov/mmwr/pdf/rr/rr5908.pdf.

Additional information

- For contraindications and precautions to use of a vaccine and for additional information regarding that vaccine, vaccination providers should consult the relevant ACIP statement available online at http://www.cdc.gov/vaccines/pubs/acip-list.htm.
- For the purposes of calculating intervals between doses, 4 weeks = 28 days. Intervals of 4 months or greater are determined by calendar months.
- Information on travel vaccine requirements and recommendations is available at http://wwwnc.cdc.gov/travel/page/vaccinations.htm.
- For vaccination of persons with primary and secondary immunodeficiencies, see Table 13, "Vaccination of persons with primary and secondary immunodeficiencies," in General Recommendations on Immunization (ACIP), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm; and American Academy of Pediatrics. Passive immunization. In: Pickering LK, Baker CJ, Kimberlin DW, Long SS eds. Red book: 2012 report of the Committee on Infectious Diseases. 29th ed. Elk Grove Village, IL: American Academy of Pediatrics.

- Administer 1 dose to persons aged 9 years and older.

For children aged 6 months through 8 years:

- For the 2012–13 season, administer 2 doses (separated by at least 4 weeks) to children who are receiving influenza vaccine for the first time. For additional guidance, follow dosing guidelines in the 2012 ACIP influenza vaccine recommendations, MMWR 2012; 61: 613–618, available at http://www.cdc.gov/mmwr/pdf/wk/mm6132.pdf.
- For the 2013–14 season, follow dosing guidelines in the 2013 ACIP influenza vaccine recommendations.

9. Measles, mumps, and rubella (MMR) vaccine. (Minimum age: 12 months for routine vaccination)

Routine vaccination:

- Administer the first dose of MMR vaccine at age 12 through 15 months, and the second dose at age 4 through 6 years. The second dose may be administered before age 4 years, provided at least 4 weeks have elapsed since the first dose.
- Administer 1 dose of MMR vaccine to infants aged 6 through 11 months before departure from the United States for international travel. These children should be revaccinated with 2 doses of MMR vaccine, the first at age 12 through 15 months (12 months if the child remains in an area where disease risk is high), and the second dose at least 4 weeks later.
- Administer 2 doses of MMR vaccine to children aged 12 months and older, before departure from the United States for international travel. The first dose should be administered on or after age 12 months and the second dose at least 4 weeks later.

Catch-up vaccination:

- Ensure that all school-aged children and adolescents have had 2 doses of MMR vaccine; the minimum interval between the 2 doses is 4 weeks.

10. Varicella (VAR) vaccine. (Minimum age: 12 months)

Routine vaccination:

- Administer the first dose of VAR vaccine at age 12 through 15 months, and the second dose at age 4 through 6 years. The second dose may be administered before age 4 years, provided at least 3 months have elapsed since the first dose. If the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.

Catch-up vaccination:

- Ensure that all persons aged 7 through 18 years without evidence of immunity (see MMWR 2007;56 [No. RR-4], available at http://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf) have 2 doses of varicella vaccine. For children aged 7 through 12 years the recommended minimum interval between doses is 3 months (if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid); for persons aged 13 years and older, the minimum interval between doses is 4 weeks.

11. Hepatitis A vaccine (HepA). (Minimum age: 12 months)

Routine vaccination:

- Initiate the 2-dose HepA vaccine series for children aged 12 through 23 months; separate the 2 doses by 6 to 18 months.
- Children who have received 1 dose of HepA vaccine before age 24 months, should receive a second dose 6 to 18 months after the first dose.
- For any person aged 2 years and older who has not already received the HepA vaccine series, 2 doses of HepA vaccine separated by 6 to 18 months may be administered if immunity against hepatitis A virus infection is desired.

Catch-up vaccination:

- The minimum interval between the two doses is 6 months.

Special populations:

- Administer 2 doses of Hep A vaccine at least 6 months apart to previously unvaccinated persons who live in areas where vaccination programs target older children, or who are at increased risk for infection.

12. Human papillomavirus (HPV) vaccines. (HPV4 [Gardasil] and HPV2 [Cervarix]). (Minimum age: 9 years)

Routine vaccination:

- Administer a 3-dose series of HPV vaccine on a schedule of 0, 1-2, and 6 months to all adolescents aged 11-12 years. Either HPV4 or HPV2 may be used for females, and only HPV4 may be used for males.
- The vaccine series can be started beginning at age 9 years.
- Administer the second dose 1 to 2 months after the **first** dose and the third dose 6 months after the **first** dose (at least 24 weeks after the first dose).

Catch-up vaccination:

- Administer the vaccine series to females (either HPV2 or HPV4) and males (HPV4) at age 13 through 18 years if not previously vaccinated.
- Use recommended routine dosing intervals (see above) for vaccine series catch-up.

13. Meningococcal conjugate vaccines (MCV). (Minimum age: 6 weeks for Hib-MenCY, 9 months for Menactra [MCV4-D], 2 years for Menveo [MCV4-CRM]).

Routine vaccination:

- Administer MCV4 vaccine at age 11–12 years, with a booster dose at age 16 years.
- Adolescents aged 11 through 18 years with human immunodeficiency virus (HIV) infection should receive a 2-dose primary series of MCV4, with at least 8 weeks between doses. See MMWR 2011; 60:1018–1019 available at: http://www.cdc.gov/mmwr/pdf/wk/mm6030.pdf.
- For children aged 9 months through 10 years with high-risk conditions, see below.

Catch-up vaccination:

- Administer MCV4 vaccine at age 13 through 18 years if not previously vaccinated.
- If the first dose is administered at age 13 through 15 years, a booster dose should be administered at age 16 through 18 years with a minimum interval of at least 8 weeks between doses.
- If the first dose is administered at age 16 years or older, a booster dose is not needed.
- For other catch-up issues, see Figure 2.

Vaccination of persons with high-risk conditions:

- For children younger than 19 months of age with anatomic or functional asplenia (including sickle cell disease), administer an infant series of Hib-MenCY at 2, 4, 6, and 12-15 months.
- For children aged 2 through 18 months with persistent complement component deficiency, administer either an infant series of Hib-MenCY at 2, 4, 6, and 12 through 15 months or a 2-dose primary series of MCV4-D starting at 9 months, with at least 8 weeks between doses. For children aged 19 through 23 months with persistent complement component deficiency who have not received a complete series of Hib-MenCY or MCV4-D, administer 2 primary doses of MCV4-D at least 8 weeks apart.
- For children aged 24 months and older with persistent complement component deficiency or anatomic or functional asplenia (including sickle cell disease), who have not received a complete series of Hib-MenCY or MCV4-D, administer 2 primary doses of either MCV4-D or MCV4-CRM. If MCV4-D (Menactra) is administered to a child with asplenia (including sickle cell disease), do not administer MCV4-D until 2 years of age and at least 4 weeks after the completion of all PCV13 doses. See MMWR 2011;60:1391–2, available at http://www.cdc.gov/mmwr/pdf/wk/mm6040.pdf.
- For children aged 9 months and older who are residents of or travelers to countries in the African meningitis belt or to the Hajj, administer an age appropriate formulation and series of MCV4 for protection against serogroups A and W-135. Prior receipt of Hib-MenCY is not sufficient for children traveling to the meningitis belt or the Hajj. See MMWR 2011;60:1391–2, available at http://www.cdc.gov/mmwr/pdf/wk/mm6040.pdf.
- For children who are present during outbreaks caused by a vaccine serogroup, administer or complete an age and formulation-appropriate series of Hib-MenCY or MCV4.
- For booster doses among persons with high-risk conditions refer to http://www.cdc.gov/vaccines/pubs/acip-list.htm#mening.

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Recommended Adult Immunization Schedule—United States - 2013

Note: These recommendations must be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

VACCINE ▼ / AGE GROUP ▶	19-21 years	22-26 years	27-49 years	50-59 years	60-64 years	≥ 65 years
Influenza [2,*]	1 dose annually					
Tetanus, diphtheria, pertussis (Td/Tdap) [3,*]	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs					
Varicella [4,*]	2 doses					
Human papillomavirus (HPV) Female [5,*]	3 doses					
Human papillomavirus (HPV) Male [5,*]	3 doses					
Zoster [6]					1 dose	
Measles, mumps, rubella (MMR) [7,*]	1 or 2 doses					
Pneumococcal polysaccharide (PPSV23) [8,9]	1 or 2 doses					1 dose
Pneumococcal 13-valent conjugate (PCV13) [10]	1 dose					
Meningococcal [11,*]	1 or more doses					
Hepatitis A [12,*]	2 doses					
Hepatitis B [13,*]	3 doses					

*Covered by the Vaccine Injury Compensation Program

- **For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; zoster vaccine recommended regardless of prior episode of zoster**
- **Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indication)**
- **No recommendation**

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.
Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.
Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 8:00 a.m. - 8:00 p.m. Eastern Time, Monday - Friday, excluding holidays.
Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), American College of Obstetricians and Gynecologists (ACOG) and American College of Nurse-Midwives (ACNM).

VACCINE ▼ / INDICATION ▶	Pregnancy	Immuno-compromising conditions (excluding human immunodeficiency virus [HIV]) [4,6,7,10,15]	HIV infection CD4+ T lymphocyte count [4,6,7,10,14,15]: < 200 cells/μL	HIV infection CD4+ T lymphocyte count [4,6,7,10,14,15]: ≥ 200 cells/μL	Men who have sex with men (MSM)	Heart disease, chronic lung disease, chronic alcoholism	Asplenia (including elective splenectomy and persistent complement component deficiencies) [10,14]	Chronic liver disease	Kidney failure, end-stage renal disease, receipt of hemodialysis	Diabetes	Healthcare personnel
Influenza [2,*]	1 dose IIV annually				1 dose IIV or LAIV annually	1 dose IIV annually					1 dose IIV or LAIV annually
Tetanus, diphtheria, pertussis (Td/Tdap) [3,*]	1 dose Tdap each pregnancy	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs									
Varicella [4,*]	Contraindicated			2 doses							
Human papillomavirus (HPV) Female [5,*]		3 doses through age 26 yrs				3 doses through age 26 yrs					
Human papillomavirus (HPV) Male [5,*]		3 doses through age 26 yrs				3 doses through age 21 yrs					
Zoster [6]	Contraindicated				1 dose						
Measles, mumps, rubella (MMR) [7,*]	Contraindicated			1 or 2 doses							
Pneumococcal polysaccharide (PPSV23) [8,9]			1 or 2 doses								
Pneumococcal 13-valent conjugate (PCV13) [10]		1 dose									
Meningococcal [11,*]	1 or more doses										
Hepatitis A [12,*]	2 doses										
Hepatitis B [13,*]	3 doses										

*Covered by the Vaccine Injury Compensation Program

- **For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; zoster vaccine recommended regardless of prior episode of zoster**
- **Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)**
- **No recommendation**

These schedules indicate the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly indicated for adults ages 19 years and older, as of January 1, 2013. For all vaccines being recommended on the Adult Immunization Schedule: a vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/pubs/acip-list.htm). Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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Footnotes — Recommended Immunization Schedule for Adults Aged 19 Years and Older—United States, 2013

1. Additional information
- Additional guidance for the use of the vaccines described in this supplement is available at http://www.cdc.gov/vaccines/pubs/acip-list.htm.
- Information on vaccination recommendations when vaccination status is unknown and other general immunization information can be found in the General Recommendations on Immunization at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm.
- Information on travel vaccine requirements and recommendations (e.g., for hepatitis A and B, meningococcal, and other vaccines) are available at http://wwwnc.cdc.gov/travel/page/vaccinations.htm.

2. Influenza vaccination
- Annual vaccination against influenza is recommended for all persons aged 6 months and older.
- Persons aged 6 months and older, including pregnant women, can receive the inactivated influenza vaccine (IIV).
- Healthy, nonpregnant persons aged 2–49 years without high-risk medical conditions can receive either intranasally administered live, attenuated influenza vaccine (LAIV) (FluMist), or IIV. Health-care personnel who care for severely immunocompromised persons (i.e., those who require care in a protected environment) should receive IIV rather than LAIV.
- The intramuscularly or intradermally administered IIV are options for adults aged 18–64 years.
- Adults aged 65 years and older can receive the standard dose IIV or the high-dose IIV (Fluzone High-Dose).

3. Tetanus, diphtheria, and acellular pertussis (Td/Tdap) vaccination
- Administer one dose of Tdap vaccine to pregnant women during each pregnancy (preferred during 27–36 weeks' gestation), regardless of number of years since prior Td or Tdap vaccination.
- Administer Tdap to all other adults who have not previously received Tdap or for whom vaccine status is unknown. Tdap can be administered regardless of interval since the most recent tetanus or diphtheria-toxoid containing vaccine.
- Adults with an unknown or incomplete history of completing a 3-dose primary vaccination series with Td-containing vaccines should begin or complete a primary vaccination series including a Tdap dose.
- For unvaccinated adults, administer the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second.
- For incompletely vaccinated (i.e., less than 3 doses) adults, administer remaining doses.
- Refer to the Advisory Committee on Immunization Practices (ACIP) statement for recommendations for administering Td/Tdap as prophylaxis in wound management (see footnote #1).

4. Varicella vaccination
- All adults without evidence of immunity to varicella (as defined below) should receive 2 doses of single-antigen varicella vaccine or a second dose if they have received only 1 dose.
- Special consideration for vaccination should be given to those who have close contact with persons at high risk for severe disease (e.g., health-care personnel and family contacts of persons with immunocompromising conditions) or are at high risk for exposure or transmission (e.g., teachers; child care employees; residents and staff members of institutional settings, including correctional institutions; college students; military personnel; adolescents and adults living in households with children; nonpregnant women of childbearing age; and international travelers).
- Pregnant women should be assessed for evidence of varicella immunity. Women who do not have evidence of immunity should receive the first dose of varicella vaccine upon completion or termination of pregnancy and before discharge from the health-care facility. The second dose should be administered 4–8 weeks after the first dose.
- Evidence of immunity to varicella in adults includes any of the following:
  - documentation of 2 doses of varicella vaccine at least 4 weeks apart;
  - U.S.-born before 1980 except health-care personnel and pregnant women;
  - history of varicella based on diagnosis or verification of varicella disease by a health-care provider;
  - history of herpes zoster based on diagnosis or verification of herpes zoster disease by a health-care provider; or
  - laboratory evidence of immunity or laboratory confirmation of disease.

5. Human papillomavirus (HPV) vaccination
- Two vaccines are licensed for use in females, bivalent HPV vaccine (HPV2) and quadrivalent HPV vaccine (HPV4), and one HPV vaccine for use in males (HPV4).
- For females, either HPV4 or HPV2 is recommended in a 3-dose series for routine vaccination at age 11 or 12 years, and for those aged 13 through 26 years, if not previously vaccinated.
- For males, HPV4 is recommended in a 3-dose series for routine vaccination at age 11 or 12 years, and for those aged 13 through 21 years, if not previously vaccinated. Males aged 22 through 26 years may be vaccinated.
- HPV4 is recommended for men who have sex with men (MSM) through age 26 years for those who did not get any or all doses when they were younger.
- Vaccination is recommended for immunocompromised persons (including those with HIV infection) through age 26 years for those who did not get any or all doses when they were younger.
- A complete series for either HPV4 or HPV2 consists of 3 doses. The second dose should be administered 1–2 months after the first dose; the third dose should be administered 6 months after the first dose (at least 24 weeks after the first dose).
- HPV vaccines are not recommended for use in pregnant women. However, pregnancy testing is not needed before vaccination. If a woman is found to be pregnant after initiating the vaccination series, no intervention is needed; the remainder of the 3-dose series should be delayed until completion of pregnancy.
- Although HPV vaccination is not specifically recommended for health-care personnel (HCP) based on their occupation, HCP should receive the HPV vaccine as recommended (see above).

6. Zoster vaccination
- A single dose of zoster vaccine is recommended for adults aged 60 years and older regardless of whether they report a prior episode of herpes zoster. Although the vaccine is licensed by the Food and Drug Administration (FDA) for use among and can be administered to persons aged 50 years and older, ACIP recommends that vaccination begins at age 60 years.
- Persons aged 60 years and older with chronic medical conditions may be vaccinated unless their condition constitutes a contraindication, such as pregnancy or severe immunodeficiency.
- Although zoster vaccination is not specifically recommended for HCP, they should receive the vaccine if they are in the recommended age group.

7. Measles, mumps, rubella (MMR) vaccination
- Adults born before 1957 generally are considered immune to measles and mumps. All adults born in 1957 or later should have documentation of 1 or more doses of MMR vaccine unless they have a medical contraindication to the vaccine, or laboratory evidence of immunity to each of the three diseases. Documentation of provider-diagnosed disease is not considered acceptable evidence of immunity for measles, mumps, or rubella.

Measles component:
- A routine second dose of MMR vaccine, administered a minimum of 28 days after the first dose, is recommended for adults who
  - are students in postsecondary educational institutions;
  - work in a health-care facility; or
  - plan to travel internationally.
- Persons who received inactivated (killed) measles vaccine or measles vaccine of unknown type during 1963–1967 should be revaccinated with 2 doses of MMR vaccine.

Mumps component:
- A routine second dose of MMR vaccine, administered a minimum of 28 days after the first dose, is recommended for adults who
  - are students in a postsecondary educational institution;
  - work in a health-care facility; or
  - plan to travel internationally.
- Persons vaccinated before 1979 with either killed mumps vaccine or mumps vaccine of unknown type who are at high risk for mumps infection (e.g., persons who are working in a health-care facility) should be considered for revaccination with 2 doses of MMR vaccine.

Rubella component:
- For women of childbearing age, regardless of birth year, rubella immunity should be determined. If there is no evidence of immunity, women who are not pregnant should be vaccinated. Pregnant women who do not have evidence of immunity should receive MMR vaccine upon completion or termination of pregnancy and before discharge from the health-care facility.

HCP born before 1957:
- For unvaccinated health-care personnel born before 1957 who lack laboratory evidence of measles, mumps, and/or rubella immunity or laboratory confirmation of disease, health-care facilities should consider vaccinating personnel with 2 doses of MMR vaccine at the appropriate interval for measles and mumps or 1 dose of MMR vaccine for rubella.

8. Pneumococcal polysaccharide (PPSV23) vaccination
- Vaccinate all persons with the following indications:
  - all adults aged 65 years and older;
  - adults younger than age 65 years with chronic lung disease (including chronic obstructive pulmonary disease, emphysema, and asthma); chronic cardiovascular diseases; diabetes mellitus; chronic renal failure; nephrotic syndrome; chronic liver disease (including cirrhosis); alcoholism; cochlear implants; cerebrospinal fluid leaks; immunocompromising conditions; and functional or anatomic asplenia (e.g., sickle cell disease and other hemoglobinopathies, congenital or acquired asplenia, splenic dysfunction, or splenectomy [if elective splenectomy is planned, vaccinate at least 2 weeks before surgery]);
  - residents of nursing homes or long-term care facilities; and
  - adults who smoke cigarettes.
- Persons with immunocompromising conditions and other selected conditions are recommended to receive PCV13 and PPSV23 vaccines. See footnote #10 for information on timing of PCV13 and PPSV23 vaccinations.
- Persons with asymptomatic or symptomatic HIV infection should be vaccinated as soon as possible after their diagnosis.
- When cancer chemotherapy or other immunosuppressive therapy is being considered, the interval between vaccination and initiation of immunosuppressive therapy should be at least 2 weeks. Vaccination during chemotherapy or radiation therapy should be avoided.
- Routine use of PPSV23 is not recommended for American Indians/Alaska Natives or other persons younger than age 65 years unless they have underlying medical conditions that are PPSV23 indications. However, public health authorities may consider recommending PPSV23 for American Indians/Alaska Natives who are living in areas where the risk for invasive pneumococcal disease is increased.
- When indicated, PPSV23 should be administered to patients who are uncertain of their vaccination status and there is no record of previous vaccination. When PCV13 is also indicated, a dose of PCV13 should be given first (see footnote #10).

9. Revaccination with PPSV23
- One-time revaccination 5 years after the first dose is recommended for persons aged 19 through 64 years with chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy); and for persons with immunocompromising conditions.
- Persons who received 1 or 2 doses of PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years or later if at least 5 years have passed since their previous dose.
- No further doses are needed for persons vaccinated with PPSV23 at or after age 65 years.

10. Pneumococcal conjugate 13-valent vaccination (PCV13)
- Adults aged 19 years or older with immunocompromising conditions (including chronic renal failure and nephrotic syndrome), functional or anatomic asplenia, CSF leaks or cochlear implants, and who have not previously received PCV13 or PPSV23 should receive a single dose of PCV13 followed by a dose of PPSV23 at least 8 weeks later.
- Adults aged 19 years or older with the aforementioned conditions who have previously received one or more doses of PPSV23 should receive a dose of PCV13 one or more years after the last PPSV23 dose was received. For those that require additional doses of PPSV23, the first such dose should be given no sooner than 8 weeks after PCV13 and at least 5 years since the most recent dose of PPSV23.
- When indicated, PCV13 should be administered to patients who are uncertain of their vaccination status history and there is no record of previous vaccination.
- Although PCV13 is licensed by the Food and Drug Administration (FDA) for use among and can be administered to persons aged 50 years and older, ACIP recommends PCV13 for adults aged 19 years and older with the specific medical conditions noted above.

11. Meningococcal vaccination
- Administer 2 doses of meningococcal conjugate vaccine quadrivalent (MCV4) at least 2 months apart to adults with functional asplenia or persistent complement component deficiencies.
- HIV-infected persons who are vaccinated also should receive 2 doses.
- Administer a single dose of meningococcal vaccine to microbiologists routinely exposed to isolates of Neisseria meningitidis, military recruits, and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic.
- First-year college students up through age 21 years who are living in residence halls should be vaccinated if they have not received a dose on or after their 16th birthday.
- MCV4 is preferred for adults with any of the preceding indications who are aged 55 years and younger; meningococcal polysaccharide vaccine (MPSV4) is preferred for adults aged 56 years and older.
- Revaccination with MCV4 every 5 years is recommended for adults previously vaccinated with MCV4 or MPSV4 who remain at increased risk for infection (e.g., adults with anatomic or functional asplenia or persistent complement component deficiencies).

12. Hepatitis A vaccination
- Vaccinate any person seeking protection from hepatitis A virus (HAV) infection and persons with any of the following indications:
  - men who have sex with men and persons who use injection or noninjection illicit drugs;
  - persons working with HAV-infected primates or with HAV in a research laboratory setting;
  - persons with chronic liver disease and persons who receive clotting factor concentrates;
  - persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A; and
  - unvaccinated persons who anticipate close personal contact (e.g., household or regular babysitting) with an international adoptee during the first 60 days after arrival in the United States from a country with high or intermediate endemicity. (See footnote #1 for more information on travel recommendations). The first dose of the 2-dose hepatitis A vaccine series should be administered as soon as adoption is planned, ideally 2 or more weeks before the arrival of the adoptee.
- Single-antigen vaccine formulations should be administered in a 2-dose schedule at either age 0 and 6–12 months (Havrix), or age 0 and 6–18 months (Vaqta). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, administer 3 doses at 0, 1, and 6 months; alternatively, a 4-dose schedule may be used, administered on days 0, 7, and 21–30, followed by a booster dose at month 12.

13. Hepatitis B vaccination
- Vaccinate persons with any of the following indications and any person seeking protection from hepatitis B virus (HBV) infection:
  - sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months); persons seeking evaluation or treatment for a sexually transmitted disease (STD); current or recent injection-drug users; and men who have sex with men;
  - health-care personnel and public-safety workers who are potentially exposed to blood or other infectious body fluids;
  - persons with diabetes younger than age 60 years as soon as feasible after diagnosis; persons with diabetes who are age 60 years or older at the discretion of the treating clinician based on increased need for assisted blood glucose monitoring in long-term care facilities, likelihood of acquiring hepatitis B infection, its complications or chronic sequelae, and likelihood of immune response to vaccination;
  - persons with end-stage renal disease, including patients receiving hemodialysis; persons with HIV infection; and persons with chronic liver disease;
  - household contacts and sex partners of hepatitis B surface antigen-positive persons; clients and staff members of institutions for persons with developmental disabilities; and international travelers to countries with high or intermediate prevalence of chronic HBV infection; and
  - all adults in the following settings: STD treatment facilities; HIV testing and treatment facilities; facilities providing drug-abuse treatment and prevention services; health-care settings targeting services to injection-drug users or men who have sex with men; correctional facilities; end-stage renal disease programs and facilities for chronic hemodialysis patients; and institutions and nonresidential daycare facilities for persons with developmental disabilities.
- Administer missing doses to complete a 3-dose series of hepatitis B vaccine to those persons not vaccinated or not completely vaccinated. The second dose should be administered 1 month after the first dose; the third dose should be given at least 2 months after the second dose (and at least 4 months after the first dose). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, give 3 doses at 0, 1, and 6 months; alternatively, a 4-dose Twinrix schedule, administered on days 0, 7, and 21–30 followed by a booster dose at month 12 may be used.
- Adult patients receiving hemodialysis or with other immunocompromising conditions should receive 1 dose of 40 µg/mL (Recombivax HB) administered on a 3-dose schedule at 0, 1, and 6 months or 2 doses of 20 µg/mL (Engerix-B) administered simultaneously on a 4-dose schedule at 0, 1, 2, and 6 months.

14. Selected conditions for which Haemophilus influenzae type b (Hib) vaccine may be used
- 1 dose of Hib vaccine should be considered for persons who have sickle cell disease, leukemia, or HIV infection, or who have anatomic or functional asplenia if they have not previously received Hib vaccine.

15. Immunocompromising conditions
- Inactivated vaccines generally are acceptable (e.g., pneumococcal, meningococcal, and influenza [inactivated influenza vaccine]), and live vaccines generally are avoided in persons with immune deficiencies or immunocompromising conditions. Information on specific conditions is available at http://www.cdc.gov/vaccines/pubs/acip-list.htm.

Catch-Up Schedule and Minimum Intervals for Adults

This catch-up schedule must be used together with the guidelines printed on the previous page(s).

Doses to be given and minimum intervals from previous dose for adults age 19 years and older				
Vaccine	**Schedule**	**Minimum Interval Between Doses**		
		Dose 1 to 2	**Dose 2 to 3**	**Booster Dose**
Tetanus, Diphtheria, Pertussis (Tdap) **Tetanus, Diphtheria (Td)**	0, 1, 7 months	4 weeks	6 months	Td: 10 years after completing the primary series or since last booster dose
		Give Tdap for one of the doses in the series		
Human Papillomavirus (HPV)	0, 1-2, 6 months	4 weeks	12 weeks and at least 6 months after first dose	
Varicella (VAR)[1]	0, 4 weeks	4 weeks		
Measles, Mumps, Rubella (MMR)[1]	0, 4 weeks	4 weeks		
Hepatitis A (HepA)	0, 6 months	6 months		
Hepatitis B (HepB)	0, 1, 6 months	4 weeks	8 weeks and at least 16 weeks after first dose	

1. **MMR and varicella vaccines**
   - MMR and varicella vaccine may be given simultaneously, otherwise they must be separated by at least 4 weeks.
   - A tuberculin skin test (TST) or interferon gamma release assay (IGRA) can be given simultaneously with any live or inactivated vaccine. If the patient already received a measles-containing or another live attenuated virus vaccine, TST or IGRA must be delayed for at least 4 weeks after vaccination. If the TST or IGRA was applied first, any vaccine, including live attenuated virus vaccines, can be given at any time.

Guidelines for Patients with an Incomplete or Nonexistent Vaccine History

- There is no need to restart a vaccine series no matter how much time has elapsed between doses.
- For refugees and immigrants, provide vaccinations as you would for any other adult patient. For translations of foreign vaccine terms and vaccine products visit the Immunization Action Coalition website at www.immunize.org/izpractices/p5122.pdf.
- Patients age 18 years and older, including foreign-born adults, do not need polio vaccination unless they are traveling to a country where wild poliovirus still exists.
- Count only documented vaccinations (i.e., including month, year, and preferably, day of vaccination). If no documentation exists, assume the patient is unvaccinated. It is always better to vaccinate when in doubt, rather than miss an opportunity to provide protection.

Give Vaccine Information Statements

When vaccinating adults with vaccines covered by the Vaccine Injury Compensation Program, a Vaccine Information Statement (VIS) must be given each time the patient receives vaccine. The date of the edition of VIS given and the date the VIS was provided to the patient must be documented in the clinic/patient record. Other required documentation includes date of vaccination, name of the vaccine, manufacturer, and lot number; and name, address, and title of the individual who gave the vaccine. Download the most current VISs from the Immunization Action Coalition website at www.immunize.org/vis.

Disease Reporting

Report suspected cases of vaccine-preventable diseases to the local health department or to the Minnesota Department of Health, P.O. Box 64975, St. Paul, MN 55164-0975, 651-201-5414 or toll-free 877-676-5414.

Resources for Vaccinating Adults

Screening Checklist for Contraindications to Vaccines for Adults
A tool to use to ensure that vaccinees do not have any contraindications or precautions for the vaccines they are receiving.
www.immunize.org/catg.d/p4065.pdf

Do I Need Any Vaccinations Today?
A patient checklist that helps identify health, social and other risk factors that indicate the need for certain vaccines.
www.immunize.org/catg.d/p4036.pdf

Guide to Contraindications and Precautions to Commonly Used Vaccines
A chart for health professionals that lists contraindications, precautions and commonly misperceived contraindications.
www.health.state.mn.us/divs/idepc/immunize/hcp/contra.pdf

MINNESOTA MDH DEPARTMENT OF HEALTH
Immunization Program
P.O. Box 64975
St. Paul, MN 55164-0975
651-201-5503 or 1-800-657-3970
www.health.state.mn.us/immunize

1. **Influenza, seasonal (TIV, LAIV)** trivalent inactivated influenza vaccine (TIV); live attenuated influenza vaccine (LAIV).
   - Give LAIV or TIV to healthy (i.e., without high-risk medical conditions) nonpregnant adults under age 50 years.
   - Give TIV to:
     - Persons with high-risk medical conditions.
     - Persons age 50 years and older.
     - Health care personnel (HCP) who care for severely immunocompromised patients in protective isolation.
2. **Tetanus and diphtheria (Td) and tetanus, diphtheria, and pertussis (Tdap)**
   - Give 1 dose of Tdap to adults age 64 years and younger in place of their next 10-year booster dose of Td. Td is recommended every 10 years as a booster for all adults.
   - Tdap is recommended for adults having close contact with infants under age 1 year including (parents, grandparents, child care staff, pregnant women after 20 weeks gestation, and HCP).
   - Tdap can be given regardless of when the last Td was given.
   - Adults with unknown or incomplete history of completing primary vaccination should complete a 3-dose primary series of Td (see page 4 for catch-up schedule). Give Tdap for 1 of the 3 doses.
   - Pregnant women not vaccinated during pregnancy should receive Tdap in the immediate postpartum period.
   - Adults age 65 years and older may also receive Tdap.
3. **Human papillomavirus (HPV2, HPV4)**
   - Give HPV2 or HPV4 to all females through age 26 years and HPV4 to males through age 21 years.
   - HPV4 is recommended for males through age 26 years who are immunocompromised or men who have sex with men.
   - HPV is given as a 3 dose series at intervals of 0, 1-2, and 6 months.
   - Ideally, vaccine should be given prior to potential exposure through sexual activity; however, sexually active persons should still be vaccinated. Inform them that they may not receive protection against all HPV types in the vaccine if previously exposed to any of them.
   - Instruct all females to continue to receive annual Pap smears.
   - HPV4 may be given to males age 22 through 26 years.
4. **Varicella (VAR)**
   - Give varicella vaccine as 2 doses separated by 4 to 8 weeks to all adults without evidence of immunity, particularly those who will have close contact with persons at high risk for serious complications (e.g., HCP and family contacts of immunocompromised persons), or at high-risk of exposure (e.g., child care personnel, teachers).
   - Evidence of immunity to varicella includes any of the following:
     - Documentation of 2 doses of varicella vaccine at least 4 weeks apart, or
     - U.S.-born before 1980, or
     - History of varicella disease verified by a health care provider, or
     - History of herpes zoster disease verified by a health care provider, or
     - Laboratory evidence of immunity.
   - When assessing immunity of HCP or pregnant women the "U.S.–born before 1980" evidence of immunity should not be considered.
     - HCP with no other evidence of immunity should be given 2 doses of varicella at least 4 to 8 weeks apart.
     - Pregnant women with no other evidence of immunity should be vaccinated upon completion of pregnancy.
5. **Zoster (ZOS)**
   - Give 1 dose of zoster vaccine to persons age 60 years and older, regardless of a previous herpes zoster infection.
   - Persons with chronic medical conditions may be vaccinated unless it is specifically contraindicated, see *Vaccines Indicated for Adults Based on Medical and Other Indications* chart on page 2.
6. **Measles, mumps, rubella (MMR)**
   - Adults born before 1957 are generally considered immune to measles and mumps.
   - Post-secondary students, persons working in health care facilities, and international travelers need a second dose at least 4 weeks after their first dose.
   - HCP born before 1957: If they lack evidence of immunity, i.e., documentation of immunization or laboratory confirmation, give 2 doses of MMR at least 4 weeks apart.
   - Issues specific to measles and mumps: Adults born in 1957 or later should receive 1-2 doses of MMR vaccine unless they have evidence of immunity, which includes:
     - Documentation of 1 or more doses of MMR (or measles vaccine), or
     - History of disease based on health care provider diagnosis, or
     - Laboratory evidence of immunity.
     - Revaccination is recommended for persons that received inactivated (killed) measles vaccine or measles vaccine of unknown type received from 1963 to 1967.
   - Rubella-specific issues: Women of childbearing age should have rubella immunity assessed and be given MMR if susceptible. If assessment is performed during pregnancy and if susceptible, give MMR upon completion of pregnancy.
7. **Pneumococcal (PPSV)**– Give pneumococcal polysaccharide vaccine (PPSV) to:
   - All adults age 65 years and older.
   - Adults younger than age 65 years with chronic cardiovascular disease, chronic pulmonary disease including asthma, diabetes mellitus, alcoholism, chronic liver disease including cirrhosis, CSF leaks, cochlear implants, anatomic or functional asplenia, HIV infection, malignancy, chronic renal failure, nephrotic syndrome, receiving immunosuppressive chemotherapy, who smoke cigarettes, or live in a nursing home or long-term care facility.
   - Timing: Give PPSV at least 2 weeks prior to an elective splenectomy or when chemotherapy or other immunosuppressive treatment is anticipated. Give PPSV to HIV positive persons as soon as possible after diagnosis.

   Revaccination
   - Once-in-a-lifetime revaccination recommended if a person was vaccinated 5 or more years ago and either:
     - Was under age 65 years when first vaccinated and is now age 65 years and older, or
     - Is under age 65 years and at highest risk for invasive pneumococcal infection: chronic renal failure or nephrotic syndrome, anatomic or functional asplenia, or immunocompromising conditions.
8. **Hepatitis A (HepA)**
   - Give 2 doses of hepatitis A vaccine 6 months apart to:
     - Persons traveling to or working in countries with intermediate to high rates of HAV.
     - Men who have sex with men.
     - Persons who use street drugs.
     - Persons with chronic liver disease.
     - Persons who receive clotting factor concentrates.
     - Persons working with HAV in research settings or with HAV-infected primates.
     - Persons in close contact (e.g., household or regular child care contact) with an international adoptee during the first 60 days after arrival of the adoptee from an intermediate or high HAV endemic area. Vaccinate at least 2 weeks prior to adoptee's arrival.
     - Other adults wishing to obtain immunity.
9. **Hepatitis B (HepB)**– Give 3 doses of hepatitis B vaccine at intervals of 0, 1, and 6 months to all high-risk adults. Indications grouped by risk are as follows:
   - Occupational: health care and public safety personnel who are exposed to blood or other potentially infectious bodily fluids.
   - Behavioral: sexually active persons who are not in a long-term mutually monogamous relationship, injection-drug users, persons with a recently acquired STD, clients of STD clinics, and men who have sex with men.
   - Medical: those with HIV infection, chronic liver disease, persons younger than age 60 years with diabetes, end-stage renal disease, or on dialysis.
   - Other: household contacts and sex partners of persons with chronic hepatitis B virus (HBV) infection, clients and staff of institutions for the developmentally disabled, jail and prison inmates, persons in drug treatment, and international travelers to countries with intermediate or high rates of HBV.
   - Higher dosing of HepB is recommended for persons undergoing hemodialysis or who are immunocompromised. Give Recombivax HB 40 mcg at intervals of 0, 1, and 6 months or Engerix-B 20 mcg at intervals of 0, 1, 2, and 6 months.
10. **Meningococcal (MCV, MPSV)**

    Meningococcal conjugate vaccine (MCV)
    - Give a 2-dose series at intervals of 0, 2 months to:
      - Persons with persistent complement component deficiency, anatomic or functional asplenia.
      - Persons with HIV infection who are at risk due to other indicators (e.g., travel to endemic areas, lab personnel working with *N. meningitidis)*.
    - Give 1 dose to:
      - Persons traveling to countries with endemic meningococcal disease. It is required for travelers to Saudi Arabia during annual Hajj.
      - Military recruits.
      - Lab personnel working with *N. meningitidis.*
      - College students through age 21 years and living in freshmen dormitories if they have not received MCV on or after their 16th birthday.
    - Give MCV every 5 years following initial vaccination for adults who remain at risk and are age 54 years and younger.

    Meningococcal polysaccharide vaccine (MPSV)
    - Give one dose of MPSV to adults age 56 years and older who have any of the above risk factors.
    - Give MPSV every 5 years to persons age 56 years or older who remain at risk for meningococcal disease.
11. **Immunocompromising conditions**
    - Inactivated vaccines generally are acceptable, e.g., pneumococcal, meningococcal, and inactivated influenza vaccine. However, the immune response and efficacy may be reduced.
    - Generally avoid live vaccines for persons with immune deficiencies or immunocompromising conditions.
    - Information on specific conditions is available at www.cdc.gov/vaccines/pubs/acip-list.htm.
12. **Selected conditions for which *Haemophilus influenzae* type b (Hib) vaccine may be used**
    - Consider 1 dose for any unvaccinated persons who have sickle cell disease, leukemia, HIV infection, or who have had a splenectomy.

Minnesota Department of Health, IC#141-0316 (01/12)
www.health.state.mn.us/immunize

CDC's National Immunization Hotline (in English and Spanish):
800-CDC-INFO (1-800-232-4636), TTY 888-232-6348

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Evidence Grading

Literature Search

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. The literature search was divided into two stages to identify systematic reviews, (stage I) and randomized controlled trials, meta-analysis and other literature (stage II). Literature search terms used for this revision are below and include literature from October 1, 2010, through December 31, 2011.

Diphtheria, tetanus; pertussis; hepatitis A and B; rotavirus; meningococcal, pneumococcal, inactivated polio virus, herpes zoster, human papillomavirus; influenza; measles, mumps, rubella; varicella; haemophilus influenzae B. The Cochrane and PubMed databases were searched. The search was limited to systematic reviews and randomized control trials.

GRADE Methodology

Following a review of several evidence rating and recommendation writing systems, ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

GRADE has advantages over other systems including the current system used by ICSI. Advantages include:

- developed by a widely representative group of international guideline developers;
- explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings;
- clear separation between quality of evidence and strength of recommendations that includes a transparent process of moving from evidence evaluation to recommendations;
- clear, pragmatic interpretations of strong versus weak recommendations for clinicians, patients and policy-makers;
- explicit acknowledgement of values and preferences; and
- explicit evaluation of the importance of outcomes of alternative management strategies.

This document is in transition to the GRADE methodology

Transition steps incorporating GRADE methodology for this document include the following:

- Priority placed upon available Systematic Reviews in literature searches.
- All existing Class A (RCTs) studies have been considered as high quality evidence unless specified differently by a work group member.
- All existing Class B, C and D studies have been considered as low quality evidence unless specified differently by a work group member.
- All existing Class M and R studies are identified by study design versus assigning a quality of evidence. Refer to Crosswalk between ICSI Evidence Grading System and GRADE.
- All new literature considered by the work group for this revision has been assessed using GRADE methodology.

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Crosswalk between ICSI Evidence Grading System and GRADE

ICSI GRADE System	Previous ICSI System	
High, if no limitation	**Class A:**	Randomized, controlled trial
Low	**Class B:**	[observational] Cohort study
	Class C:	[observational] Non-randomized trial with concurrent or historical controls
Low		Case-control study
Low		Population-based descriptive study
***Low**		Study of sensitivity and specificity of a diagnostic test
* Following individual study review, may be elevated to Moderate or High depending upon study design		
	Class D:	[observational]
Low		Cross-sectional study Case series Case report
Meta-analysis	**Class M:**	Meta-analysis
Systematic Review		Systematic review
Decision Analysis		Decision analysis
Cost-Effectiveness Analysis		Cost-effectiveness analysis
Low	**Class R:**	Consensus statement
Low		Consensus report
Low		Narrative review
Guideline	**Class R:**	Guideline
Low	**Class X:**	Medical opinion

Evidence Definitions:

High Quality Evidence = Further research is very unlikely to change our confidence in the estimate of effect.

Moderate Quality Evidence = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low Quality Evidence = Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain.

In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature will be used to inform the reader of other topics of interest. This literature is not given an evidence grade and is instead identified as a **Reference** throughout the document.

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Foreword

The Immunization work group realizes that the Centers for Disease Control and Prevention (CDC) updates immunization recommendations in January, July and October. Please reference the following Web site for the most current schedule: http://www.cdc.gov.

Introduction

The Institute for Clinical Systems Improvement (ICSI) Immunizations work group is a subgroup of the ICSI Preventive Services work group.

Vaccines are one of the great public health achievements of the 20th century. Before vaccines became widely used, infectious diseases killed thousands of children and adults each year in the United States. For example, in the early 1900s, an average of 48,000 cases of smallpox and 1,500 deaths were reported each year. The last case of smallpox in the U.S. was reported in 1949. Smallpox is the only disease that has been eradicated from the world. Before 1985, *Haemophilus Influenzae* type B (Hib) caused serious infections in 20,000 children each year. One in 200 children developed Hib disease by the age of five years. 60% of these children had meningitis and 3-6% died. In 2010, there were 23 cases of Hib disease. In 1958, more than 760,000 cases of measles and 500 deaths were reported. In 2007, there were 43 reported cases of measles and no deaths. In 1952, polio paralyzed more than 57,000 people and more than 3,000 people died. In 1994, polio was eliminated in North and South America. In the early 1940s, there was an average of 175,000 cases of pertussis per year, resulting in the deaths of 8,000 children annually. In 2002, 9,771 cases were reported.

For most Americans today, vaccines are a routine part of health care, yet pockets of vaccine-preventable diseases occur. This is partly related to a growing number of parents who are concerned that vaccines may be the cause of conditions such as autism or question whether vaccines are still necessary. These concerns have caused some parents to delay vaccines or withhold them altogether from their children.

In the past decade, the U.S. has seen an increase in the number of cases of pertussis and measles. In 2002, 9,771 cases of pertussis were reported. In 2010, more than 27,000 cases were reported with 36 deaths. In California, 10 infants aged two months and younger died from pertussis. Measles was declared eliminated from the United States in 2000. However, importations of measles from other countries still occur, and low vaccination coverage associated with parental concerns regarding the MMR vaccine puts persons and communities at risk for measles. More than 200 cases of measles were reported in the U.S. in 2011, with outbreaks seen in many states. Between March and September of 2011, 26 cases of measles (two outbreaks) were identified in two Minnesota counties (Hennepin and Dakota). Both outbreaks were linked to children who had acquired the infection in Kenya.

Our increasingly mobile world provides continued threats of importation of vaccine-preventable diseases like measles. In 2011, more than 30,000 cases of measles were reported in Europe and more than 128,000 cases in Africa.

To combat these threats, we need to continue to encourage our patients and parents to receive all recommended immunizations and to follow the scientifically based immunization schedules.

(Centers for Disease Control and Prevention, 2011a [Reference])

Vaccine Shortages

Vaccine shortages continue to occur in the United States and are the result of a number of factors including companies leaving the vaccine market, manufacturing or production problems, unexpected demand for new vaccines and changes in vaccine recommendations. On occasion, shortages necessitate temporary changes

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in recommendations for their use. Information about the shortages including projected duration and recommendations for temporary changes in the immunization schedule are provided by the Advisory Committee on Immunization Practices.

The work group recommends that all practitioners be kept abreast of the latest national information on vaccine shortage available at the Centers for Disease Control and Prevention Web site: http://www.cdc.gov/vaccines/vac-gen/shortages/default.htm.

Persons Vaccinated Outside the United States, including Internationally Adopted Children

Vaccines administered outside the United States can generally be accepted as valid if the schedule was similar to that recommended in the United States (i.e., minimum ages and intervals). Only written documentation should be accepted as evidence of previous vaccination. Written records are more likely to predict protection if the vaccines, dates of administration, intervals between doses, and the person's age at the time of vaccination are comparable to United States recommendations. If a question exists about whether vaccines administered outside the United States were immunogenic, repeating the vaccinations is usually safe and avoids the need to obtain and interpret serologic tests. If avoiding unnecessary injections is desired, serologic testing might be helpful in determining which vaccinations are needed *(Kroger, 2006 [Reference])*.

Combination Vaccines

The Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP) state a preference for the use of licensed combination vaccines over separate injection of their equivalent component vaccines. There are two exceptions:

- Separate administration of MMR and varicella vaccine is preferred at age 12 through 47 months unless the parent or caregiver expresses a preference for MMRV vaccine and the benefits and risks are discussed. See Annotation #18, "Measles, Mumps and Rubella/Measles, Mumps, Rubella and Varicella (MMR/MMRV) Vaccine," for information related to febrile seizures.
- Hib-MenCY licensed for prevention of invasive disease caused by Haemophilus influenzae type b and meningococcal serogroups C and Y is recommended for infants who are at increased risk for meningococcal disease. Meningococcal vaccine is not routinely recommended for infants who are not at increased risk for meningococcal disease. However, Hib-MenCY may be used in any infant for routine vaccination against Hib and will offer some protection against serogroups C and Y meningococcal disease. See Annotation #19, "Meningococcal Vaccine," for information related to infants who are at increased risk for meningococcal disease.

The use of combination vaccines is an effective means of simplifying the immunization schedule and decreasing the number of injections, especially for children who are behind schedule. The use of combination vaccines might improve timely vaccination coverage. Other potential advantages of combination vaccines include reducing the cost of stocking and administering separate vaccines, reducing the cost for extra health care visits, facilitating the addition of new vaccines into immunization programs, and reducing missed opportunities to vaccinate.

Licensed combination vaccines can be used whenever any components of the combination are indicated and its other components are not contraindicated and if licensed by the Food and Drug Administration (FDA) for that dose in the series. For example, DTaP-IPV vaccine is licensed for children 4 through 6 years of age for the fifth dose in the DTaP series and the fourth dose in the IPV series.

Only combination vaccines approved by the U.S. Food and Drug Administration (FDA) should be used. See "Vaccines Routinely Administered in the United States" earlier in this guideline for further information. Immunization providers should not combine separate vaccines into the same syringe to administer together unless such mixing is indicated for the patient's age on the respective product label inserts approved by the

Food and Drug Administration. The safety, immunogenicity and efficacy of such unlicensed combinations are unknown.

(Cohn, 2013 [Guideline]; Centers for Disease Control, 2010d [Guideline]; Centers for Disease Control, 2006 [Guideline]; American Academy of Pediatrics, 1999 [Guideline]; Centers for Disease Control, 1999 [Guideline])

Acknowledgments

The ICSI Immunizations guideline work group recognizes the expertise of local and national groups that provide periodic immunization recommendations. These groups include:

- The Advisory Committee for Immunization Practices of the U.S. Public Health Service (ACIP)
- The Infectious Disease Committee of the American Academy of Pediatrics (AAP)
- The American Academy of Family Physicians (AAFP)
- The Minnesota Department of Health (MDH)
- Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services

Changes are occurring rapidly and will be reviewed and acted upon by the ICSI work group as appropriate. In general, the guideline work group will support changes made by the above-mentioned groups.

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Scope and Target Population

To protect persons of all ages in the United States from infectious diseases through the use of vaccines.

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Aims

1. Increase the percentage of patients who are up-to-date with recommended immunizations. *(Annotations #1, 2, 3)*
2. Increase the percentage of patients/parents who receive education regarding immunizations. *(Annotation #3)*

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Clinical Highlights

- Utilize all clinical encounters as opportunities to assess a patient's immunization status. (*Annotations #1, 2, 3; Aim #1*)
- Administer at each clinical encounter all immunizations that are due or overdue unless true contraindications exist. (*Annotations #2, 3, 4; Aim #1*)
- Educate patients (parents, if applicable) regarding the importance of infant, childhood, adolescent and adult immunizations, the recommended schedule and the need to maintain a personal record of immunizations and childhood diseases. (*Annotation #3; Aim #2*)
- Document reasons for not administering immunizations that are clinically indicated, and flag the record for a recall appointment. (*Annotations #4, 8*)
- Document the future plan for administering immunizations. (*Annotation #7*)
- Report immunizations to immunization registries and Vaccine Adverse Event Reporting System (VAERS). *(Annotation #6)*
- Provide vaccine information sheets. *(Annotation #3)*

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Implementation Recommendation Highlights

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

- Develop tracking systems in order to establish immunization status of patients under the provider's care, with the capability to produce reminders and recalls for immunizations that are due and/or not on time. *(Annotation #8)*
  - Develop a plan for periodic medical record audits, paper medical record or electronic health records in order to track outcomes and identify barriers.
- Remove barriers to immunization services. *(Annotation #3)*
- Develop system-based protocols to include specific criteria around immunizations that may be due at the current visit, or those immunizations not on time, including a statement indicating immunization(s) may be given at any time during the visit (based on specific criteria).
  - Provide staff training and education around routine standing orders.
  - Make it clear to staff that routine standing orders are clinician orders that allow for administration of immunizations (those due or not on time).
  - Clearly define those staff who may administer these immunizations (RN, LPN, CMA, etc.).
- Develop education for providers and staff around patients at risk/high risk who require adjustments or have contradictions to specific (required) immunizations.
  - Develop criteria and alerts for tracking these patients.
  - Develop criteria in paper medical record or electronic health records for documentation of patients at risk/high risk.
- Develop a means for communicating vaccine shortages to practitioners, as well as providing updates on status of shortages. This information is available on the Centers for Disease Control and Prevention Web site (http://www.cdc.gov/vaccines/vac-gen/shortages/default.htm).
- Patient Safety: Provide education to clinicians and staff around risk factors and immunizations in all age groups. Stress the importance of reviewing this guideline and/or any of the resources listed (in this guideline) as a reference.
- Develop a system to ensure immunization information is being sent to or entered into state or local registries. *(Annotation #6)*

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Related ICSI Scientific Documents

Guidelines

- Preventive Services for Adults
- Preventive Services for Children and Adolescents
- Routine Prenatal Care

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Definition

Clinician – All health care professionals whose practice is based on interaction with and/or treatment of a patient.

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Abbreviations

DTaP – Diphtheria, tetanus toxoids and acellular pertussis vaccine

HepA – Hepatitis A vaccine

HepB – Hepatitis B vaccine

Hib – *Haemophilus influenzae* type B conjugate vaccine

HPV – Human papillomavirus vaccine

IPV – Inactivated poliovirus vaccine

LAIV – Live, attenuated influenza vaccine

MCV-4 – Meningococcal vaccine

MCV-4/MPSV4 – Meningococcal vaccine

MMR – Measles, mumps and rubella vaccine

MMRV – Measles, mumps, rubella and varicella vaccine

PCV13/PPSV23 – Pneumoccocal vaccines

RV – Rotavirus vaccine

Td – Tetanus, diphtheria toxoids

Tdap – Tetanus, diphtheria toxoids and acellular pertussis vaccine

TIV – Trivalent (inactivated) influenza vaccine

VAR – Varicella vaccine

ZOS – Zoster (shingles) vaccine

http://www.cdc.gov/vaccines/about/terms/vacc-abbrev.htm

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Algorithm Annotations

Immunization Administration Algorithm Annotations

1. Review and Update Immunization Status

Recommendation:

- Immunization status should be reviewed for all patients at each office visit.

Ask patients if they have received vaccinations elsewhere and/or review immunizations information in state or local immunization information systems (i.e., immunization registries).

Providers should only accept written, dated records as evidence of vaccination. With the exception of influenza vaccine and pneumococcal polysaccharide vaccine (PPSV), self-reported doses of vaccine without written documentation should not be accepted. Although vaccinations should not be postponed if records cannot be found, an attempt to locate missing records should be made by contacting previous health care providers, reviewing state or local immunization information systems (IIS), and searching for a personally held record. If records cannot be located, these persons should be considered susceptible and should be started on the age-appropriate vaccination schedule. Serologic testing for immunity is an alternative to vaccination for certain antigens (e.g., measles, rubella, hepatitis A, and tetanus).

Document historical vaccines in patient's medical record. At a minimum, include vaccine and date administered.

(National Vaccine Advisory Committee, 2003 [Guideline]; Poland, 2003 [Guideline])

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2. Are Immunizations Needed Today?

Compare patient's immunization history to current recommended immunization schedules to identify needed immunizations (see schedules earlier in this guideline).

Vaccine recommendations are determined after extensive studies in large clinical trials. They include studies on how vaccine recipients respond to multiple vaccines given simultaneously. The overall aim is to provide early protection for infants and children against vaccine-preventable diseases that could endanger their health and life. No scientific evidence exists to support that delaying vaccinations or separating them into individual antigens is beneficial for children. Rather, this practice prolongs susceptibility to disease, which could result in a greater likelihood of the child becoming sick with a serious or life-threatening disease. There could also be added expense (e.g., multiple office visits), additional time off from work for parents, and increased likelihood that the child will fail to get all necessary vaccinations.

For more information refer to the Childhood Immunization Schedule: Why Is It Like That? (AAP) http://www.vaccinateyourbaby.org/pdfs/Vaccine_schedule.pdf.

Patients should receive all routinely recommended immunizations.

Recommended immunizations are vaccines that the Advisory Committee on Immunization Practices has recommended to reduce the incidence of vaccine-preventable diseases in the United States. Routinely recommended immunizations are vaccines that are recommended for all persons who meet the age requirements. For example, all persons six months of age and older are recommended to receive influenza vaccine annually. Other vaccines are recommended if some other risk factor is present. For example, pneumococcal polysaccharide (PPSV) vaccine is recommended for persons 2 through 64 years of age with certain chronic medical conditions *(Centers for Disease Control, 2011b [Guideline])*.

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Patients with medical risk factors, lifestyle risk factors or certain occupations may need additional vaccines.

If the minimum interval between doses in a series has not been met, defer vaccine and schedule appointment when dose can be administered (see Catch-Up Immunization Schedule for Persons Aged 4 Months through 18 Years Who Start Late or Are More Than 1 Month Behind [CDC] or Catch-Up Schedule and Minimum Intervals for Adults [MDH]). It is not necessary to restart the series if there has been a delay between doses of vaccine in a series.

(National Vaccine Advisory Committee, 2003 [Guideline]; Poland, 2003 [Guideline])

Responding to Vaccine-Hesitant Parents

Most parents believe in the benefits of immunization for their children. However, health care providers may encounter parents who question the need for, or safety of, childhood vaccines. Such parents may choose to delay or forgo immunizing their children with some or all of the recommended vaccines. To assist parents in making fully informed immunization decisions, providers should try to understand differing views of vaccine risks and benefits, and be prepared to respond effectively to concerns and questions. There are many tools available to assist with this discussion such as:

- Talking with Parents about Vaccines for Infants

  http://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/talk-infants-bw-office.pdf
- Clear Answers & Smart Advice About Your Baby's Shots, by Ari Brown, MD, FAAP

  http://www.immunize.org/catg.d/p2068.pdf
- Immunization Action Coalition form "Decision to Not Vaccinate My Child." Intended to be reviewed and signed by the parent, the form includes information about how an unvaccinated child might get seriously ill or could spread disease to another person. A second page includes background information and reference material for health care professionals.

  http://www.immunize.org/express/issue963.asp#n4

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3. Can Needed Immunizations Be Given Today? (Educate, Reassure and Screen for Contraindications)

Educate Patient, Parent/Guardian about Vaccine

Recommendations:

- Providers should discuss with the patient the benefits of vaccines, the diseases that the vaccines prevent and any known risks from vaccines.
- Providers should follow only medically accepted contraindications.

Providers should discuss with the patient the benefits of vaccines, the diseases that the vaccines prevent, and any known risks from vaccines. These issues should be discussed in the patient's native language, whenever possible. Printed materials, accurately translated into the patient's language, should be provided. For most commonly used vaccines, the U.S. federal government has developed Vaccine Information Statements (VISs) to give to potential vaccine recipients. For vaccines covered by the National Childhood Vaccine Injury Act, including those vaccines used in children, these forms are required. These statements are available in English and other languages. Where a form is available for vaccines **not** covered by the National Childhood Vaccine Injury Act, it should be used. Ample time should be allotted with patients, parents/guardians to review written materials and address questions and concerns. Patients, parents/guardians should be encouraged to

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take responsibility for ensuring that the patient is fully vaccinated. Providers should encourage patients, parents/guardians to inform the health care professional of adverse events after the vaccine is administered and explain how to obtain medical care, if necessary. Information and assistance can be obtained by calling the CDC-INFO Contact Center (1-800-232-4636) or on the Internet at http://www.cdc.gov/vaccines.

(National Vaccine Advisory Committee, 2003 [Guideline]; Poland, 2003 [Guideline])

Assess Patient for Contraindications or Precautions

Providers should follow only medically accepted contraindications. Failure to differentiate between valid and invalid contraindications often results in the needless deferral of indicated vaccinations. Some of the most common invalid contraindications are mild illnesses, conditions related to pregnancy and breast-feeding, allergies that are not anaphylactic in nature, and certain aspects of the patient's family history. Providers should ask about any condition or circumstance that might indicate that a vaccination should be withheld or delayed. Providers should also inquire about previous adverse events temporally associated with any vaccination *(National Vaccine Advisory Committee, 2003 [Guideline]; Poland, 2003 [Guideline])*.

Health care professionals should refer to the Guide to Contraindications to Vaccinations published by the Centers for Disease Control and Prevention at http://www.cdc.gov/vaccines/recs/vac-admin/contraindications-vacc.htm.

- A contraindication is a condition in a recipient that greatly increases the chance of a serious adverse reaction. It is a condition in the recipient of the vaccine, not with the vaccine per se. In general, vaccines should not be administered when a contraindication condition is present.
  - Permanent vaccine contraindications – only two conditions are generally considered to be permanent:
    - Severe (anaphylactic) allergic reaction to a vaccine component or following a prior dose of a vaccine
    - Encephalopathy not due to another identifiable cause occurring within seven days of pertussis vaccination
  - Temporary vaccine contraindications – two conditions are temporary contraindications to vaccination with live vaccines:
    - Pregnancy
    - Immunosuppression
- A precaution is a condition in a recipient that might increase the chance or severity of a serious adverse reaction, or that might compromise the ability of the vaccine to produce immunity (such as administering measles vaccine to a person with passive immunity to measles from a blood transfusion). Injury could result, but the chance of this happening is less than with a contraindication. In general, vaccines are deferred when a precaution condition is present. However, situations may arise when the benefit of protection from the vaccine outweighs the risk of an adverse reaction, and a provider may decide to give the vaccine.
  - Temporary vaccine precautions – two conditions are temporary precautions to vaccination:
    - Moderate or severe acute illness (all vaccines)
    - Recent receipt of an antibody-containing blood product (applies only to MMR and varicella-containing vaccines; does not apply to herpes zoster vaccine)

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Simultaneously Administer All Doses of Vaccine for Which the Patient Is Eligible

Administering vaccines simultaneously (at the same visit), in accordance with recommendations from the Advisory Committee on Immunization Practices, the American Academy of Pediatrics and the American Academy of Family Physicians is safe, effective and indicated. Although the immunization schedule provides age flexibility for administering certain vaccine doses, simultaneous administration decreases the number of visits needed and the potential for missed doses, and it enables earlier protection. When indicated vaccines are not simultaneously administered, arrangements should be made for the patient's earliest return to receive the needed vaccination(s). See Annotation #2, "Are Immunizations Needed Today?" in this section for additional information regarding the recommended immunization schedule.

- Live virus vaccines (MMR, MMRV, varicella, herpes zoster and live attenuated influenza vaccine) not given simultaneously should be separated by at least four weeks.
- Combination immunizations offer the benefit of a single injection and may improve compliance and reduce morbidity *(National Vaccine Advisory Committee, 1992 [Guideline])*. See "Vaccines Routinely Administered in the United States" earlier in this guideline for further information.

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4. Document Contraindications, Deferrals or Refusals

If a vaccine is contraindicated or deferred, the provider should document the reason and flag the record for future visits.

Patients, Parents/Guardians Who Refuse Immunizations

Document the discussion and keep it in the patient's medical record. Revisit the immunization discussion at each subsequent appointment, and carefully document the discussion, including the benefits to each immunization and the risk of not being age-appropriately immunized. For unimmunized or partially immunized children, some providers may want to flag the chart to be reminded to revisit the immunization discussion, as well as to alert the provider about missed immunizations when considering the evaluation of future illness, especially young children with fever of unknown origin.

State Immunization Laws

As a core component of public health practice in the United States, vaccination programs are supported by state legal requirements. Each state has school vaccination laws that require children of appropriate age to be vaccinated for several communicable diseases. In addition to medical exemptions offered in each state, 48 states allow for religious exemptions, and 21 states allow personal belief exemptions for day care and school. For additional information on state requirements and exemptions, see Immunization Action Coalition at http://www.immunize.org/laws or Centers for Disease Control and Prevention at http://www.cdc.gov/vaccines/vac-gen/laws/default.htm.

(National Vaccine Advisory Committee, 2003 [Guideline]; Poland, 2003 [Guideline])

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5. Administer Vaccines

Immunizations should be administered by properly trained individuals. Health care professionals or others who administer vaccinations should be knowledgeable and receive continuing education in vaccine storage and handling; the recommended vaccine schedule, contraindications, and administration techniques; treatment and reporting of adverse events; vaccine benefit and risk communication; and vaccination record maintenance and accessibility. The Centers for Disease Control and Prevention sponsors distance-based training opportunities for health care professionals. Information about training is available at http://www.cdc.gov/vaccines/ed/default.htm.

(National Vaccine Advisory Committee, 2003 [Guideline]; Poland, 2003 [Guideline])

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6. Document Vaccines Given and Report Dose to Registry

Accurate record keeping helps ensure that needed vaccinations are administered and unnecessary vaccinations are not administered. The medical record at the primary care provider's office, clinic or worksite should include all vaccinations received (such as those received at a specialist's office or in another health care setting). When a health care professional who does not routinely care for a patient vaccinates that patient, the patient's primary care provider should be informed.

(National Vaccine Advisory Committee, 2003 [Guideline]; Poland, 2003 [Guideline])

Document Vaccine(s) Given

Providers of routine childhood immunizations are required by federal law (42 U.S. Code 300aa-25) to record the vaccine, the date of administration, the vaccine manufacturer, lot number, the date the Vaccine Information Statement (VIS) was given to the patient, the publication date of the Vaccine Information Statement, the signature and title of the person administering the vaccine, and the address where the vaccine was administered. It is recommended that providers of other vaccines also record this information. All information should be recorded in single summary form in the patient's record in order to allow easy retrieval of information. For additional information, see http://www.cdc.gov/vaccines/hcp/vis/about/required-use-instructions.html.

(National Vaccine Advisory Committee, 2003 [Guideline]; Poland, 2003 [Guideline])

Personal Immunization Record

Health care professionals should ensure that each patient has a handheld vaccination record that documents each vaccine received, including the date and the name of the health care professional who administered the vaccine. Health care professionals should encourage patients and/or parents/guardians to bring the patient's handheld record to each health care visit so that it can be updated.

Report Vaccine(s) Given to Immunization Information Systems (i.e., Immunization Registries)

All vaccinations administered should be reported to state or local immunization registries, where available, to ensure that each patient's vaccination history remains accurate and complete. Registries are useful for verifying the vaccination status of new patients, determining which vaccines are needed at a visit, printing official records, and providing reminders and recalls to parents/guardians and patients. For additional information, see Every Child by Two at http://www.ecbt.org/registries.

(National Vaccine Advisory Committee, 2003 [Guideline])

Report Vaccine Adverse Events

Providers should document fully any adverse event in the medical record at the time of the event, or as soon as possible. Health care professionals should promptly report all clinically significant adverse events after vaccination to the Vaccine Adverse Event Reporting System (VAERS) even if the health care professional is not certain that the vaccine caused the event. Health care professionals should be aware that patients and parents/guardians may report to Vaccine Adverse Event Reporting System; if they choose to do so, they are encouraged to seek the help of their health care professional. Report forms and assistance are available by calling 1-800-822-7967 or on the Internet at http://vaers.hhs.gov/index.

(National Vaccine Advisory Committee, 2003 [Guideline]; Poland, 2003 [Guideline])

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7. Educate Parent/Patient. Arrange Follow-Up for Future Immunizations

Discuss with the patient, parent/guardian when next vaccines are due (including vaccines that may have been deferred), and schedule appointment if possible. For additional information, refer to Annotation #3, "Can Needed Immunizations be Given Today? (Educate, Reassure and Screen for Contraindications)." Educate the patient and/or parent/guardian about vaccines.

(National Vaccine Advisory Committee, 2003 [Guideline]; Poland, 2003 [Guideline])

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8. Conduct Regular Assessments of Vaccination Coverage Rates. Develop Systems to Remind Patients and Providers When Vaccinations Are Due and to Recall Patients Who Are Overdue

Assessment of Vaccination Coverage Rates

Assessments are most effective in improving vaccination coverage when they combine chart reviews to determine coverage with the provision of results to health care professionals and staff. Provider assessment can be performed by the staff in the practice or by other organizations, including state and local health departments. Effective interventions that include assessment and provision of results may also incorporate incentives or compare performance to a goal or standard. This process is commonly referred to as AFIX (assessment, feedback, incentives and exchange of information). Coverage should be assessed annually so that reasons for low coverage in the practice, or in a subgroup of the patients served, can be identified and interventions implemented to address them.

(National Vaccine Advisory Committee, 2003 [Guideline]; Poland, 2003 [Guideline])

Reminder/Recall

Reminder/recall systems improve vaccination coverage. Patient reminder/recall interventions inform individuals that they are due (reminder) or overdue (recall) for specific vaccinations. Patient reminders/recalls can be mailed or communicated by telephone; an autodialer system can be used to expedite telephone reminders. Patients who might be at high risk for not complying with medical recommendations – for example, those who have missed previous appointments – should receive more intensive follow-up. Similarly, provider reminder/recall systems alert health care professionals when vaccines are due or overdue. Notices should be placed in patient charts or communicated to health care professionals by computer or other means. Immunization registries can facilitate automatic generation of reminder/recall notices.

Information about assessing vaccination coverage rates and reminder/recall systems is available through Centers for Disease Control and Prevention at http://www.cdc.gov/vaccines/recs/reminder-sys.htm and through the American Academy of Pediatrics at http://www2.aap.org/immunization/pediatricians/pdf/ReminderRecall.pdf. Software to assist in conducting coverage rate assessments and feedback is available at http://www.cdc.gov/vaccines/programs/cocasa/index.html *(National Vaccine Advisory Committee, 2003 [Guideline]; Poland, 2003 [Guideline])*.

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Immunization Schedule Annotations

9. Diphtheria and Tetanus Toxoids and Acellular Pertussis (DTaP/Td/Tdap) Vaccine

Td/Tdap

Adolescents and adults

A single dose of Tdap should be given routinely to adolescents (target age 11-12) who completed the recommended childhood diphtheria and tetanus toxoids, pertussis/diphtheria and tetanus toxoids, and acellular pertussis (DTP/DTaP) vaccination series. Tdap can be given regardless of the time elapsed since the last vaccine containing tetanus toxoid or diphtheria toxoid *(Centers for Disease Control, 2011i [Guideline])*.

Pregnant adolescents are recommended to receive a dose of Tdap during pregnancy, irrespective of prior history of receiving Tdap. See Pregnancy and Postpartum section for more information.

Pertussis appears to be endemic in middle and high schools *(Strebel, 2001 [Low Quality Evidence])*. Although mortality is very low in patients ages 11 to 65 years, pertussis causes substantial morbidity in this age as well as transmission to incompletely immunized infants *(Murphy, 2008 [Guideline])*. Thus, the availability of a safe tetanus-diphtheria-acellular pertussis booster (Tdap) for adolescents and adults means it should be routinely given to these age groups. In most situations, Tdap will substitute for Td. Immunization should be provided to those who may expose infants less than 12 months of age, because these infants are the most vulnerable to the disease. This cocoon strategy will maximize the effectiveness of the vaccine in reducing disease *(Centers for Disease Control, 2011i [Guideline])*.

Given the epidemiology of the disease, the most important groups to immunize with Tdap are listed below:

- All health care workers since they are at risk of transmitting pertussis to infants, adolescents, parents, grandparents or care providers of infants *(Murphy, 2008 [Reference])*.
- Middle and high school age patients
- Others with high exposure to middle and high school age patients (teachers, health care workers, etc.)
- Those who might expose infants less than 12 months of age to pertussis (pregnant women, postpartum women, new parents, siblings of infants, day care workers, health care professionals, etc.)

Primary immunization of adults 18 and older

All adults should have completed a primary Td series. A complete series includes two doses given four weeks apart and a third dose given 6-12 months after the second dose. Tdap should be used as the first dose *(Centers for Disease Control, 2011i [Guideline])*.

Repeat immunization of adults 18 and older

For all adults, a booster dose of Td is recommended every 10 years. Those who have not had a one-time dose of Tdap, or if status is unknown, the next booster dose should be Tdap. Adults 65 years and older who haven't received Tdap SHOULD be vaccinated *(Centers for Disease Control, 2011c [Guideline])*.

For patients presenting with severe or complicated trauma wounds, an additional dose is recommended if Td has not been administered within the preceding five years. If available, Tdap should be given. If the initial tetanus series is incomplete, the tetanus diphtheria status is unknown or patient is human immunodeficiency virus (HIV)-positive, tetanus immune globulin should be given in addition to starting the series *(Friede, 1997 [Reference])*.

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Pregnancy and postpartum period

All pregnant women should receive Tdap during each pregnancy irrespective of prior history of receiving Tdap. To maximize the maternal antibody response and passive antibody transfer to the infant, optimal timing for Tdap administration is between 27 and 36 weeks gestation. For women not previously vaccinated with Tdap, if Tdap not administered during pregnancy, Tdap should be administered immediately postpartum.

In addition, parents and siblings, day care providers and others caring for an infant less than 12 months of age should receive a single dose of Tdap if not previously received.

Tdap vaccination of parents and household contacts of premature infants has been advocated *(Shah, 2007 [Reference])*. Premature and low-birth-weight infants are at increased risk for severe and complicated pertussis.

(Centers for Disease Control, 2011i [Guideline])

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10. *Haemophilus influenzae b* Conjugate (Hib) Vaccine

Trade Name	Abbreviation	Carrier	Manufacturer	Schedule
ActHIB®	Hib (PRP-T)	Tetanus Toxoid	Sanofi Pasteur	2, 4, 6 and 12-15 months
Comvax®	Hib (PRP-OMP) and hepatitis B	Meningococcal outer membrane protein	Merck	2, 4 and 12-15 months
PedvaxHIB®	Hib (PRP-OMP)	Meningococcal outer membrane protein	Merck	2, 4 and 12-15 months
Hiberix®	Hib (PRP-T)	Tetanus Toxoid	GlaxoSmith Kline	15 months up to 4 years Booster dose only
Pentacel®	Hib (PRP-T), DTaP and IPV	Tetanus Toxoid	Sanofi Pasteur	2, 4, 6 and15-18 months
MenHibrix®	Hib (PRP-T) and MenCY	Tetanus Toxoid	GlaxoSmith Kline	2, 4 and 12-15 months and at increased risk*

* Recommended for children aged 2 through 18 months who are at increased risk for meningococcal disease (e.g., persistent complement component deficiencies, anatomic or functional asplenia, including sickle cell disease). See Annotation #19, "Meningococcal Vaccine," for additional information.

This information is current as of April 2013. See prescribing information for complete details of the products' licensure at http://www.immunize.org/packageinserts/. For the most up-to-date information about specific recommendation, see Child, Adolescent and Catch-Up Schedules.

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11. Hepatitis A (HepA) Vaccine

Routine

Initiation of Hepatitis A vaccine is recommended for all children between 12 and 23 months.

Hepatitis A requires two doses administered at least six months apart. It is not necessary to restart the series if the interval between doses is longer than recommended. Those 24 months and older who have started the series should complete it. Otherwise, those 24 months and older who have not started the series should be considered for vaccination if they are at increased risk. It is also recommended for those who live in areas where vaccination programs target older children, or who are at increased risk for infection, or for

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whom immunity against hepatitis A is desired. States and regions that have risk-based hepatitis A vaccination programs for children 2 to 18 years of age should continue these programs *(Fiore, 2006 [Reference])*.

Averhoff, et al. reported on a study conducted on children aged 2 to 17 years from 1995 to 2000 that has shown that vaccination decreased hepatitis A incidence *(Averhoff, 2001 [Low Quality Evidence])*.

Increased Risk

Hepatitis A vaccine is recommended for persons 12 months and older who are at increased risk for the disease, including:

- Persons traveling to or working in countries that have high or intermediate endemicity of infection
- Men who have sex with men
- Users of injectible or non-injectible illegal drugs
- Persons who have occupational risk for infection (e.g., people who work with hepatitis A-infected persons, people who use hepatitis A in a research laboratory setting). No other occupational group has demonstrated to be at increased risk.
- Persons with clotting-factor disorders who require clotting-factor concentrates, especially solvent-detergent treated preparations
- Persons with chronic liver disease
- Military personnel
- Unvaccinated persons who anticipate close personal contact with an international adoptee during the first 60 days after arrival in the United States from a country with high or intermediate endemicity.

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12. Hepatitis B (HepB) Vaccine

The ICSI work group recommends universal vaccination for those less than 40 years of age and for those age 40 and older at high risk.

High Risk

Those at high risk for exposure include the following:

- Sex partners of hepatitis B surface antigen (HBsAg) positive persons
- Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous six months)
- Persons seeking evaluation or treatment for a sexually transmitted disease (STD)
- Current or recent injection-drug users
- Men who have sex with men
- Health care personnel and public-safety workers with reasonably anticipated risk for exposure to blood or other blood-contaminated body fluids
- Persons with end-stage renal disease, including predialysis, hemodialysis, peritoneal dialysis, and home dialysis patients
- Persons with HIV infection
- Persons with chronic liver disease

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- Household contacts of HBsAg-positive persons
- Residents and staff of facilities for developmentally disabled persons
- International travelers to countries with high or intermediate prevalence of chronic hepatitis B infection
- Hepatitis B vaccine should be administered to unvaccinated adults with diabetes who are < 60 years of age
- Hepatitis B vaccine may be administered to unvaccinated adults with diabetes who are ≥ 60 years of age

Hepatitis B vaccination is recommended for all adults in the following settings:

- STD treatment facilities
- HIV testing and treatment facilities
- Facilities providing drug-abuse treatment and prevention services
- Health care settings targeting services to injection-drug users or men who have sex with men
- Correctional facilities
- End-stage renal disease programs and facilities for chronic hemodialysis patients
- Institutions and non-residential day care facilities for persons with developmental disabilities

(Centers for Disease Control and Prevention, 2011k [Guideline]; Mast, 2006 [Reference])

Schedule and Dosing Considerations

The recommended amount of hepatitis B vaccine varies by age and manufacturer and schedule. The package insert information should be consulted for details.

All infants and children not previously immunized should receive three doses of hepatitis B vaccine. Four doses may be given if the first dose is given at birth. The first and second doses should be given a minimum of four weeks apart. The second and third doses are to be given a minimum of eight weeks apart. The first and third doses are to be given at least 16 weeks apart. The last (third or fourth) dose of hepatitis B vaccine should not be given before six months of age.

Authorities recommend that whenever possible, the routine series of hepatitis B vaccination should begin at the infant's birth.

(Mast, 2006 [Reference])

There is an accelerated or alternate schedule of 0, 1, 2 and 12 months for hepatitis B vaccine (Engerix B®). This vaccine is available for use in special circumstances where faster and prolonged sero-protective levels are desired, such as neonates born of hepatitis B-infected mothers, recent exposure to the virus, or travelers to high-risk areas leaving in less than three months.

Special Considerations with Regard to Infants Born to Hepatitis B-Positive Mothers

All full-term infants born to mothers who are hepatitis B surface-antigen positive should receive hepatitis B immune globulin (HBIG) and the first dose of hepatitis B vaccine within 12 hours of birth, a second dose of hepatitis B vaccine at 1 to 2 months of age and a third dose of hepatitis B vaccine at or after 6 months of age. Infants at 9 to 15 months of age should undergo serologic tests for both surface antigen and for antibody to surface antigen.

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If the mother's hepatitis B surface antigen status is unknown, the infant should receive the hepatitis B vaccine within 12 hours of birth. The mother should be tested for her hepatitis B surface-antigen status as soon as possible after delivery. If the mother is hepatitis B surface-antigen positive, the infant should receive hepatitis B immune globulin as soon as possible but no later than one week of age.

All premature infants born to mothers who are hepatitis B surface-antigen positive should receive hepatitis B immune globulin within 12 hours of birth, as well as a dose of hepatitis B vaccine, but the infant should start the three-dose series anew when the infant is two kilograms in weight or two months of age. Infants at 9 to 15 months of age should undergo serologic tests for both surface antigen (HBsAg) and for antibody to surface antigen (HBsAg).

Special Considerations with Regard to Adolescents

There are two hepatitis B vaccine schedules that can be used among adolescents: the usual three-dose series given at 0, 1 and 6 months, or the adult 10 mcg dose, which uses a two-dose schedule given at 0 and 4-6 months. The adult 10 mcg dose is specifically for adolescents aged 11-15 years. Both schedules produce equivalent sero-protection. The two-dose series using the higher dose of vaccine is well suited to school-based delivery. Be aware, however, that the two-dose schedule does increase the operational complexity for immunization administration in a clinic serving multiple ages of children and can therefore increase resultant risk of error.

Special Considerations with Regard to Recipients of Hemodialysis and Other Immuno-suppressed Adults

Recipients of hemodialysis and other immunosuppressed adults should receive 40 mcg doses of hepatitis B vaccine especially formulated for this use. The dosing schedule is otherwise the same. The recommended schedule for Recombivax® with the dialysis formulation is 0, 1 and 6 months; however, if Engerix B® is used, the recommended schedule is 0, 1, 2 and 6 months. Sero-protection rate with Engerix B® is higher after a four-dose schedule than with a three-dose schedule. The Advisory Committee on Immunization Practices recommends that the need for booster doses of vaccine should be assessed by annual antibody testing and a booster dose given when antibody levels decline to 10 mIU/mL or less.

The Role of Post-Immunization Testing

Post-vaccination serologies are not recommended for all vaccines. Post-vaccination testing is currently recommended for high-risk individuals (those at high risk of exposure or outcome of hepatitis B if acquired) such as health care and public safety workers, chronic hemodialysis patients, HIV-infected persons, and other immunocompromised persons; and sex or needle-sharing partners of HBsAG-positive persons. Testing should be performed 1-2 months after the last dose of vaccine.

The following groups of patients should have post-immunization serologic testing for surface antigen (HBsAg) and antibody to surface antigen (HBsAg):

- Infants at 9 to 15 months of age born to hepatitis B surface-antigen positive mothers
- Health care workers who are at high risk of exposure to blood or body fluids in the workplace, between one and six months after completion of the vaccine series
- Immunocompromised patients (e.g., dialysis, AIDS patients), between one and six months after completion of the vaccine series
- Sex partners of hepatitis B surface-antigen positive patients, between one and six months after completion of the vaccine series

For universal hepatitis B immunization of newborns and adolescents, the ICSI Immunizations guideline work group endorses the recommendations of the Minnesota Department of Health, the Advisory Committee on Immunization Practice, the American Academy of Pediatrics and the American Academy of Family Practice.

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The recommendation for hepatitis B vaccination of all persons under the age of 40 years is based upon the following considerations:

- Most hepatitis B infections in the U.S. occur in young adults.
- Historically, efforts to recognize and vaccinate only young persons in hepatitis B virus risk groups have been unsuccessful.

Complications from hepatitis B vaccination are uncommon. Continued scrutiny of a potential relationship between hepatitis B vaccination and development of multiple sclerosis is ongoing. The Institute of Medicine did not find sufficient evidence of an association in its 2002 position paper addressing this question *(Stratton, 2004 [Reference])*.

Management of Postimmunization Serology Test Results

- Hepatitis B surface antibody serology should be checked in recently vaccinated health care workers or high-risk individuals one month after completion of series and also in high-risk vaccinees with **NO** prior documented serology.
  - If **sero-negative or has a previously documented negative anti-HBsAb serology**: give **one** regular dose hepatitis B virus booster only and retest anti-HBsAb serology in one month.
  - If still anti-HBsAG **sero-negative**: complete the three-dose series with the **regular or higher dos**e (40 mcg) for the remaining two doses and retest anti-HBsAb serology one month after completion of series. If still anti-HBsAG sero-negative: consider patient a non-responder. (Note: There is no evidence identifying which dose is more effective.)
- Recent data shows that the duration of immunity provided by completed hepatitis B primary series is at least 15 years or longer. Need for a booster is unclear especially in those with documented positive anti-HBs antibody *(McMahon, 2005 [Low Quality Evidence])*.

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13. Hepatitis A (HepA) and Hepatitis B (HepB) Combination Vaccine

Twinrix® contains both hepatitis A vaccine and hepatitis B vaccine, and is licensed for adults 18 years and older. Twinrix® requires three doses. The second dose should be given one month after the first, and the third dose six months after the first dose and five months after the second dose.

A dose of Twinrix® contains less hepatitis A viral antigen than a dose of single antigen adult hepatitis A vaccine. To complete the hepatitis A vaccine series, an adult patient must receive three doses of Twinrix® or two adult doses of single-antigen hepatitis A vaccine. It is not recommended to administer two doses of Twinrix® and one dose of single-antigen hepatitis B vaccine to complete the hepatitis A and B series.

(Fiore, 2006 [Reference])

In 2007, the Food and Drug Administration approved the hyperaccelerated 0, 7-, 21- to 30-day and 12-month booster schedule for Twinrix® for people needing protection in a short period of time (i.e., travelers). Seroprotection against hepatitis A and hepatitis B from the accelerated Twinrix® schedule was comparable to monovalent hepatitis A vaccine and hepatitis B vaccine schedules *(Centers for Disease Control and Prevention, 2007a [Guideline])*.

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14. Herpes Zoster/Shingles Vaccine

ZOSTAVAX®, the only currently licensed zoster vaccine, is a lyophilized preparation of a live attenuated strain of varicella, the same Oka/Merck strain used in the varicella vaccines. However, its minimum

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potency is at least 14 times the potency of single-antigen varicella vaccine. In a large clinical trial, zoster vaccine reduced the risk for developing zoster by 51.3% (95% CI = 44.2--57.6; p<0.001) *(Oxman, 2008 [High Quality Evidence]; Oxman, 2005 [High Quality Evidence])* and was 66.5% (95% CI = 47.5--79.2; p<0.001) efficacious for preventing posthepetic neuralgia. It was partially efficacious at preventing zoster with protection declining with age at vaccination from 65.5% in 60-69 year olds to 21% in those over 80 at the time of vaccination *(Oxman, 2008 [High Quality Evidence]; Oxman, 2005 [High Quality Evidence])*. It was also partially efficacious at reducing the severity and duration of pain and at preventing posthepetic neuralgia among those developing zoster *(Harpaz, 2008 [Reference])*.

Zoster vaccine is recommended for all persons aged 60 years or older who have no contraindications, including persons who report a previous episode of zoster or who have chronic medical conditions. The vaccine should be offered at the patient's first clinical encounter with his or her health care provider. It is administered as a single 0.65 mL dose subcutaneously in the deltoid region of the arm. A booster dose is not licensed for the vaccine.

The Zostavax® Efficacy & Safety Trial ("ZEST") was recently completed in persons ages 50-59. In March 2011, the Food and Drug Administration extended the indications for zoster vaccine to adults ages 50-59. However, the work group concurs with the recent ACIP recommendation and does not propose revision of existing recommendations regarding zoster vaccine *(Centers for Disease Control, 2011g [Guideline])*. The rationale for this conclusion is that there is insufficient evidence regarding duration of vaccine protection to vaccinate well before the peak of zoster incidence.

Zoster vaccination is not indicated to treat acute zoster, to prevent persons with acute zoster from developing posthepetic neuralgia, or to treat ongoing posthepetic neuralgia. Before administration of zoster vaccine, patients do not need to be asked about their history of varicella (chicken pox) or to have serologic testing conducted to determine varicella immunity *(Harpaz, 2008 [Reference])*.

Immunogenicity of zoster vaccine and trivalent inactivated influenza vaccine is not compromised when the two vaccines are administered simultaneously.

There is a recently published study that looks at the antibody response that occurred with the concomitant administration of zoster vaccine (VZV) and pneumococcal vaccine (PPV 23) in adults > 60 years old *(MacIntyre, 2010 [High Quality Evidence])*. The concomitant administration did not affect the immunogenic response to PPV 23 in those tested and both vaccine groups achieved acceptable levels of antibody titers. However, the zoster vaccine antibody response was lower in those individuals who received concomitant vaccines as compared to those who received the vaccine alone. The study recommends that these vaccines not be administered together as lower immune responses correlate with lower efficacy. It is the opinion of the work group that efforts should be made to administer these vaccines separately unless there is doubt about an individual's ability to return in a timely manner for further vaccines. In that case, given the data that indicates that acceptable immunity is reached, it would be reasonable to administer both vaccines at a single visit.

Due to lack of data, zoster vaccination is not recommended for persons of any age who have received varicella vaccine. However, health care providers do not need to inquire about varicella vaccination or disease history before administering zoster vaccine because virtually all persons currently or soon to be in the recommended age group have not received varicella vaccine *(Harpaz, 2008 [Reference])*. Adult immigrants coming from tropical climates should have a varicella titer drawn, and if it suggests previous varicella infection, patients ages 60 and older should be offered ZOSTAVAX®, and those without a positive titer should receive two doses of the varicella vaccine *(Harpaz, 2008 [Reference])*.

Zoster vaccine (live) should not be administered to:

- Persons with a history of anaphylaxis/anaphylactoid reaction to gelatin or neomycin

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- Persons with leukemia, lymphomas or other malignant neoplasms affecting the bone marrow or lymphatic system. (However, patients whose leukemia is in remission and who have not received chemotherapy [e.g., alkylating drugs or anti-metabolites] or radiation for at least three months can receive zoster vaccine.)
- Persons with AIDS or other clinical manifestations of human immunodeficiency viruses, including persons with CD4+ T-lymphocyte values less than 200 per mm^3 or less than 15% of total lymphocytes.
- Persons with clinical or laboratory evidence of other unspecified cellular immunodeficiency

  (However, persons with impaired humoral immunity [e.g., hypogammaglobulinemia or dysgammaglobulinemia] can receive zoster vaccine.)
- Persons undergoing hematopoietic stem cell transplantation (HSCT)
  - Clinicians should assess the immune status of the recipient on a case-by-case basis to determine the relevant risks.
  - If a decision is made to vaccinate with zoster vaccine, the vaccine should be administered at least 24 months after transplantation.
- Persons receiving immunosuppressant medications including:
  - Greater than 20 mg/day of prednisone or equivalent for more than two weeks
  - Greater than 0.4 mg/kg/day of methotrexate
  - Greater than 3 mg/kg/day of azathioprine
  - Greater than 1.5 mg/kg/day of 6-mercaptopurine
  - Chemotherapy or radiation
  - Tumor necrosis factor inhibitors
  - Other immune modulators
- Persons with active untreated tuberculosis
- Persons who are or may be pregnant

To date, concurrent administration of ZOSTAVAX® (Zoster Vaccine Live [Oka/Merck]) and antiviral medications known to be effective against varicella-zoster virus has not been evaluated. Concurrent administration of ZOSTAVAX® and other vaccines has not been evaluated, other than influenza and PPSV23.

Pregnancy (Category C)

- ZOSTAVAX® should not be administered to pregnant females; furthermore, pregnancy should be avoided for three months following vaccination, per manufacturer recommendations.

Use in children

- ZOSTAVAX® should not be used in children, per manufacturer recommendations.

Conditions for storage

The vaccine should be stored at an average temperature of -15°C (+5°F) or colder until it is reconstituted for injection. Any freezer, including frost-free, that has a separate sealed freezer door and reliably maintains an average temperature of -15°C or colder is acceptable for storing ZOSTAVAX®. ZOSTAVAX may be stored

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and/or transported at refrigerator temperature (2°C to 8°C, 36°F to 46°F) for up to 72 continuous hours prior to reconstitution. Vaccine stored at 2°C to 8°C (36°F to 46°F) that is not used within 72 hours of removal from -15°C (+5°F) storage should be discarded. Before reconstitution, protect from light.

The diluent is stored separately at room temperature (20°C to 25°C, 68°F to 77°F) or in refrigerator (2°C to 8°C, 36°F to 46°F). Vaccine should be used within 30 minutes of reconstitution.

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15. Human Papillomavirus (HPV) Vaccine

Human papillomavirus currently affects about 20 million Americans and has been associated with cervical, vaginal, vulvar, penile and anal cancers in addition to cancers of the head and neck *(Hoppel, 2011 [Reference])*. HPV is primarily transmitted by genital contact (usually through sexual intercourse). Other types of contact (oral-genital and manual-genital) leading to human papilloma transmission have been described. Of the cancers associated with HPV, cervical cancer is the most common cancer in women, and head and neck are the most common cancers occurring in men *(Hoppel, 2011 [Reference])*.

Human papillomavirus is the cause of invasive cervical cancer. The World Health Organization (WHO) recognizes cervical cancer as the first cancer 100% attributable to infection, with the prevalence of human papillomavirus DNA in cervical cancer biopsies from 22 countries at 99.7%. Receiving the human papillomavirus vaccine does not change the current recommendations for cervical cancer screening (Pap tests).

Local reactions are common, with 85% having pain and 25% having redness or swelling. Serious reactions appear to be rare. With almost 12,000 subjects and 9,000 controls in the prelicensure trials, no serious events were more common in the vaccine group than in the control group.

There are 12-18 syncope episodes for every 10,000 vaccinations (http://www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides-oct11/02-HPV-Gee.pdf). Numerous instances of syncope, sometimes with significant injury from falling, have been reported with this vaccine. More than half occurred within five minutes of receipt of the vaccine and 70% within 15 minutes. The Advisory Committee on Immunization Practice is recommending those being given human papillomavirus should wait in the room in a sitting or reclining position for 15 minutes *(Sutherland, 2008 [Reference])*.

The doses may be given on a 0, 2- and 6-month schedule. Minimum intervals between doses are as follows: 4 weeks between the first and second dose, 12 weeks between the second and third dose, and 24 weeks between the first and third dose. The prelicensure trials were very relaxed about schedule, and all intervals worked well. Thus, it is never necessary to restart the series. It is acceptable to administer doses beyond than 27 years of age if the series is started prior to 27 years.

Females

Two human papillomavirus vaccines are licensed: a quadrivalent vaccine, HPV4 (Gardasil), for the prevention of cervical, vaginal, vulvar, anal and orofacial cancers and genital warts; and a bivalent vaccine, HPV2 (Cervarix), for the prevention of cervical, vaginal, vulvar and orofacial cancers in females. They are licensed for use for ages 9 through 26, and the Advisory Committee on Immunization Practices recommends routine use of the vaccine for all 11- to 12-year-old females, and catch-up use of the vaccine for females ages 12 through 26 *(Markowitz, 2007 [Reference])*. The strains included in HPV4 (Gardasil) are 6, 11, 16 and 18. Strains 6 and 11 (present only in HPV4) account for 90% of venereal warts. Strains 16 and 18 are present in both HPV4 and HPV2 and account for 70% of oncogenic infections.

(Centers for Disease Control, 2010b [Guideline]).

If pregnancy occurs before the series is completed, further vaccination should occur after the pregnancy is over. In the prelicensure trials, about 1,100 pregnancies occurred in both the vaccine and control groups, and incidences of fetal wastage and fetal anomalies were similar.

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Males

The Advisory Committee on Immunization Practices (ACIP) has recently recommended the routine vaccination of boys ages 11 or 12 with three doses of quadrivalent vaccine, HPV4 (Gardasil), to protect them against HPV. The vaccine received a permissive recommendation in 2009, but it was not part of the routine ACIP recommended vaccines. On further review, it was felt that this new recommendation was justified due to increasing rates of anal cancer and head and neck cancers, as well as the direct benefit of preventing genital warts in males. It is also postulated that the vaccine will reduce male-to-female transmission of HPV due to disappointing rates of female HPV vaccinations.

Current guidelines are as follows: routine vaccination of males ages 11-12 years with 3 doses of HPV4. The vaccination series can be started beginning at age 9. Males ages 13 to 21 years who had not already received the HPV4 vaccine should also be vaccinated. Males ages 22 through 26 years of age may be vaccinated.

(Centers for Disease Control and prevention, 2011f [Guideline])

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16. Inactivated Poliovirus (IPV) Vaccine

Oral poliovirus vaccine (OPV) is no longer available in the United States but is used in increasingly successful eradication efforts worldwide *(Centers for Disease Control and Prevention, 2009 [Guideline]; Centers for Disease Control and Prevention, 2000 [Guideline])*.

Most adults living in the United States are immune as a result of vaccination received as children. Furthermore, adults in the United States, in general, have little risk of exposure to wild-type poliovirus. Vaccination is recommended for non-immune adults who are at a greater risk of exposure to wild-type polioviruses, including the following:

- Travelers to areas or countries where polio is or may be epidemic or endemic
- Members of communities or specific population groups with polio
- Laboratory workers handling specimens that may contain polio viruses
- Health care professionals in close contact with patients who may be excreting wild-type polio viruses

Fully immunized adults with high risk of exposure to wild-type virus may receive one dose of inactivated polio vaccine.

Incompletely immunized adults may receive the remaining doses of inactive poliovirus vaccine regardless of the length of time since the past doses or the forms of the vaccine.

Unimmunized adults should undergo primary immunization with the inactivated poliovirus vaccine. This is recommended over a minimum of seven months. The second dose should be given 4 to 8 weeks after the first, followed by a third dose given 6 to 12 months after the second dose.

Considerations for the unimmunized adult

If time does not allow the three-dose series over seven months, the following applies.

- If protection is needed in less than four weeks, give one dose of inactivated poliovirus vaccine.
- If protection is needed in four to eight weeks' time, give two doses of inactivated poliovirus vaccine at least four weeks apart.
- If protection is needed in eight weeks' time, three doses of inactivated poliovirus vaccine should be given, each at least four weeks apart.

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The remaining doses of vaccine to complete the primary immunization schedule should be given subsequently at the recommended intervals if the person remains at an increased risk.

(Centers for Disease Control and Prevention, 2000 [Guideline])

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17. Influenza Vaccine

Indications

Influenza vaccination of all people ages six months and older is recommended annually, through the entire influenza season, *(Nichol, 1995 [High Quality Evidence])* including women who are pregnant or will be pregnant during the influenza season. Limited safety data exist for the first trimester; however, the Advisory Committee on Immunization Practice suggests that vaccination may occur in any trimester and should be completed with inactivated injectable influenza vaccine (TIV).

Those at risk for serious complications from influenza include those who:

- have chronic heart disease,
- have chronic lung disease (including asthma and reactive airway disease),
- smoke tobacco products,
- have diabetes,
- have kidney failure,
- have illnesses that weaken the immune system,
- are taking medications that weaken the immune system,
- are children or adolescents receiving aspirin therapy,
- are pregnant,
- care for young children, or
- are children age 6 months to 2 years (who are too young to receive live attenuated influenza vaccine [LAIV]).

Children age 6 months through 8 years receiving influenza vaccine for the first time should receive two doses administered at least one month apart. For the 2011-12 influenza season, a second dose of influenza vaccine was recommended for children age 6 months through 8 years who did not receive influenza vaccine during the 2010-11 season regardless of the number of doses of influenza vaccine received in prior years. For the 2012-13 season, follow dosing guidelines in the 2012 Advisory Committee on Immunization Practices (ACIP) influenza vaccine recommendations.

(Centers for Disease Control, 2011d [Guideline])

Contraindications

Contraindications include severe allergic reaction to any component of the vaccine, including egg protein, or after previous dose of any influenza vaccine.

Although data are limited, the established benefits of influenza vaccination for the majority of persons who have a history of Guillain-Barré syndrome (GBS) and who are at high risk for severe complications from influenza justify yearly vaccination. It is prudent to avoid vaccinating persons who are not at high risk for severe influenza complications but who are known to have developed Guillain-Barré syndrome within six weeks after receiving a previous influenza vaccination.

(Centers for Disease Control, 2010d [Guideline]; Smith, 2006 Reference)

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Recommendations regarding persons with egg allergy

Persons who have experienced only hives following exposure to egg should receive influenza vaccine with the following additional measures:

- Because studies published to date involved use of inactivated injectable influenza vaccine (TIV) rather than LAIV should be used.
- Vaccine should be administered by a health care provider who is familiar with the potential manifestations of egg allergy.
- Vaccine recipients should be observed for at least 30 minutes for signs of a reaction following administration of each vaccine dose.

Other measures, such as dividing and administering the vaccine by a two-step approach and skin testing with vaccine, are not necessary.

(Centers for Disease Control, 2011d [Guideline])

Vaccine formulations

There are two licensed influenza vaccines available for use in the U.S. – inactivated injectable influenza vaccine (TIV), and live attenuated influenza vaccine (LIAV). Both the inactivated and live vaccines contain the same three influenza strains each year. For the most up-to-date information on vaccine types available, please refer to http://www.cdc.gov/flu/professionals/acip/dosage.htm#tab2. Viruses for both vaccines are grown in eggs.

Live attenuated influenza vaccine is a product that complements inactivated influenza vaccine. The live attenuated influenza vaccine is licensed for use ONLY in healthy persons ages 2 through 49 years. It is more effective in children and probably equally effective in adults. It may be the preferable vaccine to use in children in whom it is not contraindicated.

Belshe, et al. studied children 6 to 59 months of age (7,852 children) in a double-blind manner. The children either received cold-adapted trivalent live attenuated influenza vaccine or trivalent inactivated vaccine. The study concluded that live attenuated vaccine had significantly better efficacy than inactivated vaccine in children who have no contraindications *(Belshe, 2007 [High Quality Evidence])*.

Ohmit, et al. studied the two vaccines in adults in a double-blind manner. While the study was slightly underpowered, the point estimate of live attenuated influenza vaccine (LAIV) was slightly less effective. However, there was no statistically significant difference between the two vaccines *(Ohmit, 2008 [Moderate Quality Evidence])*.

Both TIV and LAIV should be stored in a refrigerator between 2-8ºC (35-46ºF) upon receipt and until use before expiration date. DO NOT FREEZE.

LAIV

Persons should NOT receive live attenuated influenza vaccine if they:

- have chronic heart disease (except hypertension),
- have chronic lung disease (including asthma and reactive airway disease),
- have diabetes,
- have kidney failure,
- have illnesses that weaken the immune system,

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- are taking medications that weaken the immune system,
- are children or adolescents receiving aspirin therapy,
- are pregnant, or
- have a history of allergy to eggs (or any vaccine component).

In clinical studies, transmission of vaccine viruses to close contacts has occurred only rarely with live vaccines (current estimated risk of getting infected with vaccine virus is approximately 0.6-2.4%). Because the live attenuated influenza vaccine viruses are attenuated and cold-adapted, infection with live attenuated influenza vaccine is unlikely to result in influenza illness symptoms since the vaccine viruses have not been shown to mutate into typical or naturally occurring influenza viruses.

Live attenuated influenza vaccine is a good alternative for healthy health care workers up to 50 years of age. Only those caring for patients in protective environments, such as bone marrow transplant wards, should not receive live attenuated influenza vaccine. For persons directly caring for a person who is severely immunocompromised and in protective isolation, inactivated vaccine is preferred over live attenuated vaccine.

Live attenuated influenza vaccine can be administered simultaneously with other inactivated vaccines or live vaccines. Live attenuated influenza vaccine may be given to persons with minor illnesses (e.g., diarrhea or mild upper respiratory tract infection with or without fever). However, if nasal congestion is present, that might limit delivery of the vaccine to the nasal lining. Consider delaying the vaccination until nasal congestion subsides. Health care workers should wear disposable gloves when administering live attenuated influenza vaccine.

Side effects of live attenuated influenza vaccine can include runny nose, headache, vomiting, muscle aches, sore throat, cough and fever (though fever is not a common side effect in adults receiving live attenuated influenza vaccine).

The effect on safety and efficacy of live attenuated influenza vaccine co-administration with influenza antiviral medications has not been studied. However, because influenza antivirals reduce replication of influenza viruses, live attenuated influenza vaccine should not be administered within 48 hours after cessation of influenza antiviral therapy, and influenza antiviral medications should not be administered for two weeks after receipt of live attenuated influenza vaccine.

(Centers for Disease Control, 2010d [Guideline]; Smith, 2006 [Reference])

TIV

Forms of TIV

- Standard dose killed vaccine for IM use. 0.5 ml in patients aged three years and older and 0.25 ml in patients aged 6 through 35 months.
- Intradermal administration with a special device. 0.1 ml intradermally for patients aged 18-64 years.
- High dose for use in patients age 65 and older. This vaccine contains four times as much antigen. The dose is 0.5 cc IM.

The immunogenicity of the intradermal vaccine is similar to the intramuscular vaccine. The high-dose vaccine does produce better antibodies in the elderly and somewhat more side effects. It is not known yet whether this vaccine is more effective in this age group.

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18. Measles, Mumps and Rubella/Measles, Mumps, Rubella and Varicella (MMR/MMRV) Vaccine

The first dose of measles, mumps and rubella (MMR) immunization is recommended between 12 to 15 months of age (minimum age 12 months).

Recommended timing for the second immunization is at 4-6 years, but it is acceptable to give as soon as four weeks after the first.

A personal or family history of convulsive disorders is not a contraindication to measles vaccination. There is good epidemiologic evidence that autism is not caused by measles-containing vaccine *(Institute of Medicine, 2004 [Reference]; Madsen, 2002 [Low Quality Evidence]; Dales, 2001 [Low Quality Evidence])*.

Adults lacking documentation of vaccination or evidence of disease who were born during or after 1957 should receive one dose of MMR. A second dose of MMR is recommended for adults who:

- were recently exposed to measles or in an outbreak setting,
- were previously vaccinated with killed measles vaccine,
- were vaccinated with an unknown vaccine during 1963-1967,
- are students in postsecondary educational institutions,
- work in health care facilities, or
- plan to travel internationally.

(Watson, 1998 [Reference])

Vaccination should not occur during pregnancy. Pregnant women who test negative for rubella immunity may need to receive another MMR vaccine postpartum. Based on community consensus, if the patient has documentation of two previous vaccinations, then a third vaccination should not be given. If two previous vaccinations have not been given, a dose of MMR should be given soon after delivery.

Combined measles, mumps, rubella and varicella vaccine (MMRV) may be provided for children 12 months through 12 years of age in lieu of separate injection of equivalent component vaccines.

For children younger than 13 years of age, the minimum interval between the first dose of varicella and a dose of MMRV (MMR and varicella in combination) is 12 weeks *(Advisory Committee on Immunization Practices [ACIP], 2006 [Guideline])*.

However, if the second dose of varicella vaccine was administered 28 days or more after the first dose, the second dose is considered valid and does not need to be repeated *(Marin, 2007 [Reference])*.

Postlicensure studies of MMRV suggest an increased risk of febrile convulsions 7 to 10 days post-vaccination in children aged 12 to 23 months who received MMRV vaccine compared to children who received MMR and varicella separately at the same time *(Centers for Disease Control and Prevention, 2008 [Guideline])*. It is estimated that one additional febrile convulsion would occur in every 2,300 children vaccinated with MMRV, compared to children who received MMR and varicella concurrently and in separate injections.

As a general rule, the Advisory Committee on Immunization Practice of the Centers for Disease Control and Prevention has stated a preference for combination vaccines over separate injections of the same antigens. However, providers who are considering administering MMRV vaccine should discuss the benefits and risks of both vaccination options with the parents or caregivers. Unless the parent or cargiver expresses a preference for MMRV vaccine, the Centers for Disease Control and Prevention recommends that MMR vaccine and varicella vaccine should be administered for the first dose. Given this information, the Immunizations work group consensus is that in most instances, separate administration of MMR and varicella vaccine is preferred at age 12 through 47 months, while at ages 4 to 6 years, the MMRV combination vaccine is preferred.

(Centers for Disease Control and Prevention, 2010f [Guideline])

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19. Meningococcal Vaccine

There are four meningococcal vaccines currently Federal Drug Administration (FDA) approved for use in the United States. Three are quadrivalent vaccines effective against serogroups A, C, W135 and Y; polysaccharide vaccine Menomune®, and two conjugated vaccines – Menactra® and Menveo®. The fourth vaccine HibMenCY (MenHibrix) protects against serogroups C and Y and *Haemophilus influenzae* type b and is recommended for children aged 2 through 18 months who are at increased risk for meningococcal disease (e.g., persistent complement component deficiencies, anatomic or functional asplenia, including sickle cell disease).

Abbreviation	Vaccine Name	Trade Name	Manufacturer	Age	Comments
HibMenCY	Meningococcal conjugate C and Y, *and Haemophilus influenzae* type B	Menactra®	GlaxoSmithKline	6 weeks through 18 months	For high-risk patients
MCV4-D	Meningococcal conjugate A, C, W and Y	Menactra®	Sanofi Pasteur	9 months through 55 years	
MCV4-CRM	Meningococcal conjugate A, C, W and Y	Menveo®	Novartis	2 through 55 years	
MPSV4	Meningococcal polysaccharide A, C, W and Y	Menomune®	Sanofi Pasteur	2 years and older	MCV4 preferred for persons 9 months through 55 years

(Cohn, 2013 [Guideline]; Centers for Disease Control and Prevention, 2011c [Guideline]; Centers for Disease Control and Prevention, 2011e [Guideline])

Routine Vaccination

Meningococcal conjugate vaccine (MCV4) is recommended for adolescents at age:

- 11 to 12 years with a booster dose at age 16 years, or
- 13 through 15 years with a booster dose at age 16 through 18 years, or
- 16 through 18 years of age. A booster dose is not needed if the first dose was administered at age 16 years or older, or
- 19 through 21 years who are first-year college students and are living in residence halls. A booster dose is not needed.

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Vaccination for Persons at Increased Risk

Persons at increased risk for meningococcal disease are recommended for routine meningococcal vaccination. Vaccine product, number of doses and booster dose recommendations are based on age and risk factor and are shown in the following table.

Age Group	Conditions that Increase Risk for Meningococcal Disease	Primary Vaccination	Booster Dose if Risk Continues
2-18 months[§]	• Persistent complement deficiencies* • Functional or anatomic asplenia • Community outbreak attributable to a vaccine serogroup	4 doses of Hib-MenCY, at 2, 4, 6, and 12-15 months	Primary dose or series completed at age: **2 months-6 years:** boost with MCV4 – 3 years after primary immunization and every 5 years thereafter **≥ 7 years:** boost with MCV4-5 years after primary immunization and every 5 years thereafter
9-23 months[¶]	• Persistent complement deficiencies* • Travel to or reside in countries where meningococcal disease is hyperendemic or epidemic • Community outbreak attributable to a vaccine serogroup	2 doses of MCV4-D, 12 weeks apart**	
2-55 years	• Persistent complement deficiencies* • Functional or anatomic asplenia	2 doses of MCV4, 8-12 weeks apart[††]	
	• Travel to or reside in countries where meningococcal disease is hyperendemic or epidemic • Community outbreak attributable to a vaccine serogroup • Microbiologists routinely exposed to isolates of *Neisseria meningitidis*	1 dose of MCV4[††]	
56 years and older	• Persistent complement deficiencies* • Functional or anatomic asplenia • Travel to or reside in countries where meningococcal disease is hyperendemic or epidemic • Community outbreak attributable to a vaccine serogroup • Microbiologists routinely exposed to isolates of *Neisseria meningitidis*	1 dose of MPSV4	Boost every 5 years with MPSV4

* Persistent complement component deficiencies (e.g., C5-C9, properdin, factor H, or factor D)

§ Infants and children who received Hib-MenCY and are travelling to areas with high endemic rates of meningococcal disease such as the African "meningitis belt" are not protected against serogroups A and W-135 and should receive a quadrivalent meningococcal vaccination licensed for children aged ≥ 9 months prior to travel. Children aged 9 through 18 months with persistent complement deficiencies may receive either HibMenCY or MCV4-D.

¶ Because of high risk for invasive pneumococcal disease, children with functional or anatomic asplenia should not be immunized with MenACWY-D (Menactra) before age 2 years to avoid interference with the immune response to the pneumococcal conjugate vaccine (PCV) series. Children aged 9 through 18 months with persistent complement deficiencies may receive either HibMenCY or MCV4-D.

** If an infant is receiving the vaccine prior to travel, two doses may be administered as early as eight weeks apart.

†† If MenACWY-D is used, it should be administered at least four weeks after completion of all PCV doses.

HIV positive adolescents aged 11 through 18 years should receive a two-dose primary series of MCV4, at least eight weeks apart. Patients of other ages with human immunodeficiency virus are likely to be at increased risk for meningococcal disease and may elect vaccination.

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Colleges may elect to target their vaccination campaigns to all matriculating freshmen to facilitate vaccination of those at higher risk or those previously unvaccinated. The vaccines are safe and immunogenic and can be provided to non-freshmen college students who want to reduce their risk for meningococcal disease and have not been previously vaccinated.

While the risk is relatively lower for adults aged 20 through 55 years who are not at increased risk for meningococcal disease, persons who wish to decrease their risk for meningococcal disease may elect to be vaccinated with the meningococcal conjugate vaccine.

(Cohn, 2013 [Guideline])

Revaccination

The unconjugated meningococcal polysaccharide vaccine (MPSV4) is thought to give protection for at least two to three years but no more than five years. The meningococcal conjugated vaccine (MCV4) is thought to give protection for at least five years.

Persons with increased risk who were first vaccinated at less than four years of age with the unconjugated meningococcal polysaccharide vaccine should be considered for revaccination after two to three years with the conjugated vaccine.

(Cohn, 2013 [Guideline])

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20. Pneumococcal Vaccine

The information on the 2012 Centers for Disease Control and Prevention immunization schedules are not current. The 2013 schedules, which are expected for release in February 2013, will include the information shown below.

Vaccine	Trade Name	Manufacturer
Pneumococcal conjugate (PCV13)	Prevnar13	Pfizer
Pneumococcal polysaccharide (PPSV23)	Pneumovax 23	Merck

PCV13

Routine vaccination of children:

- PCV13 is indicated for children age six weeks through 59 months and is administered at 2, 4, 6, and 12-15 months.
- Children age 14 through 59 months who have completed the series with PCV7 should receive a single supplemental dose of PCV13.

Vaccination of persons with high-risk conditions

Persons with the high-risk conditions shown below are recommended to receive either PCV13 or PPSV23 or both vaccines.

Categories of high-risk conditions

1. Chronic heart disease, chronic lung disease, diabetes mellitus, adults ≥ 19 years: alcoholism, chronic liver disease (cirrhosis), asthma, cigarette smoking.
2. Candidate for or recipient of cochlear implant, cerebrospinal fluid leak.
3. Functional or anatomic asplenia: sickle cell disease, other hemaglobinopathy, congenital or acquired asplenia; immunocompromising conditions: congenital or acquired immunodeficiency (including B-

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(humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease); HIV infection; chronic renal failure and nephrotic syndrome; leukemia, lymphoma, Hodgkin disease, generalized malignancy, solid organ transplant, multiple myeloma; iatrogenic immunosuppression (e.g., diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy).

Vaccination of children age 2 through 18 years with high-risk conditions

Age	High-Risk Category	Recommendations
24 through 71 months	1, 2 and 3	1 dose PCV13 if 3 doses PCV were received previously, or 2 doses ≥ 8 weeks apart if < 3 doses of PCV were received previously
6 through 18 years	2 and 3	1 dose PCV13 may be administered
2 through 18 years	1, 2 and 3	1 dose PPSV23 ≥ 8 weeks after last PCV dose
	3	PPSV23 booster ≥ 5 years after previous dose

Vaccination of adults (age 19 years and older) with high-risk conditions

Although PCV13 is licensed by the Food and Drug Administration (FDA) for persons age 50 years and older, the Advisory Committee on Immunization Practices (ACIP) recommends PCV13 for adults age 19 years and older with immunocompromising conditions. Greater immune response was demonstrated when PCV13 was administered before PPSV23.

<table>
<tr><th>High-Risk Category</th><th>PPSV23 Vaccine History</th><th colspan="2">Recommendations</th></tr>
<tr><td rowspan="2">1</td><td>0</td><td colspan="2">PPSV23</td><td rowspan="6">PPSV23 at ≥ 65*

Adults who received a dose of PPSV23 at age ≥ 65 years do not need another dose.</td></tr>
<tr><td>1</td><td colspan="2"></td></tr>
<tr><td rowspan="2">2</td><td>0</td><td colspan="2">PCV13 1st, PPSV23 ≥ 8 weeks later</td></tr>
<tr><td>1</td><td colspan="2">PCV13 ≥ 1 year after PPSV23</td></tr>
<tr><td rowspan="3">3</td><td>0</td><td>PCV13 1st, PPSV23 ≥ 8 weeks later</td><td>PPSV23 #2*</td></tr>
<tr><td>1</td><td>PCV13 ≥ 1 year after PPSV23</td><td>PPSV #2 ≥ 8 weeks after PCV 13*</td></tr>
<tr><td>2</td><td colspan="2">PCV13 ≥ 1 year after PPSV23</td></tr>
</table>

*Additional doses of PPSV23 should be administered ≥ 5 years after previous PPSV23 dose.

(Centers for Disease Control and Prevention, 2010e [Guideline]; Centers for Disease Control and Prevention, 2012 [Guideline])

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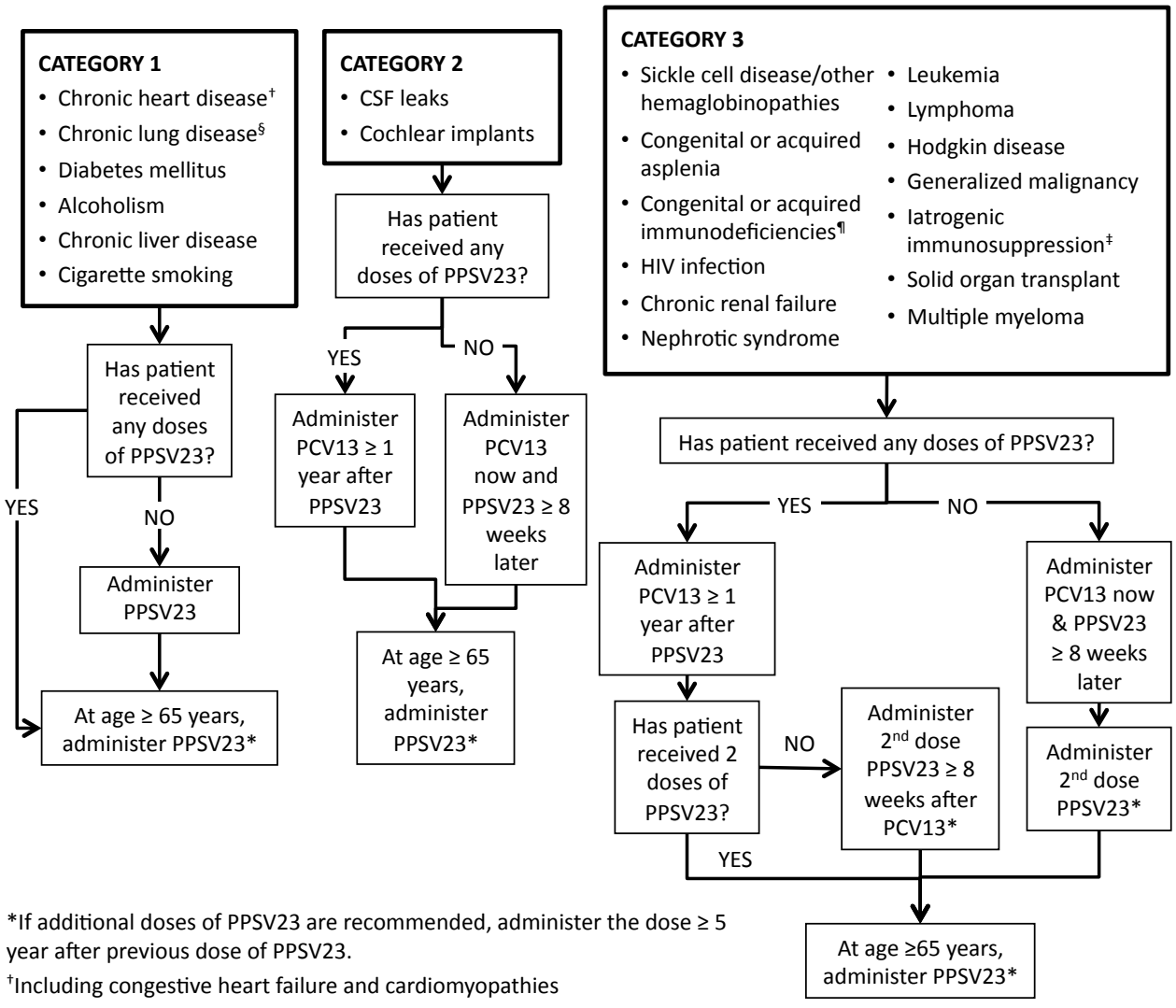
PNEUMOCOCCAL VACCINE RECOMMENDATIONS FOR ADULTS AGE 19 YEARS AND OLDER – Flowchart

PCV13 (Prevnar13, Pfizer), PPSV23 (Pneumovax 23, Merck)

- Healthy adults do not need PPSV23 until age 65 years.
- Adults with the conditions shown below are recommended to receive PPSV23 before age 65 years. Adults in categories 2 and 3 are also recommended to receive PCV13.
- Adults who received a dose of PPSV23 on or after age 65 years do not need additional doses.



*If additional doses of PPSV23 are recommended, administer the dose ≥ 5 year after previous dose of PPSV23.

†Including congestive heart failure and cardiomyopathies

§Including chronic obstructive pulmonary disease, emphysema, and asthma

¶Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease)

‡Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy

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21. Rotavirus Vaccine

Trade Name	Abbreviation	Manufacturer	Dose	Schedule*	Notes
RotaTeq	RV5	Merck	2 mL, oral solution	2, 4, 6 months of age	Oral starting at 6 weeks of age or older, with subsequent doses at least 4 weeks apart. First dose by 14 weeks 6 days (before 15 weeks of age) and no doses after 8 months of age
Rotarix	RV1	GlaxoSmithKline	1 mL	2, 4 months of age	Oral starting at 6 weeks of age or older, with second dose at least 4 weeks after first dose. First dose by 14 weeks 6 days (before 15 weeks of age) and no doses after 8 months of age

*Recent ACIP recommendations for both rotavirus vaccines include changes for the maximum age for the first dose (14 weeks 6 days) and the maximum age for the final dose of the series (8 months 0 days) (*Cortese, 2009 [Guideline]*).

Special Consideration

Safety and effectiveness have not been evaluated when Rotarix® is administered for the first dose and RotaTeq® is administered for the second dose, or vice versa. If both types of rotavirus vaccine are given to the infant in the first two doses, or if the type of vaccine used for the first dose is unknown, a third dose is recommended.

Severe Combined Immunodeficiency Disease (SCID) and intussusception is a contraindication to either rotavirus vaccine.

DNA fragments of porcine circavirus 1 and 2 have been in both forms of rotavirus vaccine. The porcine circaviruses have never been shown to cause human disease, and experts hold that their presence in the vaccines poses no harm. Any theoretical risk of their presence is more than balanced by the prevention of rotavirus diarrhea.

(Centers for Disease Control and Prevention, 2010a [Guideline])

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22. Varicella Vaccine

A household contact study examining varicella transmissions concludes that the varicella vaccine is effective in preventing moderate and severe disease and 80% effective in preventing all disease *(Seward, 2004 [Low Quality Evidence])*.

A case control study of 339 children 13 months or older who were clinically diagnosed as having chicken pox and who also had a polymerase chain reaction (PCR) test result that was positive for varicella-zoster virus DNA concluded that the effectiveness of the vaccine decreases after one year *(Vázquez, 2004 [Low Quality Evidence])*.

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Catch-up regimens*

Age	Schedule	Notes
12 months up to 13 years of age	12 months or older; 4-6 years of age	Minimum interval of 12 weeks; 2nd dose should occur before starting kindergarten or 1st grade
13 years and older	2 doses at least 28 days apart	

* Vaccination occurs when evidence of immunity does not exist.

A catch-up second dose of varicella vaccine is recommended for all children, adolescents and adults who received only one dose previously. The second dose of varicella vaccine improves individual protection and reduces the risk of school outbreaks. Providers should use every encounter to assess the need for a catch-up second dose of varicella vaccine, especially in those persons who received varicella vaccine between the ages of 12 months through 12 years at a time when only one dose had been recommended.

Evidence of immunity to varicella includes:

- documentation of age-appropriate varicella vaccination, which is one dose of vaccine for 4-year-old children, 12 months or more of age and two doses of vaccine for school-aged children, adolescents and adults;
- history of health care provider diagnosis of varicella illness (if a mild or atypical case, providers should seek epidemiologic link with a typical case or laboratory evidence obtained at the time of the illness);

  Any history of disease should be accepted only if it occurred before 1995 *(Perella, 2009 [Low Quality Evidence])*. With the marked reduction in varicella disease, many of the varicella-like rashes are caused by other viruses, and the positive predictive nature of a varicella rash is low.
- history of health care provider diagnosis of herpes zoster;
- serologic evidence of immunity or culture evidence of infection; or
- born in the United States before 1980.

It is cost effective to do immune status testing for all persons 13 years of age and older, who believe they are non-immune, before vaccinating. More than 75% of them will be immune. The prevaccination testing will also substantially reduce the average number of needle sticks that patients in this range need. For most, that number will be only one *(Nordin, 1998 [Low Quality Evidence])*.

No harm is done in immunizing already immune patients, and they will receive a booster effect.

If the immunization schedule is interrupted, there is no need to restart. The second injection should be given.

The teratogenic potential of the varicella vaccine is unknown. Pregnancy, therefore, is an absolute contraindication.

Special indications

Special consideration for varicella vaccination should be given to:

- those who have close contact with persons at high risk for severe disease (health care workers and family contacts of immunocompromised persons);
- those who are at high risk for exposure or transmission to others (such as teachers of young children; child care employees; residents and staff members of institutional settings, including correctional

institutions; college students; military personnel; adolescents and adults living in households with children; non-pregnant women of childbearing age; and international travelers);

- non-immune family members living with a non-immune, pregnant or immune deficiency person – they should be immunized to lessen the risk of wild-type virus varicella in the immune deficient person; and
- children who are aged less than 18 who have conditions requiring treatment with chronic salicylates – they should be given the immunization to lessen their risk of Reye's Syndrome from wild-type virus varicella infections.
- While the currently formulated vaccine is not licensed for postexposure prophylaxis, evidence supports its effectiveness in the first three days after exposure and its use would confer little risk *(Mor, 2004 [High Quality Evidence])*.
- Assessment for evidence of varicella immunity is recommended for all pregnant women. Women who do not have evidence of immunity to varicella should be given the first dose of varicella before discharge from the hospital. The second dose should be given four to eight weeks later. Women should avoid conception for one month after each dose of varicella. Two reports from the pregnancy registry for Varivax® show no abnormal features from the occurrence of congenital varicella syndrome or other birth defects related to vaccine exposure *(Shields, 2001 [Reference]; Wilson, 2008 [Reference])*.

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23. Vaccinations for High-Risk Patients

Vaccine Considerations for Special Case Patients

Experience with vaccine use in immunocompromised persons and persons with chronic, underlying disease is limited. Each situation should be evaluated on an individual basis. Some general guidelines follow, which may help in making immunization decisions.

Prematurity

Prematurity alone is not a contraindication to routine immunization, and normal schedules can begin when the infant is clinically stable and has attained a weight of at least 1,000 grams (see Annotation #12, "Hepatitis B [HepB] Vaccine," for special considerations with hepatitis B vaccine).

Patients Receiving Immunosuppressant Medications

Many medications suppress the immune system. Use of certain immunosuppressant medications may be a contraindication to administration of certain vaccines, particularly live viral vaccines.

As a general rule, avoid administering live viral vaccines (rotavirus, MMR, varicella, zoster, LAIV) to persons receiving the following medications (or dosage of medication listed):

- Corticosteroids
  - Children greater than 2 mg/kg/day or 20 mg/day prednisone or equivalent for greater than two weeks
  - Adults 20 mg/day prednisone or equivalent for greater than two weeks
- Chemotherapy or radiation
- Methotrexate
  - Greater than 0.4 mg/kg/day

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- Azathioprine
  - Greater than 3 mg/kg/day
- 6-Mercaptopurine
  - Greater than 1.5 mg/kd/day
- Tumor necrosis factor inhibitors (adalimumab, entanercept, infliximab, etc.)
- Other immune modulators

Immunodeficiencies

Live viral (rotavirus, LAIV, MMR, zoster and varicella) vaccines are contraindicated in patients with immunodeficiencies. Immunocompromised persons can and should receive inactivated vaccines, but their response to these vaccines may be suboptimal. Normal siblings of immunocompromised children should not receive live oral polio vaccine (but may receive IPV) and may receive other live vaccines (e.g., MMR, varicella). The work group recognizes that live oral polio vaccine is no longer available in the United States; however, other countries are still using this type of poliovirus vaccine.

HIV-Positive Patients

Human immunodeficiency virus (HIV) patients should receive routine adult and pediatric vaccines as recommended except for live attenuated vaccines in certain situations as noted below. In addition, human immunodeficiency virus (HIV)-positive adults should receive 23-polyvalent pneumococcal and influenza vaccines. Those who get the pneumococcal vaccine when their CD4 is less than 200 cells/μL should have this repeated once, especially if the CD4 has increased greater than 200 cells/μL. Inactivated influenza vaccine should be administered to all human immunodeficiency virus (HIV)-infected persons annually during influenza season. Human papillomavirus (HPV) vaccine is not contraindicated and can be used where indicated by age and schedule. *Haemophilus influenzae* type B conjugate vaccine is recommended for all children. All human immunodeficiency virus (HIV) infected patients who do not have evidence of prior exposure to hepatitis B should be immunized with hepatitis B vaccine, followed by anti-HBs titers one month after last dose to document response. All human immunodeficiency virus (HIV)-infected adults who are hepatitis A-susceptible and have risk factors for hepatitis A should receive hepatitis A vaccination. All human immunodeficiency virus (HIV)-positive children should receive hepatitis A vaccine per pediatric schedule. A two-dose primary conjugated meningococcal vaccine series is recommended for persons living with HIV.

Live-virus vaccines have to be used with caution in persons living with HIV and their receipt in such patients depends on the immune status of the patient. MMR and varicella vaccines can be administered to immunologically intact persons who are non-immune to measles and /or varicella. The live attenuated varicella vaccine has been shown to be safe and immunogenic in HIV-infected children greater than or equal to 8 years old with CD4+ counts greater than or equal to 15%. However, live attenuated vaccines including MMR, varicella, nasal influenza, herpes zoster, yellow fever and oral typhoid vaccines are contraindicated for persons with **severe immunosuppression** with CD4 < 200 cells/μL in adults or less than 15% in children.

Asplenics (Patients with No Spleen or Dysfunctional Spleen Including Sickle Cell Disease)

Anatomic or functional asplenia

Persons with anatomic asplenia (congenital or acquired) or functional asplenia including sickle cell disease are at increased risk for infection by encapsulated bacteria, especially by *Streptococcus pneumoniae*, *Neisseria meningitidis* and *Haemophilus influenzae* type B.

In addition to the routinely recommended vaccines, asplenic patients should also receive Hib, meningococcal, and pneumococcal vaccine. The optimal timing for administering these vaccines depends on when the splenectomy occurs and if chemotherapy is administered.

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Timing of Initial Vaccination	
Elective splenectomy	At least two weeks prior
Emergency splenectomy	Two weeks after the splenectomy or at hospital discharge
If chemotherapy is being given **after** splenectomy	Three months after completion of chemotherapy or radiation
If chemotherapy is being given **before** splenectomy	One month after splenectomy

Vaccination recommendations for patients 19 years and older with anatomic or functional asplenia.

<table>
<tr><th>Vaccine</th><th colspan="2">Primary Vaccination</th><th colspan="2">Revaccination</th></tr>
<tr><td>Hib</td><td colspan="2">1 dose</td><td colspan="2">None</td></tr>
<tr><td>Meningococcal</td><td>19 years and older</td><td>2 doses MCV4 ≥8 weeks apart</td><td colspan="2">MCV4 every 5 years</td></tr>
<tr><td rowspan="4">Pneumococcal</td><td>PPSV23 History</td><td></td><td colspan="2"></td></tr>
<tr><td>0 doses</td><td>PCV13 1st, PPSV23 ≥8 weeks later</td><td rowspan="2">PPSV23 dose #2 ≥ 5 years after previous dose</td><td rowspan="3">PPSV23 dose #3 at ≥ 65 years and ≥ 5 years after previous dose</td></tr>
<tr><td>1 dose</td><td>PCV13 ≥ 1 year after PPSV23</td></tr>
<tr><td>2 doses</td><td colspan="2">PCV13 ≥ 1 year after PPSV23</td></tr>
<tr><td>Influenza</td><td colspan="4">Annually</td></tr>
</table>

Hib	*Haemophilus influenzae* type B
MCV4	Meningococcal conjugate A, C, W, and Y
MPSV4	Meningococcal polysaccharide A, C, W, and Y
PCV13	Pneumococcal conjugate 13-valent
PPSV23	Pneumococcal polysaccharide 23-valent

(Centers for Disease Control and Prevention, 2011h [Guideline])

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6140a4.htm

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The Aims and Measures section is intended to provide guideline users with a menu of measures for multiple purposes which may include the following:

- population health improvement measures
- quality improvement measures for delivery systems
- measures from regulatory organizations such as Joint Commission,
- measures that are currently required for public reporting,
- measures that are part of Center for Medicare Services Physician Quality Reporting initiative, and
- other measures from local and national organizations aimed at measuring population health and improvement of care delivery.

This section provides resources, strategies and measurement for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Aims and Measures
- Implementation Recommendations
- Implementation Tools and Resources

Aims and Measures

1. Increase the percentage of patients who are up-to-date with recommended immunizations.

   Measures for accomplishing this aim:

   a. Percentage of patients who turn two during the measurement year and have the following immunization status:

      - Four DTaP/DT
      - Three IPV
      - One MMR
      - Three Hib
      - Three hepatitis B
      - One VAR, or documented chicken pox disease
      - Four pneumococcal
      - Two hepatitis A
      - Rotavirus:
        - Two doses of the two dose vaccine, or
        - One dose of the two dose and two doses of the three dose vaccine, or
        - Three doses of the three dose vaccine
      - Two influenza

   (HEDIS 2011 by National Committee for Quality Assurance Measure)

   b. Percentage of patients who by age 13 years were up-to-date with recommended adolescent immunizations:

      - One HPV – Human papillomavirus vaccine by age 13 (for females)
      - One MCV4 – Meningococcal
      - One Tdap – Tetanus, diphtheria toxoids and acellular pertussis vaccine
      - One influenza vaccine within the last year

   c. Percentage of adult patients, 19 years and older, who are up-to-date with the following immunizations:

      - One Td or Tdap in the last 10 years
      - Varicella – two dose or history of disease up to year 1995
      - PPSV23 for patients 65 and older
      - One influenza
      - Herpes zoster/shingles (patients 60 years and older)

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2. Increase the percentage of patients/parents who received education regarding immunizations.

   Measure for accomplishing this aim:

   a. Percentage of patients or parents (if patient younger than 18 years of age) who receive education regarding the importance of immunizations and recommended immunization schedules.

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Measurement Specifications

Measurement #1a

Percentage of patients who turn two during the measurement year and have the following immunization status:

- Four DTaP/DT
- Three IPV
- One MMR
- Three Hib
- Three hepatitis B
- One VAR, or documented chicken pox disease
- Four pneumococcal
- Two hepatitis A
- Rotavirus:
  - Two doses of the two dose vaccine, or
  - One dose of the two dose and two doses of the three dose vaccine, or
  - Three doses of the three dose vaccine
- Two influenza

(HEDIS 2011 by National Committee for Quality Assurance Measure)

Population Definition

Children who turn two during the measurement year.

Data of Interest

$$\frac{\text{\# of children in the denominator who are up-to-date with their primary series of immunizations}}{\text{\# of children in the medical group's practice reaching the age of two years within the reporting month}}$$

Numerator/Denominator Definitions

Note: Dosing schedule is subject to change, depending on manufacturer's recommendations. See Immunization tables (pages 8 through 10) and corresponding annotations for specific administration criteria.

Numerator: Number of infants and children in the denominator who are up-to-date with recommended immunization(s).

- Four DTaP/DT
- Three IPV
- One MMR

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- Three Hib
- Three hepatitis B
- OneVAR, or documented chicken pox disease
- Four pneumococcal
- Two hepatitis A
- Rotavirus:
  - Two doses of the two dose vaccine or
  - One dose of the two dose and two doses of the three dose vaccine or
  - Three doses of the three dose vaccine
- Two influenza

Denominator: A child reaching the age of two years within the specified time period and in the medical group's practice. "In the medical group's practice" is defined as a child who has been seen two or more times by the medical group (including office visits and urgent care) by his/her second birthday. At least one visit should be after the child reaches 15 months of age.

Method/Source of Data Collection

Select a random sample of the eligible population for data collection. The suggested sample size for each medical group is at least 10 each month. If the medical group identifies a total of fewer than 10 children, then all identified children are to be included.

The medical record of each child is reviewed to determine if each of the required immunizations is documented. A child should be considered on time with the immunization if and only if a date and type of vaccination are documented in the medical record.

Time Frame Pertaining to Data Collection

The suggested time period is a calendar month.

Notes

This is a HEDIS 2011 outcome measure for Childhood Immunization Status by National Committee for Quality Assurance (NCQA).

Full specifications for this measure can be obtained from NCQA at http://www.ncqa.org.

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Measurement #1b

Percentage of patients who by age 13 years were up-to-date with recommended adolescent immunizations:

- One HPV – Human papillomavirus vaccine by age 13 (for females)
- One MCV4 – Meningococcal
- One Tdap – Tetanus, diphtheria toxoids and acellular pertussis vaccine
- One influenza within the last year

Population Definition

Patients who reach their 13th birthday during the specified measurement period.

Data of Interest

$$\frac{\text{\# of patients who are up-to-date with immunizations}}{\text{\# of patients 13 years of age}}$$

Numerator/Denominator Definitions

Numerator: Number of patients who are up-to-date with following immunizations:

- One HPV – Human papillomavirus vaccine (for females)
- One MCV4 – Meningococcal
- One Tdap – Tetanus, diphtheria toxoids and acellular pertussis vaccine

Denominator: Number of patients who reach their 13th birthday during the specified measurement period. Measurement period can be monthly, quarterly or annual.

Method/Source of Data Collection

Select patients who reached their 13th birthday within the specified measurement period. Measurement period can be monthly, quarterly or annual.

If using paper records, select a minimum of 30 records to review.

Review medical records to determine whether patients were up-to-date with immunizations.

Time Frame Pertaining to Data Collection

The suggested time period is annual.

Notes

This is an outcome measure, and improvement is noted as an increase in the rate.

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Measurement #1c

Percentage of adult patients, 19 years and older, who are up-to-date with the following immunizations:

- One Td in the last 10 years
- Varicella – two doses or history of disease up to year 1995
- PPSV23 for patients 65 and older
- One influenza within last year
- Herpes zoster/shingles (patients 60 years and older)

Population Definition

Patients 19 years and older during the specified measurement period.

Data of Interest

$$\frac{\text{\# of patients who are up-to-date with immunizations}}{\text{\# of patients 19 years of age and older}}$$

Numerator/Denominator Definitions

Numerator: Number of patients who are up-to-date with following immunizations:

- One Td in the last 10 years
- Varicella – two doses or history of disease up to year 1995
- PPSV23 for patients 65 and older
- One influenza
- Herpes zoster/shingles (patients 60 years and older)

Denominator: Number of patients 19 years and older during the specified measurement period. Measurement period can be monthly, quarterly or annual.

Method/Source of Data Collection

Select patients who were 19 years and older within the specified measurement period. Measurement period can be monthly, quarterly or annual.

If using paper records, select a minimum of 30 records to review.

Review medical records to determine whether patients were up to date with immunizations.

Time Frame Pertaining to Data Collection

The suggested measurement period is annual.

Notes

This is an outcome measure, and improvement is noted as an increase in the rate.

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Measurement #2a

Percentage of patients or parents (if patient younger than 18 years) who receive education regarding the importance of immunizations and recommended immunization schedules.

Population Definition

Patients, any age, eligible for immunizations.

Data of Interest

$$\frac{\text{\# of patients (or parents) who are provided education}}{\text{\# of patients eligibile for immunizations}}$$

Numerator/Denominator Definitions

Numerator: Number of patients or parents (if patient younger than 18 years) who receive education regarding the importance of immunizations and recommended immunization schedules.

Denominator: Number of patients, any age, who were eligible for immunizations.

Method/Source of Data Collection

Select patients any age within the specified measurement period. Measurement period can be monthly, quarterly or annual.

If using paper records, select a minimum of 30 records to review.

Review medical records to determine whether patients or parents (if patient younger than 18 years) received education regarding the importance of immunizations and recommended immunization schedules.

Time Frame Pertaining to Data Collection

The suggested measurement period is annual.

Notes

This is an outcome measure, and improvement is noted as an increase in the rate.

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Implementation Recommendations

Prior to implementation, it is important to consider current organizational infrastructure that address the following:

- System and process design;
- Training and education; and
- Culture and the need to shift values, beliefs and behaviors of the organization.

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline:

- Develop tracking systems in order to establish immunization status of patients under the provider's care, with the capability to produce reminders and recalls for immunizations that are due and/or not on time. *(Annotation #8)*
  - Develop a plan for periodic medical record audits, paper medical record or electronic health records in order to track outcomes and identify barriers.
- Remove barriers to immunization services. *(Annotation #3)*
- Develop system-based protocols to include specific criteria around immunizations that may be due at the current visit, or those immunizations not on time, including a statement indicating immunization(s) may be given at any time during the visit (based on specific criteria).
  - Provide staff training and education around routine standing orders.
  - Make it clear to staff that routine standing orders are clinician orders that allow for administration of immunizations (those due or not on time).
  - Clearly define those staff who may administer these immunizations (RN, LPN, CMA, etc.).
- Develop education for providers and staff around patients at risk/high risk who require adjustments or have contradictions to specific (required) immunizations.
  - Develop criteria and alerts for tracking these patients.
  - Develop criteria in paper medical record or electronic health records for documentation of patients at risk/high risk.
- Develop a means for communicating vaccine shortages to practitioners, as well as providing updates on status of shortages. This information is available on the Centers for Disease Control and Prevention Web site (http://www.cdc.gov/vaccines/vac-gen/shortages/default.htm).
- Patient Safety: Provide education to clinicians and staff around risk factors and immunizations in all age groups. Stress the importance of reviewing this guideline and/or any of the resources listed (in this guideline) as a reference.
- Develop a system to ensure immunization information is being sent to or entered into state or local registries. *(Annotation #6)*

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Implementation Tools and Resources

Criteria for Selecting Resources

The following tools and resources specific to the topic of the guideline were selected by the work group. Each item was reviewed thoroughly by at least one work group member. It is expected that users of these tools will establish the proper copyright prior to their use. The types of criteria the work group used are:

- The content supports the clinical and the implementation recommendations.
- Where possible, the content is supported by evidence-based research.
- The author, source and revision dates for the content is included where possible.
- The content is clear about potential biases and when appropriate conflicts of interests and/or disclaimers are noted where appropriate.

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Implementation Tools and Resources Table

Author/Organization	Title/Description	Audience	Web Sites/Order Information
American Academy of Family Physicians (AAFP)	Provides information on health topics, including immune system, vaccines and vaccine-preventable diseases.	Health Care Professionals; Patients and Families	http://familydoctor.org/family-doctor/en.html
American Academy of Pediatrics (AAP)	Provides immunization information supported by scientific research and includes policy statements on immunization issues.	Health Care Professionals; Patients and Families	http://www2.aap.org/immunization/index.html
American Academy of Pediatrics (AAP)	**"Refusal to Vaccinate"** documentation form.	Health Care Professionals; Patients and Families	http://www2.aap.org/immunization/pediatricians/pdf/RefusaltoVaccinate.pdf
Ari Brown, MD	**Clear Answers & Smart Advice About Your Baby's Shots:** 6-page publication that answers questions parents ask about vaccines.	Patients and Families	http://www.immunize.org/catg.d/p2068.pdf
Ari Brown, MD and Michele Hakakha, MD	**Expecting 411: Clear Answers & Smart Advice for Your Pregnancy:** Book, includes chapter on immunizations.*	Patients and Families	To purchase book: https://windsorpeak.com/sites/expecting411/
Ari Brown, MD, and Denise Fields	**Baby 411: Clear Answers & Smart Advice for Your Baby's First Year:** Book, includes chapter on immunizations.*	Patients and Families	To purchase book: https://windsorpeak.com/sites/expecting411/
Ari Brown, MD, and Denise Fields	**Toddler 411 Clear Answers & Smart Advice for Your Toddler:** Book, includes chapter on immunizations.*	Patients and Families	To purchase book: https://windsorpeak.com/sites/expecting411/
Centers for Disease Control and Prevention	**CDC-INFO Contact Center:** Toll-free number for questions about immunization and vaccine-preventable diseases.	Health Care Professionals; Patients and Families	English and Spanish: (800) CDC-INFO or (800) 232-4636, TTY: (888) 232-6348
Centers for Disease Control and Prevention	**Guide to Vaccine Contraindications and Precautions**	Health Care Professionals; Patients and Families	http://www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm
Centers for Disease Control and Prevention	**Immunization Information Systems (IIS):** Provides IIS state contacts, programmatic resources, and technical information.	Health Care Professionals; Patients and Families	http://www.cdc.gov/vaccines/programs/iis/index.html
Centers for Disease Control and Prevention	**MMWR:** Online publication of Morbidity and Mortality Weekly Reports on federal monitoring of epidemic and endemic health conditions.	Health Care Professionals; Patients and Families	http://www.cdc.gov/mmwr

* Non-government resource *Return to Table of Contents*

Author/Organization	Title/Description	Audience	Web Sites/Order Information
Centers for Disease Control and Prevention	**Parents Guide to Childhood Immunization:** 68-page booklet introduces parents to 14 childhood diseases and the 10 vaccines that can protect children from them.	Patients and Families	To order a free booklet or print a copy: http://www.cdc.gov/vaccines/pubs/parents-guide
Centers for Disease Control and Prevention	**Storage and Handling:** Guidelines for correct vaccine storage and handling.	Health Care Professionals; Patients and Families	http://www.cdc.gov/vaccines/recs/storage/default.htm
Centers for Disease Control and Prevention	**Travelers' Health:** Recommendations and educational materials on the prevention of disease and injury for international travel.	Health Care Professionals; Patients and Families	http://www.cdc.gov/travel
Centers for Disease Control and Prevention	**Vaccination Coverage in the U.S.:** National immunization rate information.	Health Care Professionals; Patients and Families	http://www.cdc.gov/vaccines/stats-surv/imz-coverage.htm
Centers for Disease Control and Prevention	**Vaccine Information Statements:** Vaccine fact sheets. DTap, Hepatitis, Hib, Influenza, HPV, MMR, MMRV, Menongococcal, PCV13, PPSV23, Polio, Rotavirus, Shingles, Td/Tdap, Varicella.	Health Care Professionals; Patients and Families	English: http://www.cdc.gov/vaccines/pubs/vis/ English and other languages: http://www.immunize.org/vis/?f=9
Every Child by Two	Organization devoted to raising awareness of the critical need for timely immunizations.	Health Care Professionals; Patients and Families	http://www.ecbt.org/
Every Child by Two	**Vaccinate Your Baby:** Features news and information for parents who wish to learn the truth about immunization and how best to protect their children from vaccine-preventable diseases.	Patients and Families	http://www.vaccinateyourbaby.org/
Every Child by Two	**Vaccinate Your Baby:** Video FAQs	Patients and Families	http://www.vaccinateyourbaby.org/faq/index.cfm
Immunization Action Coalition (IAC)	Non-profit organization that promotes immunization for all people against vaccine-preventable diseases by creating and distributing educational materials that enhance the delivery of safe and effective immunization services.	Patients and Families; Health Care Professionals	http://www.immunize.org/vis/
Immunization Action Coalition (IAC)	**"Decision to Not Vaccinate My Child"** documentation form.	Health Care Professionals; Patients and Families	http://www.immunize.org/catg.d/p4059.pdf

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Author/Organization	Title/Description	Audience	Web Sites/Order Information
Immunization Action Coalition (IAC)	**Immunization Registries (IIS)**	Health Care Professionals; Patients and Families	http://www.immunize.org/registries/
Immunization Action Coalition (IAC)	**"Quick Chart of Vaccine Preventable Disease Terms in Multiple Languages"**	Health Care Professionals; Patients and Families	http://www.immunize.org/catg.d/p5122.pdf
Immunization Action Coalition (IAC)	**State immunization Web sites**	Health Care Professionals; Patients and Families	http://www.immunize.org/states/
Immunization Action Coalition (IAC)	**Suggestions to Improve Your Immunization Services**	Health Care Professionals; Patients and Families	http://www.immunize.org/catg.d/p2045.pdf
Immunization Action Coalition (IAC)	**Vaccine Information Sheets (VIS)** in English and other languages.	Health Care Professionals; Patients and Families	http://www.immunize.org/vis/
Immunization Action Coalition (IAC)	**Vaccine Package Inserts**	Health Care Professionals; Patients and Families	http://www.immunize.org/packageinserts/
Institute for Vaccine Safety	Provides an independent assessment of vaccines and vaccine safety with the goal of preventing disease using the safest vaccines possible. Includes information on vaccine components.	Patients and Families; Health Care Professionals	http://www.vaccinesafety.edu/
Minnesota Community Measurement	The mission of Minnesota Community Measurement is to accelerate the improvement of health by publicly reporting health care information.	Patients and Families; Health Care Professionals	http://www.mncm.org/site/
Minnesota Department of Health	**Immunization:** Includes links to the MN Immunization Information Connection (MIIC), the MN Vaccines for Children Program, MN immunization rates and MN immunization laws.	Patients and Families; Health Care Professionals	http://www.health.state.mn.us/divs/idepc/immunize/index.html
Martin Myers, MD, and Diego Pineda, MS	**Do Vaccines Cause That?! A Guide for Evaluating Vaccine Safety Concerns:** Science-based answers to parents' questions about the safety of vaccines. Book also available.	Patients and Families	http://www.dovaccinescausethat.com/ To purchase book: http://www.immunizationinfo.org/bookstore

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Author/Organization	Title/Description	Audience	Web Sites/Order Information
National Network for Immunization Information (NNii)	Provides current, science-based, extensively reviewed immunization information. This site notes that it receives no funding from pharmaceutical companies.	Patients and Families; Health Care Professionals	http://www.nnii.org
Paul Offit, MD, and Charlotte Moser	**Vaccines and Your Child, Separating Fact from Fiction:** Book, answers questions about the science and safety of modern vaccines, how vaccines work, how they are made, and how they are tested, separating the real risks of vaccines from feared but unfounded risks.*	Patients and Families	To purchase book: http://www.cup.columbia.edu
U.S. Department of Health and Human Services	Provides resources from federal agencies about vaccines across the lifespan.	Patients and Families	http://www.vaccines.gov/
U.S. Food and Drug Administration	**Center for Biologics Evaluation and Research (CBER)**. Includes vaccine licensure information including the approval letter, package insert and other supporting documents.	Patients and Families; Health Care Professionals	http://www.fda.gov/cber
Vaccine Education Center at Children's Hospital of Philadelphia (CHOP)	Provides complete up-to-date information about vaccines. Includes educational materials for patients and families. This site notes that it receives no funding from pharmaceutical companies.	Patients and Families; Health Care Professionals	http://www.vaccine.chop.edu http://www.chop.edu/service/vaccine-education-center/order-educational-materials/order-educational-materials.html#booklets
Vaccine Education Center at Children's Hospital of Philadelphia (CHOP)	**Vaccines and Your Baby:** Online video series, physicians from CHOP explain how vaccines work and how they are made, describes several vaccines and the diseases they prevent.*	Patients and Families	http://www.chop.edu/video/vaccines-and-your-baby/home.html
Vaccine Education Center at Children's Hospital of Philadelphia (CHOP)	**Vaccines: Separating Fact from Fear:** Online video series answers questions many parents have about vaccines. Contains stories of several parents whose children suffered vaccine-preventable diseases.*	Patients and Families	http://www.chop.edu/video/vaccine-separating-fact-from-fear/home.html

* Non-government resource

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The subdivisions of this section are:

- References
- Appendices

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Links are provided for those new references added to this edition (author name is highlighted in blue).

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Appendix A – Guide to Contraindications and Precautions to Commonly Used Vaccines

Vaccine	Contraindications[1]	Precautions[1]
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever • Infant weighing less than 2000 grams (4 lbs, 6.4 oz)[2]
Rotavirus (RV5 [RotaTeq], RV1 [Rotarix])	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Severe combined immunodeficiency (SCID) • History of intussusception or of uncorrected congenital malformation of the gastrointestinal tract that would predispose the infant to intussusception	• Moderate or severe acute illness with or without fever • Altered immunocompetence other than SCID • Chronic gastrointestinal disease[3] • Spina bifida or bladder exstrophy[3]
Diphtheria, tetanus, pertussis (DTaP) **Tetanus, diphtheria, pertussis (Tdap)**	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP or DTaP (for DTaP); or of previous dose of DTP, DTaP, or Tdap (for Tdap)	• Moderate or severe acute illness with or without fever • Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus toxoid-containing vaccine • History of arthus-type hypersensitivity reactions after a previous dose of tetanus or diphtheria toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid containing vaccine • Progressive or unstable neurologic disorder (including infantile spasms for DTaP), uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized **For DTaP only:** • Temperature of 105° F or higher (40.5° C or higher) within 48 hours after vaccination with a previous dose of DTP/DTaP • Collapse or shock-like state (i.e., hypotonic hyporesponsive episode) within 48 hours after receiving a previous dose of DTP/DTaP • Seizure within 3 days after receiving a previous dose of DTP/DTaP • Persistent, inconsolable crying lasting 3 or more hours within 48 hours after receiving a previous dose of DTP/DTaP
Tetanus, diphtheria (DT, Td)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever • GBS within 6 weeks after a previous dose of tetanus toxoid-containing vaccine • History of arthus-type hypersensitivity reactions after a previous dose of tetanus or diphtheria toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid containing vaccine
***Haemophilus influenzae* type b (Hib)**	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Age younger than 6 weeks	• Moderate or severe acute illness with or without fever
Inactivated poliovirus vaccine (IPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever • Pregnancy
Pneumococcal (PCV13 or PPSV23)	• For PCV13, severe allergic reaction (e.g., anaphylaxis) after a previous dose of PCV7 or PCV13 or to a vaccine component, including to any vaccine containing diphtheria toxoid • For PPSV23, severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever
Measles, mumps, rubella (MMR)[4]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, or long-term immunosuppressive therapy[5] or patients with human immunodeficiency virus [HIV] infection who are severely immunocompromised)[6] • Pregnancy	• Moderate or severe acute illness with or without fever • Recent (within 11 months) receipt of antibody-containing blood product (specific interval depends on product)[7] • History of thrombocytopenia or thrombocytopenic purpura • Need for tuberculin skin testing[8]

(continued on page 2)

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Vaccine	Contraindications[1]	Precautions[1]
Varicella (Var)[4]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, primary or acquired immunodeficiency, or long-term immunosuppressive therapy[5] or patients with HIV infection who are severely immunocompromised)[6] • Pregnancy	• Moderate or severe acute illness with or without fever • Recent (within 11 months) receipt of antibody-containing blood product (specific interval depends on product)[7] • Receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination; avoid use of these antiviral drugs for 14 days after vaccination.
Hepatitis A (HepA)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever
Influenza, inactivated injectable (IIV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any influenza vaccine or to a vaccine component, including egg protein	• Moderate or severe acute illness with or without fever • History of GBS within 6 weeks of previous influenza vaccination • Persons who experience only hives with exposure to eggs should receive IIV with additional safety precautions found in the 2012–13 ACIP influenza recommendations, pages 613–618 at www.cdc.gov/mmwr/pdf/wk/mm6132.pdf.
Influenza, live attenuated (LAIV)[4]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any influenza vaccine or to a vaccine component, including egg protein • Conditions for which the ACIP recommends against use, but which are not contraindications in vaccine package insert: immune suppression, certain chronic medical conditions such as asthma, diabetes, heart or kidney disease, and pregnancy[9]	• Moderate or severe acute illness with or without fever • History of GBS within 6 weeks of previous influenza vaccination • Receipt of specific antivirals (i.e., amantadine, rimantadine, zanamivir, or oseltamivir) 48 hours before vaccination. Avoid use of these antiviral drugs for 14 days after vaccination.
Human papillomavirus (HPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever • Pregnancy
Meningococcal: conjugate (MCV4), polysaccharide (MPSV4)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever
Zoster (HZV)	• Severe allergic reaction (e.g., anaphylaxis) to a vaccine component • Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, or long-term immunosuppressive therapy[5] or patients with HIV infection who are severely immunocompromised). • Pregnancy	• Moderate or severe acute illness with or without fever • Receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination; avoid use of these antiviral drugs for 14 days after vaccination.

Footnotes

1. Vaccine package inserts and the full ACIP recommendations for these vaccines should be consulted for additional information on vaccine-related contraindications and precautions and for more information on vaccine excipients. Events or conditions listed as precautions should be reviewed carefully. Benefits of and risks for administering a specific vaccine to a person under these circumstances should be considered. If the risk from the vaccine is believed to outweigh the benefit, the vaccine should not be administered. If the benefit of vaccination is believed to outweigh the risk, the vaccine should be administered. Whether and when to administer DTaP to children with proven or suspected underlying neurologic disorders should be decided on a case-by-case basis.
2. Hepatitis B vaccination should be deferred for preterm infants and infants weighing less than 2000 g if the mother is documented to be hepatitis B surface antigen (HBsAg)-negative at the time of the infant's birth. Vaccination can commence at chronological age 1 month or at hospital discharge. For infants born to women who are HBsAg-positive, hepatitis B immunoglobulin and hepatitis B vaccine should be administered within 12 hours of birth, regardless of weight.
3. For details, see CDC. "Prevention of Rotavirus Gastroenteritis among Infants and Children: Recommendations of the Advisory Committee on Immunization Practices. (ACIP)" *MMWR* 2009;58(No. RR–2), available at www.cdc.gov/vaccines/pubs/acip-list.htm.
4. LAIV, MMR, and varicella vaccines can be administered on the same day. If not administered on the same day, these vaccines should be separated by at least 28 days.
5. Immunosuppressive steroid dose is considered to be 2 or more weeks of daily receipt of 20 mg prednisone or equivalent. Vaccination should be deferred for at least 1 month after discontinuation of such therapy. Providers should consult ACIP recommendations for complete information on the use of specific live vaccines among persons on immune-suppressing medications or with immune suppression because of other reasons.
6. HIV-infected children may receive varicella and measles vaccine if CD4+ T-lymphocyte count is >15%. (Source: Adapted from American Academy of Pediatrics. Immunization in Special Clinical Circumstances. In: Pickering LK, ed. *Red Book: 2012 Report of the Committee on Infectious Diseases.* 29th ed. Elk Grove Village, IL: American Academy of Pediatrics: 2012.)
7. Vaccine should be deferred for the appropriate interval if replacement immune globulin products are being administered (see Table 5 in CDC. "General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)" at www.cdc.gov/vaccines/pubs/acip-list.htm.)
8. Measles vaccination might suppress tuberculin reactivity temporarily. Measles-containing vaccine can be administered on the same day as tuberculin skin testing. If testing cannot be performed until after the day of MMR vaccination, the test should be postponed for at least 4 weeks after the vaccination. If an urgent need exists to skin test, do so with the understanding that reactivity might be reduced by the vaccine.
9. For a complete list of conditions that CDC considers to be reasons to avoid getting LAIV, see CDC "Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," 2010. *MMWR* 2010;59(No. RR-8), available at www.cdc.gov/vaccines/pubs/acip-list.htm.

* Adapted from "Table 6. Contraindications and Precautions to Commonly Used Vaccines" found in: CDC. "General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)." *MMWR* 2011; 60(No. RR-2), p. 40–41, and from Atkinson W, Wolfe S, Hamborsky J, eds. Appendix A. *Epidemiology and Prevention of Vaccine-Preventable Diseases* (www.cdc.gov/vaccines/pubs/pinkbook/index.html).
† Regarding latex allergy: some types of prefilled syringes contain natural rubber latex or dry natural latex rubber. Consult the package insert for any vaccine given.

ICSI has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report, Clinical Practice Guidelines We Can Trust (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI policy regarding Conflicts of Interest is available at http://bit.ly/ICSICOI.

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The ICSI Patient Advisory Council meets regularly to respond to any scientific document review requests put forth by ICSI facilitators and work groups. Patient advisors who serve on the council consistently share their experiences and perspectives in either a comprehensive or partial review of a document, and engaging in discussion and answering questions. In alignment with the Institute of Medicine's triple aims, ICSI and its member groups are committed to improving the patient experience when developing health care recommendations.

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The next scheduled revision will occur within 24 months.

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ICSI Document Development and Revision Process

Overview

Since 1993, the Institute for Clinical Systems Improvement (ICSI) has developed more than 60 evidence-based health care documents that support best practices for the prevention, diagnosis, treatment or management of a given symptom, disease or condition for patients.

Audience and Intended Use

The information contained in this ICSI Health Care Guideline is intended primarily for health professionals and other expert audiences.

This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in their individual case.

This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

Document Development and Revision Process

The development process is based on a number of long-proven approaches and is continually being revised based on changing community standards. The ICSI staff, in consultation with the work group and a medical librarian, conduct a literature search to identify systematic reviews, randomized clinical trials, meta-analysis, other guidelines, regulatory statements and other pertinent literature. This literature is evaluated based on the GRADE methodology by work group members. When needed, an outside methodologist is consulted.

The work group uses this information to develop or revise clinical flows and algorithms, write recommendations, and identify gaps in the literature. The work group gives consideration to the importance of many issues as they develop the guideline. These considerations include the systems of care in our community and how resources vary, the balance between benefits and harms of interventions, patient and community values, the autonomy of clinicians and patients and more. All decisions made by the work group are done using a consensus process.

ICSI's medical group members and sponsors review each guideline as part of the revision process. They provide comment on the scientific content, recommendations, implementation strategies and barriers to implementation. This feedback is used by and responded to by the work group as part of their revision work. Final review and approval of the guideline is done by ICSI's Committee on Evidence-Based Practice. This committee is made up of practicing clinicians and nurses, drawn from ICSI member medical groups.

Implementation Recommendations and Measures

These are provided to assist medical groups and others to implement the recommendations in the guidelines. Where possible, implementation strategies are included that have been formally evaluated and tested. Measures are included that may be used for quality improvement as well as for outcome reporting. When available, regulatory or publicly reported measures are included.

Document Revision Cycle

Scientific documents are revised every 12-24 months as indicated by changes in clinical practice and literature. Each ICSI staff monitors major peer-reviewed journals every month for the guidelines for which they are responsible. Work group members are also asked to provide any pertinent literature through check-ins with the work group midcycle and annually to determine if there have been changes in the evidence significant enough to warrant document revision earlier than scheduled. This process complements the exhaustive literature search that is done on the subject prior to development of the first version of a guideline.

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